Implementation and evaluation of a computerised anticoagulation decision support tool for managing atrial fibrillation

Rima Hijazeen

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Abstract

Background: Anticoagulation therapy for patients with atrial fibrillation (AF) remains a national challenge. A decision support tool (DST) was developed to assist healthcare professionals (HCPs) in the appropriate prescribing of anticoagulants in patients with AF. This thesis aimed to evaluate the utility of the DST and associated patient decision aid (PDA) for anticoagulant decision making in clinical practice.

Methods: This study involved a series of sequential stages in the evaluation of the DST. Semi-structured interviews were conducted with forty-seven HCPs to explore their perceptions of anticoagulation prescribing decision. Using a vignette, the perspective of HCPs on the potential utility of the DST and associated PDA were explored using both semi-structured interviews and questionnaires. Second interviews were conducted approximately eight weeks from the initial contact to explore HCPs' perspectives on the actual utility from implementing the DST and associated PDA in routine clinical practice. The perspectives of a group of AF patients' who had experienced the DA during consultation were explored using semi-structured interviews and questionnaires.

Results: Qualitative themes elicited during initial contact revealed that anticoagulants prescribing decision can be suboptimal. Findings from the pre-intervention evaluation showed that the DST has potential to improve the quality of anticoagulants decision process. Findings from post-intervention evaluation demonstrated improvements in anticoagulants decision-making in clinical practice. Findings from fourteen patients revealed that the DA was effective in facilitating a quality decision that was informed and consistent with personal values and expectations.

Conclusions: This study demonstrated the positive impact the DST can have on the quality of anticoagulants decision-making in clinical practice and provides a unique contribution to the existing CDSS research. The ever-increasing demand for a quality decision-making process in clinical practice is a fertile environment for clinicians and policymakers to consider the potential impact that the DST and associated PDA can offer.

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Chapter 1: Introduction

This thesis presents a mixed method study to evaluate the utility of a computerised decision support tool for anticoagulation management in atrial fibrillation (AF) from healthcare professionals' (HCPs) and patients' perspectives. An overview of AF and a description of anticoagulation therapy use are provided in section 1.1. Barriers to optimal use of anticoagulation therapy in clinical practice are discussed in section 1.2. After this, the decision support tool (DST) is introduced in section 1.3, and background to the research is provided in section 1.4. Introduction to the study and organisation of the thesis is outlined in section 1.5.

1.1 Overview of atrial fibrillation and anticoagulation therapy use

Atrial fibrillation (AF) is the most prevalent cardiac arrhythmia and represents a global problem (Feinberg et al., 1995; Hu and Sun, 2008; Kannel and Benjamin, 2008; Lip et al., 2012; Lloyd-Jones et al., 2010). As the population ages, the number of individuals with AF is set to increase substantially (Go et al., 2001). In the United States (U.S.) the number of patients with AF is projected to increase to more than 3 million by the year 2020 (Go et al., 2001). Similarly, in the European Union, the prevalence of AF is forecast to increase substantially from more than 8.8 million to more than 17.9 million in 2060 (Krijthe et al., 2013). The latest prevalence estimates of AF in England were calculated using known age, and sex distributions of AF diagnosed in a Swedish region and found that 1.36 million

people in England have AF (Public Health England, 2015). This number is equal to 2.4% of the population (Public Health England, 2015).

In the United Kingdom (UK), the SAFE (Screening for Atrial Fibrillation in the Elderly) study revealed that the overall prevalence of AF in individual aged over 65 was 7.2% (Hobbs et al., 2005). Atrial fibrillation prevalence was higher in men compared to women, 7.8% versus 6.8% respectively, and was found to increase with age; affecting 4.6% of individual aged between 65 and 74, and 10.3% in individual aged over 75 (Hobbs et al., 2005). The age-adjusted prevalence of AF was higher in men compared to women; 5.5% to 11.3% in men aged less than 75 and over 75 respectively, and 3.8% to 9.8% in women aged less than 75 and over 75 respectively (Hobbs et al., 2005). Similar trends in the age-adjusted prevalence of AF was reported in the ATRIA (AnTicoagulation and Risk Factors in Atrial Fibrillation) study (Go et al., 2001). The authors from the ATRIA found that the age-adjusted prevalence of AF was higher in men compared to women; 3.0% versus 1.7% in the age 65 to 69 and 11.1 % versus 9.1 % in the age 65 to 69 respectively (Go et al., 2001).

Atrial fibrillation is a significant independent risk factor for stroke (Atrial Fibrillation Investigators, 1994; Kimura et al., 2005; Ruigómez et al., 2002; Thygesen et al., 2009; Wolf et al., 1991). The follow-up Framingham Study showed that the risk of stroke increased significantly with age in the individual with AF compared to a risk of stroke caused by other cardiovascular conditions (Wolf et al., 1991). Strokes related to AF can be twice more likely to be severe, disabling, and fatal than strokes related to non-AF (Kimura et al., 2005; Lin et al. 1996; Thygesen et al., 2009). In a study by Wolf et al. (1998), to investigate the impact of AF on mortality, findings revealed that the adjusted relative mortality risk was approximately 20% higher in patients with AF than matched peers

without AF in all age-sex strata (Wolf et al., 1998). More recent findings showed that about 50% of AF-related stroke patients die within one year (Marini et al. 2005).

AF-related strokes can be prevented with appropriate antithrombotic therapy (Hart et al., 2007; Lip and Tello-Montoliu, 2006; Mathew et al., 2009; Petersen et al. 1989). Current UK national guidance from the National Institute for Health and Care Excellence (NICE) and international guidance from the European Society of Cardiology (ESC) clinical practice guidelines on AF management recommend the use of oral anticoagulation (OAC) therapy, either a vitamin-K antagonist (VKA) or a non-VKA oral anticoagulants (NOACs), for patients with a CHA_2DS_2-VASc risk score of 1 or more in men, and 2 or more in women, except those at truly low risk (CHA2DS2-VASc score=0) (Camm et al., 2012; NICE clinical guideline 180, June 2014; NICE TAG 355 Edoxaban, 2015).

Despite the overwhelming evidence of the benefit of anticoagulation therapy in reducing the risk of thromboembolism, several studies published registry data which showed variation and under-utilisation of anticoagulants across all stroke risk categories (Albers et al., 1996; Go et al., 1999; Levy et al., 1999; Stafford and Singer, 1998; Teo et al., 1998). These findings of the under-utilisation of anticoagulation therapy in moderate to high-risk patients were corroborated by other more recent prospective observational trials (Glazer et al., 2007; Nieuwlaat et al., 2006; Ogilvie et al., 2010).

More recent data from The EURObservational Research Programme Atrial Fibrillation (EORP-AF) Pilot Registry provided data regarding the management and treatment of AF by cardiologists in European Society of Cardiology (ESC) member countries (Lip et al., 2014). Oral anticoagulation therapy was used in approximately 80% of patients overall, most frequently VKA (71.6%), with NOACs being used for just 8.4% of patients.

In the UK, an AF study in 1857 general practices with a practice population of 13.1 million, had 231833 (1.76%) patients with a history of AF estimated the number of patients with AF who were receiving anticoagulation therapy at the time of the study (Cowan et al., 2013). Findings revealed that 132099(57%) of the AF population had a $CHADS_2$ score ≥2; only 72 211 (54.7%) received an anticoagulation therapy, and of those not prescribed anticoagulation therapy, 79.9% were prescribed an antiplatelet. This study reported that the use of anticoagulation therapy was less in the elderly (for $CHADS_2$≥2, 47.4% of patients ≥80 years, compared with 64.5% for patients aged <80 years, $p<0.001$). And that antiplatelet uptake was more prevalent among elderly patients (Cowan et al., 2013).

A further study in UK general practices (11 general practices, practice population of 105000, had 2259 (2.15%) patients with a history of AF) was conducted to risk stratify patients and identify antithrombotic therapy received (Shantsila et al., 2015). Overall, 1935 (85.7%) of the AF population had a CHA_2DS_2-VASc score ≥2, in which, only 50.9% (985/1935) were prescribed OAC, in 9.4% (182/1935) OAC was recorded as contraindicated, and 5.6% (108/1935) declined OAC. Consequently, 39.7% (768/1935) of the patients with AF with a CHA_2DS_2-VASc score of ≥2 were not receiving appropriate OAC (Shantsila et al., 2015). Further evidence of the under-utilisation of anticoagulation therapy in eligible AF patients was supported with findings from large-scale studies conducted in UK general practices (Barra and Fynn, 2015; Cowan et al., 2013; Holt et al., 2013; Scowcroft et al., 2013).

In 2014, NICE updated AF clinical guideline (CG180) to recommend NOACs as first line options alongside warfarin for nonvalvular AF and that antiplatelet agent (aspirin) should not be used as monotherapy to prevent non-valvular AF-related stroke. Despite this, the Sentinel Stroke National Audit Programme (SSNAP) audit data for April–June 2015 (one year after the publication of NICE CG180) found that patients with AF were still not

receiving optimal anticoagulation (SSNAP, 2015). Findings revealed that more than one in five patients admitted to hospital because of stroke were known to have AF prior to admission with less than half (45.6%) were taking anticoagulants, and over a quarter (27.9%) were still taking aspirin (SSNAP, 2015). Findings from SSNAP means that NICE guidance on preventing AF-related stroke was not fully implemented, and many patients are receiving suboptimal treatment to prevent AF-related stroke (SSNAP, 2015).

1.2 Barriers to anticoagulation therapy uptake in clinical practice

Anticoagulation therapy prescribing is multifaceted with many intervening factors in which the target is not straightforward (Murray et al., 2011) causing additional challenges in the decision-making process in everyday practice (Ansell et al., 2001; Murray et al., 2011). Barriers to optimal use of anticoagulation therapy can be categorised into; healthcare professional-related, patient-related, and healthcare system-related (Decker et al., 2012; Murray et al., 2011).

1.2.1 Healthcare professional-related barriers

Registry data offered valuable insights into HCPs' adherence to guideline recommendations, where patterns of anticoagulants and aspirin therapy use among patients with AF can provide perceptions about the uptake of guideline recommendations. For example, observational worldwide data from the Global Anticoagulant Registry in the FIELD (GARFIELD-AF) registry, collected between 2009 and 2011, indicated that at diagnosis, 55.8% of patients overall were given a VKA for stroke prevention: 45.2% received a VKA alone, and 10.6% received both a VKA and an antiplatelet drug (Kakkar et al., 2013). A minority of patients (4.5%) received a NOAC. Just over one-quarter (25.3%) of the patients received an antiplatelet drug alone, and 14.4% received none of these antithrombotic drugs. Overall, 40.7% of patients with a CHA2DS2-VASc score ≥2

did not receive anticoagulant therapy; conversely, 38.7% of patients with a score of 0 received anticoagulant therapy. The comparable figures for EORP-AF registry data collected from ESC member countries between 2012 and 2013, demonstrated under use of oral anticoagulation across all stroke risk categories with minimal use of NOACs and a trend towards more aspirin use in the presence of a high HAS-BLED score (Lip et al., 2014).

The development of guidelines alone does not ensure implementation in practice (Camm et al., 2015). For instance, physician failure to balance the risks and benefits of anticoagulation in AF patients may lead to underestimation of patient stroke risk and overestimation of bleeding risk (Cowan et al., 2013; Decker et al., 2012), which explains the trend towards more aspirin use (Kakkar et al., 2013; Lane and Lip, 2008; Lip et al., 2014; Mant et al., 2007; Prystowsky et al., 2010; Shantsila et al., 2015).

Factors such as, lack of knowledge of expanded eligibility for anticoagulation therapy, lack of confidence in, and awareness of the potential use of NOACs, and uncertainties among general practitioners (GPs) and other specialist clinicians about the most appropriate use of anticoagulants were commonly reported barriers to optimal use of anticoagulation therapy in Hess et al. (2014), Verdino et al. (2015), and Peterson et al. (2002).

Compared to GPs and other specialist clinicians, cardiologists were more likely to prescribe appropriate oral anticoagulants in-line with guideline recommendations (Lip et al., 1996; Vassilikos et al., 2010; Turakhia et al., 2013). Inter-specialty differences in therapy selection between cardiologists and other specialist clinicians and GPs can explain variation in the prescription of anticoagulants (Hess et al., 2014; Lip et al., 1996; Turakhia et al., 2013; Vassilikos et al., 2010).

1.2.2 Patient-related barriers

Findings from the Atrial Fibrillation AWareness And Risk Education (AF AWARE) group survey found that patients have limited awareness and insufficient understanding of the risks associated with AF which revealed inadequate information provision and education (Aliot et al., 2010). These findings are in agreements with The West Birmingham Atrial Fibrillation Project on patient knowledge and perceptions of AF and anticoagulant therapy (Lane et al., 2006; Lip et al., 2002). These studies suggested that better adherence to guidelines and better patient education around the risk and benefits of treatments are needed to improve anticoagulation management in clinical practice (Lane et al., 2006; Lip et al., 2002).

However, several studies regarded under-prescribing of OACs in eligible AF patients to the patient's clinical and non-clinical characteristics, such as, patient's risk of bleeding, advanced age, risk of falls, comorbidities, patients' reluctance, and cognitive impairment (Lane and Lip, 2008; Lin et al., 2008; Nicholls et al., 2014; Pugh et al, 2011; Sinnaeve et al., 2012; Verdino, 2015; White et al., 1999).

1.2.3 Healthcare system-related barriers

Unlike the controlled setting in clinical trials where all expertise and resources are dedicated to providing efficient therapeutic intervention, in routine clinical practice, there are barriers to delivering anticoagulation to an equivalent standard of that achieved in clinical trials (Bungard et al., 2000; Sudlow et al., 1995).

Breakdown in communication between medical specialities and healthcare settings was identified by Decker et al., (2012) as a real world barrier to optimal anticoagulants management in clinical practice.

Time is a limiting factor for delivering adequate consultation during outpatient clinical encounters (Deveugele et al., 2002, Hess et al., 2014; Tai-Seale et al., 2007). The decision

to initiate an OAC and the need to educate patients about AF and associated risks takes considerable time and resources (Hess et al., 2014). Data from videotape analysis from multiple primary care practices in the United States revealed that primary care physician visits lasted on average about 17.4 minutes (Tai-Seale et al., 2007). The physician visit length is less in the UK and other European countries, 9.4 and 10.7 minutes respectively (Deveugele et al., 2002). Consequently, this time pressure may result in negative implication for the quality of patient care (Braddock et al., 1999; Fiscella and Epstein, 2008; Tarn et al., 2008).

1.3 Intervention to improve anticoagulation prescribing in clinical practice

Decision support systems have the potential to improve the way medicine is practised, and the patient is cared for (Kawamoto et al., 2005; Wyatt and Liu, 2002).

The Keele Anticoagulation Therapy Decision Support Tool (DST) is an example of computerised decision support resources designed to support HCPs' decision making in stroke prevention in atrial fibrillation.

In 2014, a joint working group was formed between NICE (National Institute for Health and Care Excellence), Boehringer Ingelheim Ltd and Prescribing Decision Support Ltd (PDS) at Keele to collaborate in the development and dissemination of a tool that would support anticoagulation decision-making in patients with atrial fibrillation. The group's aims were to:

- Support the uptake and use of the NICE atrial fibrillation guideline (NICE CG180) and associated patient decision aid (PDA).
- To make the national guidance more accessible by re-purposing paper-based NICE clinical guidance and associated PDA on anticoagulation therapy into an interactive and dynamic software application.

- Support a patient-centred approach so patients can participate in an informed discussion with a HCP about their values and preferences.

Having agreed on the aims of the project, the joint working group mapped out NICE clinical guidance into a series of algorithms and decision trees. These algorithms comprise the tool's 'logic'. Once the logic was validated, multiple layers of content and text were generated, for example, individual treatment recommendations, and alerts. Decision points were also incorporated, such as treatment contraindications, warnings and dose options. The logic and text were then coded into the software to create a prototype version of the tool. The prototype then underwent a series of interface design and technical tests and consultation with clinical advisors and the joint working group. Following testing, the tool was submitted for review by the NICE endorsement process. The endorsement was received in October 2015, and the tool was made available to UK HCPs – free-to-use, unrestricted access – in November 2015, and has been updated to incorporate edoxaban (NICE TA355) and re-endorsed by NICE.

The resulting tool is set up as a software application that can be run in all major web browsers, and users can access via their computer or touch screen tablet device. The tool encourages partnership between HCPs and their patients when reaching a decision about the use of anticoagulation therapy to reduce their risk of stroke. The tool is available free and can be accessed at www.anticoagulation-dst.co.uk

The interactive tool is in two parts: the first part allows a HCP to feed in patient health information into the online tool, which then provides individualised prescribing recommendations based on the NICE clinical guidelines (CG 180). Each recommendation

is supported by reason, important management considerations, treatment side-effects, and is referenced. The second part incorporates NICE's PDA; this provides a practical basis for patients to participate in an informed discussion with a HCP about their treatment choices in atrial fibrillation, taking into account the options available, their individual needs and preferences and potential benefits and risks.

The following screen shots can guide the reader through the main screens of the DST and follow the decision-making process of a hypothetical patient:

Mrs Brown was born on 27/04/1948 (69-year-old), weight 88 Kg, who has hypertension (controlled), poorly controlled diabetes for 10 years, and she has been diagnosed AF three years ago. No previous stroke, bleedings or thromboembolism events.

Current medication: Ramipril 10 mg, aspirin 75 mg, simvastatin 40 mg, metformin 500 mg, pioglitazone 30 mg, and warfarin 7.5 mg a day.

Laboratory tests: Creatinine clearance (CLcr) 45 ml/min, liver function tests within normal limits. Her previous INRs are in and out of range from 1.8-5.6 (from ten previous readings). Today is 3.3. Time in the therapeutic range (TTR) 62%. Alcohol history: None. No known drug allergies (NKDA).

Once the HCP printed the DST URL link www.anticoagulation-dst.co.uk into the search bar, the DST homepage shows up (Figure 1.1). This screen provides a brief description of the DST development, validation and endorsement by NICE as described earlier. The top icons (Important Information, References, Links, Help, and Terms & Conditions) can open into a new window to provide the user with further information when needed as shown in figures 1.2, 1.3, 1.4, 1.5, and 1.6.

Within this screen the user has two options; create new patient profile or open existing patient profile for follow up visit.

Figure 1. 1: The decision support tool homepage

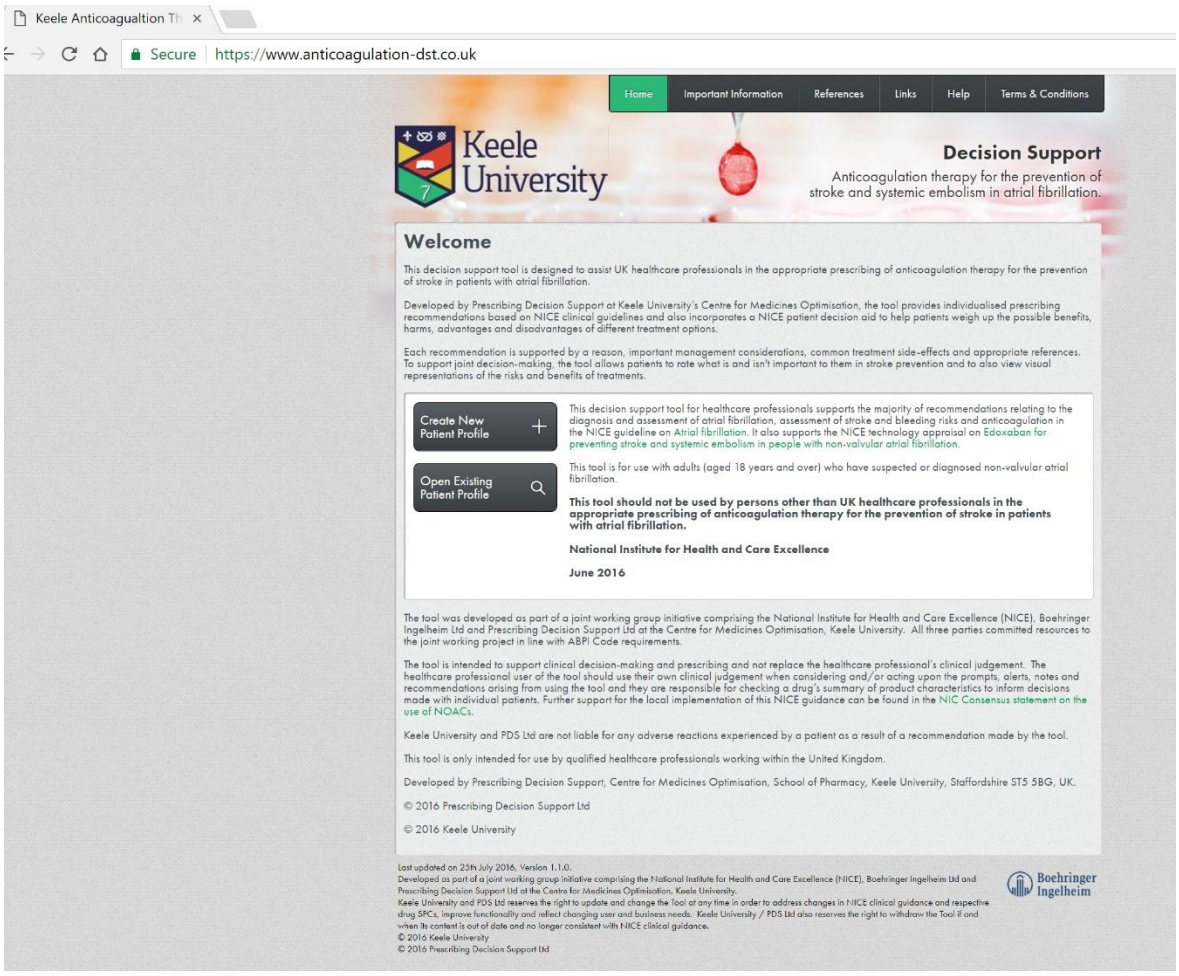


Figure 1. 2: Important information screen

Figure 1. 3: References screen

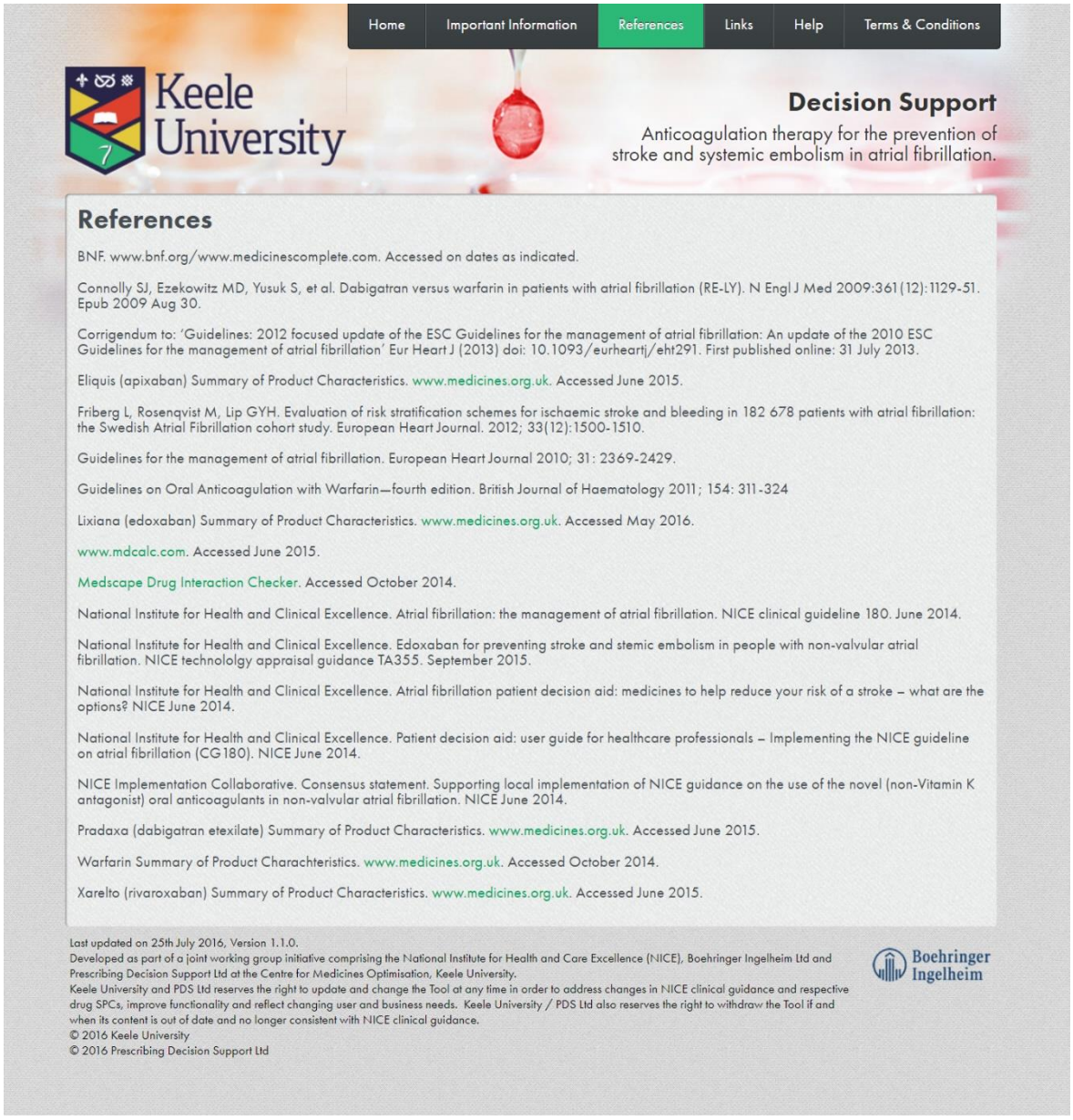


Figure 1. 4: Links screen

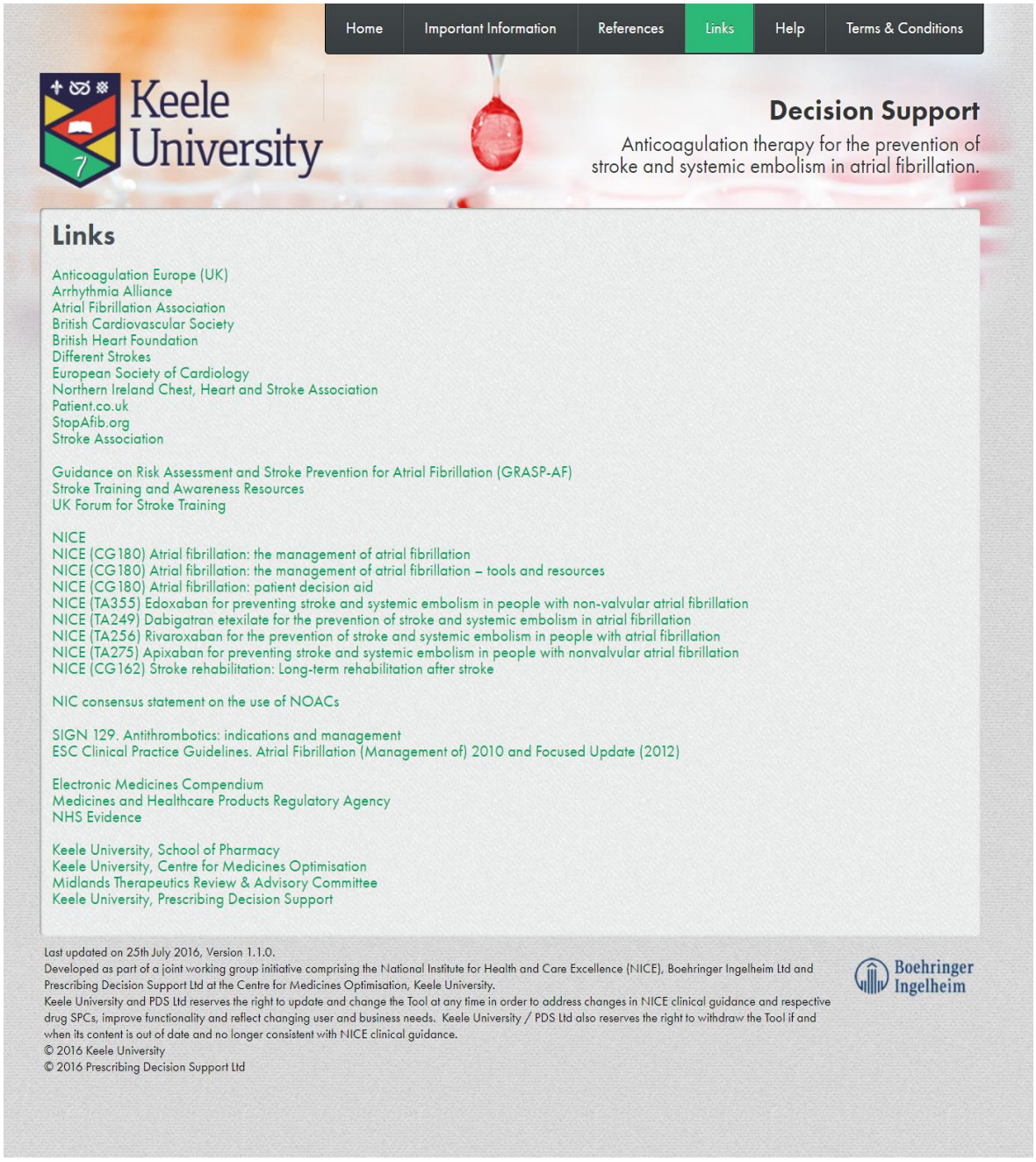


Figure 1. 5: Help screen

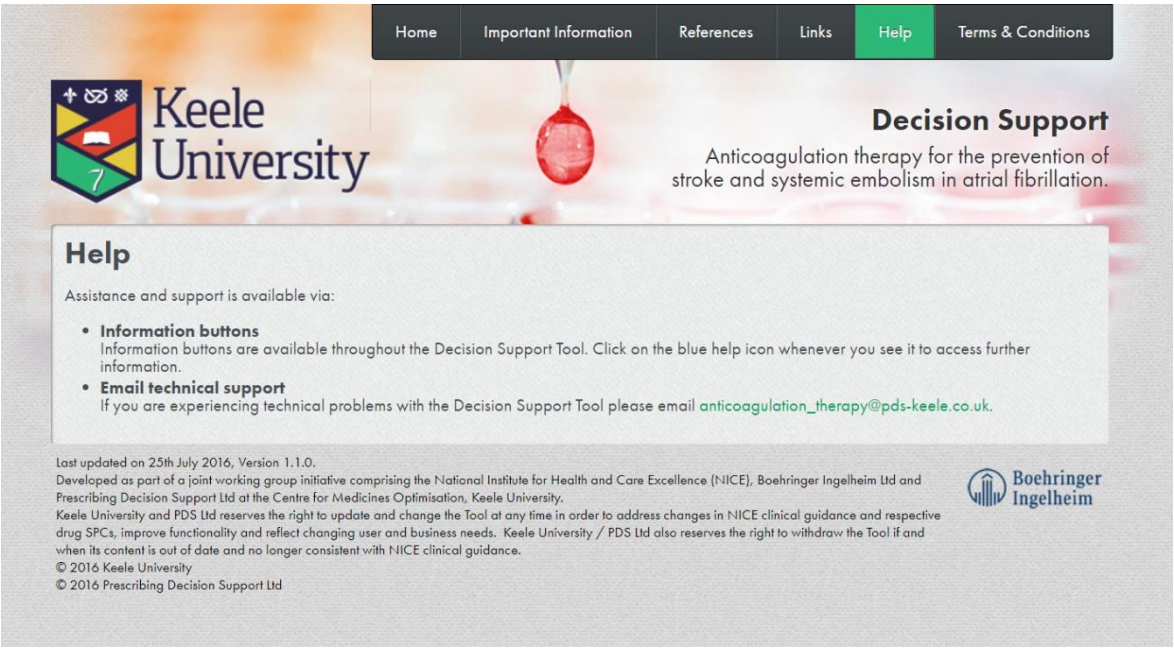
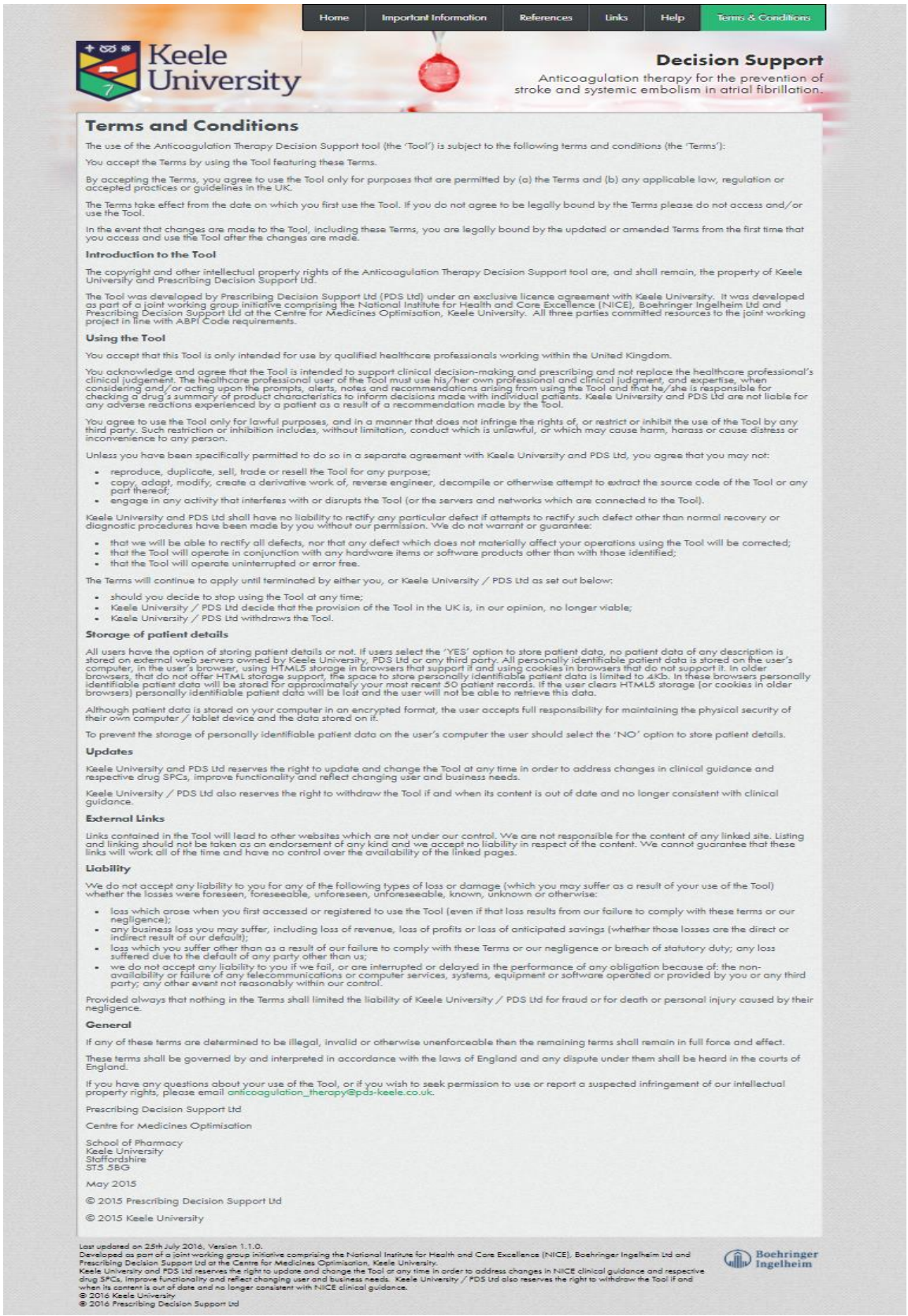
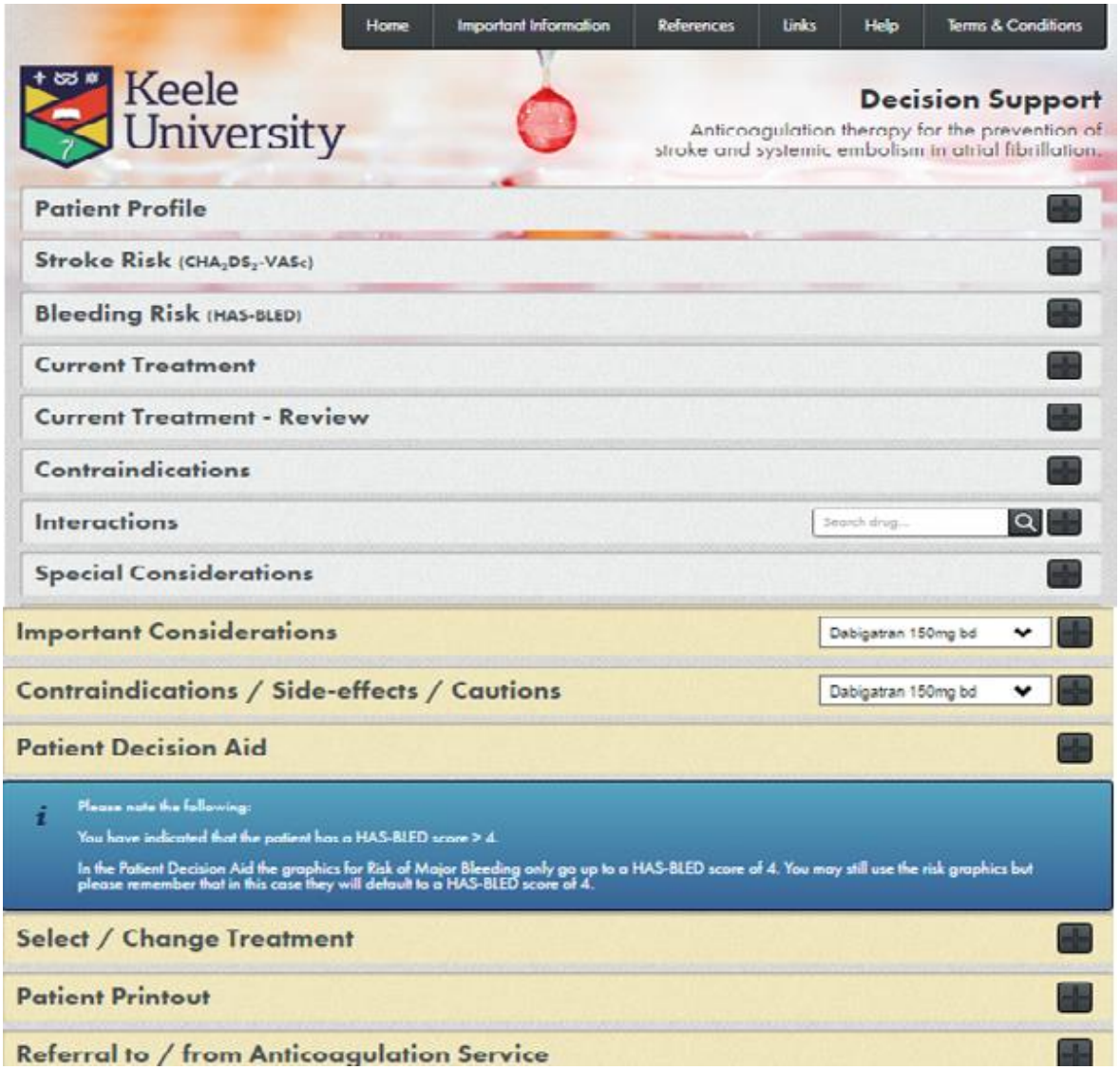


Figure 1. 6: Terms & Condition screen



The DST consists of sequential expandable screens that allow the HCP to fill in patient demographics and health information before making the treatment decision including; patient profile, stroke and bleeding risks, current treatment, current treatment review, contraindications, interactions, and special considerations as shown in figure 1.7.

Figure 1. 7: The DST main screens



In the Patient Profile screen, the HCP can fill in patent's identifiers including; patient's name and date of birth. Patient weight need to be selected from a drop-down menu. A blue information button can provide the user with additional information when needed. For example, clicking the blue information button next to the question "Do you wish to store patient details?" can open a new window to explain in detail what happens if the user chooses 'yes' or 'no' option (Figure 1.9).

Clicking on proceed button enables the user to move on into next screen.

Figure 1. 8: The Patient Profile screen

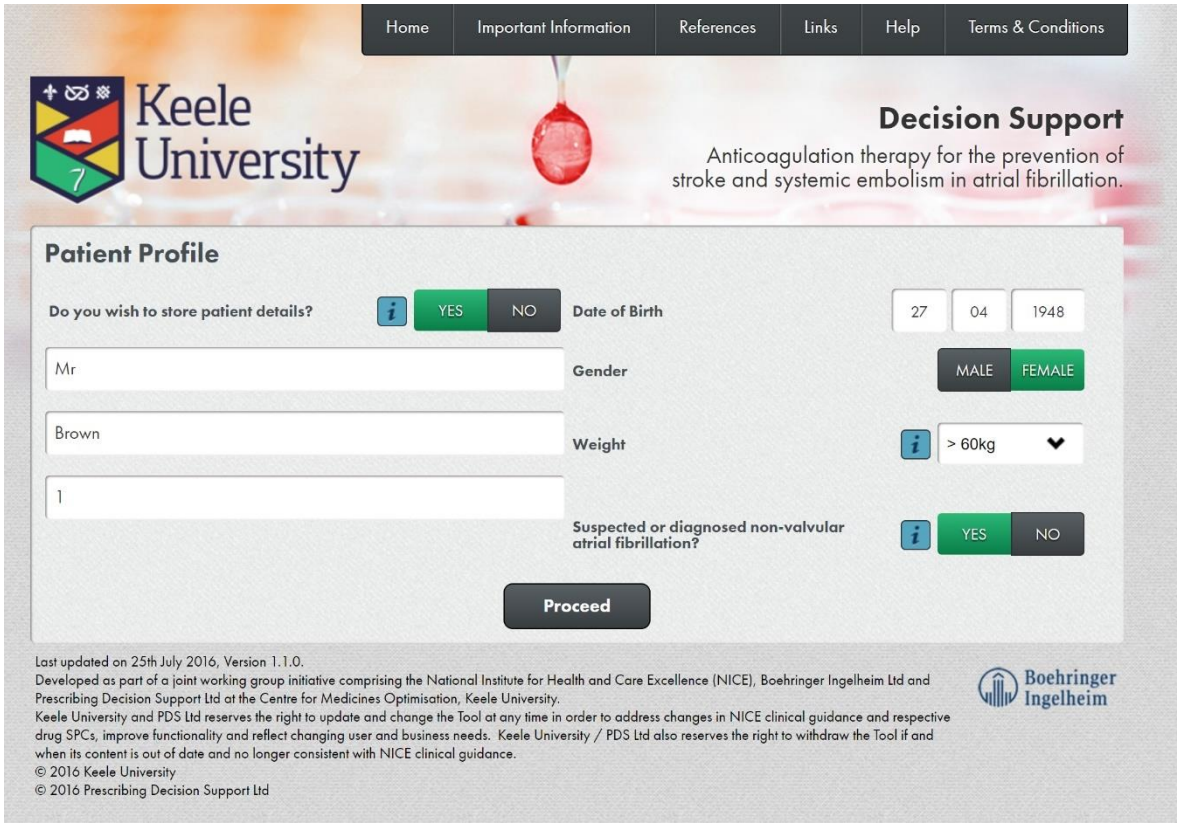
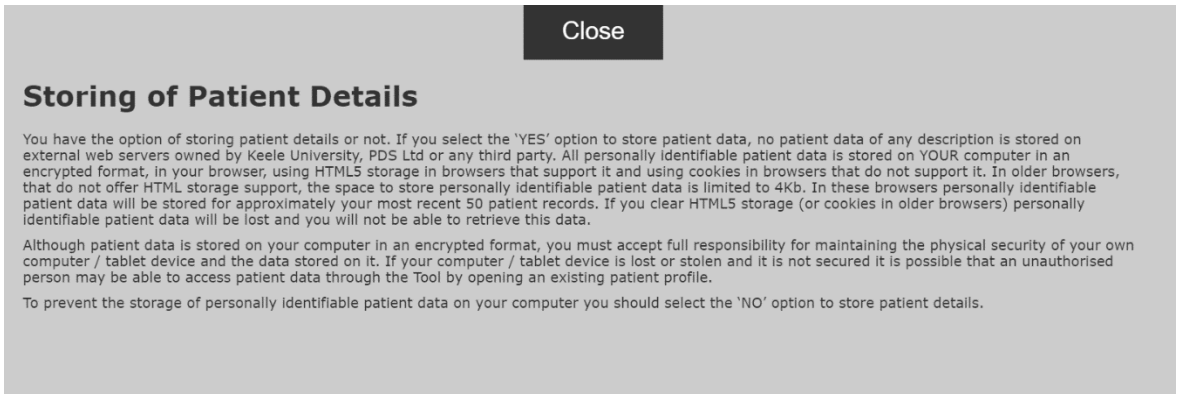
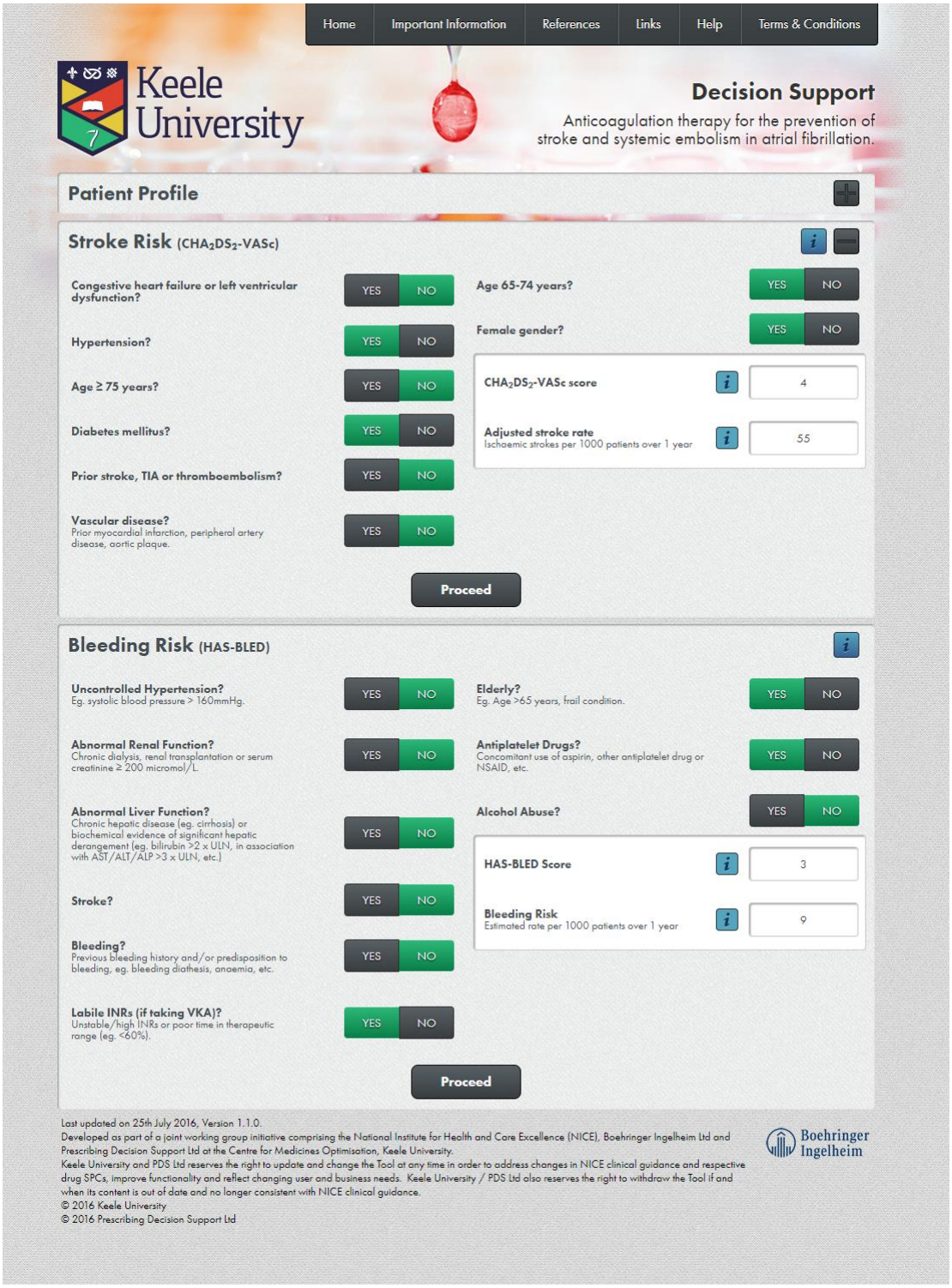


Figure 1. 9: Storing of Patient Details 'i' button



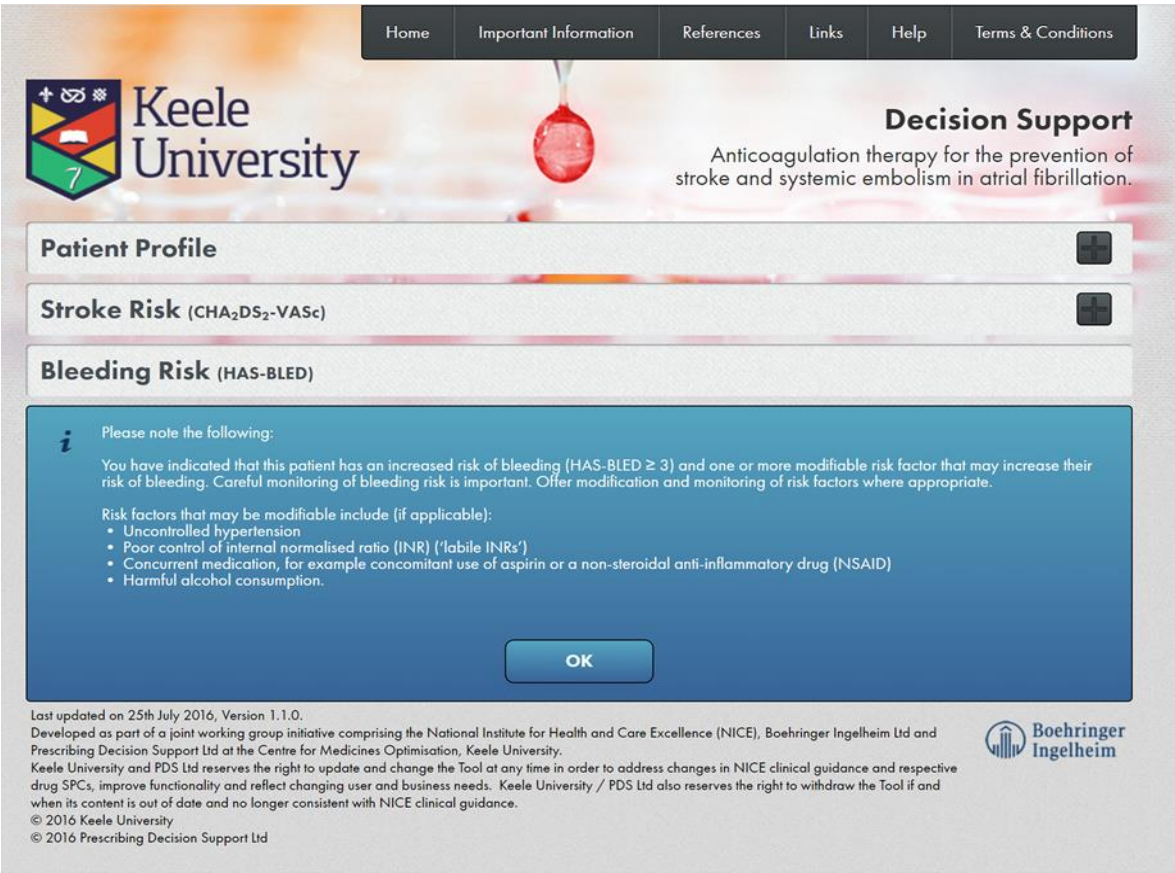
As shown in figure 1.10, the DST allows assessment of patient's stroke and bleeding risk using the updated version of the risk assessment scores. It takes the HCP to tick the boxes to find out patients' stroke and bleeding risk scores.

Figure 1. 10: Assessment of patients' stroke and bleeding risks



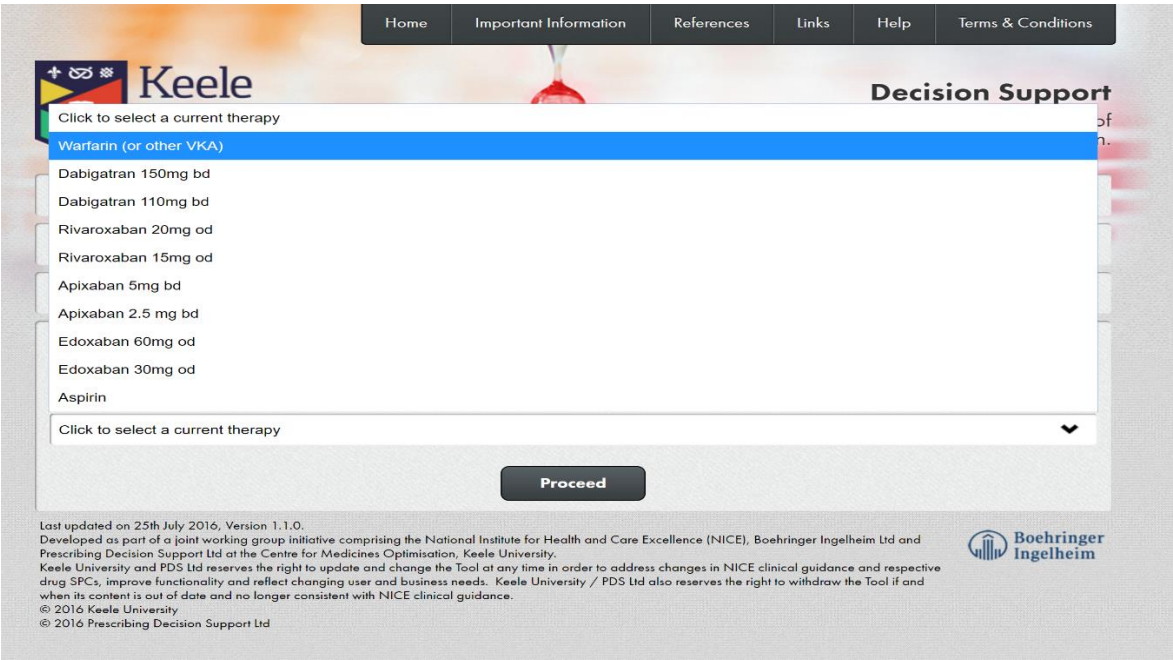
Also, the DST flags up alert box to show the user an important message, as shown in figure 1.11.

Figure 1. 11: Example of alert box



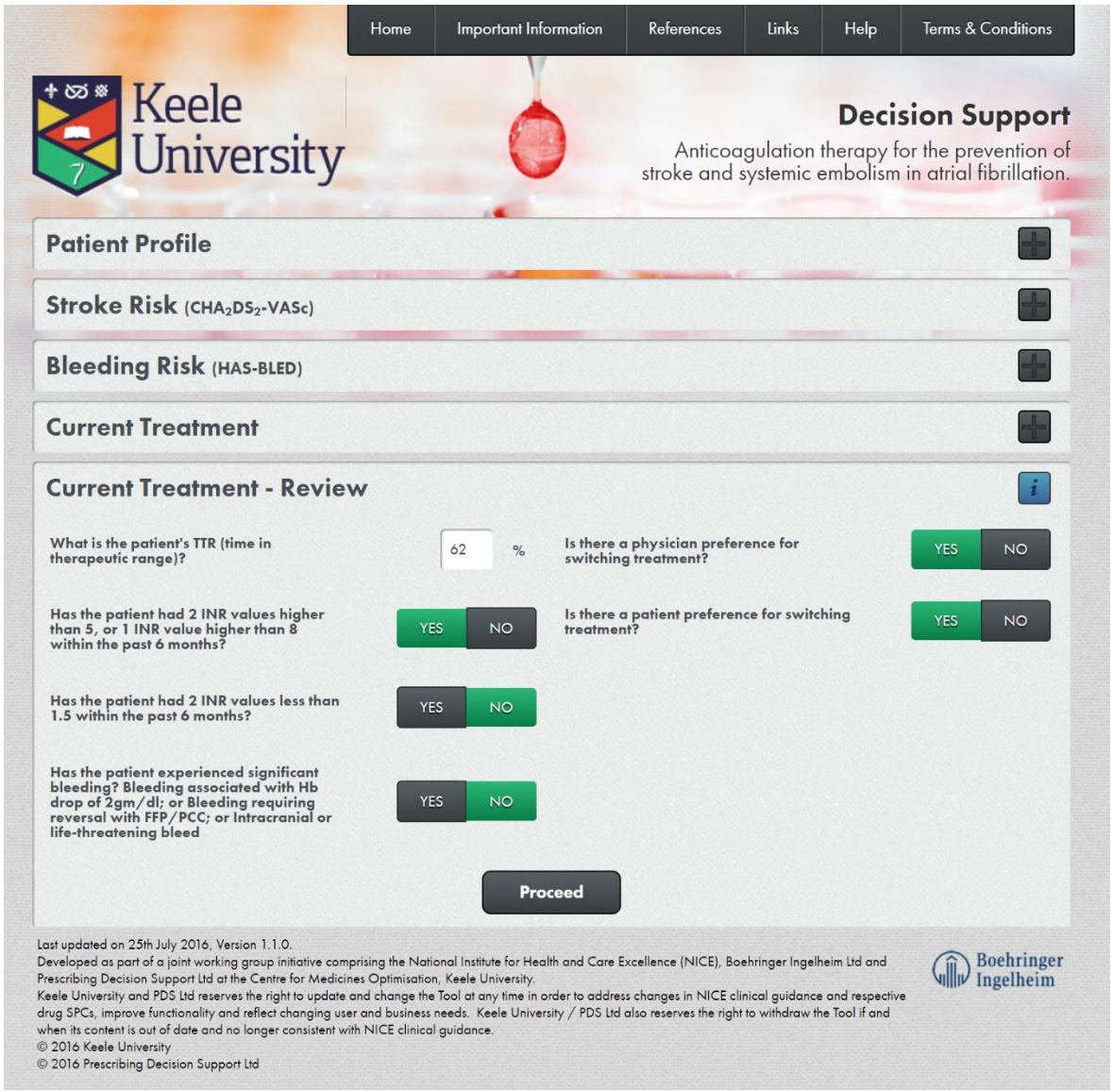
The next screen shows the options of anticoagulants treatment (figure 1.12).

Figure 1. 12: Current Treatment screen



As the patient was using warfarin next screen involved assessment of warfarin treatment as shown in figure 1.13.

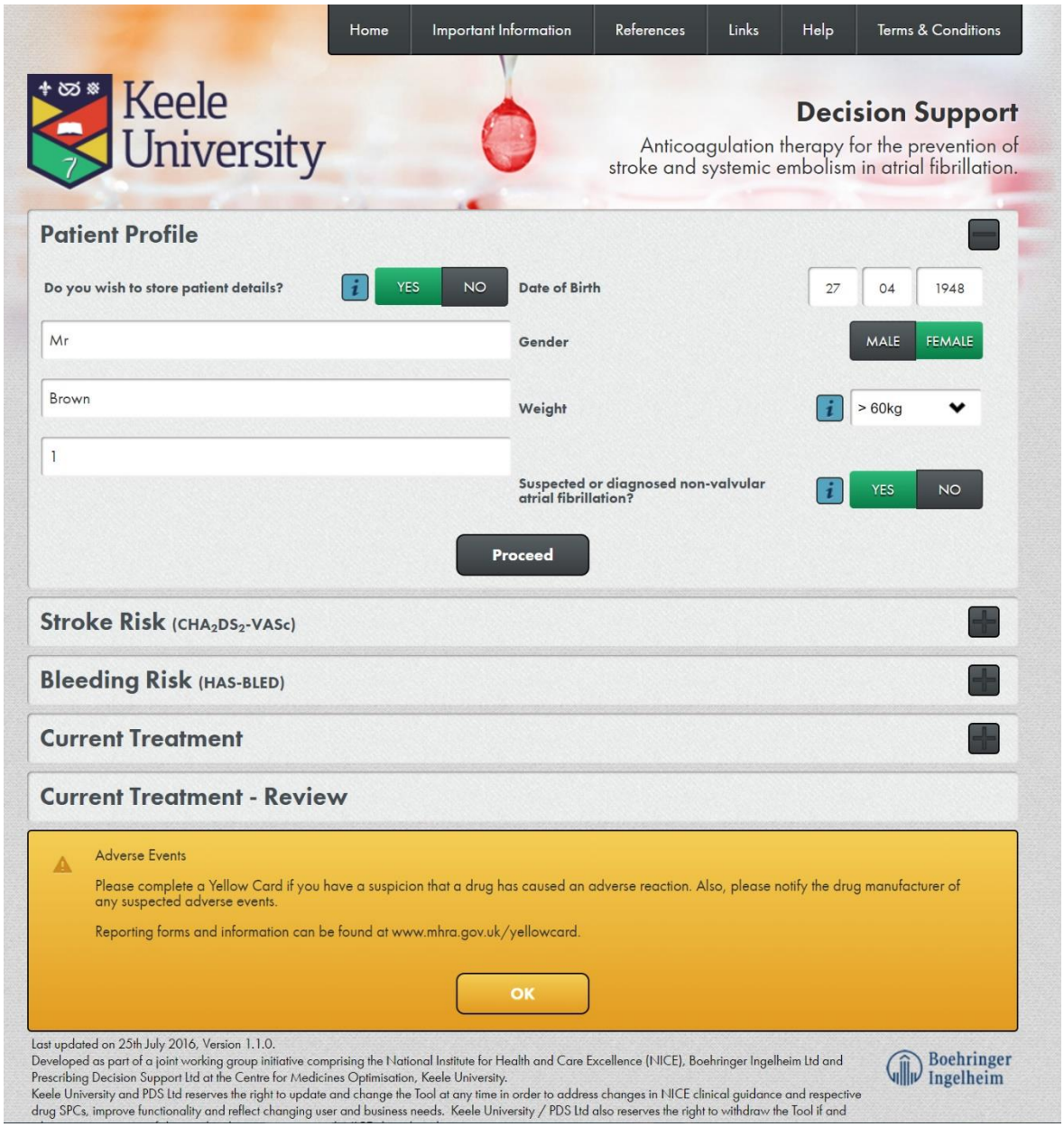
Figure 1. 13: Current Treatment-Review screen



If for example Mrs Brown was not on warfarin, the next screen (Contraindications) would be displayed.

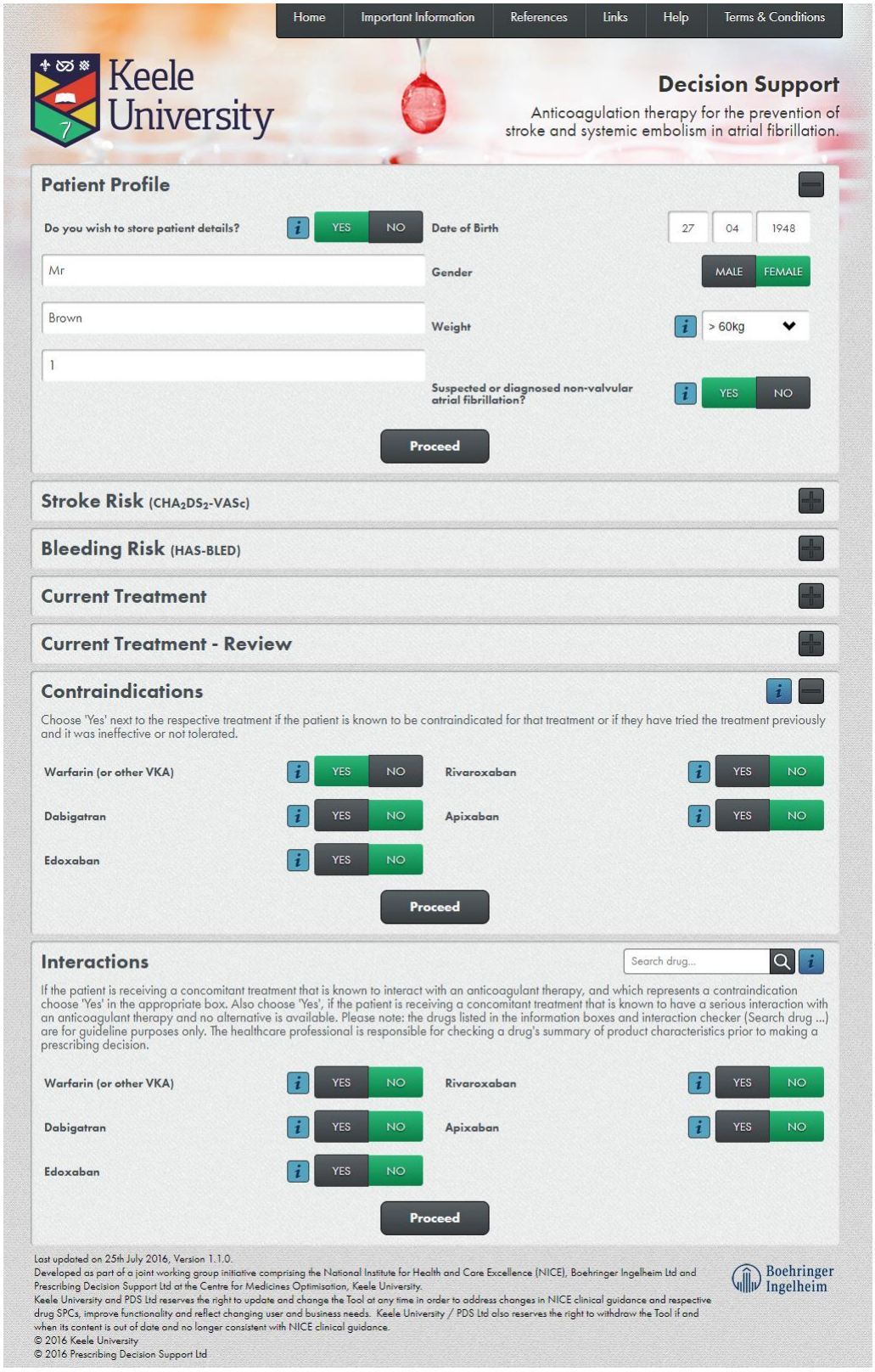
In this example the selection of anticoagulant treatment has automatically generated an alert message to remind the HCP to complete the yellow card if there was a suspicion that a drug has caused an adverse reaction, as shown in figure 1.14.

Figure 1. 14: Yellow Card alert message



The next screen shows the options of anticoagulants treatment (Figure 1.15). This screen allows HCP to choose 'Yes' next to the respective treatment if the patient is known to be contraindicated for that treatment or if they have tried the treatment previously and it was ineffective or not tolerated.

Figure 1. 15: Contraindications and Interactions screens



The contraindications screen enables the HCP to choose ‘yes’ if the patient is receiving a concomitant treatment that is known to interact with an anticoagulant therapy, and which represents a contraindication or if the patient is receiving a concomitant treatment that is known to have a serious interaction with an anticoagulant therapy and no alternative is available. The HCP can use the drugs listed in the information boxes and interaction checker (Figures 1.15 and 1.16) for checking a drug-drug interaction prior to making a prescribing decision. Also, from the special considerations screen, the HCPs can decide whether the patient cannot be recommended certain anticoagulants (due to a contraindication) or it may affect the recommended dose of an oral anticoagulant (Figure 1.17).

Figure 1. 16: Drugs' interaction checker

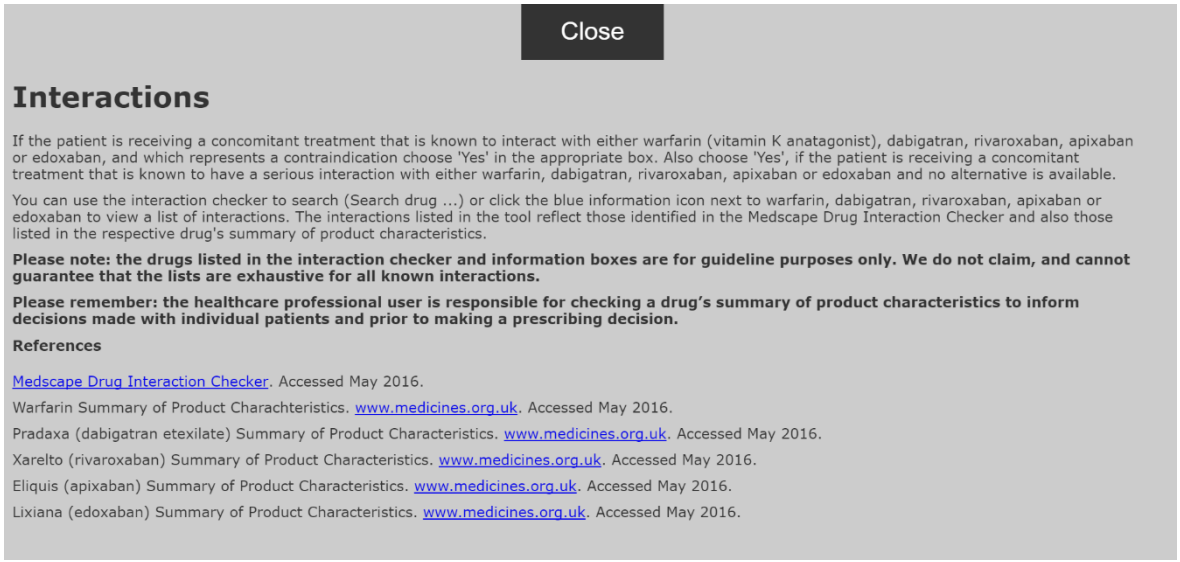
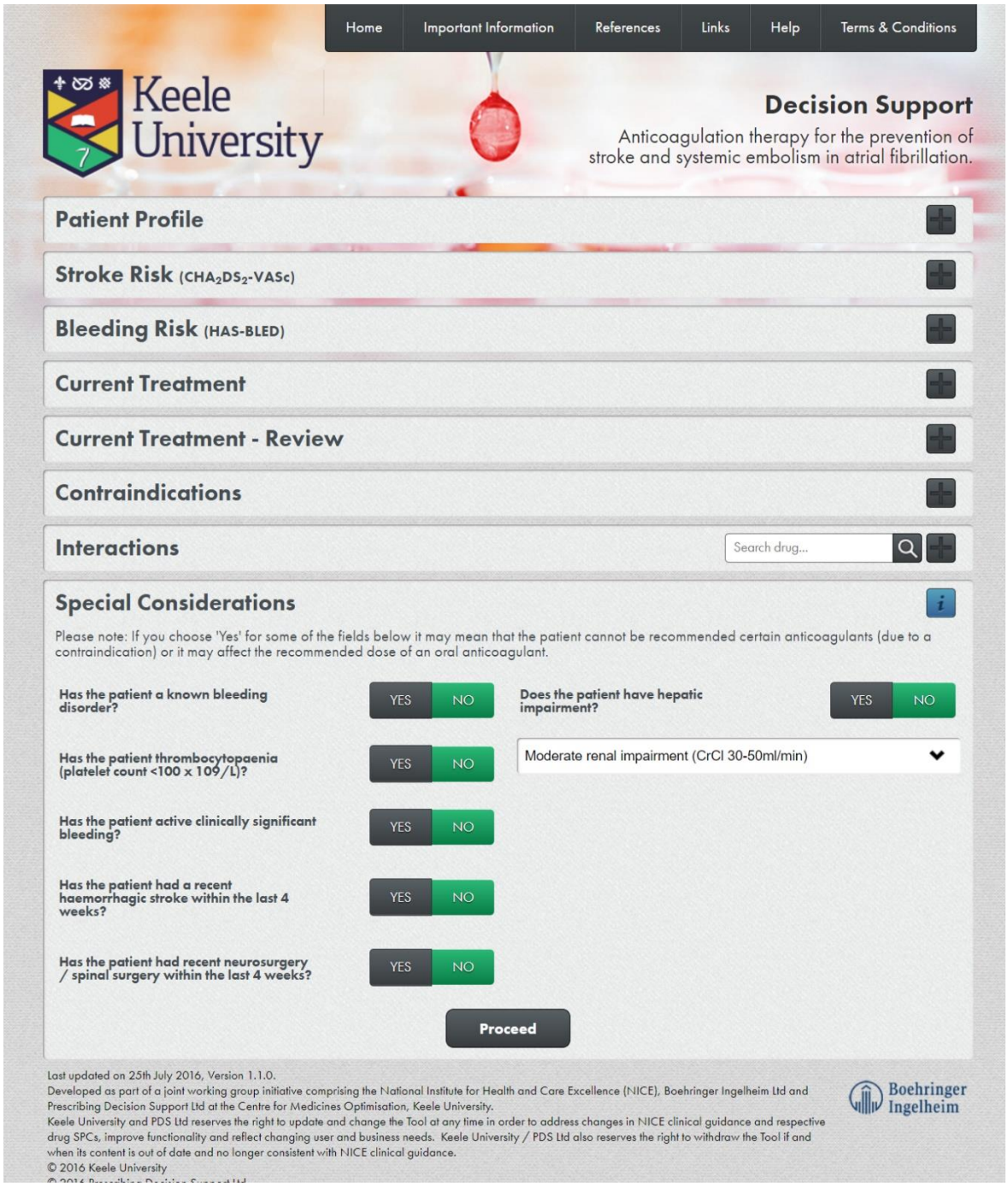


Figure 1. 17: Special Consideration screen

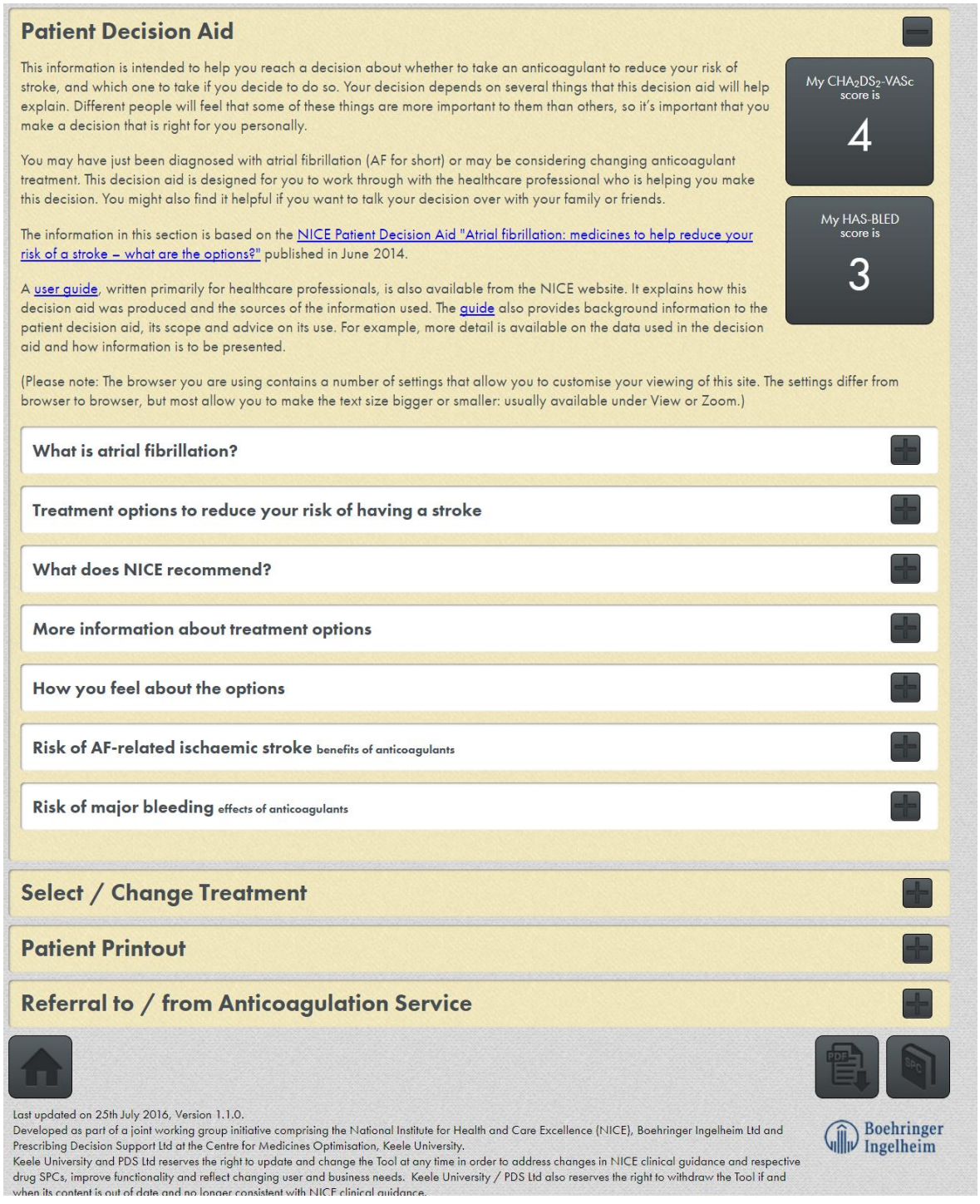


Treatment recommendation screen provides individualised prescribing recommendations based on the NICE clinical guidelines (CG 180). Each recommendation is supported by reason, important management considerations, treatment side-effects, and is referenced (Figure 1.18).

Figure 1. 18: treatment Recommendation screen

The second part of the DST incorporates NICE's PDA; this provides a practical basis for patients to participate in an informed discussion with a HCP about their treatment choices in atrial fibrillation, taking into account the options available, patients' individual needs and preferences and potential benefits and risks (Figures 1.19, 1.20, 1.21, 1.22, 1.23).

Figure 1. 19: The Patient Decision Aid



The DA considers the questions people with AF most often want to think about and discuss with their HCP when deciding on which option to choose (not taking anything, taking warfarin or taking a NOAC) (Figure 1.20). Then the HCP can further discuss patient's values and preferences (Figure 1.21) to help the patient to make a decision that is right for him/her personally. The graphics in figures 1.22 and 1.23 are different ways of showing the risk of AF-related ischaemic stroke and risk of major bleeding over 1 year. The ability to switch between "No Treatment" and "Anticoagulant" helps to explain the benefits and effects of anticoagulants; and switch between the 'faces' or bar charts to see the risk in different formats.

Within the DA is a patient printout screen which provides a printout material for patients including the graphics presented in figures 1.22 and 1.23, and information leaflets about AF and treatment.

Figure 1. 20: Information about treatment options screen

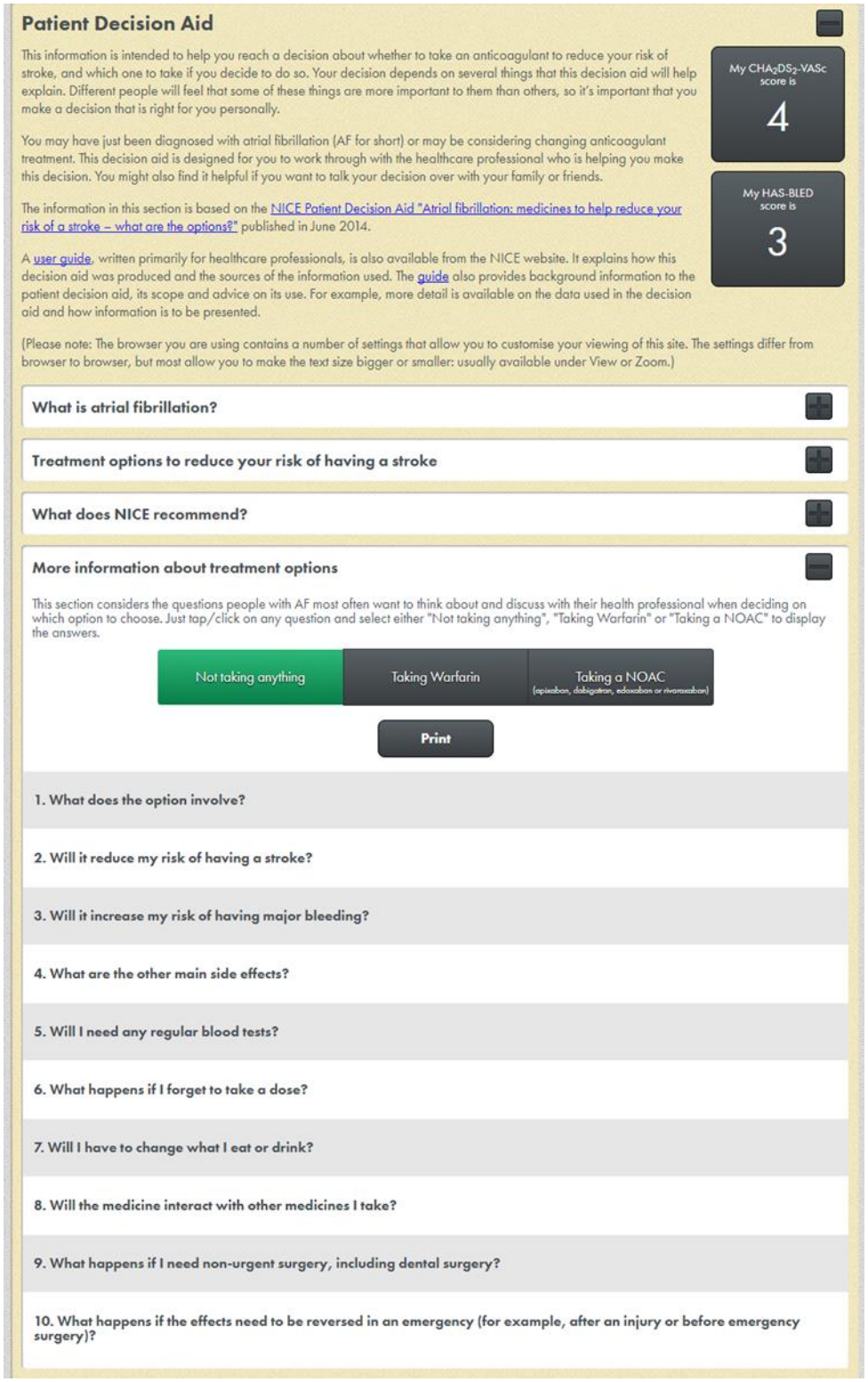


Figure 1. 21: Values and Preferences screen

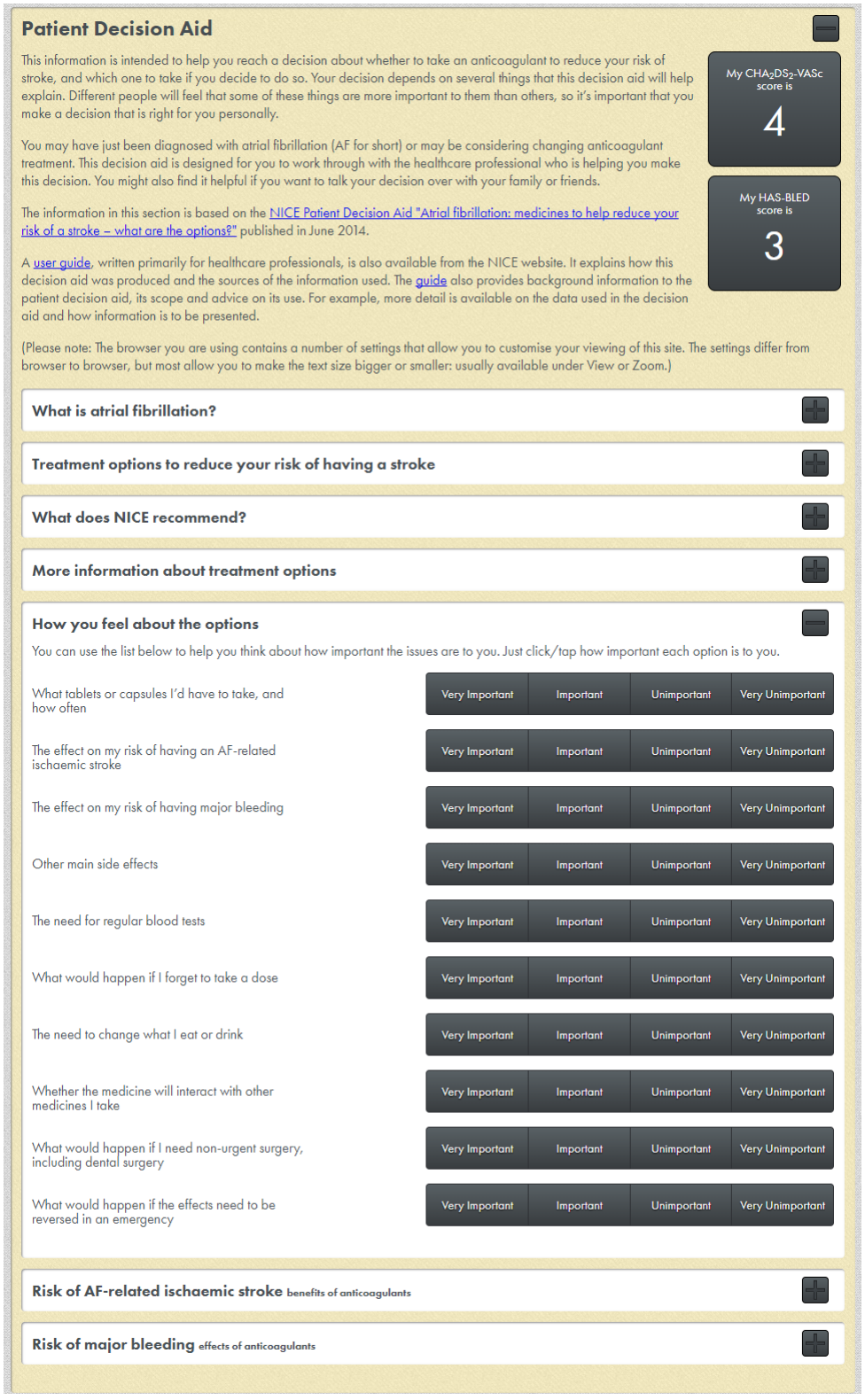


Figure 1. 22: Benefits of anticoagulants graphics

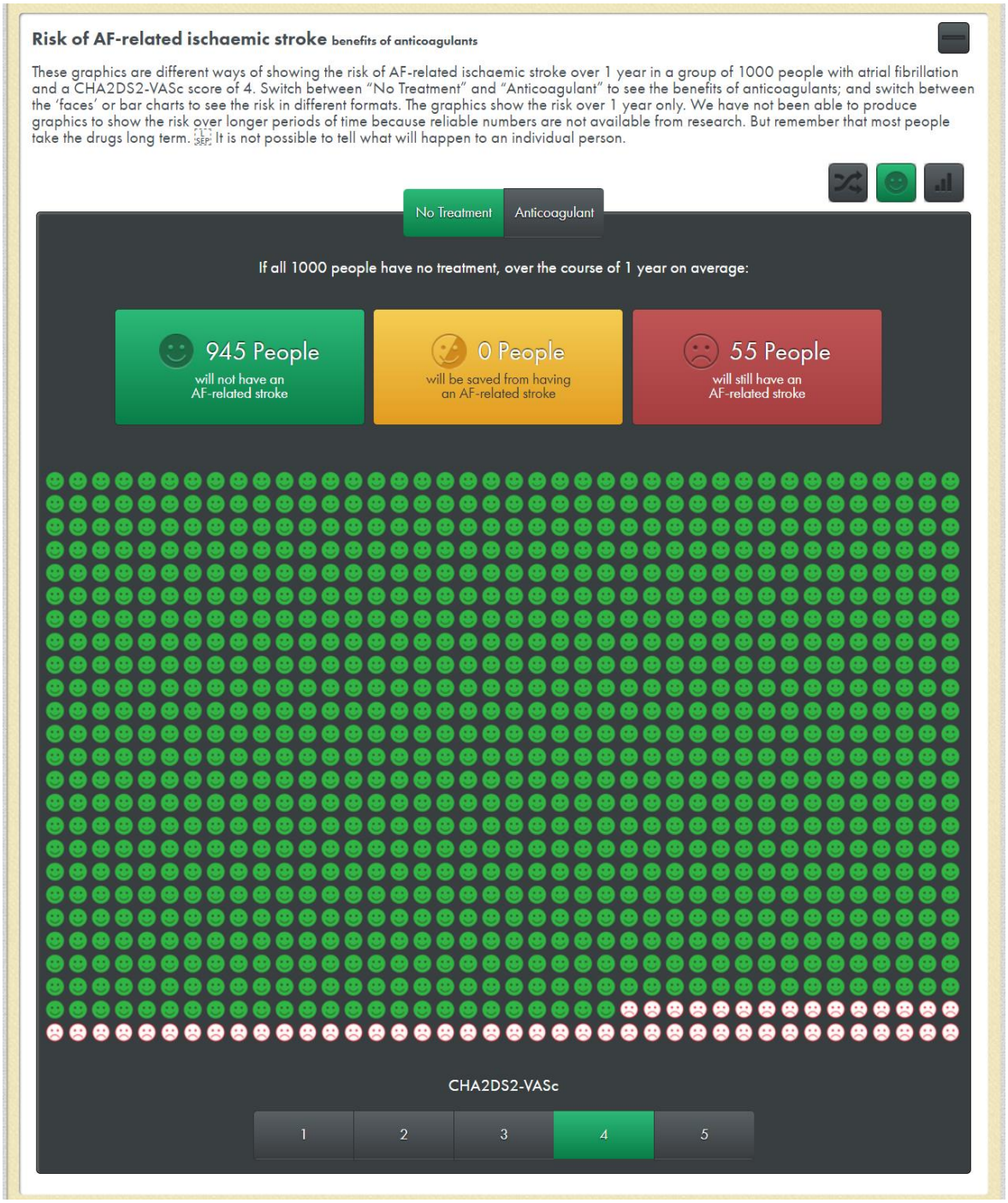


Figure 1. 23: Effects of anticoagulants graphics

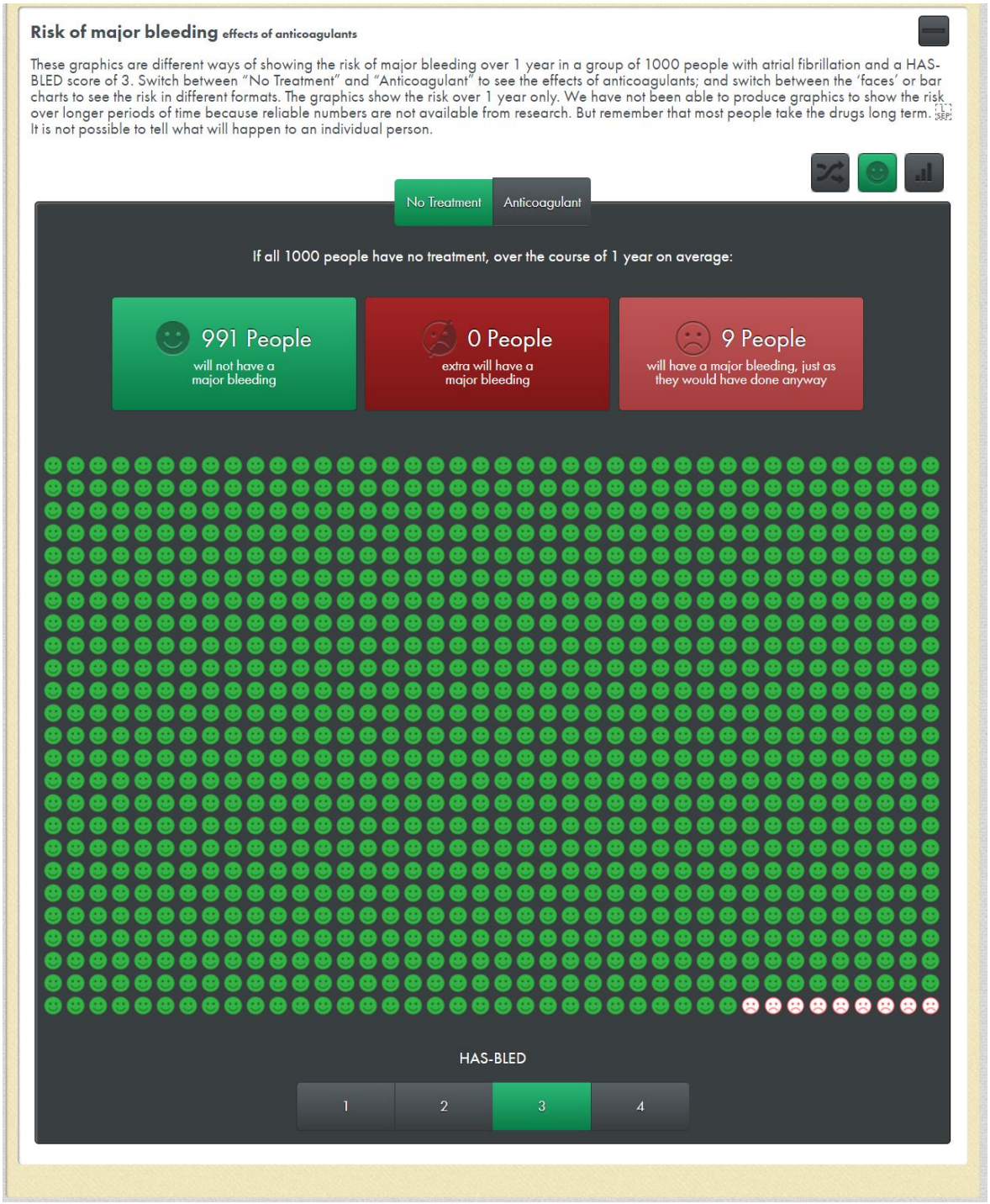
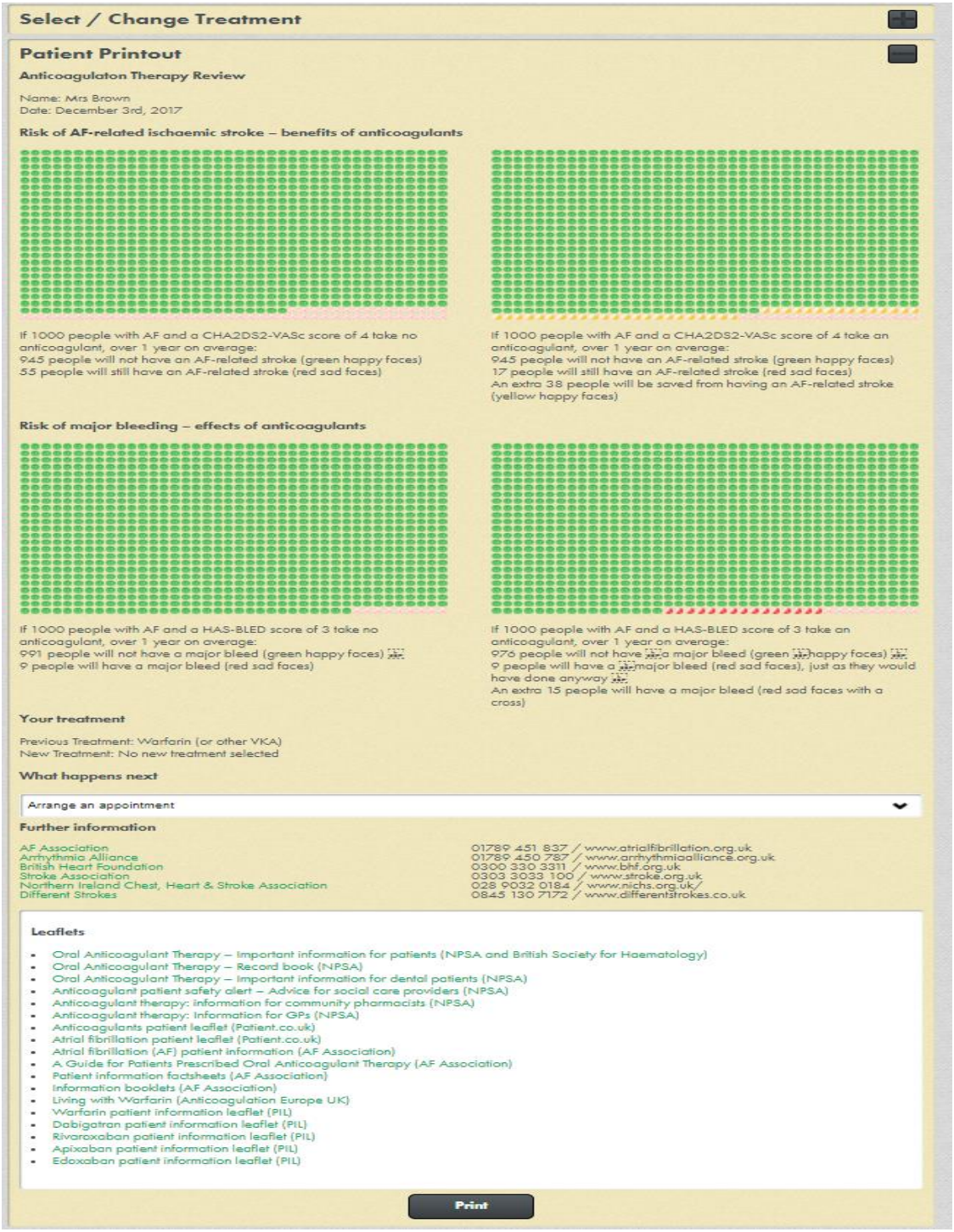
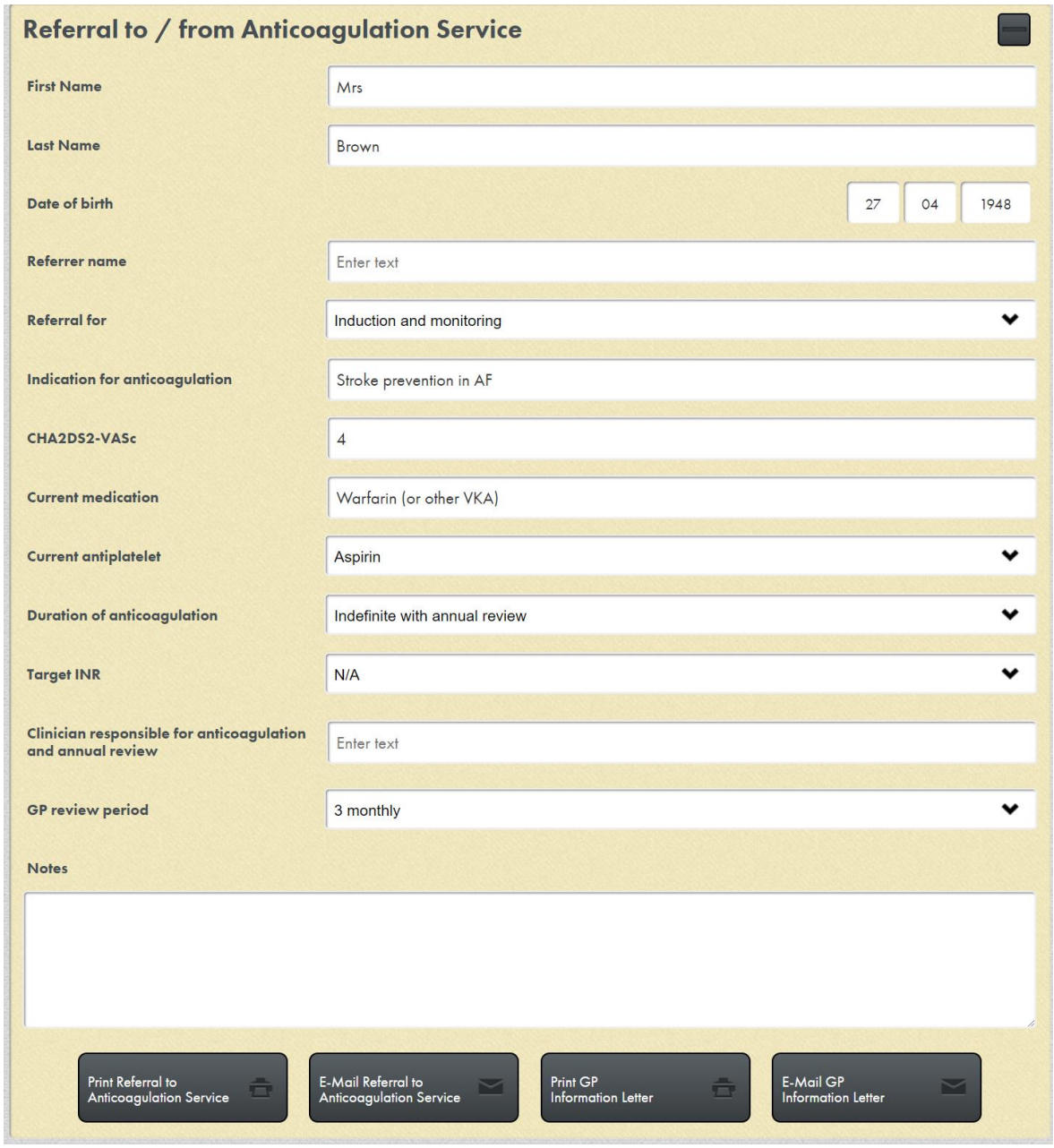


Figure 1. 24: Patient Printout screen



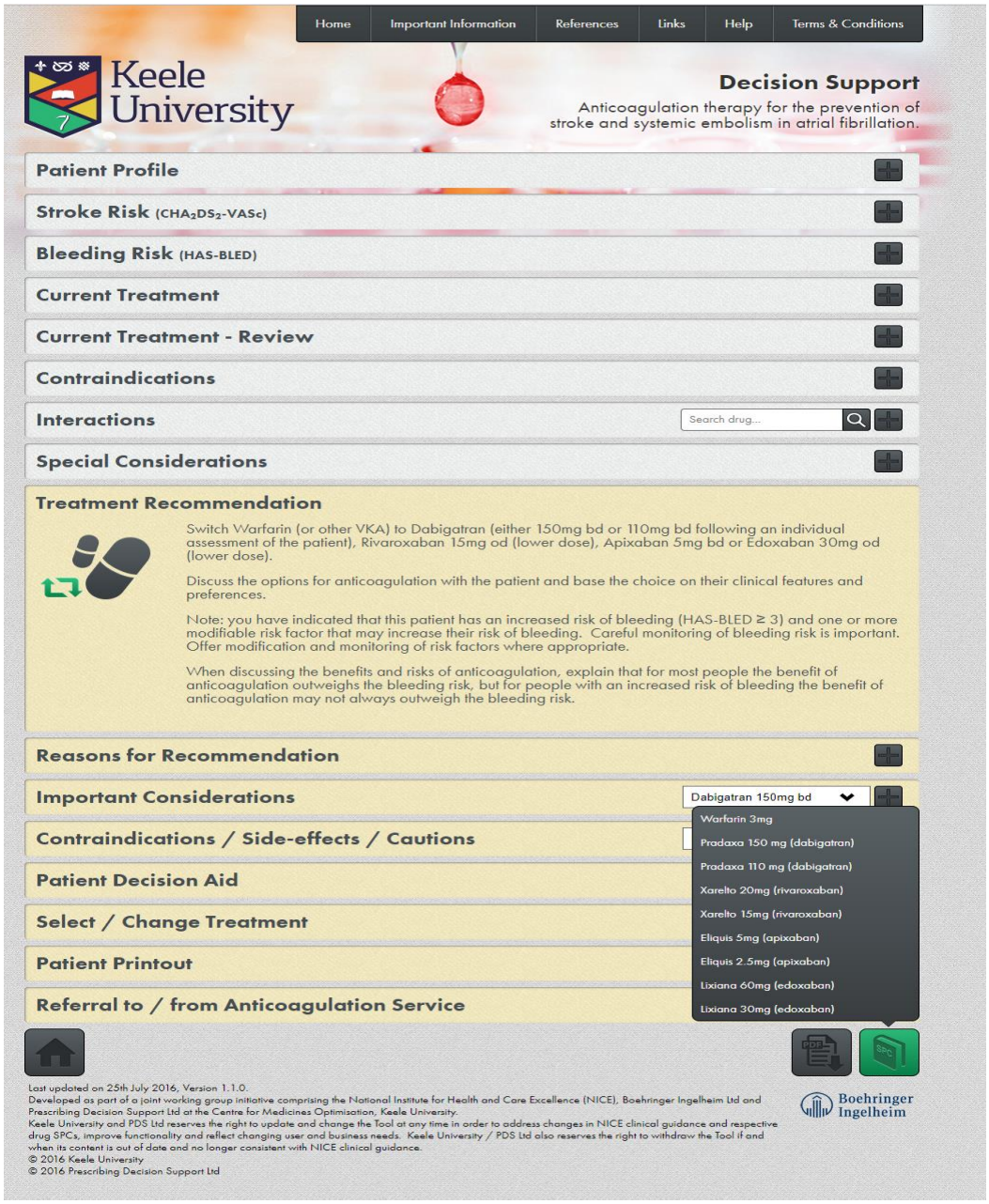
Referral screen is the final screen in the DST (Figure 1.25). This screen facilitates the referral process of patients between the primary and secondary settings by offering the HCP the option to contact the anticoagulation service or GP.

Figure 1. 25: Referral screen



The PDF icons on the right-hand side at the bottom of the screen offers the ability to print out the whole screens as a PDF document and attach it to patient medical record. The SPC icon (Summary of Product Characteristics) enables the HCP to access the SPC for all available anticoagulant options (Figure 1.26).

Figure 1. 26: the SPC and PDF icons



1.4 Background to the research

This thesis presents a description of a mixed method study that utilized a sequential exploratory design. In its broadest terms the study set out to investigate the assumption that a computerised decision support tool and associated patient decision aid support anticoagulation decision-making in patients with AF. The Keele Anticoagulation Therapy Decision Support Tool was developed by a collaborative effort to assist HCPs in the appropriate prescribing of anticoagulation therapy for the prevention of stroke in patients with AF. It was launched in November 2015. The basis for the development of the DST and associated PDA was to:

- Provide computer decision-support for anticoagulation decision-making in clinical practice
- Improve the quality of anticoagulants decision-making made by all grades of HCPs in clinical practice
- Encourage patients' involvement in the treatment decision in a shared decision-making consultation

The research described within this thesis evaluates these aspects.

1.4.1 The research questions

In what way does the use of the DST influence anticoagulants prescribing?

How the DST can achieve its effects and what content and design criteria are important to the intervention?

How can the DA stimulate patients to take a more active role in decision making?

1.4.2 Research aim

The aim of this study was to evaluate the utility of the DST and associated PDA in anticoagulation decision making and decision quality.

1.4.3 Research objectives

The study objectives were to:

- Identify the suboptimal determinants in anticoagulation therapy decision making process and explore the evidence that the intervention (the DST in our case) might have the desired effect through exploratory design
- Assess the components of the DST to improve understanding of how the intervention works
- Explore HCPs' perspectives post implementation process in clinical practice and to identify potential and actual barriers to its implementation
- Assess patients' perspectives of the usefulness of the DA in decision making process and quality of the decision made

1.5 Introduction to the study and organisation of the thesis

This study originated from a research interest in evaluating a computerised decision support tool for anticoagulation management in AF from HCPs' and patients' perspectives (as discussed in section 4.5.1). Gaps in the existing research on evaluative studies of decision support systems (DSSs) for anticoagulation management (discussed in chapter two) supported a need for this. A feasibility pilot study conducted on a small scale is presented in chapter three. A mixed-method approach to the study was taken. The rationale for this, methodological considerations, the specific aims of the study and the methods

used are discussed in chapter four. The initial stage of the study involved a series of semi-structured interviews with a sample of HCPs who are involved in anticoagulation management. The analysis of the findings and how these relate to the literature is discussed in chapter five. These findings revealed the suboptimal determinants in anticoagulation therapy decision making in clinical practice. The second set of interviews with the HCPs was conducted after introducing the DST to explore their initial perspectives of the potential utility of the DST in anticoagulants prescribing decision. The analysis of the findings and how these relate to the literature is discussed in chapter six. The third stage of the study concerned HCPs who implemented the DST into their routine practice and their perspectives on its impact on the decision-making process and decision quality. This stage was undertaken for comparison with their perspective from stage two, as discussed in section 4.5.1. The analysis of the findings and how these relate to the literature is discussed in chapter seven. The fourth stage of the study concerned patients who experienced the DST and associated patient decision aid (PDA) in consultation and their perspectives on improving decision making process and decision quality. This stage was undertaken for comparison with HCPs' perspectives, as discussed in section 4.5.1. The analysis of the findings and how these relate to the literature from this stage of the study is discussed in chapter eight. In chapter nine an overview of the research findings and the significance of these findings is discussed, together with the research strengths, limitations, and reflexive issues.

Chapter 2: Impact of decision support systems on anticoagulation management: A review of the literature

In this chapter, a review of the literature on the impact of decision support systems (DSSs) on anticoagulation management is presented, which begins in section 2.1 with the definitions of the DSSs followed by an overview of DSSs impact on medication management, care process and patient health outcomes. This leads into a discussion of barriers and facilitators associated with DSSs implementation in clinical practice as presented in section 2.2. A discussion of the approach taken toward searching and reviewing the literature is presented in sections 2.3 and 2.4. The findings are broadly divided into two main topics: rationale for undertaking decision support system research and impact of patient decision aids (PDAs) on anticoagulation management.

Gaps in the literature that are relevant to this study are highlighted in summary in the final section of the chapter.

2.1 Definition of decision support systems

Sim et al. (2001) defined DSSs as ‘a software that designed to be a direct aid to clinical decision-making, in which the characteristics of an individual patient are matched to a computerised clinical knowledge base, and patient-specific assessments or recommendations are then presented to the clinician or the patient for a decision’ (P. 4). This definition includes any computer-based decision support system that uses case-based

reasoning and clinical data to; interpret tests, suggest a diagnosis, provide alerts and reminders, present evidence-based recommendations, and propose a set of actions (Berner and La Lande, 2007; Musen et al., 2001).

Computerised decision support system (CDSS) architecture consists of three key components: (1) the system knowledge base; that contains the medical facts or rules in computer-readable format, (2) the inference engine; that represents the algorithms used to generate patient-specific advice, (3) and the user interface; that the users interact with, in order to enter information and view the system's recommendations (Berner and La Lande, 2007; Spooner, 2007). Despite the seeming simplicity of its component, CDSSs are complex technologies that vary widely in design, function, and use (Berlin et al., 2006). Previous reviews (Berlin et al., 2006; Garg et al., 2005; Kawamoto et al., 2005) described the broad range of the CDSS features and the clinical scenarios in which they are used for. Berlin et al., (2006) reported 74 different CDSSs that varied considerably in context of use, knowledge-base or data sources, nature of decision support offered, information delivery, and impact on workflow.

2.1.1 Types of Decision Support systems

A clinical decision-support system is a computerized program that uses case-based reasoning and clinical data or knowledge to help healthcare professionals in making a clinical diagnosis, selecting proper therapy, or supporting other healthcare decisions (Berner and La Lande, 2007; Musen et al., 2001). A wide variety of systems that can potentially support clinical decisions ranging from computerised to non-computerised CDSS as well as from basic to advanced systems (Kuperman et al., 2007; Musen et al., 2001). Basic CDSS supports medications interaction, duplication, allergies, and provides population-based dosing, while advanced CDSS supports individualised dosing and

provides evidence-based personalised guidance and recommendations (Kuperman et al., 2007). Systems can be tools for: health information management; supporting clinical workflow and disease management; alerting systems, or suggestion systems (Hug et al., 2007).

2.1.1.1 Tools for health information management

Health care information management includes the collection, storage, integration, retrieval, analysis, and dissemination of clinical and administrative data necessary to assist in everyday clinical workflow (Haug et al., 2007; Vogel, 2014). Information management is important, time consuming, and costly aspect for healthcare providers and healthcare organisations (Musen et al., 2014; Vogel, 2014).

Health-care information system (HCIS) is a comprehensive electronic patient information system designed to make clinical information, administrative data, and patient records available when and where needed (Haug et al., 2007; Musen et al., 2014; McDonald et al., 2014; Yasnoff, 2014). The purpose of HCIS is to support access, use, and management of patient records that healthcare providers need to complete any healthcare decisions effectively (McDonald et al., 2014; Yasnoff, 2014). HCIS facilitates communication among multiple healthcare providers. Furthermore, it assists in the organisation, storage, management, integration of large amount of clinical, administrative, and financial data collected by different users from different healthcare settings (McDonald et al., 2014; Vogel, 2014; Yasnoff, 2014). The Health Evaluation through Logical Processes (HELP) system is an important exemplar of healthcare information management system (Haug et al., 2007; Musen et al., 2014). It is a clinical information system includes a computer-based patient record, alerts, reminders, and other decision support subsystems developed at LDS Hospital in Salt Lake City (Musen et al., 2014). The HELP system logics used rule-based

approaches as a means of setting rules that relate specific patient information to appropriate actions for practitioners to follow (Haug et al., 2007; Vogel, 2014). HELP system demonstrated the feasibility of encoding and processing medical knowledge and patient information by computers (Vogel, 2014) and has led to the successful development, implementation, and testing of expert decision support systems, to name few; diagnostic decision support systems and computerized laboratory alerting systems (Haug et al., 2007).

2.1.1.2 Tools supporting clinical workflow and disease management

The Electronic Health Record (EHR) was developed as a response to the growing volume and complexity of both patients' clinical data and the medical information needed to assimilate and manage this data (Haug et al, 2007). EHR allows an easy access to individual patient's data, for example, demographics, medical history, medication, and laboratory test results. It addressed many of data entry and workflow-related challenges and has shifted the focus from data entry to data access and user interaction (Haug et al, 2007). The use of EHR has much supported the growing use of CDSS (McKibbon et al., 2011).

Increasing ease of access to computers and the growing dependency on computers to keep some of the medical workflow contributed significantly to the widespread availability of CDSSs to medical practitioners (Berlin et al., 2006; Berner and La Lande, 2007; Haug et al., 2007; Sim et al., 2001). A variety of programs to assist with drug dosing, clinical diagnosis, reminders, and other relevant health decisions have been developed to maintain part or all of the clinical workflow (Berlin et al., 2006; Haug et al., 2007). Several studies have demonstrated that CDSSs are able to influence HCPs performance, patients' management, and health care outcomes in many clinical areas (Balas and Boren, 2007; McKibbon et al., 2011).

Musen et al. (2014) categorised CDSS into two categories based on the function provided by the system into diagnostic decision support systems and those that are designed to assist with disease managements and patient consultation.

Diagnostic decision support system

Diagnostic decision support system (DDSS) is "a computer-based algorithm that assists a clinician with one or more component steps of the diagnostic process" (Miller and Geissbuhler, 2007, p 101). DDSSs are tools to enhance and support, rather than replace practitioner's diagnostic capabilities (Miller, 1994). The author of 1994 assumed that the user passively interacts with the system and carefully chosen patient information to assist with the problems encountered in the diagnostic process (Miller, 1994). There are systems for general diagnosis, and systems for diagnosis in specialized clinical domains such as interpretation of electrocardiogram (ECG) tracings (Willems et al., 1994). HEME program for diagnosis of haematological disorders was one of the earliest simple DDSS used to assist the interpretation of blood gas results (Miller, 1994; Miller and Geissbuhler, 2007). MYCIN (Shortliffe, 1976) and Leeds Abdominal Pain System (de Dombal et al., 1972) are well-known exemplar of early computer-based diagnostic systems which were designed in an attempt to discriminate among a group of important diagnostic things using selected medical data (Miller and Geissbuhler, 2007).

Alerting systems

Alerting systems are CDSS designed to test and monitor specific patient medical information against predefined criteria (Bradshaw et al., 1989; Haug et al., 2007). If the

data meet the criteria, the system then alerts the healthcare provider (Bradshaw et al., 1989; Haug et al., 2007). Computerised alerting systems are usually integrated within EHR and monitor laboratory results and detect and alert for abnormalities in the data acquired (Bradshaw et al., 1989; Haug et al., 2007). Bradshaw and colleagues have developed the first computerized laboratory alerting system as a typical example to monitor and alert for the presence of life-threatening conditions for hospitalized patients (Bradshaw et al., 1989). The system was evaluated in practice and has been improved to increase its effectiveness in communicating alerts to healthcare providers (Bradshaw et al., 1989). In 1991, Rind and colleagues presented another computerized laboratory alerting system about rising serum creatinine values in patients receiving potentially nephrotoxic medications or renal excreted therapy. The application was evaluated for its capacity to affect physician behaviour and the clinical workflow to contribute to safe patient care (Rind et al., 1991)

Computerized detection and alert system to detect adverse drug events is another alerting application designed to improve quality of patient care (Classen et al., 2005; Evans et al., 1991; Haug et al., 2007). This type of decision support intervention has become a standard part of computerised pharmacy systems (Classen et al., 2005; Evans et al., 1991). This adverse drug event (ADE) system continuously monitors patient medical profile for ADE occurrences (Classen et al., 2005; Evans et al., 1991). The system is integrated within the inpatient pharmacy dispensing systems and it checks ordered medications with other patient medications, laboratory results, and patient vital signs and other symptoms entered at the bedside for analysis to determine possible ADEs (Classen et al., 2005; Evans et al., 1991). The information captured with the system is used to alert the healthcare provider or pharmacist, who can then change therapy based on the alert massage (Classen et al., 2005; Evans et al., 1991). Findings from Classen et al., (2005) and Evans et al., in (1991) demonstrated the potential value of computer monitors especially when embedded to

health information systems. Several studies demonstrated the effectiveness of using computerised alerting systems to detect ADEs and have significantly affected research in this arena (Bowman et al., 1994; Jha et al., 1998; Raschke et al., 1998). A recent alerting application designed to work in the anticoagulation clinic (Rocha et al., 2007). The aim is to maintain each patient's INR within a specified therapeutic range. The computerised alerting application uses a rule-based system that alerts healthcare provider for dangerously altered INRs score so that immediate action can be taken (Rocha et al., 2007).

Suggestion systems

Suggestion system is another category of CDSS (Hug et al., 2007). This type of computer-based support systems passively responds to physician input or patient-specific information when advice needed (Hug et al., 2007; Musen et al., 2014).

Healthcare providers typically activate the system, respond to screens requests by filling patient specific information, and wait for suggestions from the system. Following the interactive communication with the system, it then frames recommendations using its knowledge base (Hug et al., 2007). The value of CDSS lies in the development of well-designed system to assist in the process of decision-making tasks (Hug et al., 2007; Musen et al., 2014). A number of computer-based decision support systems for providing patient-specific recommendations have been integrated into patient care workflow offer opportunities to reduce medical errors, improve patient safety, enhance drug selection and dosing, as well as, improve preventive care (Hug et al., 2007; Jimison et al., 2007; Musen et al., 2014).

Patient decision aids

Computer-based decision support system for patient is a new movement in the field of decision support interventions (Gillispie and Ellis, 1993; Jimison et al., 2007; Skinner et al., 1993). The number and diversity of products to support patients' health information needs is expanding rapidly to provide less expensive and easy accessible supports (Jimison et al., 2007). Unlike books, audiotapes, searchable health information databases, and health web sites which are generic and not tailored to patient specific needs, computerised-based approaches showed to provide information tailored to individual patient's need (Consoli et al., 1995; Jimison et al., 2007) and have further advantages of interactivity, and effectiveness (Consoli et al., 1995; Gillispie and Ellis, 1993; Skinner et al., 1993) to assist patients in health assessment, disease management, and medication knowledge in preparation for shared decision making (Consoli et al., 1995; Jimison et al., 2007). The knowledge provided by decision aids ranges from general healthcare information to, information about medications, and disease management (Brody et al., 1989; Greenfield et al., 1985). Several studies have shown that patient access to health information can empower patients to take a more active role in their own health care decisions and to provide the necessary knowledge to enhance their decision making leading to better healthcare process and outcomes (Brody et al., 1989; Consoli et al., 1995; Gillispie and Ellis, 1993; Greenfield et al., 1985; Jimison et al., 2007; Skinner et al., 1993).

2.1.2 Decision support systems: a look in the past

Decision support systems (DSSs) were the result of a number of factors, which are: emerging computer technologies; growing awareness of the importance to support decision making process; and a desire for better information (Sprague, 1993). DSSs have been applied to many different fields, including manufacturing, accounting, human resources,

and marketing (Bidgoli, 1989). In 1994, Finlay underscored crucial and a comprehensive description of DSS. He described DSS as the use of computers to: assist in decision making process; improve the effectiveness of decision making process; and support rather than replace user judgment (Finlay, 1994). The history of DSS can be traced back to the origin of electronic data processing systems and information technology and has been simply defined by most experts as a series of integrated computer software used by managers to improve the effectiveness of decision making with semi-structured and un-structured tasks (Bidgoli, 1989).

Leeds Abdominal Pain System

Leeds University abdominal pain system is an early computer-aided diagnostic system which was developed by de Dombal and colleagues at the University of Leeds to help clinicians towards their own diagnosis of the acute abdominal pain (de Dombal et al., 1972). The system used sensitivity, specificity, disease-prevalence data for various signs and symptoms, and Bayes' theorem test to calculate the probability of seven possible explanations for acute abdominal pain., but the system showed limited success when it was implemented more broadly (de Dombal et al., 1972).

CASNET

CASNET is another successful exemplar of medical expert system based upon causal basis, which was designed to assist in the consultation and diagnosis of glaucoma (Weiss et al., 1978). It has been developed based on causal-associational network (CASNET) models of disease presented in hierarchical organization in three main components: observations of a patient, pathophysiological states, and disease classifications which can then be causally related, forming a network between patient findings and pathophysiologic states for reasoning the diagnosis and treatment of glaucoma (Weiss et al., 1978).

MYCIN

In the early 1970s, Shortliffe applied rule-based expert systems through his development of MYCIN for diagnosis and treatment of severe bacterial infections (Shortliffe, 1976). MYCIN is an example of knowledge-based CDSSs operated using an inference engine, and series of knowledge base of approximately 600 rules (Musen et al., 2001). The system worked in a goal-directed reasoning in an IF – THEN method to search its knowledge base (Musen et al., 2001). Shortliffe's MYCIN program was a brilliant, pioneering effort in this regard (Miller and Geissbuhler, 2007) .The system was evaluated by Yu and colleagues in the late 1970s and it succeed to prove its efficiency to perform at the expert level on challenging cases (Yu et al., 1979).

The initial successes of systems such as MYCIN (Yu et al., 1979), CASNET (Weiss et al., 1978), and the Leeds abdominal pain system (de Dombal et al., 1972) in the early 1970s revealed the feasibility of encoding and processing medical knowledge by computers (Carter, 2007; Musen et al. 2014).

Most early computer-based decision-support tools were rarely used by health practitioners and were viewed with barriers which have limited the ultimate success of CDSS to date (Miller, 1996; Miller and Geissbuhler, 2007; Yu et al., 1979). These include: narrow domains, for instance, a program like CASNET was developed to provide support to the domain experts whose knowledge and experience were used to develop the system, so experts may not use it, but generalists are less likely to use a system with restricted scope (Miller, 1996). Knowledge base construction and maintenance per se is another serious barrier to the success of a CDSS (Miller and Geissbuhler, 2007). Shortliffe's MYCIN program became out of date and lost its long-term value and viability because it was seen as challenging to maintain and no effort was made to update its knowledge base over time

(Hardin and Chhieng, 2007; Miller and Geissbuhler, 2007; Yu et al., 1979). MYCIN was one of the early successful example used rule-based system, which used "if–then" rule systems to identify microorganisms that caused bacteraemia and meningitis (Shortliffe, 1976). However, such systems can be challenging to maintain due to the fact that it was constructed using thousands of rules (Yu et al., 1979). An additional barrier to the wide use of early computer-assisted medicine selection, such as MYCIN, was the fear of legal liability for having erred in selecting the proper medicine or making wrong diagnosis (Yu et al., 1979).

The history of using CDSSs in the practice of medicine is a mixed one of remarkable creativeness together with small gains and limited deployment (Carter, 2007; Engle, 1992).

Although most early computer assisted programs were never used clinically, they paved the way for a great deal of research to set up which CDSS characteristics and architectures are most strongly associated with clinical effectiveness (Berlin et al., 2006; Musen et al., 2014) and what barriers to adoption (Moore and Loper, 2011).

2.1.3 Clinical decision support systems promise in clinical practice

The number of computer-based clinical support systems to improve healthcare and services is expanding rapidly (Berner and La Lande, 2007; Jao and Hier, 2010; McKibbon et al., 2011). Over the past few years, the emphasis in clinical decision support has much broadened from its earlier limited application in diagnostic systems to a much broader range of applications (Berner and La Lande, 2007; Miller and Geissbuhler, 2007). Moreover, the access and use of CDSSs are increasing in all aspects of clinical workflow to support practitioners' health decisions and improve their clinical practices (Berlin et al., 2006; Garg et al., 2005; Hunt et al., 1998; Jaspers et al., 2011; Johnston et al., 1994). The enthusiasm for the potential of CDSSs to improve healthcare has encouraged a growing

literature on CDSS evaluation studies (Berlin et al., 2006; McKibbon et al., 2011). As more CDSS reached the implementation stage, a review of clinical trials of their effectiveness is possible to provide an estimate of what could be the value of these computerised interventions in healthcare and health services (Garg et al., 2005; Haug et al., 2007; Kawamoto et al., 2005).

The following section reviews the results of randomised controlled trials (RCTs) and systematic reviews that focus on evaluation of CDSSs. The main emphasis is on changes in clinical performance and outcomes at the level of physician-patient interaction.

2.1.3.1 Medication management through computer-based decision support systems

To what extent does the use of CDSS for medication management impact the various outcomes of interest including health care process, clinical outcomes and non-clinical outcomes?

This section summarises the evidence on the impact of CDSSs on all phases of the medication management process, in particular, systems that provide support to one of the following processes; prescribing and ordering medications, order communication, dispensing, administration, monitoring including patient adherence/compliance as well as patient education, and reconciliation. The first RCT was published in 1976, over 40 years ago (McDonald, 1976). Later, sufficient RCTs were available to provide evidence related to CDSS impact on medication management (Bailey et al., 2007; Bell et al., 2010; Berner et al., 2006; Bertoni et al., 2009; Bloomfield et al., 2005; Christakis et al., 2001; Cobos et al., 2005; Davis et al., 2007; Demakis et al., 2000;Dexter et al., 2001; Dexter et al., 2004;

Evans et al., 1994; Field et al., 2009; Fiks et al., 2009; Feldstein et al., 2006; Feldstein et al., 2006a; Feldstein, 2006b; Filippi et al., 2003; Flottorp et al., 2002; Fortuna et al., 2009; Frances et al., 2001; Johnson et al., 2010; Frank et al., 2004; Fretheim et al., 2006; Gill et al., 2009; Gilutz et al., 2006; Graumlich et al., 2009; Gurwitz et al., 2008; Hetlevik et al., 1999; Hicks et al., 2008; Holbrook et al., 2009; Holman et al., 1996; Javitt et al., 2005; Javitt et al., 2008; Krall et al., 2004; Kucher et al., 2005; Kuilboer et al., 2006; Lester et al., 2006; Linder et al., 2009; Lo et al., 2009; Martens et al., 2007; Matheny et al., 2008; McDonald, 1976; McGregor et al., 2006; Meigs et al., 2003; Montgomery et al., 2000; Murray et al., 2004; Overhage et al.,1997; Overhage, Tierney, and McDonald, 1996; Palen et al., 2006; Paul et al., 2006; Persell et al., 2008; Peterson et al., 2007; Plaza et al., 2005; Quinn et al., 2008; Raebel et al., 2005; Raebel et al., 2007a; Raebel et al., 2007b; Rollman et al., 2002; Rood et al., 2005; Rosenbloom et al., 2005; Rosser et al., 1992; Rothman et al., 1996; Roumie et al., 2006; Safran et al., 1995; Sequist et al., 2005; Shojania et al., 1998; Tamblyn et al., 2003; Tamblyn et al., 2010; Terrell et al., 2009; Tierney et al., 2003; Tierney et al., 2005; Van Wyk et al., 2008; Weir et al., 2003; White et al., 1984; Zanetti et al., 2003).

Changes in process measured in these studies generally dealt with reminders about recommended medications or vaccines (Bailey et al., 2007; Christakis et al., 2001; Dexter et al., 2001; Dexter et al., 2004; Fortuna et al., 2009; Frank et al., 2004; Overhage et al., 1997; Rosser et al.1992; Zanetti et al. 2003), dose adjustments (Peterson et al. 2007; Rood et al. 2005), recommended laboratory monitoring for medications prescribed or chronic disease management (Feldstein et al. 2006; Feldstein et al. 2006; Holbrook et al. 2009; Javitt et al. 2008; McDonald 1976; Raebel et al. 2005;Rood et al. 2005), and 'inappropriate' medications avoided (Feldstein et al., 2006; Field et al., 2009; Raebel et al., 2007; Raebel et al., 2007; Tamblyn et al., 2003; Terrell et al., 2009).

A CDSS that advised against use of potentially inappropriate medications and recommended safer substitute therapies in emergency department (ED) was evaluated in a RCT (Terrell et al., 2009). The support was provided only when a physician in the intervention group attempted to prescribe any of the targeted inappropriate medication for senior patient who was being discharged from the ED (Terrell et al., 2009). Sixty-three emergency physicians were randomised to receive or not receive alerts to disrupt intended prescriptions of any of the targeted inappropriate medications (Terrell et al., 2009). The primary outcome measured showed that decision support significantly reduced the proportion of ED visits by senior patients that resulted in an inappropriate prescription (3.9% vs. 2.6%; p = 5.02; OR 50.55, 95% CI 50.34 to 0.89), where the secondary outcome of interest showed that the proportion of prescribed medications that were potentially inappropriate was significantly reduced, from 5.4% to 3.4% (p = 5.006; OR 50.59, 95% CI 50.41 to 0.85), with an ARR 2.0% (95% CI 50.7 to 3.3%). However, no clinical outcomes were measured in this study (Terrell et al., 2009).

Holbrook et al., (2009) randomised 511 adult patients with type 2 diabetes receiving either usual care or intervention involving shared access to an electronic decision-support system to support the primary care of diabetes. The primary outcomes measured were changes in process of care and other clinical outcomes of the quality of diabetes care. Improvement in monitoring was seen significantly more in the intervention group than in the control group. Number of visits to the healthcare provider was increased significantly more in the intervention group than in the control group (difference of 0.66, 95% CI 0.37 to 1.02, p<0.001). 3). Measures of satisfaction, usefulness, ease of use, and preference for computer-based intervention were also positively impacted by the CDSS intervention (Holbrook et al., 2009). Rosenbloom et al., (2005) studied the effect of interface design on user-initiated access to educational and patient information during clinical care. Control

participants, however, passively accessed the CDS tool while intervention participants actively received active notification to access the CDS and found that the active alerts were more effective (Rosenbloom et al., 2005).

2.8.1 Process Changes—Prescribing

Much research has been done to evaluate changes in process related to prescribing in hospital and primary care settings. With respect to the process changes measured in the prescribing studies, changes in prescribing and compliance with reminders, guidelines, and standard practice were the most common outcomes for hospital- and primary care-based studies.

Paul and colleagues evaluated TREAT; a computerized decision support system for improving antibiotic treatment in hospital setting in a RCT (Paul et al., 2006). Findings showed statistically significant improvements in appropriate antibiotic prescribing for both intention to treat analysis (64.5% vs. 72.7%, RRR 13%, $p< 0.05$) and for per protocol analysis (64.5% vs. 85.1%, RRR 32%, $p< 0.05$).

More RCTs were conducted in primary care setting found improvements in prescribing with the introduction of CDSS (Bell et al., 2010; Berner et al., 2006; Christakis et al., 2001; Davis et al., 2007; Feldstein et al., 2006; Feldstein et al., 2006; Filippi et al., 2003; Lester et al., 2006; Martens et al., 2007; Palen et al., 2006; Raebel et al., 2007; Raebel et al., 2007; Tamblyn et al., 2003; Van Wyk et al., 2008) as defined by improve clinician adherence to national asthma guidelines in the primary care setting (Bell et al., 2010), improving nonsteroidal anti-inflammatory drug (NSAID) prescribing safety in the outpatient setting for the intervention versus the control group, where intervention participants prescribed more safely than controls after receiving the CDSS (0.23 vs. 0.45 [$F = 4.24$, $p < 0.05$]) (Berner et al., 2006), improve the antibiotic prescribing practices for

otitis media in children (Christakis et al., 2001), significant improvements in prescribing practices for a wide range of common paediatric conditions (Davis et al., 2007). Results showed that the proportion of prescriptions dispensed in accordance with evidence improved from 38% at baseline to 42% following the intervention while the control group improved only from 39% at baseline to 40% (Davis et al., 2007), reducing the co-prescribing of interacting medications, especially reducing rates of inappropriate prescribing of warfarin with interacting drugs in the outpatient setting (Feldstein et al., 2006), improving osteoporosis management by improve clinician adherence to guideline-recommended osteoporosis care post-fracture (Feldstein et al., 2006), positively changing the antiplatelet drug-prescribing behaviour among general practitioners in diabetic patients (Filippi et al., 2003), significant improvement in secondary prevention of hyperlipidaemia using computer-assisted physician-directed intervention in primary care settings (Lester et al., 2006), improving GPs' prescribing behaviour through implementation of prescribing guidelines by means of a reactive computer reminder system (Martens et al., 2007), improving prescribing practices in the outpatient setting by increasing prescribers' adherence to laboratory monitoring recommendations for patients prescribed selected medications (Palen et al., 2006), improving prescribing safety using computerized tool that alerted pharmacists when patients aged 65 and older were newly prescribed potentially inappropriate medications (Raebel et al., 2007), improve prescribing safety during pregnancy using computerized tool that alerted pharmacists when pregnant patients were prescribed pregnancy risk category D or X medications (Raebel et al., 2007), reducing the rate of initiation of potentially inappropriate prescriptions in primary care when having computer-based access to complete drug profiles and alerts about potential prescribing problems (Tamblyn et al., 2003), and significantly improving dyslipidaemia management by GPs using the alerting version of the CDSS (Van Wyk et al., 2008). On the other hand,

other RCTs sought to conclude that the prescribing practices were changed and improved with CDSSs implementation and they did not show differences (Flottorp et al., 2002; Frances et al., 2001; Fretheim, Aaserud, and Oxman, 2006; Linder et al., 2009; Rollman et al., 2002)

2.1.4 Adherence to guidelines and recommended practice

Computerised decision support systems (CDSSs) impact on practitioner compliance with best practice, disease management guidelines, and recommended practices were studied in a RCTs and they showed statistically significant improvements in compliance (Bailey et al., 2007; Berner et al., 2006; Bertoni et al., 2009; Gill et al., 2009; Hicks et al., 2008; Tamblyn et al., 2010): one RCT used computerized reminders as an effective way in changing physician prescribing behaviour (Bailey et al., 2007). This study succeeds to demonstrate that the use of computerized alert is an effective means to increase adherence to secondary prevention guidelines for coronary heart disease (Bailey et al., 2007), Bertoni et al., (2009) showed that guidelines-based decision support may improve primary care physician adherence to the lipid management guidelines. Similarly, Gill et al., (2009) examined the impact of lipid management decision support tools integrated into an electronic medical record (EMR) in primary care practices and findings showed improvement in the management of hyperlipidaemia and other chronic diseases. In the same way, a RCT was conducted to examine the effectiveness of CDSS designed to improve hypertension care and outcomes in primary care patients (Hicks et al., 2008). This study concluded that the use of CDSS to practitioners significantly improved Joint National Committee (JNC) guideline adherent medication prescribing (Hicks et al., 2008). Another RCT of adherence to nonsteroidal anti-inflammatory drugs (NSAIDs) prescribing guidelines in primary care clinic documented more complete assessment of patient

gastrointestinal risk from NSAIDs and intervention participants prescribed more safely than controls after receiving the CDSS for NSAID prescribing (Berner et al., 2006).

However, Tierney et al., (2005) and Tierney et al., (2003) found the use of computer-generated evidence-based care of asthma and chronic obstructive pulmonary disease (Tierney et al., 2005) and the use of computerised evidence-based cardiac care guidelines had no effect on adherence to the guidelines and the delivery of evidence-based care for these conditions.

2.8.3 Non-clinical Outcomes

Many studies looked at non-clinical outcomes for interventions aimed at the prescribing phase, as follow; Rosenbloom et al., (2005) assessed usability issues related to CDSS, satisfaction and correlates of satisfaction were measured by Graumlich et al., (2009), Holbrook et al., (2007), Man-Son-Hing et al., (1999), and Rothman et al., (1996). Use and measures correlated with use were assessed in a study by Bertoni et al., (2009). Participants' attitudes and perceptions were assessed by Johnson et al., (2010). Patient knowledge as secondary outcome was assessed in a before-after design by Holbrook et al., (2007), Man-Son-Hing et al., (1999), Quinn et al., (2008), and Thomson et al., (2007). Holbrook et al., (2007), Man-Son-Hing et al., (1999), and Thomson et al., (2007) reported decision conflict. Patient anxiety was assessed in a study by Thomson et al., (2007).

Decision aid tools used in the selected trials did not have a consistent and predictable mode of positive outcomes. For example, patient knowledge significantly improved in a study by Holbrook and colleagues (Holbrook et al., 2007), Man-Son-Hing et al., (1999), and Quinn et al., (2008) but not in the study by (Thomson et al., 2007). In Thomson trial, they reported that the use of the decision aid did not have a significant impact on AF patients anxiety levels (Thomson et al., 2007). Man-Son-Hing et al., (1999) Rothman et al., (1996)

reported low satisfaction level in the decision made using decision aid tool. In contrast, encouraging level of patient satisfaction was reported in trials by Holbrook et al., (2007) and Thomson et al., (2007) and no difference in satisfaction levels were detected for patients or physicians using the application compared with usual care (Graumlich et al., 2009). Rosenbloom and colleagues (Rosenbloom et al., 2005) found that highly visible hyperlinks significantly increased the use of educational material and patient information. Johnson and colleagues measured perceptions of pharmacists to alerts on e-prescriptions; they found some information and comments related to allergy useful (Johnson et al., 2010)

2.1.4.1 Impact on care process and patient health outcomes

In 1994, Johnston and colleagues have conducted a comprehensive review of the evidence from 28 controlled trials published between 1974 and 1992 of the effects of CDSSs on clinician performance and patient outcomes. Within this review, studies were classified according to the targeted workflow CDSS was intended to support, and they concluded that clinician performance (a measure of the process of care) and/or patient outcomes (including any aspect of patient well-being) were significantly improved using a computer-assisted dosing, computer-aided diagnosis, or preventive care reminder systems (Johnston et al., 1994). In addition to the 28 studies previously reviewed by Johnston et al., (1994), Hunt et al. (1998) updated earlier review and identified 40 new studies which met the review inclusion criteria. They locate a total of 68 controlled trials published between 1992 and 1998 to determine whether using the CDSS had affected health care practitioner performance and/or patient outcomes (Hunt et al., 1998). This updated review documented substantial improvement in the quantity and quality of included studies and made a robust evidence of the positive impact the CDSSs had in supporting health decisions within different healthcare settings (Hunt et al., 1998).

In 1994, Garg and colleagues conducted a third consecutive SR of controlled trials to update previous reviews on the effects of CDSSs on practitioner performance and/ or patient outcomes, and they locate 100 studies which confirmed previous conclusions of the systems efficiency in improving practitioner performance when the CDSS were used as diagnostic systems, reminder systems, disease management systems, and drug-dosing or prescribing systems (Garg et al., 2005).

Kaplan (2001) reviewed CDSSs literature, with a focus on evaluation. The emphasis was to assess systems performance or to focus on changes in clinical performance that could affect patient care (Kaplan, 2001). There were 27 studies reported in this review paper, most of the evaluation studies concern systems for alerts or reminders, while others concern the use of computer-based guidelines, and diagnosis. The CDSS literature clearly reflects a general consensus that clinical decision support systems are thought to have the potential to improve care, or at least effective in changing practice behaviours (Kaplan, 2001).

Researches into the impact of CDSS on healthcare practitioner performance and patient outcomes are constantly evolving (Garg et al., 2005; Hunt et al., 1998; Jaspers et al., 2011; Johnston et al., 1994). Jaspers et al., (2011) examined the evidence based on a critical appraisal of SRs focusing on CDSS impact on clinical workflow, and they conclude that the majority of evidence showed that CDSSs are generally having a great capacity to alter physician performance, influence the process of care, and are effective to some degree in improving patient outcomes.

Despite broad recognition of the merits of CDSSs, they are not always utilised even if they are available (Giguere et al., 2012; Koskela et al., 2016). Several studies and review articles have been conducted to identify the factors that clinicians perceive as hindering

and facilitating implementation. To this end, the discussion now turns to consider the factors influencing the use of these systems in routine clinical practice.

2.2 Barriers and facilitators to implementing decision support systems in clinical practice

Several studies suggested that CDSSs that are designed to delivering evidence-based clinical knowledge, using high sensitivity alerts, and a straightforward recommendation that is well presented in an acceptable format at the point of care are considered essential to realise the full potential of a CDSS intervention (Heathfield and Wyatt, 1993; Jao and Hier, 2010; Murray et al., 2004; Osheroff et al., 2007). Furthermore, functional and technical maintenance of the decision support system and regular testing of the knowledge-base and clinical rules are additional pre-requisites for long term successful implementation in clinical practice (Kawamoto et al., 2005; Scheepers-Hoeks et al., 2011). These success factors when exist, would compensate for the time required to use the system (Goud et al., 2008), and decrease efforts needed by healthcare provider to receive and react on system alerts and recommendations (Kawamoto et al., 2005; Osheroff et al., 2007; Varonen et al., 2008).

The introduction of CDSS in clinical practice, even when highly promising, is far from straightforward (Scheepers-Hoeks et al., 2011). Rather, individual and institutional perceptions and contextual factors can hinder the integration of CDSSs into the routine clinical workflow (Giguere et al., 2012; Koskela et al., 2016). Besides the lack of success factors described earlier, there are additional barriers classified into four domains using a previously published scheme (Sittig et al., 2006): (1) Healthcare system-related barriers; (2) clinician-related barriers; (3); patient-related barriers and (4) CDSS-related barriers

2.2.1 Healthcare system-related barriers

The introduction of CDSSs into an organised context requires negotiating with all involved parties and addressing the particularities of specific workplaces (Moja et al., 2014). A successful integration of CDSS requires changes in healthcare system policies, practices, and technology of an entire clinic (Bidgoli, 1989). Moxey's studies on barriers to integration of CDSSs found that the quality and quantity of the information technology (IT) infrastructure provided, and the way in which the CDSSs were implemented, were key factors impacting on the uptake into clinical practice (Moxey et al., 2010).

Studies reported consistently that limited computer availability at the point of care was found to impede CDSS use (Eccles et al., 2002; Van Der Sijs et al., 2006). Nonetheless, Heathfield and Wyatt's studies on the introduction of CDSSs suggest the need to go beyond approaches focused on the technology systems (Heathfield and Wyatt, 1993). Rather, the acceptance and attitudes of technology play an essential role in the development and integration of CDSSs into a routine clinical workflow (Heathfield and Wyatt, 1993). Jao and Hier (2010) related successful integration of CDSS into practitioner's workflow to the motivational effect of the organisation's enthusiasm and access to technical support, sufficient training, and education.

2.2.2 Clinician-related barriers

Walter and Lopez (2008) study of physician acceptance of information technologies showed that physician's perceived threat to professional autonomy was a barrier to CDSS adoption in clinical practice. Other studies indicated that the degree of physician acceptance of a CDSS seems to be correlated with their attitudes of their professional role, and the computer's role in disease management (Carter, 2007; Murray et al., 2004; Rousseau et al., 2003; Subramanian et al., 2004).

Factors such as; insufficient level of computer skills among clinicians, lack of incentives, lack of awareness, and time constraints, were reported consistently to hinder successful implementation in clinical practice (Bidgoli, 1989; Carter, 2007; Murray et al., 2004; Rousseau et al., 2003; Trivedi et al., 2009). As described in Patterson et al., (2005), the utility of CDSS is limited by; physician's preferences to use other information sources over CDSS (e.g. preference to consult colleagues), and resistance to change existing practices.

2.2.3 Patient-related barriers

The patient-doctor relationship seemed to be the most important patient-related factor for the adoption of CDSSs in clinical practice (Kortteisto et al., 2012; Martens et al., 2008; Moxey et al., 2010; Sittig et al., 2006; Varonen et al., 2008 Zheng et al., 2005). The literature reports mixed effects from using CDSSs on doctor-patient interaction. For instance, previous studies found that the use of CDSS during the consultation might interfere with the doctor-patient relationship in that CDSS was seen to detract from the doctor-patient interaction (e.g. loss of eye contact) (Harrison et al., 2009; Varonena et al., 2008; Zheng et al., 2005). Findings from other studies indicated that computers had mainly positive effects on physician–patient interactions during clinical encounter and hence contributed to better quality of patient care, and increased satisfaction with the consultation (Bomba and de Silva 2001; Bomba et al., 2004; Callen et al., 2005; Chan and McGlade 2003; Hsu et al., 2005).

Patient preferences and attitudes were found consistently to impact on the successful implementation of CDSS in clinical practice (Kortteisto et al., 2012; Moxey et al., 2010; Sittig et al., 2006; Varonen et al., 2008).

2.2.4 Decision support system-related barriers

The most predominant barrier cited was the practitioner's lack of time to use the CDSS (Harrison et al., 2009; Lugtenberg et al., 2015; Moxey et al., 2010; Peek et al., 2011). Time constraints, particularly, was found as having a considerable impact on the clinician's decision to use the system in routine clinical practice (Robertson et al., 2011; Short et al., 2004; Toth-Pal et al., 2008). Moreover, factors related to the CDSS content, presentation, and flexibility within the system were found to act as a barrier to implementation in the study of Hor et al. (2010). Murray et al. (2004) noted the complexity of a CDSS was found to hinder its use by healthcare providers.

Clayton and Hripcsak (1995) reported that stand-alone systems which need double data entry once into the medical record system, and again, into the CDSS could limit the usefulness of such systems (Berner and Lande, 2007; Clayton and Hripcsak, 1995). Several studies concluded that CDSSs designed with narrow domains and restricted focus were less successful compared to systems that cover multiple domains (Carter, 2007; Clayton and Hripcsak, 1995). This could even be true of earlier systems covering single domain which, as Miller (1996) and others justified have limited the ultimate success of CDSS to date (Clayton and Hripcsak, 1995; Miller, 1996; Miller and Geissbuhler, 2007; Yu et al., 1979).

On the other hand, unwanted CDSS alerts appearing at inappropriate times in the workflow were a key factor to use and acceptability (Berner and Moss, 2005; Keeffe et al., 2005; Sittig et al., 2008; Weingart et al., 2003). Also, the high frequency of alerts was perceived by clinicians as annoying and intrusive to the consultation; as a consequence, providers felt they become desensitised to alerts and missed important information (Moxey et al., 2010).

In summary, these barriers stem from the complex nature of clinical practice which combines complex responsibilities in a challenging work environment with a complex computerised decision support tools (Smelcer et al., 2009). Therefore, addressing many of

CDSSs- related barriers, (e.g. user interface design, workflow, data entry, and type of decision support provided) can contribute significantly to improving systems utility on healthcare processes and patient outcomes (Keeffe et al., 2005; Rousseau et al., 2003; Sittig et al., 2008).

2.3 Literature review method

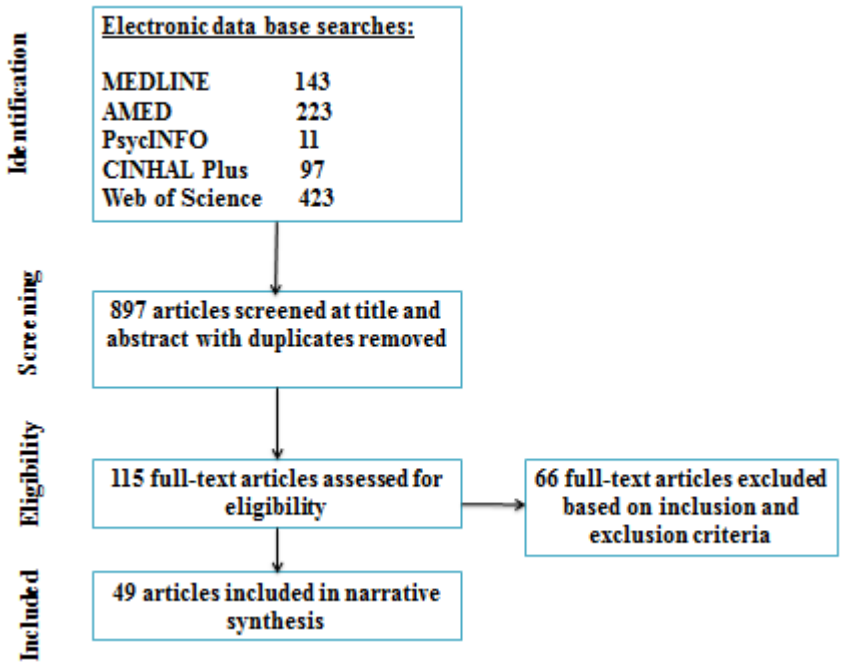
2.3.1 Literature search strategy

A literature search was performed in 2013 and repeated at regular intervals (most recently December 2017) to identify literature on the impact of CDSSs on anticoagulation management. The search strategy was developed in consultation with the research team and involved using Boolean operators for combinations of the following keywords: "decision support system", "computerised decision support", "decision aid", "anticoagulation therapy", "anti-thrombotic", "warfarin", "new oral anticoagulants", "novel oral anticoagulants", "atrial fibrillation", "evaluation", "impact", "influence", and "assessment". Equivalent terms in thesauruses or Mesh browsers were used wherever possible. No limits were placed on language or on methodological terms as all study designs were considered.

Search strategies were specific to each database in order to retrieve the most relevant articles to the research key question. The search strategy involved searching the following journal databases and electronic resources websites for literature published between 1950 and 2017.The databases that were searched included: Allied and Complementary Medicine (AMED) from 1950, Cumulative Index to Nursing and Allied Health Literature (CINAHL Plus) from 1950, MEDLINE from 1950, PsycINFO from 1950, and Web of Science from 1950. In addition, searches of these databases were supplemented with manual searching of reference lists contained in all included articles and in relevant review articles.

A total of 897 journal articles, reports and reviews were identified through the whole literature searching process. The papers initially selected considered some aspect of decision support in anticoagulation management. These were all preliminarily screened by title and abstract to identify CDSS research in anticoagulation management. One hundred and fifteen were then screened against further specific inclusion and exclusion criteria. Forty-nine studies were finally selected for inclusion in the review. As illustrated in figure 2.1

Figure 2. 1: Database search results and screening process



The literature on the impact of DSSs on anticoagulation management is quantitative, and despite a thorough search being made, qualitative studies are absent. One of the reasons for this is because electronic databases use a restricted number of keywords, which usually describe the general or broad-based topic areas and methodologies (Barbour and Barbour, 2003). Although Thesauri provide definitions of the terms used to index material, these are unlikely to correspond with researchers' specific interests and focus (Barbour and Barbour, 2003), and subsequently, it is possible that some relevant papers were overlooked.

2.3.2 Inclusion and exclusion criteria

The inclusion criteria were intended to be broad. Any English language articles were included that were predominantly concerned with measuring impact of DSSs on aspects of anticoagulation management, which included review articles of research studies and articles that commented on research studies. However, studies that did not report original research (e.g., editorials, commentaries, letter to the editor, abstract from conferences, research theses or study protocol) or, where a full paper had not been published, were not included. Articles were included if they concerned evaluating the utility of DSS on anticoagulation management, or on anticoagulation decision-making process, or impact of patient decision aids on patient-related outcomes. Articles were not included that concerned DSS impact on anticoagulation therapy in conditions other than non-valvular atrial fibrillation. Studies devoted only to the description of decision analysis aspects of the system, system development, or validation were excluded.

As the literature search completed it become evident that there were only a small number of CDSS studies on anticoagulation management. In response, and to increase the understanding of how CDSSs in anticoagulation management have been evaluated, a decision was taken to include all study designs. Identifying the strengths and weaknesses

of designs and how they had been addressed would help inform the overall design of the study within this thesis.

2.3.3 Overview of the key characteristics of included studies

Using the pre-defined inclusion and exclusion criteria, titles and abstracts were examined for potential relevance to the key search terms, and the whole paper was examined where doubt remained. As a result, a total of forty-nine studies were included for data abstraction. These papers are discussed under two main headings: impact of DSSs on attributes of anticoagulation management (section 2.3.4) and impact of patient decision aids (PDAs) on attributes of decision and decision-making process (section 2.4).

Tables 2.1 and 2.2, outline the included studies main characteristics. The next sections provide a summary of the content of table 2.1. Thirty-one of the studies were undertaken in the last decade, highlighting that the use of DSSs in anticoagulation management is relatively new.

Table 2. 1: key characteristics of the studies included in the literature review

Author(s) and country	Study design and sample	CDSS category and aim of Study	Key outcome measures	Results
Arts et al., (2017). Dutch	**A cluster randomised trial.** 18 GP practices were randomised into one of the following three groups: 1. Received no messages (control group) 2. Received messages that could be declined without documenting justification (intervention 1) 3. Received messages that could only be declined if justification was documented (intervention 2)	Clinical decision support system for the selection of anticoagulation treatment To assess the effect of integrating a DSS on guideline adherence	Guideline adherence, as the percentage of patients treated in accordance with the guideline.	Guideline adherence differed between the control and intervention groups at baseline (Control: 42%, Intervention: 50%, P = 0.04). At the end of the study, both groups had improved, by 8% and 5% respectively. There was no statistically significant difference between groups (Control:50%, Intervention: 55%, P = 0.23)
Eckman et al., (2016). United States	**A cluster randomised trial.** Involving 15 primary care practices and 1,493 adults with non-valvular AF. Intervention n=801. Control n=692.	Clinical decision support system- Atrial Fibrillation Decision Support Tool (AFDST)- for the selection of anticoagulation treatment To investigate whether the provision of AFDST would improve thrombo-prophylaxis for AF patients	The proportion of patients with antithrombotic therapy that was discordant from AFDST recommendation	At baseline, 41.8% (335/801) of the intervention practices' patients had discordant care, whereas 42.1% (291/692) of patients in the control practices had care that was discordant from AFDST recommendations. At 1-year follow-up, the proportion of patients with discordant care dropped to 41.1% (329/801) and 40% (277/692) in the intervention and control practices, respectively. In non-stratified analyses, changes in discordant care were not significantly different between the intervention group and control groups.

Author(s) and country	Study design and sample	CDSS category and aim of Study	Key outcome measures	Results
Pandya et al., (2016). Australia	**A prospective cohort study** was conducted across 2 hospitals in the wider Sydney over a period of 12 months. 205 patients participated in the study	Clinical decision support system for the selection of anticoagulation treatment To evaluate the impact of the computerized antithrombotic risk assessment tool (CARAT) on anti-thrombotic utilization for thrombo-prophylaxis in patients with non-valvular atrial fibrillation	The proportion of patients prescribed antithrombotic therapy at baseline (pre-CARAT) and at discharge (post-CARAT) To compare the treatment recommendations generated by CARAT with the antithrombotic therapies actually prescribed by clinicians (post-CARAT)	The CARAT recommended a change in baseline therapy for 51.8% of patients. Among anticoagulant-eligible patients (ie, where the risk of stroke outweighed the risk of bleeding) using, the CARAT recommended an upgrade to warfarin in 60 (30.8%) patients. For those in whom the bleeding risk outweighed the stroke risk, the CARAT recommended a downgrade from warfarin to safer alternatives (eg, aspirin) in 37 (19%) patients. Discharge therapy observed a marginal increase in anticoagulation prescription in eligible patients (n=116; 57.8% vs 64.7%, P =0.35) compared to baseline.
Harper et al., (2015). New Zealand	**A prospective cohort study** 3660 patients on oral anticoagulants; one-third of patients managed by doctors and two thirds by pharmacists.	Computerised anticoagulant algorithm to predict appropriate warfarin dosing To evaluate the effectiveness of a computerised self-adjusting anticoagulant algorithm to predict appropriate warfarin dosing	The time in the therapeutic range (TTR) The outcome of adherence to the computer dosing algorithm The percentage of time the clinicians over-ride the algorithm and the impact of their intervention on anticoagulant control.	A TTR of 72.9% was achieved for all patients. The TTR was significantly better in patients managed by pharmacists than doctors (75.1% versus 67.4%, p<0.0001). The computer algorithm provides appropriate dose recommendations for INR results from 1.5 to 4. Users administered a dose that differed from the computer recommendation 23.3% of the time. The doctors adjusted the dose more frequently (28.2% versus 21.1% of tests) and made larger dose changes than the pharmacists. This is in part due to the action of the doctors overriding the algorithm.

Author(s) and country	Study design and sample	CDSS category and aim of Study	Key outcome measures	Results
Woller et al., (2015). United States	**A retrospective nested cohort study.** 2591Patients on warfarin were enrolled into the study	Computerized clinical decision support for warfarin dose adjustment To compare warfarin management before and after implementation of CDS in a large health care system	TTR and INR variability before and after implementation of CDSS. Outcomes of major bleeding, thrombosis, and health care utilization.	Implementation of CDS significantly improved TTR (from 63.99% to 65.13%; P = 0.04) and reduced out-of-range INRs (from 42.39% to 39.97%; P < .001). Fewer outcomes of venous thromboembolism (relative risk [RR] 0.41; P < .001), emergency department visits (RR 0.62; P < .001), and hospitalizations (RR 0.62; P < .001) were reduced after CDS implementation period compared with the pre-CDS period. Major haemorrhage was more frequent after CDS implementation (RR 1.42; P= 0.01).
Deitelzweig et al., (2014). United States	**A retrospective cohort study.** Data from 48,260 patients were included in the retrospective analysis study from the period from January 2004 to June 2010.	Clinical decision support system for the selection of anticoagulation treatment To assess whether decision tool can be used for anticoagulant treatment selection by incorporating patient's absolute risk for stroke and bleeding to identify the agent with the lowest net risk.	Treatment recommendations based on combining stroke and bleeding risks of utilizing the aid at a US managed care population level.	The Clinical Decision Aid can be used for anticoagulant treatment selection. Data from 48260 patients were included in the analysis. HAS-BLED score was (2.17 vs 1.39; P = 0.001) and a higher mean CHA2DS2-VAScscore (3.35 vs 2.05; P= 0.001) than did the baseline. Based on a 2:1 bleeding-to-stroke risk ratio, 70.50% of patients would be recommended treatment with apixaban; 25.86%, no treatment; 3.62%, acetylsalicylic acid; and 0.01%, dabigatran 150 mg, if the Clinical Decision Aid were to be used for anticoagulant treatment selection.

Author(s) and country	Study design and sample	CDSS category and aim of Study	Key outcome measures	Results
Nielsen et al., (2014). Denmark	**A retrospective cohort study.** The data was acquired from January 2010 till December 2012 and consists of 837 patients assigned to self-monitoring	A dynamic decision support algorithm for prediction of future INR values and optimal warfarin dose to stay on INR target To evaluate the decision support algorithm retrospectively applied on a cohort of self-monitored patients	Time in therapeutic range Model suggested dosage of warfarin	The accuracy of the model predictions measured as median absolute error was 0.53 mg/day (interquartile range from 0.25 to 1.0). The model suggests a more adequate dose in more than 70% of the incidents when INR measurements are outside TR.
Almeman and Rasool, (2013) Saudi Arabia	**A prospective before- after study.** A random sample of 70 patients in the centre. For each patient, INR values were taken before and after the installation of Coagclinic™.	CoagClinic™ is web based software for warfarin management. To compare the efficacy of Coagclinic™ dosing with physician dosing	Time in therapeutic range	The percentage of patients kept at the TTR by physicians was 26 %, compared to71 % for the software within six month of its application A significant difference ($p = 0.015$) was found between physicians' dosing and the dosing generated by the computer software
Ferret et al., (2013). France	**A retrospective cohort study.** The rules were applied on 14,748 medical records from a community hospital.	Computerised tools for detecting adverse drug events To detect whether the computerised system can detect ADE	Adverse drug events related to INR elevation by review of the detected cases.	49 cases were detected, among which 11 cases were ADEs The predictive positive value of the rules is 22.44%, mostly related to antibiotics and amiodarone introduction.

Author(s) and country	Study design and sample	CDSS category and aim of Study	Key outcome measures	Results
Grzymala-Lubanski et al., (2013) Sweden	**A retrospective cohort study.** 53.779 warfarin treated patients from 125 centres using the Swedish national quality registry AuriculA.	Computerised dosing assistance within the Swedish national quality registry AuriculA To evaluate the performance of a computerized dosing algorithm.	The resulting INR value was compared between dose suggestions arising from the algorithm that were accepted and those that were manually changed INR value	The algorithm suggestions were superior to manual dosing regarding percent samples within the target range 2-3 (hit-rate) or deviation from INR 2.5 (mean error). Of the seven possible outcomes from the algorithm, six were significantly superior and one equal to the manually changed doses
Borgman et al., (2012) United States	**A randomised pilot trial.** Prospectively studied 26 subjects to compare PerMIT-guided management with routine anticoagulation service management	PerMIT, a novel decision support tool for genotype based warfarin initiation and maintenance dosing To assess its efficacy for improving warfarin management	Warfarin dose INR value	In comparison to control subjects, patients in the PerMIT study arm demonstrated a 3.6-day decrease in the time to reach a stabilized INR within the target therapeutic range (4.7 vs. 8.3 days, $p = 0.015$). A 12.8% increase in time spent within the therapeutic interval over the first 25 days of therapy (64.3% vs. 55.3%, $p = 0.180$) A 32.9% decrease in the frequency of warfarin dose adjustments per INR measurement (38.3% vs. 57.1%, $p = 0.007$).
Dimberg et al., (2012) Sweden	**A retrospective cohort study.** Retrospective cohort study of medical records from 791 patients with atrial fibrillation on warfarin treatment from two centres, with previously manual warfarin dosing regimens centres using the Swedish national quality registry AuriculA.	Computerised dosing assistance within the Swedish national quality registry AuriculA To assess whether the web based dosing system, compared to manual dosing, would improve the TTR	TTR	In centre 1, the mean TTR was significantly increased after the introduction of computerised dosing, from 64.3% (95% CI 58.8–69.8) to 71.3%, $p< 0.03$. In centre 2, a high TTR of 73.6% was maintained after the implementation, 74.0% INR tests were prescribed significantly more frequent after the introduction of computerised dosing in both centres; 20% more often at centre 1 and 21% at centre 2.

Author(s) and country	Study design and sample	CDSS category and aim of Study	Key outcome measures	Results
Nieuwlaat et al., (2012) United States	**A randomised controlled trial.** Patients were randomised to have warfarin dose adjustment done according to recommendations of the existing warfarin dosing algorithm or to those of the computerised system. 541 patients were randomised to computerised system and 527 to the algorithm.	DAWN AC; a computerised warfarin dosing system To test if the computerised system was non-inferior to the existing algorithm	Maintenance control of the INR (TTR)	The mean TTR was 71.0% for the computerised system and 71.9% (SD 22.9) for the algorithm (difference 0.9% [95% confidence interval: –1.4% to 4.1%]; p-value for non-inferiority= 0.002; p-value for superiority=0.34).
Rasmussen et al., (2012) Denmark	**A randomised controlled trial.** 54 patients were randomised equally into 3 groups. Patients in two groups had dosages of anticoagulation treatment calculated in a computer system by an algorithm specific to each group. The third group received traditional anticoagulation treatment by physicians.	CoaguTel; a computer aided management system for warfarin management To test the use of CoaguTel to improve the time to reach and the time spent within the therapeutic target range compared to traditional oral anticoagulant therapy by physicians.	INR value Time in therapeutic range	Patients randomised to computer-assisted anticoagulation system reached the therapeutic target range after 8 days compared to 14 days by prescriptions from physicians (p = 0.04). Time spent in the therapeutic target range did not differ between groups.

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Cafolla et al., (2011) Italy	**A before-after study.** The study analysed data of 1876 patients managed with each of the two modalities for eight months.	Zeus, is a mathematical algorithm designed to suggest doses and time to next visit for patients on warfarin. To compare the efficacy and safety of this algorithm dosing OAT with manual dosage decided by an expert physician	Time in therapeutic range Number of INR tests	Time in therapeutic range (TTR) was significantly ($p<0.0001$) higher during the algorithm dosing period in comparison with the TTR during manual management period (62.3% vs 50.3%). The number of INR tests above 5 was significantly ($p<0.001$) reduced by algorithm suggested prescriptions in comparison with manual dose (254 vs 537 times). The anticoagulant drug amount prescribed according to the algorithm suggestions was significantly ($p<0.0001$) lower than that of the manual method. The number of clinical events observed in patients during the algorithm management time was significantly ($p<0.05$) lower than that in those managed with the manual dosage.
Wess et al., (2011) United States	**A pilot usability testing study.** 8 primary care physicians were recruited into the study. After completing the AF-DST simulation, participants completed the 19-item Computer System Usability Questionnaire (CSUQ)	AF-DST (By Eckman et al 2016) The purpose of this study was to pilot test the usability of the AF-DST	CSUQ scores	Users found the AF-DST to be helpful and had high CSUQ scores (mean item score, 6.3). Usability testing identified 6 positive and 14 negative critical incidents. Participants felt that the AF-DST guided them toward the correct decision. Training level appeared to affect how the AF-DST was used, in particular, how users interacted with the AFDST

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Gouin-Thibault et al., (2010) France	**Observational study.** Over a 13-month period (June 1, 2006–June 30, 2007), 307 patients aged 70 and older were enrolled. Of the 307 patients, 108 were assigned to the CGD group and 199 to the standard care group.	Computerized dosing system for elderly To determine the effect of computer-generated dosing group (CGD) on anticoagulation quality	Time in therapeutic range	The proportion of time within therapeutic INR range 2.0 to 3.0 was significantly greater in the Computer-managed group than in the physician-managed group (59% vs 48%, P=0.004). When a wider INR range was analysed (1.8–3.2), the proportion of time within range was 73% versus 64% (P=0.006). Use of the computer was associated with fewer days with INRs greater than 3, a smaller percentage of INRs of 4 or greater, a longer time to the first INR of 4.0 or greater, and a smaller mean number of INRs per month than physician-managed group (all P<0.01).
Papaioannou et al., (2010) Canada	**A retrospective comparison feasibility study.** The MEDeINR system was piloted the in six long-term care (LTC) homes in Ontario, Canada. All128 residents who were taking warfarin were included. Three-months of INR data prior to MEDeINR was collected via a retrospective chart audit, and three-months of INR data after implementation of MEDeINR was captured in the central computer database.	MEDeINR electronic decision support system for warfarin dosing To evaluate the MEDeINR system in a pre-post implementation design by examining the impact on warfarin management	Time in therapeutic range Time in sub/supra-therapeutic ranges based on all INR measures for every resident on warfarin. The number of monthly INR tests	Overall, the TTR increased during the MEDeINR phase (65 to 69%, P=0.14), but was only significantly increased for one home (62% to 71%, p <0.05) The percentage of time in supra-therapeutic decreased from 14% to 11%, p = 0.08); there was little change for the sub-therapeutic range (21% to 20%, p = 0.66). Overall, the average number of INR tests 30 days decreased from 4.2 to 3.1 (p < 0.0001) per resident after implementation of MEDeINR.

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Poller et al., (2009). Australia, Austria, Belgium, Denmark, France, Israel, Italy, Portugal, Slovenia, Spain, and UK.	**A randomised controlled trial.** A five-year international randomised clinical study of assistance with the DAWN AC program compared with manual dosage in 2,631 patients have been performed at 13 anticoagulation centres mainly in the EU. Manual dosed, n=1,316 and Computer assisted, n= 1,315	DAWN AC; is a computer-dosage programs. To assess safety based on the comparison of bleeding or thrombotic events with DAWN AC compared with manual dosage	Time in therapeutic range The number of INR tests Bleeding and thrombotic events	The TIR for all results in the manual group was 63.4% but for the computer-assisted group was 66.8%. The TTR difference between manual and computer dosage arms was statistically significant after adjusting for gender, age, clinical indication and target INR rang, $p<0.001$ In the DAWN group there was a significant increase of 2.3 visits per patient with DAWN control ($p=0.0005$) in number of INR tests DAWN proved as safe clinically as manual dosage by experienced medical staff. Minor bleedings were similar in the two groups. There was a small non-significant reduction in thrombotic events with computer-assistance as opposed to a similar small non-significant increase in major bleeding
Poller et al., (2008a). Belgium, Germany, Italy, Poland, Portugal, and Spain	**A randomised controlled trial.** A total of 10 421 patients were recruited in the 5-year study and were randomised into the two arms, 5131 in the manual group and 5290 in the PARMA 5 assisted dosage.	PARMA 5; a computer-assisted dosage program. To compare PARMA 5 safety and effectiveness with manual dosage	Frequency of INR testing TTR Adverse events; haemorrhage and thrombo-embolic event	INR tests numbered 167 791 with manual and 160 078 with PARMA 5 dosage. With PARMA 5 there was overall a non-significant reduction in clinical events Success in achieving 'time in target INR range' was also significantly greater with PARMA 5 compared with the dosage by experienced medical staff.

Author(s) and country	Study design and sample	CDSS category and aim of Study	Key outcome measures	Results
Poller et al., (2008b). Australia, Austria, Belgium, Denmark, France, Germany, Israel, Italy, Poland, Portugal, Slovenia, Spain, and UK	**A randomised controlled trial.** A randomised study of dosage of two commercial computer-assisted dosage programs (PARMA-5 and DAWN AC) vs. manual dosage at 32 centres with an established interest in oral anticoagulation in 13 countries. In total, 13 219 patients participated, 6503 patients being randomised to medical staff and 6716 to computer-assisted dosage.	Computer-assisted dosage programs (PARMA-5 and DAWN AC) The aim was to investigate whether clinical benefit or safety from thrombotic or bleeding events resulted from use of computer-assisted dosage as compared with manual dosage by experienced medical staff.	The safety and effectiveness of computer-assisted dosage were compared with those of medical staff dosage: Frequency of INR testing Time in therapeutic range Adverse events; haemorrhage and thrombo-embolic event	Time in target INR range was significantly improved by computer assistance as compared with medical staff dosage at the majority of centres ($P < 0.001$). Computer assistance in oral anticoagulant dosage did not significantly affect the frequency of INR tests. The difference between the manual dosage and computer-assisted dosage arms in TTR was statistically significant after adjusting by computer program, gender, age, clinical indication, and target INR range [difference in TTR of 1.2%, $P < 0.001$]. There was a greater incidence of clinical events in the manual dosage arm (555) than in the computer-assisted dosage arm (513), but after adjusting for covariates, this difference was not significant (IRR = 0.90; 95% CI 0.80–1.02; $P = 0.10$). The number of clinical events recorded in the first 3 weeks of patients entering the study was also less in the computer-assisted dosage arm (8.6 events per 100 patient-years) than in the manual dosage arm (12.3 events per 100 patient-years). The IRR was 0.7 (95% CI 0.48–1.04), $P = 0.06$.

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Onundarson et al., (2007) Iceland	**Cross sectional analysis** of analogous patient treated in two separate time periods. Data from 2006 was compared to original data available from 1992. 941patients on warfarin (2006) compared to 241 comparable patients from 1992	software-assisted warfarin dosing To evaluate if laboratory parameters of OA intensity had improved in by using a computer software-assisted dosing practice in comparison to previous practice of manual specialist-based dosing 14 years earlier.	INR and TTR	Over 14 years, the time within target range increased in all three anticoagulated groups, i.e. in AF patients from 46% to 81%. Only 1% of the treatment time is now spent at INR < 1.5 compared to 7% previously (P < 0.0001) and 0.4% of the treatment time at INR > 4.0 presently compared to 2.8% in the past (P < 0.0001). INR-targets are better achieved with the current software-assisted dosing practice and extreme low and high values are less common than previously
Wess et al., 2007 United States	**A retrospective, observational cohort trial.** A retrospective cohort analysis of 6123 patients from January 1997 through May 2002	A decision support tool for anticoagulation recommendation. To predict the performance of the tool	Adverse events; haemorrhage and thrombo-embolic event	The CDSS recommended warfarin for 49% of patient however, only 9.9%received warfarin. There was a trend towards a decreased hazard for stroke with actual warfarin treatment without significant increase in gastrointestinal haemorrhage In patients for whom the tool recommended no warfarin, receipt of warfarin was associated with statistically significant increased hazard of gastrointestinal bleeding (p= 0.03)
Wurster and Doran, 2006. United States	**A before-after study.** A random sample of 40 patients in the centre. For each patient, INR values were taken before and after the installation of CoagClinic™.	CoagClinic™ is web based software for warfarin management. To evaluate the potential benefits of utilizing decision support software on anticoagulation therapy	INR in the target range Complications related to anticoagulation therapy	For the baseline phase, INR compliance for the patient population was 34%. For the intervention phase, INR compliance for the study population was 67%, representing an improvement of 97% (p < 0.01). During a 1-year follow-up period, complications related to anticoagulation therapy were reduced by 91% (p < 0.01).

Author(s) and country	Study design and sample	CDSS category and aim of Study	Key outcome measures	Results
Mitra et al., (2005). United States	**A randomised controlled trial.** A total of 30 patients receiving warfarin were randomised to either clinician dosing or computer-aided warfarin dosing for the duration of their hospitalization. The computer-dosed group (n=14). Clinician dosages group (n=16).	DAWN AC; is a computer-dosage programs. To determine whether computer-aided dosing of warfarin is superior to physician dosing to maintain a patient within a target INR	Percentage of days in a therapeutic anticoagulation range The number of blood draws to maintain a target INR of 2.0–3.0	The proportion of time that patients were in therapeutic INR range was significantly longer in the computer-aided group than in Physician-aided group (61.7% vs. 44.1%, respectively, P < 0. 05, 95% confidence interval, 0.113– 0.238). There was no significant difference in the number of blood draws between the two groups (P= 0.170).
Manotti et al., (2004) Italy	**A before-after pilot trial.** 181 patients were followed before and after the implementation of the dosing decision support system by their GPs	Computer-aided dosing decision support system To assess the impact on anticoagulation management	TTR in before-after design	No significant difference between the two periods in TTR emerged (65.9% before compared to 66.1% with computer-aid).
Marco et al., (2003). Spain	**A prospective randomised trial** Patients were randomly assigned to receive computer-generated doses (n=8,352) or traditionally fixed doses (n=7,586) as they entered the study.	GAO software for acnocoumarol dosing To assess the impact on anticoagulation therapy management	The proportion of time spent in the target INR range	The computer matched the traditional dosing, achieving a small but statistically significant greater efficacy in maintaining patients within the INR target range. The percentage of INR determinations over 5.5 was very low in both groups.

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Oppenkowski et al., (2003). UK	**A retrospective cohort trial.** Analysis of 12 months of clinical data from 10 primary care centres using BAP-PC within an oral anticoagulation clinic. Data were analysed for a total of 367 patients	The Birmingham Anticoagulation Programme for Primary Care (BAP-PC) is a computer-aided decision support system for warfarin dosing To assess the quality of dosing decisions based on the derived INR	TTR and adverse events	On average, patients spent 69% of time in the therapeutic range (range, 60–76%). Patients were seen on average every 27 days (range, 24–30). The average point prevalence was 86% (range, 76–100%). In total, 33 adverse events were reported (0–13/practice). Serious adverse events ranged from 0 to 1 for each practice.
Barber et al., (2001). UK	**A cohort observational trial.** A total of 92 patients were enrolled into three periods; GP-led service (Jan–June 1997), Nurse-led service Transition (July–Dec 1998), and Nurse-led service (Jan–June 1999).	INR Star is a warfarin dosing software To compare GP-led oral anticoagulation monitoring with a nurse-led service involving near patient testing and computerized decision support.	INR value	The nurse-led CDSS service provided anticoagulation control equivalent to the traditional GP-led service, with identical mean INR values and a nonsignificant trend towards improvement in all other parameters. Recording of indications for anticoagulation and target INR ranges were significantly improved using CDSS.
Manotti et al., (2001). Italy	**A prospective randomised trial.** Two separate sets of patients from five anticoagulant clinics were studied: 335 patients in the stabilization phase and 916 patients in the maintenance phase. Patients were randomised to a computerized system or to physician group.	PARMA is a computer-aided dosing decision support system To test whether a computer-based decision support system to initiate and maintain oral anticoagulant treatment can improve the laboratory quality of therapy.	The percentage of patients reaching a stable state of anticoagulation during each of the first three months of treatment The percentage of time individuals spent within the TTR (maintenance phase). Patient visit per year	Patients in the computer-aided dosing group achieved a stable state significantly faster ($p<0.01$) and they spent more time within the therapeutic range during maintenance ($p<0.001$) than controls. The favourable effect of computer-aided dosing was mainly due to a reduction of the time spent below the therapeutic range and was associated with an increase of mean INR value, of anticoagulant drug dosage, and with a reduction of the number of appointments per patient (all changes significant: $p<0.001$).

Author(s) and country	Study design and sample	CDSS category and aim of Study	Key outcome measures	Results
Fitzmaurice et al., (2000). UK	**A randomised controlled trial.** A total of 224 patients were recruited from 12 primary care practices (9 interventions and 3 controls). Two control populations were used: intra-practice controls (n=102) and inter-practice controls (n=143), and 122 intervention patients	Anticoagulation Management Support System (Sof-top Information Systems). To test the efficacy and safety of using a CDSS for oral anticoagulation monitoring within nurse-led primary care clinics.	INR and TTR	A significant difference in percentage of time spent in range was found between the 2 groups during the study period ($P < 0.001$), with a significant improvement in proportion of time spent in range for intervention patients (paired t test, $P<0.008$). There was also an improvement in both control populations, and, when the improvements were compared across the 3 populations, there were no significant differences in these improvements in the proportion of time spent in range.
Ageno and Turpie, (1998). Canada	**A randomised, prospective trial.** A total of 101 patients were randomised to be controlled by the computerized system (n=50) or standard manual monitoring (n=51) by trained personnel.	DAWN AC; is a computer-dosage programs. To assess the accuracy and clinical utility of a computer-based dosage program	Comparison of number of INR tests, mean INR values in the two groups, test interval, the percentage of INRs within the therapeutic range, and percentage of dose adjustments	The average number of INR tests per patient was 16.9 in the standard manual monitoring group and 14.1 in the computer-controlled group, with a 16.6% reduction The average test interval was greater in the computer adjusted group (20.23 days), as compared with the manual dosed group (17.03 days), with an 18.8% difference. The percentage of dose adjustments performed by the healthcare professionals was 47.4%, whereas the computer needed 31.3% dose adjustments, a statistically significant 34.0% reduction ($p=0.02$). The percentage of INRs within the therapeutic range (2.5–3.5) was 51.5% in the manual dosed group and 49.6% in the computer dosed group (not statistically significant). The percentage of INRs within a slightly wider range (2.3–3.7), which is considered a satisfactory range, was similar in the two groups, being 64.6% in the manual group and 64.9% in the computer group.

Author(s) and country	Study design and sample	CDSS category and aim of Study	Key outcome measures	Results
Fitzmaurice et al., (1998). UK	**A prospective cohort study.** 29 patients were seen in a total of 208 appointments during the 12-month study period.	A computerised anticoagulation support system (evaluated by Ryan et al., 1989). To assess the clinical utility of this model in anticoagulation monitoring.	INR and TTR Adverse events	The mean percentage of patients within therapeutic range was 72% A total of 111/208 (53.4%) of INRs were within therapeutic range. There were no adverse events throughout the study period
Poller et al., (1998). Denmark, Norway, Portugal, and UK	**A randomised controlled trial.** In five European centres 285 patients were randomly assigned to the computer-generated-dose group (n=137) or traditional-dose group (n=148).	DAWN AC; is a computer-dosage programs. To compare the benefits of computer generated anticoagulant dosing with traditional dosing decided by experienced medical staff in achieving target INRs.	INR and TTR	Computer-generated dosing was significantly beneficial overall in achieving target INR (P=0.004) The mean time within target INR range for all patients and all ranges was 63.3% (SD 28.0) of days in the computer-generated-dose group compared with 53.2% (27.7) in the traditional-dose group. For the stabilisation patients alone, computer-generated doses led to a non-significant benefit in all INR ranges, whereas in the stable patients the benefit was significant (p=0.02)
Vadher et al., (1997a). UK	**A randomised controlled trial.** 148 inpatients requiring start of warfarin treatment were randomly assigned to the intervention group (n=72) and to control group (n=76).	A computerised decision support system for initiation and control of warfarin therapy To determine whether a computerised dosing system improves quality of anticoagulant control achieved by trainee doctors	Median time to therapeutic range, stable dose, and person time spent in the therapeutic range.	Median time to reach international normalised ratio of >2 was not significantly different in the two groups (3 days). Median time to achieve a stable dose was significantly lower in intervention than in controls (7 v 9 days, P = 0.01) without excessive over/under treatment with anticoagulant. Patients in intervention group spent greater proportion of time in therapeutic range, both as inpatients (59% v 52%) and outpatients (64% v 51%).

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Vadher et al., (1997b). UK	**A randomised controlled trial.** 81 out-patients (group A, therapeutic range 2-3) and 96 out-patients (group B, therapeutic range 3-4.5) were randomised to management by a nurse-practitioner or by trainee doctors. 37 patients in group A and 50 patients in group B were randomised to be managed by the nurse-practitioner. 44 patients in group A and 46 patients in group B were randomised to be managed by the clinicians.	A computerised decision support system for initiation and control of warfarin therapy (evaluated by Vadher et al., 1997a) To investigate the quality of anticoagulant control achieved by a nurse-practitioner using a CDSS with that achieved by trainee doctors without CDSS in a hospital-based anticoagulant clinic.	Time spent in the therapeutic range Dose suggestion acceptance	In group A, patients in the nurse-practitioner group spent a longer time in the therapeutic range than those in the clinician group (60.7% compared with 51.6%). Dose suggestion acceptance in the nurse-practitioner group (88%) was higher compared with agreement between the CDSS and the clinicians (60%). In group B, patients in the clinician group spent a slightly longer time in the therapeutic range (70% compared with 67.6%). Acceptance of dose suggestion was lower in the nurse-practitioner group (67%) compared with agreement between the CDSS and the clinicians (73%)
Fitzmaurice et al., (1996). UK	**A randomised controlled trial.** 49 patients were enrolled over 12 months; two control populations were used. In practice A, all patients were dosed by the practice DSS providing historical control (n=26). In practice B, 23 patients were randomised to 9 controls, 14 interventions.	A computerised decision support system; DOS-based programme (Anticoagulation Management Support System, Warwick) To test the effectiveness of using DSS for oral anticoagulation monitoring in primary care	INR and mean recall times (No of appointment) Adverse events	There were significant improvements in INR control from 23% to 86% (P>0.001) in the practice A (all patients were dosed by the DSS). In the practice B, logistic regression showed a significant trend for improvement in intervention patients which was not apparent in the hospital-dosed patients (P<0.001). Mean recall times were significantly extended in patients from practice A (24 days to 36 days) (P=0.033). Adverse events were comparable between hospital and practice-dosed patients

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Galloway et al., (1995). UK	**A prospective cohort study.** 210 patients were enrolled into The study.	Computer-aided dosing decision support system (evaluated by Ryan et al., 1989) To assess whether the introduction of computer programs for the control of oral anticoagulation improves the quality of anticoagulant control in hospital clinics.	Hospital workload Number of patients seen in the anticoagulant clinics Management by non-medical staff Achieving target INR	Decreasing in the hospital anticoagulant clinic workload The total number of patients seen in the hospital anticoagulant clinic decreased by 2% from 3475 to 3405. Overall, 46% of patients had INR results within the therapeutic range, this included 55% of patients whose target INR was 2-3 and 13% of patients whose target INR was 3-4.5 were in the therapeutic range. The percentage of patients now in range for these two groups has increased to 72% and 57%, respectively. This improvement in anticoagulant control was only statistically significant for those patients whose target INR range was 3-4.5 ($p<0.001$)
Margolis et al., (1994). Uruguay	**A before-after cohort study.** Data were collected and compared from three periods; (1) Pre-computer phase: nine months of prospectively collected data before the use of the software (n=91). (2) Computer phase 1(implementation of the software): the first six months of use of the program (n=107). (3) Computer phase 2: the last nine months of use of the software (n=132).	warfarin 2.0; is a computer-based for warfarin management To examine whether the introduction of the DSS helps to achieve a good anticoagulation level	Number of patients in the therapeutic range Number of under-treated patients Number of patients over-treated	The number of patients in the therapeutic range +/- 0.5 (2.0 to 4.0) significantly increased from 65.7% to 75.8% (p=0.03) The number of patients being over-treated decreased to 2.8% for the last three months. This figure is significantly smaller than the pre-computer phase: 9.90%, p=0.0045. The number of undertreated patients increased in the last period to values slightly greater than the pre-computer phase.

Author(s) and country	Study design and sample	CDSS category and aim of Study	Key outcome measures	Results
Poller et al., (1993). UK	**A pilot randomised trial.** 186 patients were randomised to of three systems. Patients in the customary dosing group n=64, Charles group n=57, Coventry group n=53, and Hillingdon n=12.	Three previously evaluated CDSSs for warfarin dosing (Wilson and James, 1984; Ryan et al., 1989); the Hillingdon system, the Charles system, and the Coventry system To compare the effectiveness of three computerised systems that are currently used for assisting warfarin control with the customary dosing method used by experienced medical staff	INR value	Overall, there was no significant difference in the control achieved by computerised dosage programs and traditional dosing method (p = 0.57). For patients assigned a 3-4.5 target band, computerised dosing was more effective in maintaining the INR within range (on 56% and 58.6% of visits for the Charles and Coventry systems, respectively) than traditional dosing (36.8% of visits). This achieved significance (p = 0.044). For the 2-3 range patients dosed using the traditional method seemed to be slightly better-INR values within range on 59.7% of visits, followed by the Hillingdon system 59.4%, the Charles at 56.8%, and Coventry at 51.5%, but the differences were not significant (p = 0.62).
Ryan et al., (1989). UK	**A prospective cohort trial.** Implementation of a computerised system for decision support in three anticoagulation clinics. N= 688 patients	A computer assisted dosage for warfarin therapy. To assess whether the introduction of computer programs for the control of oral anticoagulation improves the quality of warfarin control	INR value	Patients' conditions have been better controlled with more consistent prescribing. The mean INR have progressively moved nearer to the midpoint of the therapeutic range, and a 38% improvement was achieved in the results of INR falling within the recommended therapeutic ranges.

Author(s) and country	Study design and sample	CDSS category and aim of Study	Key outcome measures	Results
Wilson and James, (1984). UK	**A before-after trial.** Comparison of 132 patients managed manually in August-September 1982 and by computer in August-September 1983	A computer assisted dosing system. To assess the impact of introducing the dosing system on work and performance	Anticoagulation therapy management	Computer assisted warfarin treatment seems to be at least as good as treatment managed manually
Abbrecht et al., (1982). United States	**A prospective trial.** A computer-assisted group of 10 patients was compared with a control group of 10 patients who did not receive computer assistance.	A computer-assisted method for individualized anticoagulation To evaluate a new computer- assisted method for individualizing warfarin therapy	TTR	The average number of days required to first reach the therapeutic range was greater for the computer-assisted than for the control patients ($P < 0.05$). The program-assisted group remained within the therapeutic range for a much larger percentage of the time ($P < 0.01$).

Abbreviations: CCDSS, computerized clinical decision support system; INR: International Normalised Ratio, TTR: Time in the Therapeutic Range

2.3.4 Country of origin and healthcare setting

Twenty-five percent of the studies were undertaken in the United Kingdome (n=11) and 23% of the studies were undertaken in the United States (n=10), the remainder in Australia (n=1), Canada (n=2), Denmark (n=2), Dutch (n=1), Europe (n=4), France (n=2), Iceland (n=1), Italy (n=3), New Zealand (n=1), Saudi Arabia (n=1), Spain (n=1), Sweden (n=2), and Uruguay (n=1).

Thirteen of the studies were set in hospitals (n=13) (Abbrecht et al., 1982; Borgman et al., 2012; Ferret et al., 2013; Gouin-Thibault et al., 2010; Marco et al., 2003; Margolis et al., 1994; Mitra et al., 2005; Pandya et al., 2016; Poller et al., 1993; Rasmussen et al., 2012; Wilson and James, 1984; Vadher et al., 1997a; Vadher et al., 1997b) and thirteen were conducted in primary care (Ageno and Turpie, 1998; Arts et al., 2017; Eckman et al., 2016; Fitzmaurice et al., 1996; Fitzmaurice et al., 1998; Fitzmaurice et al., 2000; Galloway et al., 1995; Harper et al., 2015; Manotti et al., 2004; Niiranen and Yli-Hietanen, 2008; Wess et al., 2007; Wess et al., 2011; Wurster and Doran, 2006). Six were set in specialised anticoagulation clinics (Almeman and Rasool, 2013; Galloway et al., 1995; Manotti et al., 2001; Nielsen et al., 2014; Nieuwlaat et al., 2012; Ryan et al., 1989;) and ten studies were undertaken in centres with a special interest in oral anticoagulation management (Cafolla et al., 2011; Deitelzweig et al., 2014; Dimberg et al., 2012; Grzymala-Lubanski et al., 2013; Onundarson et al., 2007; Poller et al., 1998; Poller et al., 2008a; Poller et al., 2008b; Poller et al., 2009; Woller et al., 2015). Papaioannou et al., (2010) conducted the study in a long-term care home.

Except for three studies (Arts et al., 2017; Galloway et al., 1995; Wess et al., 2011), the effectiveness of prescribing decision support systems on the quality of anticoagulation was the most studied effect of CDSSs on anticoagulation management. The next section

identifies each researcher's rationale in the included studies for the implementation and subsequent evaluation of their CDSS in anticoagulation management.

2.3.5 Rationale for undertaking decision support system research

All of the studies refer to the challenges of anticoagulation prescribing in an era where there are rapid expansion of clinical guidelines, risk assessment tools and with the introduction of the newer oral anticoagulants. Several authors quote the unique challenges of anticoagulation therapy management in clinical practice. For instance, physicians' concerns about the bleeding risk associated with anticoagulants, complexities associated with warfarin dosing, lack of experiences, and the unique risk-benefit profile for each oral anticoagulants, indicating that these add considerably to the difficulties of guideline implementation (Arts et al., 2017; Borgman et al., 2012; Deitelzweig et al., 2014; Eckman et al., 2016; Ferret et al., 2013; Fitzmaurice et al., 2000; Mitra et al., 2005). Several authors cited the need to reduce the reliance on specialist delivery of anticoagulation care, enabling other HCPs to manage clinics and decrease hospital workloads as a driver for CDSSs implementation and research (Fitzmaurice et al., 1996; Fitzmaurice et al., 1998; Fitzmaurice et al., 2000; Galloway et al., 1995). One study evaluated the impact of computerised tools for adverse drug event (ADE) detection (Ferret et al., 2013). The authors used a previously constructed decision tree and applied rules to detect potential overdose in VKA. They cited usefulness for the identification of ADEs and its challenge to detect as reasons for developing computerised decision rules for the identification of ADEs in large medical databases (Ferret et al., 2013).

Eighty-one percent of the studies (n=36) assessed CDSSs impact on warfarin monitoring and dosing (Abbrecht et al., 1982; Ageno and Turpie, 1998; Almeman and Rasool, 2013; Barber et al., 2001; Borgman et al., 2012; Cafolla et al., 2011; Dimberg et al., 2012;

Fitzmaurice et al., 1996; Fitzmaurice et al., 1998; Fitzmaurice et al., 2000; Galloway et al., 1995; Gouin-Thibault et al., 2010; Grzymala-Lubanski et al., 2013; Harper et al., 2015; Manotti et al., 2001; Manotti et al., 2004; Marco et al., 2003; Margolis et al., 1994; Mitra et al., 2005; Nielsen et al., 2014; Nieuwlaat et al., 2012; Onundarson et al., 2007; Oppenkowski et al., 2003; Papaioannou et al., 2010; Poller et al., 1993; Poller et al., 1998; Poller et al., 2008a; Poller et al., 2008b; Poller et al., 2009; Rasmussen et al., 2012; Ryan et al., 1989; Vadher et al., 1997a; Vadher et al., 1997b; Woller et al., 2015; Wurster and Doran, 2006), that could advise to monitor the drug effect at certain time intervals and advice specific dose adjustments based on this monitoring and the patient's characteristics.

2.3.6 Type of decision support intervention and functionality

Table 2.1 shows the types of CDSSs used and how they supported the clinician. All CDSSs that provide recommendations to healthcare providers regarding the initiation, modification, monitoring, or discontinuation of anticoagulation therapy, based on in vivo monitoring and the patient's characteristics were considered.

Decision support systems that were evaluated in the included studies were used to facilitate evidence-informed medication use (Arts et al., 2017; Borgman et al., 2012; Deitelzweig et al., 2014; Eckman et al., 2016; Ferret et al., 2013; Fitzmaurice et al., 2000; Mitra et al., 2005), reduce the incidence of harmful adverse events (Ferret et al., 2013; Fitzmaurice et al., 1996; Fitzmaurice et al., 1998; Poller et al., 2008; Poller et al., 2008; Oppenkowski et al., 2003; Wess et al., 2007), and improve healthcare system efficiency (Fitzmaurice et al., 2000; Galloway et al., 1995). Overall, the process of care was improved in all studies with measurable outcomes, and the CDSSs significantly improved the proportion of time in the therapeutic INR range for initiation therapy. The consensus within the selected studies is

that CDSSs provide an encouraging means of improving the quality of anticoagulants dosing and monitoring.

In this review, the majority of CDSSs are stand-alone computer systems (39/43, 91%). More than half were used by physicians for decision making, (28/43, 65%), the rest by other healthcare professionals. Recommendations were usually delivered at the time of care (31/43, 72%) on a desktop or laptop computer. Pilot testing was done in 28% (12/43), training was provided to users in 44% (19/43), and the authors were the developers of the CDSS in 44% (19/43) of studies. Only eighteen CDSSs were commercial, more than half being locally developed (25/43, 58%). The most common method of decision-support was via pop up alerts, which provided suggestions to the clinicians regarding monitoring, dosing and treatment options. As indicated in table 2.2

Table 2.2: Computerised decision support system characteristics for trials of anticoagulation management

Study	Design			Data entry source					CCDSS users				Methods for delivery of recommendations				Other characteristics				
	Stand Alone	Integrated with EMR	Integrated with CPOE	Automated through EMR	Project staff	Existing staff	Practitioner/decision-maker	Other data entry	Trainees	Physicians	Advanced Practice Nurses	Pharmacists/other HCPs	Desktop/Laptop computer	Project staff	Existing non-prescribing staff	Other Methods	Pilot tested	Users trained	Authors as developers	Feedback at time of care	CCDSS suggested diagnoses/ treatments/procedures
Arts et al., 2017	-	+	-	+	-	-	+	-	-	+	-	-	+	-	-	-	-	+	+	+	+
Eckman et al., 2016	+	-	-	-	-	+	-	-	-	+	-	-	+	-	-	-	+	+	+	+	+
Pandya et al., 2016	+	-	-	-	+	-	-	-	-	-	-	+	+	+	-	-	-	-	+	+	+
Harper et al., 2015	+	-	-	-	-	-	+	-	-	+	-	+	+	-	+	-	+	+	-	+	+
Woller et al., 2015	-	+	-	+	-	-	+	-	-	-	-	-	+	+	-	-	-	-	-	-	+
Deitelzweig et al., 2014	+	-	-	-	+	-	-	-	+	-	-	-	+	+	-	-	-	-	+	-	+
Nielsen et al., 2014	+	-	-	-	+	-	-	-	-	-	-	-	+	+	-	-	-	-	+	-	+
Almeman and Rasool, 2013	+	-	-	-	-	-	+	-	-	+	-	-	+	-	-	-	-	-	-	-	+

Study	Design			Data entry source					CCDSS users				Methods for delivery of recommendations				Other characteristics				
	Stand Alone	Integrated with EMR	Integrated with CPOE	Automated through EMR	Project staff	Existing staff	Practitioner/decision-maker	Other data entry	Trainees	Physicians	Advanced Practice Nurses	Pharmacists/other HCPs	Desktop/Laptop computer	Project staff	Existing non-prescribing staff	Other Methods	Pilot tested	Users trained	Authors as developers	Feedback at time of care	CCDSS suggested diagnoses/ treatments/procedures
Ferret et al., 2013	+	-	-	-	+	-	-	-	+	-	-	-	+	-	-	-	-	-	+	-	-
Grzymala-Lubanski et al., 2013	-	+	-	+	-	-	-	-	-	+	+	-	+	-	-	-	-	+	-	+	+
Borgman et al., 2012	+	-	-	-	-	-	+	-	-	+	-	+	+	-	-	-	+	+	-	+	+
Dimberg et al., 2012	+	-	-	-	+	-	-	-	+	-	-	-	+	+	-	-	-	-	-	-	+
Nieuwlaat et al., 2012	+	-	-	-	-	-	+	-	-	+	-	-	+	-	-	-	-	+	-	+	+
Rasmussen et al., 2012	+	-	-	-	-	-	+	-	-	+	-	-	+	-	-	-	-	-	-	+	+
Cafolla et al., 2011	+	-	-	-	-	-	+	-	-	+	-	-	+	-	-	-	-	-	+	+	+
Wess et al., 2011	+	-	-	-	-	-	+	-	-	+	-	-	+	-	-	-	+	+	+	+	+

Study	Design			Data entry source					CCDSS users				Methods for delivery of recommendations				Other characteristics				
	Stand Alone	Integrated with EMR	Integrated with CPOE	Automated through EMR	Project staff	Existing staff	Practitioner/decision-maker	Other data entry	Trainees	Physicians	Advanced Practice Nurses	Pharmacists/other HCPs	Desktop/Laptop computer	Project staff	Existing non-prescribing staff	Other Methods	Pilot tested	Users trained	Authors as developers	Feedback at time of care	CCDSS suggested diagnoses/ treatments/procedures
Gouin-Thibault et al., 2010	+	-	-	-	-	-	+	-	-	+	-	-	+	-	-	-	-	+	+	+	+
Papaioannou et al., 2010	+	-	-	-	-	+	+	-	-	+	-	+	+	-	+	-	+	+	+	+	+
Poller et al., 2009	+	-	-	?	?	?	?	?	-	+	-	-	?	?	?	?	?	+	?	+	+
Poller et al., 2008a	+	-	-	?	?	?	?	?	-	+	-	-	?	?	?	?	?	+	?	+	+
Poller et al., 2008b	+	-	-	?	?	?	?	?	-	+	-	-	?	?	?	?	?	+	?	+	+
Onundarson et al., 2007	+	-	-	?	?	?	?	?	?	?	?	?	?	?	?	?	-	-	?	+	+
Wess et al., 2007	+	-	-	-	+	-	-	-	-	-	-	-	+	+	-	-	-	-	+	-	+
Wurster and Doran, 2006	+	-	-	-	-	+	+	-	-	+	-	-	+	-	-	-	-	+	-	+	+

Study	Design			Data entry source					CCDSS users				Methods for delivery of recommendations				Other characteristics				
	Stand Alone	Integrated with EMR	Integrated with CPOE	Automated through EMR	Project staff	Existing staff	Practitioner/decision-maker	Other data entry	Trainees	Physicians	Advanced Practice Nurses	Pharmacists/other HCPs	Desktop/Laptop computer	Project staff	Existing non-prescribing staff	Other Methods	Pilot tested	Users trained	Authors as developers	Feedback at time of care	CCDSS suggested diagnoses/ treatments/procedures
Mitra et al., 2005	+	-	-	?	?	?	?	?	-	+	-	-	? ?	?		?	?	?	?	+	+
Manotti et al., 2004	+	-	-	-	-	-	+	-	-	+	-	-	+	-	-	-	+	+	-	+	+
Marco et al., 2003	+	-	-	-	-	-	+	-	-	+	-	-	+	-	-	-	-	-	-	+	+
Oppenkowski et al., 2003	+	-	-	-	-	+	-	-	-	+	-	-	+	-	-	-	-	-	+	-	+
Barber et al., 2001	+	-	-	-	+	-	+	-	-	-	-	-	+	-	-	-	-	+	-	+	+
Manotti et al., 2001	-	+	-	+	-	-	+	-	-	+	-	-	+	-	-	-	+	-	+	+	+
Fitzmaurice et al., 2000	+	-	-	-	-	-	-	+	-	-	-	+	+	-	-	-	+	+	-	+	+

Study	Design			Data entry source				CCDSS users				Methods for delivery of recommendations				Other characteristics				
	Stand Alone	Integrated with EMR	Integrated with CPOE	Automated through EMR	Project staff	Existing staff	Practitioner/decision-maker	Trainees	Physicians	Advanced Practice Nurses	Pharmacists/other HCPs	Desktop/Laptop computer	Project staff	Existing non-prescribing staff	Other Methods	Pilot tested	Users trained	Authors as developers	Feedback at time of care	CCDSS suggested diagnoses/ treatments/procedures
Ageno and Turpie, 1998	+	-	-	-	-	+	-	-	+	-	-	+	-	-	-	-	-	-	+	+
Fitzmaurice et al., 1998	+	-	-	-	-	+	-	-	-	+	-	-	-	+	-	-	+	-	+	+
Poller et al., 1998	+	-	-	-	-	-	+	-	+	-	-	+	-	-	-	+	+	-	+	+
Vadher et al., 1997a	+	-	-	-	+	-	-	-	-	+	-	-	+	-	-	+	-	+	+	+
Vadher et al., 1997b	+	-	-	-	+	-	-	-	-	+	-	-	+	-	-	+	-	+	+	+
Fitzmaurice et al., 1996	+	-	-	-	-	+	-	-	-	+	-	-	-	+	-	+	+	-	-	+
Galloway et al., 1995	+	-	-	-	-	-	+	-	+	+	+	+	-	+	-	-	-	-	-	+
Margolis et al., 1994	+	-	-	-	-	-	+	-	+	-	-	+	-	-	-	-	-	+	-	+

Study	Design			Data entry source				CCDSS users				Methods for delivery of recommendations				Other characteristics				
	Stand Alone	Integrated with EMR	Integrated with CPOE	Automated through EMR	Project staff	Existing staff	Practitioner/decision-maker	Trainees	Physicians	Advanced Practice Nurses	Pharmacists/other HCPs	Desktop/Laptop computer	Project staff	Existing non-prescribing staff	Other Methods	Pilot tested	Users trained	Authors as developers	Feedback at time of care	CCDSS suggested diagnoses/ treatments/procedures
Poller et al., 1993	+	-	-	-	-	-	+	-	+	-	-	+	-	-	-	-	-	-	+	+
Ryan et al., 1989	+	-	-	-	-	-	+	-	+	-	-	+	-	-	-	-	-	+	+	+
Wilson and James, 1984	+	-	-	-	-	-	+	+	-	-	-	+	-	-	-	-	-	+	+	+
Abbrecht et al., 1982	+	-	-	-	-	-	+	-	+	-	-	+	-	-	-	-	-	+	-	+

Abbreviations: CCDSS, computerized clinical decision support system; CPOE, computerized order entry system; EMR, electronic medical record; Symbol key: + = characteristic present; - = characteristic absent; ? = unstated or uncertain.

2.3.7 Methodological aspects of CDSSs studies

Five research designs have been used in the included studies. They are: randomised controlled trial (18/43, 42%) (Ageno and Turpie, 1998; Arts et al., 2017; Borgman et al., 2012; Eckman et al., 2016 Fitzmaurice et al., 1996; Fitzmaurice et al., 2000; Manotti et al., 2001 Marco et al., 2003; Mitra et al., 2005; Nieuwlaat et al., 2012; Poller et al., 1993; Poller et al., 1998; Poller et al., 2008a; Poller et al., 2008b; Poller et al., 2009; Rasmussen et al., 2012; Vadher et al., 1997a Vadher et al., 1997b); prospective observational design (8/43, 19%) (Abbrecht et al., 1982; Barber et al., 2001; Fitzmaurice et al., 1998; Galloway et al., 1995; Gouin-Thibault et al., 2010; Harper et al., 2015; Pandya et al., 2016; Ryan et al., 1989); retrospective observational design (9/43, 21%) (Deitelzweig et al., 2014; Dimberg et al., 2012; Ferret et al., 2013; Grzymala-Lubanski et al., 2013; Nielsen et al., 2014 Oppenkowski et al., 2003; Papaioannou et al., 2010; Woller et al., 2015; Wess et al., 2007); a prospective before-after design (6/43, 14%) (Almeman and Rasool, 2013; Cafolla et al., 2011; Manotti et al., 2004; Margolis et al., 1994; Wilson and James, 1984; Wurster and Doran, 2006); usability design (1/43, 2%) (Wess et al., 2011) and a cross sectional analysis design (1/43, 2%) (Onundarson et al., 2007). Table 2.1 illustrates the variety of research methods used in the CDSSs studies.

Randomised controlled trials (RCTs) are considered the “gold standard” for reporting the effects of interventions (Guyatt et al., 1995). Authors state that a well conducted RCT eliminates the effects of confounding variables and are regarded as best placed to answer questions regarding the effect a CDSS has on changing practice or improving patient outcomes (Campbell et al., 2007; Liu and Wyatt, 2011). Despite the assertions in the literature regarding the superiority of the RCT as a research method and its feasibility in CDSS research, only 42% of the included studies in this literature review utilised this

design. Lui and Wyatt (2011) reported that only 6.7% of information system studies conducted between 2006-2010 were RCTs. However, the use of RCTs to evaluate a CDSS in a busy clinical environment can be associated with key methodological issues (Liu and Wyatt, 2011). For example, the implementation of CDSS intervention on an organisational level, and randomising patients within the same clinic raises the concern of contaminating the control group with intervention from the CDSS group, which could obscure the true effect (Lui and Wyatt, 2011). Moreover, lack of blinding, lack of protection against contamination and incomplete follow-up are likely to create a high risk of bias that is seen as key to internal validity that can be difficult to implement in clinical practice (Nieuwlaat et al., 2011). This suggests that although RCTs are purported to be a suitable method for informatics research, the challenges they pose in the CDSS research may cause many researchers to use alternative research method to evaluate the impact of CDSSs.

Eighteen studies have used RCTs for evaluation of the effect of CDSS on oral anticoagulant management. Two studies randomised clinical sites, rather than patients, which is an accepted method to minimise cross-over effects (Arts et al., 2017; Eckman et al., 2016). In our review, cluster RCTs showed an effect similar to RCTs. However, finding an improvement while not using cluster randomisation could indicate that there is a CCDSS effect. The reason for the use of RCTs in health care research is that the random allocation of participants accounts for potential bias (Nieuwlaat et al., 2011). When considering the risk of bias in CDSS research, researchers are concerned with developing a research method that separates the effects of the CDSS from confounding variables. Table 2.1 above reveals that many RCTs reported no statistically significant difference between the control and intervention groups. This could have been due to cross contamination and the availability of the clinical guideline for all treating clinicians (Fitzmaurice et al., 2000; Mitra et al., 2005; Poller et al., 1993). Cluster RCTs are regarded better to manage the

contamination that results from the physician's experience of implementing the intervention and the effect this may have on the control group (Eccles et al., 2003). The cluster RCT by Arts et al., (2017) and Eckman et al., (2016) randomised GP practices to either control or intervention groups. This had the effect of not only randomising the clinical setting but all the medical staff within them and eliminating any performance bias during the study (Eccles et al., 2003). Cluster RCTs are complex and expensive to implement in that the cost and effort required often make them difficult to implement (Eccles et al., 2003; Liu & Wyatt, 2011). This is the most likely reason there were only two in the selected studies.

Non-experimental design studies are the predominant design identified in this literature review (25/43, 58%). They are also the leading research method in the general CDSS research (Liu and Wyatt, 2011). These additional research methods offer an alternative when the RCT is not feasible or acceptable (Craig et al., 2008). CDSSs are considered to be a complex intervention to implement as they fulfil the criteria developed by Campbell et al., (2000). In CDSS research, practitioner behaviours and patient outcomes are often the targets of the evaluation, and in a busy, unpredictable clinical environment they can be difficult to implement (Campbell, M. et al., 2000; Craig et al., 2008). There is some consensus in the literature which suggests a suite of alternative research methods can be used to effectively measure the impact of CDSSs (Campbell, M. et al., 2000; Craig et al., 2008; Eccles et al., 2003). They are uncontrolled before-after studies, controlled before-after studies and other pragmatic approaches, such as retrospective and prospective cohort design.

Before and after studies that have assessed the use of CDSSs in anticoagulants management are considered the leading research method in the general CDSS research (Liu and Wyatt, 2011). Before and after studies are a relatively easy research method to

develop and implement when a new CDSS system is introduced (Liu and Wyatt, 2011). Researchers concerned with understanding the impact of the CCDSS, firstly take measurements before the system implementation to get a baseline measure, then at some time after the implementation the same measures are retaken (Grimshaw et al., 2000). A comparison between the results is then analysed, and any change is assumed to have occurred because of the intervention (Grimshaw et al., 2000). This is called uncontrolled before and after design. The six included before-after studies describe the use of "before", "pre-intervention" or "pre-test" and are regarded as using an uncontrolled before-after method (Almeman and Rasool, 2013; Cafolla et al., 2011; Manotti et al., 2004; Margolis et al., 1994; Wilson and James, 1984; Wurster and Doran, 2006). None of the before-after studies used a controlled before-after design as defined in the literature (Grimshaw et al., 2000).

When considering the quality of uncontrolled before-after studies, performance bias is a concern as those involved in the study knew about their participation as this may have changed their performance. In the studies by Almeman and Rasool, (2013), Cafolla et al., (2011), Margolis et al., (1994), Wilson and James, (1984) and Wurster and Doran, (2006) there was no awareness of the research in the clinic. However, in the study by Manotti et al., (2004) the physicians knew that the study was taking place. Before and after studies by their design are conducted over a longer period than studies using other methods, for example, the study by Wilson and James, (1984) was conducted over a one-year period. During this time, it is likely that there were several factors helped to improve clinician knowledge of clinical guidelines about the dosing and monitoring of patients on oral anticoagulants. Therefore, it may not be possible to isolate other effects from the impact of the CDSS when studies are conducted over long periods.

Of the before-after studies, only three CCDSSs were locally developed (Almeman and Rasool, 2013; Manotti et al., 2004; Wurster and Doran, 2006), the majority being commercial. Of the six before-after studies two reported that some or all their outcome measures achieved no statistical significance (Manotti et al., 2004; Wilson and James, 1984). The other before-after studies (n=4) presented statistically significant results demonstrating the success of their systems (Almeman and Rasool, 2013; Cafolla et al., 2011; Margolis et al., 1994; Wurster and Doran, 2006). There is some evidence to suggested that uncontrolled before-after studies may overestimate the effects of an intervention (Grimshaw et al., 2000). There may be bias inherent within studies where the CDSSs have been developed by the research team and tested where they work (Cafolla et al., 2011; Margolis et al., 1994).

One study included in the literature review used a time series analysis as part of a before-after cohort study (Margolis et al., 1994). Interrupted time series studies collect data multiple time points before and after the implementation of the intervention (Margolis et al., 1994). The analysis, which compares the data points after the intervention enable the effect of the CDSS to be shown (Margolis et al., 1994). This study investigated the impact of CDSS to achieve a good anticoagulation level, avoiding both undertreatment and overtreatment. The study took place over a 24-month period during which there were three distinct phases. Phase one was the baseline "pre-intervention" period, which lasted nine months. After a one-month gap, phase two began lasting six months and included the introduction of the intervention to optimise treatment of outpatients with warfarin including patient education. Finally, after a gap of one-month, phase three began with the introduction of the CCDSS; lasting nine months. Of the three key outcome measures, there were statistically significant changes in two: The number of patients in the therapeutic range, the number of patients being overtreated decreased significantly in the last three

months but not the number of patients being undertreated. In general terms warfarin prescribing patterns improved over time. However, the analysis in this study revealed that during the CDSS phase the degree of concordant prescribing was higher than the underlying trend because there was no consideration given to the experience of the prescribing physician as a possible confounder.

The remaining studies in this literature review utilise a prospective observational design (Abbrecht et al., 1982; Barber et al., 2001; Fitzmaurice et al., 1998; Galloway et al., 1995; Gouin-Thibault et al., 2010; Harper et al., 2015; Pandya et al., 2016; Ryan et al., 1989) and a retrospective observational design (Deitelzweig et al., 2014; Dimberg et al., 2012; Ferret et al., 2013; Grzymala-Lubanski et al., 2013; Nielsen et al., 2014 Oppenkowski et al., 2003; Papaioannou et al., 2010; Woller et al., 2015; Wess et al., 2007). Again, these studies like many others in this literature review failed to address confounding variables. The most likely confounders to affect the care of patients in the intervention arm are patient characteristics (e.g. age, gender, and disease severity), and clinician's characteristics (e.g. the experience level of the clinicians treating the patients in the study). Failure to adequately manage confounders can create a fundamental flaw in the design of a study (Liu and Wyatt, 2011).

Despite the predominance of non-experimental studies in CDSS research, several authors discount the method as a means of contributing to the CDSS evidence base as the risk of bias is unacceptably high (Liu and Wyatt, 2011). The challenges of conducting RCTs in CDSS research make this relatively easy research method appealing. However due to the intrinsic risk of bias identified in reviewed studies, one cannot draw any firm conclusions about the effectiveness of the CDSSs under investigation.

In conclusion, sufficient studies were available to provide evidence related to CDSS impact on anticoagulation management process. The intention of this review was to highlight key research findings and gaps in the literature.

The key research findings found in the literature concerned CDSSs role in guiding anticoagulation therapy prescribing practices such as assisting in drug selection and dosing suggestions, flagging adverse drug reactions, reducing toxic drug levels and time to therapeutic control, reducing medication errors and changing prescribing in accordance with guideline recommendations. This review has provided evidence that CDSSs can improve health care process measures in the hospital and primary care settings. The reviewed studies explored the impact of CDSSs on key decision points in anticoagulants prescribing process and emphasised the diversity of studies, intervention outcomes and methods used. However, results were not consistent among studies, even when evaluating the same drug or the same CDSS. This may relate to many factors, including variation in the study design, research setting, population characteristics, and CDSS design and workflow integration. The heterogeneity of outcomes in these studies is important, adding a great breadth to the field of CDSSs contributions to healthcare system and patient care outcomes.

The reviewed studies are varied in methods although many RCTs exist. The RCTs were focused on evaluating changes in prescribing practice reflected by patients INR score and time spent on the target INR range. The RCTs were positive 72% of the time while the non-experimental studies were positive 84% of the time. The impact of a CDSS on decision and decision-making process are not investigated in any of the identified studies. Qualitative studies are absent across all settings. This provides support for the aim of this study, which is discussed further in section 4.5.1 of the methodology chapter.

2.4 Impact of patient decision aids on anticoagulation decision making

According to the International Patient Decision Aids Standards (IPDAS) Collaboration (Elwyn et al., 2006), patient decision aid (PDA) is defined as an evidence-based tool designed to prepare individuals to participate in making specific and deliberated choices among options in ways they prefer. The ultimate goal of patient decision aids is to improve decision making by providing structured guidance in the steps of decision making and communication of patient's informed values with others involved in the decision (e.g. clinician) (Elwyn et al., 2006).

Decision aids for AF have been developed to provide AF patients with information regarding risks and benefits of therapy and to help them clarify their preferences regarding treatment options (Eckman et al., 2016; Fatima et al., 2016; Fraenkel et al., 2011; Holbrook et al., 2007; Hong et al., 2013; Kaiser et al., 2015; Man-Son-Hing et al., 1999; McAlister et al., 2005; Protheroe et al., 2000; Saposnik and Joundi, 2016; Thomson et al., 2002). The decision aids focused on the provision of information to patients to be able to effectively communicate their questions, concerns, and preferences to their physicians. Some of these decision aids were designed to conform to the IPDAS, in terms of the description of treatment options, presentation of outcome probabilities, helping patients to clarify their values, and to prepare them to participate in the decision-making process (Fraenkel et al., 2011; Hong et al., 2013; Kaiser et al., 2015; Saposnik and Joundi, 2016). Table 2.3, outlines the included studies main characteristics. The next sections provide a summary of the content of table 2.3.

2.4.1 Overview of the key characteristics of included studies

Only five decision aids for anticoagulation management were examined for efficacy (Fraenkel et al., 2012; Holbrook et al., 2007; Man-Son-Hing et al., 1999; McAlister et al.,

2005; Protheroe et al., 2000; Thomson et al., 2007). In total, six papers that specifically evaluated the effectiveness of these decision aids were identified from the electronic database searches. Of these, five were RCTs (Fraenkel et al., 2012; Holbrook et al., 2007; Man-Son-Hing et al., 1999; McAlister et al., 2005; Thomson et al., 2007) and one was an observational study (Protheroe et al., 2000). Decision aids for anticoagulation management used different formats and content and were compared to a variety of control interventions. Both Man-Son-Hing (1999) and McAlister (2005) compared different versions of an audio-guided workbook decision aid to usual care. In Man-Son-Hing (2004), the DA consists of an audio-booklet that was designed to be used by patients at home before the consultation. The audio-booklet describes the potential consequences of AF-associated stroke or transient ischemic attack, provides patient- specific estimates of stroke risk and illustrates the potential benefits and risks of warfarin and aspirin associated with each patient's baseline risk. In McAlister (2005), the updated version of the audio-booklet DA used by Man-Son-Hing was compared to usual care. Thomson (2007) compared a computerised decision aid applied in shared decision-making clinic to evidence-based paper guidelines applied as direct advice. The computerised decision aid describes the individualised benefits and potential harms of warfarin and aspirin treatment and individualised risk and a section to support shared decision making. Holbrook (2007) compared three different decision aid formats (decision board, decision booklet with audiotape, or interactive computer program) and graphic presentation of the probability data for benefits and harms (pie graph or pictogram). Identical information was included in each type of decision aid. The information was divided into three sections: description of outcomes, treatment choices (no treatment, warfarin or aspirin) and the probability of stroke and major bleeding, each explained in terms of severity and impact. Protheroe (2000) used individualised decision analysis combining probability and utility assessments

into a decision tree. The decision tree presents tailored absolute annual risks of a thromboembolic, relative risk reduction, and the probability of side effects if warfarin treatment was given. Fraenkel (2012) compared a computerised decision aid to standard care. The computerised DA was designed to include information about treatment options (warfarin or aspirin), presentation of outcome probabilities, and a section to help patients to clarify their values. In addition to these criteria, the tool was designed to prepare patients to participate in the decision-making process and to communicate effectively with their clinicians.

Although the identified DAs used a different framework for development, they were found to focus on a similar type of outcome measures. Elwyn et al., (2006) and O'Connor et al., (2009) identified two measurable outcomes - attributes of the decision (e.g. knowledge, risk perceptions, and value congruence with chosen option) and attributes of the decision process (decisional conflict, patient-practitioner communication, participation in decision making, satisfaction with the decision process, anxiety, and adherence to chosen option).

Table 2. 3: key characteristics of the DAs studies included in the review

Author(s) and country	Study design, sample, and intervention	CDSS category	Key outcome measures	Results
Fraenkel et al., (2012) United States	**A clustered randomised controlled trial** 135 participants were assigned to the intervention (n=69) or control group (n=66) Patients in the intervention arm were able to discuss their values and opinions with their clinicians.	The decision support tool includes education about AF and stroke, the different treatment options (aspirin, warfarin or both), and why treatment for NVAF involves a choice. Participants were provided with individualized information regarding their risk of stroke and bleeding and the sequelae of these outcomes.	Decisional conflict sub-scales; informed and values clarity subscales Knowledge Patient-clinician communication Change in treatment	Participants in the intervention group had lower scores on the informed (mean difference = -11.9, 95% confidence interval CI = -21.1 to -2.7) and values clarity subscales (mean difference = -14.6, 95% CI = -22.6 to -6.6). Greater proportions of intervention participants knew medications for reducing stroke risk (61% vs 31%, P < 0.001) and side effects (49% vs 37%, P = 0.07). Stroke (71% vs 12%) and bleeding risk (69% vs 20%) were discussed more frequently in the intervention than control group (P < 0.001). Five intervention participants expressed a preference for medication that was not concordant with their current treatment plan. There was no change in treatment plan in either group.

Author(s) and country	Study design, sample, and intervention	CDSS category	Key outcome measures	Results
Holbrook et al., (2007). Canada	**A randomised controlled trial.** 98 patients were randomised using 3 × 2 factorial design to investigate the effects of decision aid format (decision board, decision booklet, or interactive computer program) and graphic presentation (pie graph or pictogram) of the probability data for benefits and harms	The decision aid includes; description of outcomes, treatment choices (no treatment, warfarin, or aspirin) and probability of stroke and major bleeding, each explained in terms of severity and impact	Knowledge Decisional conflict scale (DCS)	Knowledge of atrial fibrillation improved significantly ($p < 0.01$) after the decision aid intervention regardless of the format or graphic presentation of the decision aid Un-blinding of the treatment name resulted in 36% of the participants changing their initial choice ($p < 0.001$) Participants showed a reasonable comfort with the treatment decisions as indicated in the mean total score on the Decisional Conflict Questionnaire of 2.1 (SD 0.4)
Thomson et al., (2007) United Kingdom	**A randomised controlled trial.** 109 Participants were randomised to either computerised decision aid (intervention n=53) or evidence-based paper guidelines (control n=56).	The decision aid includes; presentation of the individualised benefits and potential harms of treatment (warfarin or aspirin) using both graphical and numerical forms of presentation followed by a shared decision-making component.	Decisional conflict scale (DCS) Anxiety Knowledge scores Decision-making preference	DC was lower in the computerised decision aid group immediately after the clinic; mean difference -0.18 (95% CI -0.34 to -0.01). There was a significant fall in anxiety immediately after the clinic (mean change pre-clinic to post-clinic of -4.57 (95% CI -6.30 to -2.84)) but non-significant reduction (p=0.98). Although the overall knowledge scores improved slightly post-clinic, by three months they were back to pre-clinic levels; there was no difference between decision aid and guidelines groups at any point. Participants in DA group not already on warfarin were much less likely to start warfarin than those in the guidelines arm (4/16, 25% compared to the guidelines group 15/16, 93.8%, RR 0.27, 95% CI 0.11 to 0.63).

Author(s) and country	Study design, sample, and intervention	CDSS category	Key outcome measures	Results
McAlister et al., (2005). Canada (Updated version of DA evaluated by Man-Son-Hing et al.,1999)	**A cluster randomised trial.** A total of 219 patients in the intervention group (Decision aid) and 215 patients in the control group (usual care) were evaluated at 3-month follow-up.	The decision aid consists of a booklet and audiotape that are designed to be self-administered by patients at home. The booklet describes the potential consequences of stroke, provides patient-specific estimates of stroke risk, and illustrates the potential benefits and risks of warfarin and aspirin	Change in antithrombotic therapy at 3 months	In the control group, there was a 3% decrease over 3 months in the number of patients receiving therapy appropriate to their risk of stroke. In the intervention group, the number of patients receiving therapy appropriate to their stroke risk increased by 9%. A 12% absolute improvement in the number of patients receiving appropriate care in the intervention group compared with the control group at 3 months ($p = 0.03$). The beneficial effect of the decision aid did not persist ($p = 0.44$ for differences between study arms after 12 months).

Author(s) and country	Study design, sample, and intervention	CDSS category	Key outcome measures	Results
Protheroe et al., (2000) United Kingdom	**Observational study.** 97 participated in decision making using decision analysis.	The decision analysis combines individualised decision analysis, individualised absolute annual risks of a thrombo-embolic, relative risk reduction and the probability of side effects, and treatment options and their possible consequences	Patients' treatment preferences after individualised decision analysis Comparison of these preferences with treatment guidelines	Among these 97, the decision analysis indicated that 59 (61%; 95% CI 50% to 71%) would prefer anticoagulation treatment—considerably fewer than those who would be recommended treatment according to guidelines. There was marked disagreement between the decision analysis and guideline recommendations Of 38 patients whose decision analysis indicated a preference for anticoagulation, 17 (45%) were being prescribed warfarin; on the other hand, 28 (47%) of 59 patients were not being prescribed warfarin although the results of their decision analysis suggested they wanted to be.
Man-Son-Hing et al., (1999) Canada	**A randomised controlled trial.** A total of 287 patients were randomised to receive the decision aid (n=139) or usual care (n=148).	An audio booklet decision aid contains descriptions of the consequences of a minor stroke, a major stroke, and a major haemorrhage; the blood monitoring required for warfarin therapy; and the 2-year probabilities of stroke and major haemorrhage for patients taking aspirin or warfarin.	Patients' ability to make choices regarding antithrombotic therapy 6-month adherence to these decisions Knowledge Satisfaction with the decision-making process Decisional conflict	More patients in the DA group made a choice about antithrombotic therapy than in the control group (99% vs 94%; *P*=.02). After 6 months, a similar percentage of patients were still taking their initial choice of antithrombotic therapy (95% vs 93%; *P*=.44). Patients in the DA group were more knowledgeable and had more realistic expectations about the risk of stroke and haemorrhage (in the DA group, 53%-80% correctly estimated different risks; in the control group, 16%-28% gave correct estimates). Decisional conflict and satisfaction were similar for the 2 groups.

2.4.2 Effects of decision aids on attributes of the decision

The identified studies used measures like knowledge test results, accuracy of risk perceptions, and value congruence with the chosen option to assess whether the patient decision aid improved the match between the chosen option and the features that mattered most to the informed patient (Fraenkel et al., 2012; Holbrook et al., 2007; Man-Son-Hing et al., 1999; McAlister et al., 2005; Protheroe et al., 2000; Thomson et al., 2007).

Five of the six studies examined the effects of decision aid interventions on patient knowledge. In the comparison of patient decision aids to usual care (Fraenkel et al., 2012; Holbrook et al., 2007; Man-Son-Hing et al., 1999; McAlister et al., 2005), patients exposed to decision aids demonstrated significantly greater knowledge scores of treatment-related information. Thomson et al., (2007) found that knowledge scores after the intervention improved slightly, but by three-month follow-up, they had returned to pre-intervention levels and that there were no significant differences between the decision aid and guideline groups at any point.

Four of six studies examined the effects of including probabilities in decision aids on the accuracy of patients' perceived probabilities of outcomes (Holbrook et al., 2007; Man-Son-Hing et al., 1999; McAlister et al., 2005; Thomson et al., 2007). Two studies assessed perceived probabilities in words (Fraenkel et al., 2012; Protheroe et al., 2000). Patients who received detailed information with descriptions of outcomes and probabilities were more likely to have accurate risk perceptions than those who did not receive this information (Fraenkel et al., 2012; Holbrook et al., 2007; Man-Son-Hing et al., 1999; McAlister et al., 2005; Protheroe et al., 2000; Thomson et al., 2007). Moreover, the six identified studies showed that the addition of an explicit values clarification exercise in a DA improved agreement between values and chosen option (Fraenkel et al., 2012;

Holbrook et al., 2007; Man-Son-Hing et al., 1999; McAlister et al., 2005; Protheroe et al., 2000; Thomson et al., 2007).

2.4.3 Effects of decision aids on attributes of the decision process

Concerning the effect of DAs on decision process criteria, only one trial evaluated the extent to which a patient decision aid can help patients to recognise that a decision needs to be made, understand that values affect the decision, and discuss values with their practitioner (Fraenkel et al., 2012). While the reviewed studies evaluated the impact of using DAs on patient participation in the decision about treatment (Fraenkel et al., 2012; Holbrook et al., 2007; Man-Son-Hing et al., 1999; McAlister et al., 2005; Protheroe et al., 2000; Thomson et al., 2007), none focused on DAs impact on helping patients become involved in preferred ways.

Five studies measured patients' self-report of uncertainty about which therapy to choose and evaluation of the factors contributing to the uncertainty; feeling informed, clear about personal values and feeling supported in decision making (Fraenkel et al., 2012; Holbrook et al., 2007; Man-Son-Hing et al., 1999; McAlister et al., 2005; Thomson et al., 2007). The measures used to evaluate these criteria were subscales of the previously validated Decisional Conflict Scale (DCS) (O'Connor 1995). The decision aids scored less on decisional conflict than the usual care group. Reductions ranged from -0.09 to -14.6 out of 100. Smaller reductions were noted in Man-Son-Hing et al., (1999) and McAlister et al., (2005) but were not statistically significant, and larger reductions were noted in Fraenkel et al., (2012) and were statistically significant. Three trials used the DC subscales. Fraenkel et al., (2012) used the feeling informed and clear about values subscales and Man-Son-Hing et al., (1999) and McAlister et al., (2005) used the DC subscale for feeling informed, clear about values, certain about choice, and supported in decision making. The mean difference

(MD) in feeling uninformed about options, benefits, and harms was -11.9, -0.21, and -0.2 in the three trials (Fraenkel et al., (2012), Man-Son-Hing et al., (1999) and McAlister et al., (2005)) that compared patient decision aids to usual care. For these trials, the MD in feeling clear about values was -14.6, -0.11, and -0.1, respectively. The MD for feeling unsupported and uncertain was -0.05 and -0.01 in Man-Son-Hing et al., (1999) and 0.0 and 0.1 in McAlister et al., (2005).

Four trials assessed the effects of decision aids on the patients' preferred options or their uptake of options. While Protheroe et al., (2000) demonstrated a significant increase in uptake of warfarin of 61%, Man-Son-Hing et al., (1999) showed a non-significant reduction of uptake of warfarin of 25%. On the other hand, two trials evaluated the proportion of patients choosing the preferred option that was appropriate relative to their level of risk and found no significant difference between the DA and usual care groups (Fraenkel et al., 2012; McAlister et al., 2005)

Two studies (Fraenkel et al., 2012; Man-Son-Hing et al., 1999) compared the effects of decision aids to usual care regarding participation in decision making and found that DAs can increase patient involvement in the process of decision-making and promote patient–clinician communication. Satisfaction with the decision-making process was measured in two trials. Man-Son-Hing et al., (1999) evaluated satisfaction with the process of decision making, on six scales measuring satisfaction with information and satisfaction with practitioner treatment, and found no statistically significant difference between groups. Holbrook et al., (2007) found that patients in the decision aid group were more satisfied compared to patients in the usual care group. One trial reported patient satisfaction as an outcome (Man-Son-Hing et al., 1999). They found that the use of the decision aid did not significantly affect patients' satisfaction with their physician consultations.

Man-Son-Hing 1999, measured continuance with the chosen option (warfarin versus aspirin) at six months and found no significant difference between the DA and usual care groups.

Only two trials reported anxiety as an outcome (Fraenkel et al., 2012; Thomson et al., 2007). The study by Fraenkel et al., (2012) measured anxiety by the response to the previously validated Spielberger State Anxiety Index and found no significant difference between groups administered a decision aid versus usual care (MD -0.38, *P*-value 0.48). In Thomson et al., (2007), anxiety fell significantly in both groups pre- to post-clinic (MD -4.57), but there was no evidence of a significant difference in anxiety between the two groups (*P*-value = 0.98).

2.4.4 Methodological aspects of PDA studies

Of the six studies that were identified, five were RCTs (Fraenkel et al., 2012; Holbrook et al., 2007; Man-Son-Hing et al., 1999; McAlister et al., 2005; Thomson et al., 2007) and one was an observational study (Protheroe et al., 2000). Two studies used cluster randomisation at the level of the family physician (Fraenkel et al., 2012; McAlister 2005). This design can be helpful to avoid contamination that may occur if the same clinician delivering the intervention also delivered usual care. This trial also accounted for their randomised clusters in the analysis, weighting the analysis accordingly; thus their allocation was considered with a low risk of bias.

Two types of bias were most prevalent in studies concerned with evaluating PDAs in clinical practice. Firstly, blinding of patients to the intervention received was not possible with this type of intervention, nor was it possible to blind the intervention facilitator, inevitably raising the risk of bias (Clarkesmith et al., 2013). Researcher bias might have occurred in the reviewed studies, whereby the clinicians delivering the intervention and

usual care could behave differently towards a group unintentionally affecting the study outcome (Clarkesmith et al., 2013; O'Connor et al., 2009). However, blinding the data analyst or research facilitator to which intervention arm the patient was assigned to was possible, in principle, and was undertaken in one trial (McAlister, 2005). Four trials did not state whether their data analyst was blinded to which group the patients were randomised to (Man-Son-Hing 1999; Thomson 2007) or indeed whether the clinician who was delivering the intervention also carried out the analysis, which inevitably could increase the risk of bias. Another key methodological issue is the choice of outcome measures. A large variety of process measures were obtained, making it hard to compare results of individual studies (Clarkesmith et al., 2013).

When considering the quality of the observational study, interviewer bias is a concern as those involved in the study knew about their participation as this may have changed their behaviour and inadvertently affecting the study outcome (Protheroe et al., 2000).

In conclusion, fewer studies were found that were exclusively concerned with patients' perspectives on the effect of PDAs for anticoagulant therapy on attributes of the decision and decision process. Subsequently, the intention here was to highlight key research findings and gaps in the literature.

The findings of studies often concerned more than one outcome. These were decision conflict (patient's uncertainty in making health-related decisions), patient knowledge, patient satisfaction, decision-making preference, and anxiety. None of these studies seemed to have explored patients' perspectives on effects of decision aids on attributes of the decision and decision-making process in depth. Subsequently, there are gaps in the literature that are of relevance to this study. This is discussed further in section 4.5.1 of the methodology chapter.

2.4.5 Summary

This literature review identified and reviewed 49 studies that have evaluated the impact of CDSSs on anticoagulation management in patients with AF. The results of the majority of these studies identified a statistically significant impact on clinical care with the use of a CDSS. All research findings demonstrated an increase in guideline adherence that ensured patients received the correct treatment. Some studies also demonstrated that for patients with AF the attributes of the decision-making process (for example, knowledge, anxiety, DC score, communication, and level of involvement) showed favourable results. While the majority of the included studies showed significant improvement, an analysis of the methodological quality revealed a high risk of bias in all but few studies.

This review demonstrated that there is insufficient evidence to draw definitive conclusions regarding the impact of CDSS on anticoagulation management in AF patients. Thus, more trials are needed to examine the impact of CDSS on anticoagulation management in AF patients and the mechanisms by which they are successful. Furthermore, this literature review informed the selection of appropriate research methods to evaluate the CDSSs in this study, and highlighted the need for qualitative trial to explore in-depth HPs' and patients' perspectives on effects of CDSS on attributes of the decision and decision-making process, which may provide a more accurate assessment of the impact of the intervention. The research methods chapter that follows will describe the study that was undertaken to evaluate the CDSS under consideration. The rationale for the research, which based on the current clinical context and current gaps in the evidence will be described in detail together with the research methods employed.

Chapter 3: Pilot study

In this chapter, a pilot study is presented. This begins in section 3.1 with a discussion of theoretical consideration and rational relevant to conducting a pilot study. In section 3.2 the method used in this pilot study is discussed in brief, starting with a discussion of the aims of the pilot. This leads into a discussion of ethical approval, participant recruitment, data collection, data analysis, and confidentiality. In section 3.3 an overview of the pilot findings and the significance of these findings are discussed. Key points are summarised in the final section of the chapter.

3.1 Introduction

A pilot study, is a preliminary, exploratory study conducted on a small scale before the main research to evaluate feasibility so that the design of the research, purpose, approaches and research instruments can be checked, modified and improved (Lancaster et al., 2004; Smith, 2005; Teijlingen and Hundley, 2001; Thabane et al., 2010). Lancaster et al., (2004) suggested that evaluative studies of the effectiveness of an intervention conducted in an under researched area or in a new setting should be preceded by a small pilot to assess the feasibility of a definitive trial. In a pilot study, a future study, or part of a future study, is conducted on a smaller scale. For that reason, it is agreed that all pilot studies are feasibility studies, but not all feasibility studies are pilot studies (Eldridge et al., 2016).

One of the advantages of conducting a pilot study is to give the research team evidence that the main research project is worth doing. A pilot can also identify any issues that indicate a change to the study protocol is needed (Teijlingen and Hundley, 2001). However, a pilot

study has some limitations including the possibility of making inaccurate predictions or incorrect assumptions based on the data generated (Lancaster et al., 2004).

3.2 Pilot study methodology and methods

The choice of research methodology and methods adopted in this pilot study follows the main study methodology and designs (as discussed in chapter four).

3.2.1 Aims

The overall purpose of this pilot study was to assess the feasibility of the main study and to test whether the components of the main study can all work together to generate results.

Specifically, this involved:

- Assessing acceptability of the intervention to potential users
- Exploring the attitudes of potential users towards the intervention
- Identifying any problems in the design and conduct of the study, and ensuring that study processes are acceptable (consent process, recruitment procedures, willingness to participate, interview format and questions)
- Examining interview topic guide question (e.g., subjects provide no answer, multiple answers, qualified answers, or unanticipated answers to study questions)
- Investigating how the decision support tool (DST) will be implemented
- Gaining insights into HCPs recruitment
- Assessing participants' acceptability of recruitment procedure and data collection approaches
- Assessing willingness of participants to recruit patients

- Assessing how realistic are the eligibility criteria
- Gaining insights into the time needed to conduct the interview and complete a questionnaire collect and analyse data
- Gaining insights into the time required to transcribe the interview and analyse data
- Gaining insights into facilities (e.g. computer and access to the internet) needed to conduct interviews at HCPs' workplace that help the study

3.2.2 Local Research Ethics Committee approval

An application to conduct the pilot study was submitted to the local research ethics committee at Keele University. Approval for this study was granted at a meeting on 21 November 2013, included as appendix one. The application was accompanied by the HCP Information Sheet, the consent form, the interview topic guide for stage one, the interview topic guide for stage two, the interview topic guide for stage three, questionnaires (attaches as appendices four to nine).

3.2.3 Recruitment of participants

With the main study practical approaches and procedures in mind, two HCPs were approached for this pilot study.

3.2.4 Conducting the interviews

Data collection methods, stages, and instruments planned to be used in the main study were examined. Interviews took place face-to-face in HCPs workplace at their convenience. Both interviews lasted nearly an hour and a half. The interview began with a brief statement in the form of summary points about the pilot study objectives, why the research was being conducted, and an overview of research stages.

Participants were also informed about the total duration of the interview and that it would be digitally recorded. Participants were asked to sign a consent form for participating in the pilot research before the interview started. Reconfirmation of consent to participate and consent to use of quotes was obtained verbally at the end of the interview, supported by signing a consent form for the use of quotes. One copy was retained by the research participant, and one copy was retained for the research file. The researcher used a laptop computer to demonstrate the prototype version of the DST using a vignette to show how the tool works and explore the different screens within the tool. The interview guides and questionnaires intended to be used in the main study were tested at this pilot stage (included as appendices four to nine). Self-administered questionnaires were completed by participants and checked for completion immediately during the interviews. No technical problems occurred with the digital recorder during the interviews.

Participants were also assured about issues of confidentiality and anonymity during the research process and data analysis and reporting.

The researcher practised how to reflect and make notes after each interview. These notes included any relevant comments and suggestions made by interviewees after the audio recorder was switched off.

3.2.5 Data analysis

The interviews were recorded with a digital recorder. Notes were taken during the interview. The researcher verbatim transcribed all interviews. The audio file and transcripts were stored safely on the university network and a password encrypted laptop computer, and the file names were coded. Audio files on the recorder were deleted. The typed transcriptions were anonymised replacing any names with a number.

Thematic framework analysis was used to classify, organise, and analyse data as described in chapter four.

Questionnaires were anonymised replacing any names with a research number. The Statistical Package for the Social Sciences (SPSS) software program was downloaded on the university network and a password encrypted laptop computer, and the output documents from analysis were saved on password protected files.

3.2.6 Confidentiality

In the interests of all research participants' confidentiality and anonymity, measures were adhered to (as described in methodology chapter).

3.3 Results and discussion

For this pilot purpose and practical constraints, two participants were recruited and interviewed to assess the feasibility of the main study. They were; a GP and a haematology consultant. Both participants were male and had thirty and ten years of experiences in the field respectively.

The preliminary evaluative outcomes were encouraging. Qualitative findings from this pilot study acknowledged positive responses of the potential utility of the DST in anticoagulation management. Participants revealed that the tool has the potential to improve and support prescribing decision-making process and encourage prescribers to involve patients in prescribing decision.

Pilot participants found the system easy to learn, reasonably quick, clear, straight forward, and easy to navigate.

The pilot study confirmed that trial processes were efficient, the intervention was acceptable (to potential research participants) and that the outcome measures were

appropriate. The pilot trial also provided prospective evidence that potential HCPs will value the DST and be willing to implement the tool in practice if they were asked to do so. Feedback from the pilot respondents revealed that the questionnaires format and presentation are considered acceptable. The questions used in the interview guide were found clear and appropriate, as such, elicited the sort of answers we were looking for from the interview guide.

Furthermore, this pilot allowed the researcher to assess the process of the study. Both recruitment approach and the conduct of interviews were examined and found acceptable to the pilot participants. The pilot study indicates important implications for the resources needed to conduct the main study including time and costs. For example, allow the researcher to estimate the time required to fill out the questionnaire and complete the interview and estimate the costs of travelling. Verbatim transcribing of the interviews by the researcher was a lengthy process and time consuming, so the decision was made to approach a transcribing company for the purpose.

The decision was made to continue with the main study design and procedures. And that the pilot participants will not participate in the main study to avoid bias, influence, and familiarity.

3.4 Chapter summary

This pilot study provided an opportunity to confirm the feasibility of the suggested methodologies and to assess the practicalities of conducting the full-scale research design in the chosen settings. Findings revealed that the study is feasible, the research instruments are appropriate and the overall approach is acceptable to HCPs.

The pilot trial also provided prospective evidence to support the usefulness of the DST in anticoagulation management that will be tested in adequately powered multi-centre investigations. Methodology and methods for the main study are now presented in the following chapter.

Chapter 4: Methodology and research methods

This chapter describes and justifies the methodological approaches and research methods used in this study. This begins in section 4.1 with a discussion of theoretical considerations relevant to the choice of a mixed-method approach. This is followed by a discussion of the mixed methods research paradigm. The use of qualitative and quantitative research methods is then discussed and justified. The use of the broad principles of thematic framework approach and questionnaires as practical approaches to this study is then discussed.

In section 4.5 the methods used in this study are discussed in detail, starting with a discussion of the aims of the study. The work preceding conducting the study is described. This leads into a discussion of ethical approval, recruitment, data collection, data analysis and confidentiality. Key points are summarised in section 4.8.

4.1 Research methodology

4.1.1 Choice of research methodology

This study was an evaluative research of the utility of a decision support tool for anticoagulation management. Campbell et al., (2000) defined computerised decision support systems (CDSSs) as an example of a complex intervention. Conventionally, double-blind, randomised controlled trials are used to evaluate complex interventions (Bradley et al., 1999; Campbell et al., 2000; Craig et al., 2008; Pope and Mays, 1995). However, there are situations in which this method is unrealistic, impractical or inappropriate and other well-designed methods have to be employed instead (Bradley et

al., 1999; Campbell et al., 2000; Craig et al., 2008; Pope and Mays, 1995). In recent years, there has been growing evidence of the need for a range of methodologies to evaluate complex interventions (Bradley et al., 1999; Campbell et al., 2000). For instance, in 2015, the Medical Research Council (MRC) recommended using an iterative, phased approach that harnesses qualitative and quantitative methods for conducting and reporting process evaluation of complex interventions (Moore et al., 2015).

The logic behind mixing methods is that neither method is sufficient in itself to address research purposes and questions fully, and when data from both methods are integrated or combined at some stage of the research process, they complement each other (Creswell, et al. 2004; Foss and Ellefsen, 2002; Johnson and Onwuegbuzie, 2004). Therefore, a balance between the two approaches is needed to obtain a rich and comprehensive picture of the situation under investigation (Creswell, et al. 2004; Foss and Ellefsen, 2002).

The strength of mixing qualitative and quantitative methods is to balance the flexibility of qualitative exploration with the fixed nature inherent from quantitative approaches (Kroll and Neri, 2009). According to Foss and Ellefsen, (2002) 'Combining these approaches in one study is like combining overview with insight, breadth with depth, and micro with the macro to yield a richer and more complex understanding of research data' (p. 245).

A mixed methods approach was chosen for this study as the best means to answer the different aspects of the research questions and to combine the strengths and insights of each research method. This study was a staged approach that separated the different questions being asked in an attempt to evaluate the utility of the DST in anticoagulation management. An initial qualitative approach was undertaken to explore the anticoagulation therapy decision making context to identify the suboptimal determinants in the decision-making process. Following the first study, a pre-interventional evaluation of

the DST was conducted to collate evidence on its potential usefulness in anticoagulation management. This study evolved into a mixed-method design to provide a more comprehensive understanding of the design features of the tool influencing the anticoagulant decision-making process, than would have been achieved with only a single method approach. Further study was conducted to understand more about actual experiences of implementing the DST into routine care from the perspectives of both HCPs and their patients. Therefore, the research aims and objectives require a combination of both qualitative and quantitative methods to provide testable results from the quantitative approach and detailed coverage of the topic under study from qualitative approach (Bryman, 2006).

For this study, it was not possible to use randomisation or control groups because each intervention sites may implement the DST in a different way that fits with their local context and have their protocols which make it difficult to compare with other sites.

4.1.2 Research Paradigm

Guba and Lincoln (1994) have defined paradigms of inquiry as the worldviews or belief systems that guide researchers, not only in choices of methods but in ontology and epistemology of inquiry. The concept of a paradigm is based on three interrelated and essential questions (Guba and Lincoln, 1994). The first is the ontological question; what is the form and nature of reality? And what is there that can be known about it? The second is the epistemological question; what is the relationship between the knower and what can be known? This question is about how knowledge is construed which depends on how reality is viewed. Thirdly, the methodological question is about how can the inquirer go about finding out whatever he or she believes can be known about (Guba and Lincoln, 1994).

Heron and Reason (1997) added the axiology question which outlines what is intrinsically valuable in human life, in particular, what sort of knowledge, if any, is intrinsically valuable?

Overall, a paradigm is a patterned set of assumptions concerning reality (ontology), knowledge of that reality (epistemology), and the particular techniques to be used in approaching that reality (methodology) (Guba and Lincoln, 1994).

Positivism and interpretivism/constructionism hold distinctive ontological (view of reality), epistemological (view of knowing and the relationship between enquirer and to-be-known), methodological (view of mode of inquiry), and axiological (view of what is valuable) views (Guba and Lincoln, 2005; Heron and Reason, 1997).

Traditionally, positivism and constructionism underpin quantitative and qualitative research respectively (Denzin and Lincoln, 2005). Qualitative and quantitative methods are seen as two distinct research methodologies belong to two different paradigms, which are distinguished using different dichotomies, such as, subjectivity-objectivity, induction-deduction, relativism-realism, and holism-reductionism respectively (Bryman, 2006b; Tashakkori and Teddlie, 1998).

Researchers in different paradigms hold different assumptions about human nature, the nature of knowledge claims, the nature of reality, the relationship between reality, individuals and culture, and the relationship between inquirer and object of inquiry (Tashakkori and Teddlie, 1998). The contradictions make it clear that the purposes of these paradigms are different and explain why some social scientists would consider that using them together is incongruent (Sandelowski, 2000; Tashakkori and Teddlie, 1998).

Currently, the paradigm debate is becoming less relevant as many researchers in social sciences and health research have adopted the view of paradigm relativism, or the use of

whatever philosophical and or methodological approach works for the particular research question(s) instead of relying on one method exclusively (Bowling, 2014; Bradley et al., 1999; Bryman, 2006a; Campbell et al., 2000; Creswell et al., 2003; Johnson and Onwuegbuzie, 2004).

4.1.2.1 Pragmatism: Mixed methods research

The primary philosophy of mixed research is that of pragmatism (Johnson, Onwuegbuzie and Turner, 2007). Mixed methods research offers a third methodological movement which proposes that the paradigm debate (as described in section 4.1.2) is over and replaced by a pragmatic approach, given the fundamental role of pragmatism in overcoming the incompatibility theory (Scott and Briggs, 2009; Tashakkori and Teddlie, 1998). Creswell (2013a) highlighted that pragmatism gives researchers methodological freedom of choice. Pragmatism refers to 'mixed methods' contains elements of both the quantitative and qualitative approaches (Patton, 1990; Tashakkori and Teddlie, 1998).

Pragmatically oriented researchers consider the research question to be more important than the method used or the paradigm which underlies the method and believe that research methods should follow research questions to get useful answers (Tashakkori and Teddlie, 1998).

Mixed methods research is the third research paradigm in educational research and health service research. It moved beyond quantitative versus qualitative research arguments and is not to replace either of these approaches but rather to draw on the strengths and minimise the weaknesses of both in a single research study (Creswell, 2013; Johnson and Onwuegbuzie, 2004). By employing both quantitative and qualitative approaches within the same framework, mixed method research has the potential to reduce some of the

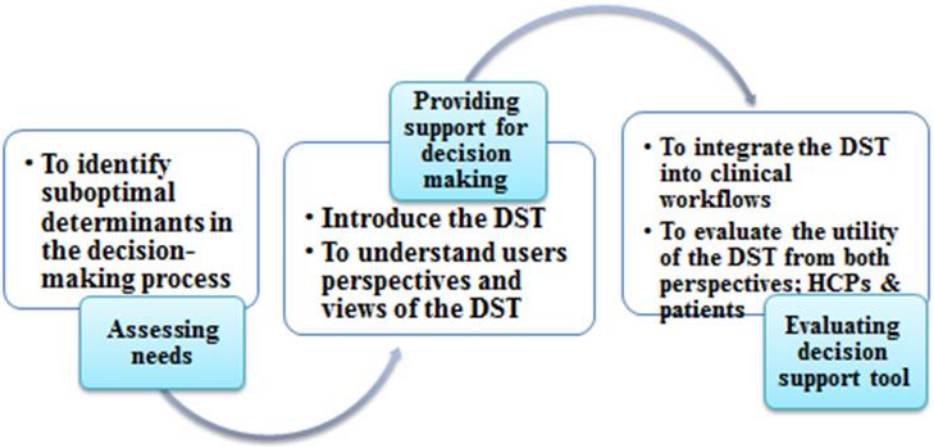
weakness associated with each approach and incorporate the strengths of both methodologies (Bryman, 2006a; Creswell, 2013; Johnson and Onwuegbuzie, 2004).

Mixed methods research has been summarised by Johnson et al., (2007) as the type of research in which a researcher or team of researchers combine (s) elements of qualitative and quantitative research approaches (e.g. use of qualitative and quantitative viewpoints, data collection, analysis, inference techniques) for the broad purposes of breadth and depth of understanding and corroboration.' (Johnson et al., 2007, p. 123)

4.1.3 Research design

The evaluative approach adopted in this study follows the Ottawa Decision Support Framework (ODSF) (O'Connor et al., 1998) as illustrated in figure (4.1). The study was designed to have three stages, quantitative and qualitative, to address different aspects of the research question; with both elements acting as complementary parts of the whole study, and as stand-alone studies at some stages (O'Cathain et al., 2007). The main design framework of the entire study is called sequential exploratory design, as follow; a descriptive qualitative study, concurrent triangulation (qualitative and quantitative approaches) study, qualitative study, followed by concurrent triangulation (qualitative and quantitative approaches) study.

Figure 4. 1: The evaluative study framework



The study design incorporates elements of concurrent triangulation and sequential expansion. It involves the use of both qualitative and quantitative methods in sequence to study a research problem with the purpose of seeking exploration of participants' attitudes, experiences, and views to best understand research problems, becoming, in effect, a sequential exploratory design (Greene et al., 1989; Tashakkori and Teddlie, 1998). Moreover, at some stages during the entire research, it concurrently triangulates both qualitative and quantitative methods to seek corroboration of results from the different methods to best understand the research matter (Greene et al., 1989; Tashakkori and Teddlie, 1998).

4.1.4 Sampling

A purposive convenience sample was used for the entire study (Ritchie et al., 2003; Teddlie and Yu, 2007). Purposive sampling may be defined as selecting individuals based on particular purposes associated with answering research questions due to the unique information they can provide that cannot be obtained from other available participants (Brannen and Halcomb, 2009; Ritchie et al., 2003; Tashakkori and Teddlie, 1989; Teddlie and Yu, 2007). Convenience sampling involves selecting participants, who are both

accessible and willing to participate in the study (Brannen and Halcomb, 2009; Ritchie et al., 2003; Tashakkori and Teddlie, 1989; Teddlie and Yu, 2007). The most common drawback of this scheme is that the sample is not representative of the whole population and the possible risk of sampling bias (Ritchie et al., 2003).

As explained earlier in section (4.1.3), the same sample will be used throughout the sequential research stages. In mixed methods sampling strategies, this is called identical sequential sample (Onwuegbuzie and Collins, 2007; Sandelowski, 2000). Identical sampling design used when the researcher intends to use same participants for both methods. Sequential is related to the implementation sequences of qualitative and quantitative approaches (Onwuegbuzie and Collins, 2007; Sandelowski, 2000). The decision on the selected framework design is justified by the research aims, objectives, and study design.

4.2 Data collection approaches

4.2.1 Qualitative Research Methods

Qualitative research originated in relativism, which believes that reality is only knowable through socially constructed meanings, and there is no single social reality, but a series of alternative social constructions (Bryman, 2006b; Tashakkori and Teddlie, 1998). Qualitative-oriented researchers believe that facts and values are not distinct and findings are influenced by the researcher's perspective and values (Ritchie, 2003). Against the wider backdrop, qualitative research has been associated with interpretivism (Ritchie and Lewis, 2003). Those practising qualitative research proposed that perception and knowledge of the world relate to human interpretations and understanding of phenomena being studied, and they emphasise on the human interpretative aspects of knowledge about the world (Ritchie, 2003).

Qualitative research methods request interviewees' views and experiences on a particular issue and strive for in-depth understanding of the interviewees' responses (Pope et al., 2002; Ritchie, 2003). The key strength of using qualitative research methods is that it can identify a broad range of anticipated and actual outcomes, and uncover aspects that could have been missed (Ritchie, 2003; Smith, 2005). Creswell (2009) distinguished between quantitative and qualitative approaches for data enquiry; he noted that quantitative data techniques are data condensers, while qualitative techniques are data enhancers.

Qualitative research is primarily an exploratory research used to discover underlying motivations, values, attitudes and perceptions (Pope et al., 2002; Ritchie, 2003). According to Pope et al., (2002) the aim of qualitative research is not to predict, but rather to define and clarify events and experiences and to describe the context in which the study operates. Qualitative research is, however, not without its weaknesses and while it provides depth and insight of people's own experience of phenomena, it is often criticised as soft and unscientific (Ritchie, 2003). The primary limitation is that, unlike quantitative research, the findings produced by qualitative approaches are less generalizable to the population under study (Johnson and Onwuegbuzie, 2004) and research findings are more subjected to the researcher's personal biases (Johnson and Onwuegbuzie, 2004; Foss and Ellefsen, 2002). Denzin and Lincoln (1994) argued that qualitative researchers cannot give a reliable account of their findings because there are no definitive meanings or explanations to be captured. In response to these criticisms, scholars in qualitative research attempted to shape qualitative research methods, in particular, efforts were put to stress the importance of rigour in data collection and analysis (Ritchie, 2003).

4.2.1.1 Methods of data collection in qualitative research

Qualitative research covers a broad range of approaches directed at providing an in-depth and interpreted understanding of the phenomena under study, by observing, listening, and

learning about people's experiences, perspectives, and stories (Ritchie, 2003). Generally speaking, there are different ways in which data can be generated, such as, biographical methods, individual interviews, paired interviews, and focus groups (Ritchie, 2003). Choosing between them turns on three key factors; the type of data sought, the subject area, and the nature of research participants (Lewis, 2003).

Qualitative interviews types can be distinguished by; the order, wording, and technique in which questions are followed up and are commonly referred to as being structured, semi-structured or unstructured (Arthur and Nazroo, 2003). Structured interview involves the use of highly fixed structured questions which are presented to interviewees in the same way, with no variation in question-wording to ensure consistency in approaches and issues covered (Arthur and Nazroo, 2003). However, data produced from structured interviews were criticised for being not sufficiently comprehensive (Bowling, 2014). An unstructured interview is often described as a form of guided conversation with the intention to combine structure with flexibility (Legard et al., 2003). In the semi-structured or semi-standardised interview, the interviewer asks key questions, in the same way, each time and probes for further information (Arthur and Nazroo, 2003). To combine structure and flexibility and to mark a distinction between highly structured interviews and unstructured interviews, the interviews conducted in this study have been described as being semi-structured.

The semi-structured interview is described as thematic and topic centred instrument where the researcher uses topics or themes to cover during the interview rather than a structured list of questions (Patton, 1987). In semi-structured interviews, the topics of interest that the researcher intends to cover are usually drafted into a thematic and topic centred guide using specific, non-leading, open-ended questions (Bowling, 2014). Because semi-structured interviews are conducted face-to-face, the interviewer can probe thoroughly for

responses and clarify any ambiguities, to explore the reasoning behind the views expressed (Bowling, 2014).

Meanwhile, Ritchie, (2003) recommended the use of a semi-structured interview design in the exploratory study for the following reasons: (1) it allows the researcher to explore the range and depth of participants' perspectives, (2) it allows interviewees from different settings answer the same questions; thus increasing comparability of responses and enabling the researcher provide clear inferences from this study, (3) it permits the supervisory team to see and review the questions used in the evaluation, (4) it facilitates processing, management, and analysis of the data and, (5) it allows the interviewees to arrange the interviews at their convenience, thus it is more accessible to potential participants who are very busy people (Ritchie, 2003).

A further qualitative method available to researchers, that of email correspondence (Foster 1994). Email correspondence is a valuable tool in revealing respondents' workplace experiences (Cooper, 2000; Parris, 2008). This method provides a way to capture respondents' day-to-day experiences as they occurred (Kralik et al., 2000). Its use allows an opportunity for research participants to reflect on research process via a method which many are comfortable and competent in using. Furthermore, email correspondence allows ease of following the chronological order of the discussion process as it is marked with date and time (Kralik et al., 2000). The potential time savings in transcription as data collection and transcription occurred at the same time (Foster 1994) and the potential access to a wide geographical area are additional advantages of email correspondence (Parris, 2008). Nevertheless, attention must be given to the ethical issues of electronic communication, as well as establishing relationship with research participants to encourage them to share their experiences with the researcher (Kralik et al., 2000).

4.2.1.2 Qualitative data process: Thematic framework approach

There are several approaches that can be followed to carry out analysis of qualitative data; the categories may be derived inductively or deductively (Pope et al., 2000). A grounded theory approach is an example of inductive analysis (Pope et al., 2000). The term grounded theory is used to describe the inductive process of identifying categories as they emerge from the data, through the process of analysis (Pope et al., 2000; Ritchie and Spencer, 1994). This is a particularly useful analytical approach to use when little is known about a subject, with the emphasis on the development of theory as the outcome of the analysis (Pope et al., 2000). A different way to carry out qualitative data analysis is to use a deductive approach, in that theory or categories were defined in advance (Pope et al., 2000; Ritchie and Spencer, 1994).

The framework approach of analysis is an example of deductive analysis (Pope et al., 2000). This approach allows the researcher to define categories at the start of the process and it enables inclusion of new themes that may emerge from the data and examine them using a process called constant comparison, in which each item is checked or compared with the rest of the data to establish analytical categories (Pope et al., 2000). An important component of this process is deviant case analysis of any cases that do not fit the emerging themes, in that resultant explanations can aid refining the characteristics of themes (Pope et al., 2000). With the framework approach, data analysis can stop at the level when no new themes emerged from data and saturation achieved (Ritchie and Spencer, 1994).

For this particular study, a grounded theory approach is not appropriate, as there is extensive literature on the topic under study. Therefore, thematic framework analysis was used.

The process of the thematic framework is based on identifying themes and categories which are usually drafted into an interview guide before conducting interviews with relevant participants. Themes from subsequent interviews are compared with those already identified, which is a challenging iterative process and a core element of the analysis approach known as a constant comparison. Ongoing data collection can further refine the characteristics of themes. The constant comparison technique is used to compare themes identified from further data collection with those already identified to further refine categories (Pope et al., 2000; Ritchie and Lewis, 2003). A crucial component of this process is the between-case comparison that aimed to identify the variety of experience between respondents so that resultant explanations can aid refining the characteristics of themes (Pope et al., 2000).

In thematic framework approach, data analysis is an integral part of the research process and should begin at the same time as data collection. The researcher typically continues to interview participants until no new themes emerge, a point known as theoretical saturation. However, knowing when this stage can be reached is difficult, since every new interview might modify existing category or produce a new theme (Pope et al., 2000). Description of how this was done is presented in section 4.6.1 of this chapter.

4.2.1.3 Qualitative data analysis

There are two different approaches to qualitative data analysis, manual or computer assisted methods, and these have been widely debated in the social sciences literature (Bringer, Johnston and Brackenridge, 2004; Morison and Moir, 1998; Welsh, 2002). The use of Computer Assisted Qualitative Data Analysis Software (CAQDAS) is well established in qualitative methodology data analysis (Bringer et al., 2004). Some researchers suggested that CAQDAS can enhance rigour and make the analysis of qualitative data more systematic and facilitate an accurate and transparent data analysis

process. The tools available in CAQDAS can assist in organising data, checking for consistency in coding, keeping records and examining relationships (Bringer et al., 2004; Morison and Moir, 1998; Welsh, 2002).

While there is a range of software available to aid in the analysis of qualitative data, NVivo (QSR International Pty Ltd, Doncaster, Victoria, Australia) has been used successfully in the analysis of grounded theory studies as described by Bringer et al., (2006). While the use of NVivo can add rigour to the analysis process; much has been written expressing concern that the software may guide researchers in a particular direction of analysis (Seidel, 1991). It is often thought to be a grounded theory approach to data analysis (Bringer et al., 2006), in that the memoing tools in NVivo facilitate theory building from the data (Bringer et al., 2006). Taking grounded theory approaches to data analysis will create homogeneity in qualitative data analysis methods across the social sciences (Barry, 1998; Hinchliffe et al., 1997). Barry, (1998) commented that using CAQDAS may distance the researcher from the data and encourage quantitative analysis of qualitative data.

While the searching facilities in NVivo allow the researcher to carry out quick and accurate searches of particular terms, Brown et al., (1990) indicated that the availability of multiple synonyms would limit retrieval of information and make it difficult to recover all responses (Brown et al., 1990).

Based on the argument that applying computer software to qualitative data analysis raises important issues that go to the heart of the data analysis approach to be used in the analysis of qualitative findings, the decision was made to use manual analysis of qualitative findings throughout the entire project. Description of the interview data analysis is described in section 4.6.1.2 of this chapter.

4.2.1.4 Quality in qualitative research

Whilst terms such as validity and reliability are often used to describe quality in quantitative research, concepts of validity and relevance can be used to judge quality in qualitative research (Mays and Pope, 2000). However, Lewis and Ritchie (2003) continued to use terms other than reliability and validity but with a similar sense to judge quality in qualitative research. For example, they used confirmability of findings, trustworthiness, consistency or dependability of the evidence to describe the quality of qualitative findings. In this sense, internal confirmability or consistency matters of the likely recurrence or replication of the original data if similar studies were undertaken, while external confirmability or consistency relates to the extent to which values and quality of the research findings are agreed or replicated between researchers (Lewis and Ritchie, 2003).

Validity refers to the correctness of the qualitative evidence or precession of qualitative findings (Lewis and Ritchie, 2003). Traditionally, validity has two distinct dimensions, either internal validity, concerned with whether the investigator is investigating what they purport to investigate; or external validity, which refers to the extent to which research findings are applicable or generalisable to the wider population or other settings (Lewis and Ritchie, 2003). Guba and Lincoln (1994) refer to credibility and transferability for the internal and external validity of qualitative methods.

Mays and Pope (2000) offer a complete and comprehensive list of strategies which can be used to improve validity and quality in qualitative research, including:

- Triangulation as indicator of validity by comparing findings from two or more different research methods or, two or more data sources

- Respondent validation can be used to see if participants felt that the account produced by the researcher summed up their general experience
- Providing clear exposition of methods of data collection and analysis so that others can decide whether the findings are generalisable.
- Reflexivity and attention to negative cases in the findings as important measures to assess the quality of qualitative findings.
- Fair dealing; where the research design ensures that a wide range of perspectives are presented ensuring that the viewpoint of one group is not presented as the ultimate truth.

Fade (2003) suggested that researchers need not to demonstrate all of the quality measures but that issues of quality are discussed so that readers can assess the quality of the findings.

Reflexivity is presented in next section as a practical approach to achieve quality in qualitative methods.

4.2.1.5 Reflexivity

Reflexivity is a widely accepted concept that is fundamental to quality in qualitative research methodology (Lambert et al., 2010). It is commonly used as a pragmatic approach to prevent prior knowledge distorting the researcher's perceptions of the data (Cutcliffe and McKenna, 2002; Kingdon, 2005). It is perceived as the researchers' acknowledgement and self-awareness of their actions and decisions on the research they undertake that may inevitably impact upon the meaning and context of the experience (Kingdon, 2005). In reflexivity, researchers tend to reflect continuously on how their actions, values and perceptions impact upon the research setting and may affect data collection and analysis (Horsburgh, 2003). Lambert et al., (2010) indicated that reflexivity is an important part of transparency within a study and is an accepted method where qualitative researchers can

validate their research practices and reduce researcher influence on the study, ensuring the transparency and quality of research inquiry.

Record-keeping, memo-taking and journal-keeping have been suggested as an effective way of maintaining reflexivity (McGhee et al., 2007). Keeping a record of one's thoughts, feelings and activities associated with the research process helps to demonstrate a methodological and theoretical appreciation and self-awareness of interactions between the researcher and participants (McGhee et al., 2007). This reflexive journal sensitises researcher to self-prejudice and subjectivities while informing the researcher on the impact of these influences on the credibility of the research outcomes (Horsburgh, 2003). In this case, the reader of the final research report can assess any concerns about objectivity and interpretations of outcomes. Practical application of reflexivity in this study is discussed in chapter nine, section (9.2).

4.2.2 Quantitative research methods

Quantitative research originated in the positivist paradigm which believes in single reality, that is objective and discovered through observation and experimentation (Guba and Lincoln 1994; Johnson and Onwuegbuzie, 2004). Positivist oriented researchers view knowledge as separate and independent from individuals (Schwandt, 1994) and state that social phenomena, questions, and events are quantifiable and knowledge could be achieved only through conducting scientific inquiries (Creswell, 2009).

Quantitative research is known as the traditional scientific approach to research that underpins the positivist paradigm for inquiry of knowledge (Guba and Lincoln, 1994; Tashakkori and Teddlie, 1998). Quantitative research places considerable value on objectivity, prediction and control (Jack and Clarke, 1998). A distinguishing feature of the

quantitative research is the collection of numerical data and quantifiable information that, in turn, can be subjected to statistical analysis (Carr, 1994).

Quantitative research methods offer a systematic and more formal process which focuses on measuring quantities and examine relationships among attributes which are investigated using scientifically rigorous procedures (Bowling, 2014). In general, the values of quantitative research are the objectivity and generalisability of research findings, repeatability of the research process, and the ability to apply statistical measures to establish the significance of associations and differences between research participants (Creswell, 2009; Foss and Ellefsen, 2002; O'Cathain et al., 2007). The quantitative approach is, however, not without its weaknesses, Foss and Ellefsen (2002) found that the use of survey (questionnaire) reflects researcher priorities and views instead of participant's view which then can lead to bias and false representation. Another fundamental limitation of the quantitative approach is that the responses on opinions and perceptions are converted into numbers for analysis, and the results consist of a series of vague statistical answers to the questions under investigation (Carr, 1994; Foss and Ellefsen, 2002).

4.2.2.1 Methods of data collection in quantitative research

Strategies of inquiry associated with quantitative research include; experimental and non-experimental research design (Bowling, 2014). Survey research is a type of non-experimental design that concerns providing a numeric description of trends, attitudes, or opinion of a population by studying a sample of that population (Creswell, 2009). It includes quasi-experiment and longitudinal studies using a questionnaire for data collection, with the intent of generalisation from a sample to a population (Creswell, 2009). On the other hand, experimental research design aims to study the effect of treatment

(intervention) on the outcome, with the intent of controlling for all other factors that might affect the outcome (Bowling, 2014; Creswell, 2009).

4.2.2.2 Survey methods: Questionnaire

A survey is a means of collecting information, from a representative sample of the population as accurately and precisely as possible, with the intent to measure attitudes, knowledge, and behaviour (Bowling, 2014). A significant advantage of questionnaires method is that they can be answered in natural settings, are relatively economical, can be used to estimate certain population parameters, aim to analyse cause-effect relationships, and can be used to test a statistical hypothesis about a population (Bowling, 2014).

The questionnaire can be structured or semi-structured (Bowling, 2014). The later includes fixed questions with few response codes, to be used flexibly by the interviewer and gives space to enable the respondent to raise questions and issues not covered by the questionnaire (Bowling, 2014). While structured questionnaire involves the use of fixed questions along with pre-coded response choices designed to be used in the same way with all respondents (Bowling, 2014). While the use of questionnaire allows researchers to collect unambiguous answers, leading to greater ease of data collection and analysis, the use of pre-coded responses may force respondents to choose an inappropriate answer that might not reflect their view (Bowling, 2014). Moreover, the use of a standardised wording, terms, and concepts of questions may not always elicit the same responses from different respondents (Bowling, 2014). In addition to their weaknesses, there is also a scope of bias, for example, interviewer bias, framing bias; which is related to the insufficient comprehensiveness of the pre-coded choices, and social desirability bias; which reflects the respondent tendency to provide a positive image (Bowling, 2014).

4.2.2.3 Validity and reliability of quantitative data in questionnaire

One key measure of the quality of questionnaire method is the validity of the responses; in other words, is the questionnaire truly measuring what it purports to measure? Another key measure is the reliability of responses: is the questionnaire measuring things consistently or reproducibly? (McColl et al., 2001)

Reliability refers to the reproducibility and consistency of the measurement scale (McColl et al., 2001). Tests of reliability assess the extent to which scale items measure the same construct through formal statistical measures of homogeneity or what called internal consistency and repeatability (Bowling, 2014). Repeatability may be assessed through the test-retest process (Bowling, 2014). Test-retest reliability is the most logically straightforward measure of reliability (McColl et al., 2001). It involves checking whether the same answer is obtained if the question is asked of the same individual at two points in time, and then the test of the stability of the measure; in which it is not expected to change by repeated administration of the instrument (Bowling, 2014).

As with reliability, validity is another key measure the survey researcher needs to pay careful attention to (McColl et al., 2001). Validity refers to whether the questionnaire and its associated response options are measuring what they purport to measure and whether the information yielded is valid (McColl et al., 2001). This type of validity is known as internal validity. However, external validity refers to the ability for generalisation of the research findings to the wider population (Bowling, 2014).

Failure to assure the validity and reliability of the findings may cause the research to be questioned for quality or even rejected as invalid (Bowling, 2014).

The questionnaires used through the different stages of the research study consist entirely of previously tested and validated questions that have been successfully used before.

4.2.2.4 Quantitative data processing and analysis

In preparation for analysis, quantitative data need to be sorted and coded to reduce large quantities of information into a form that can be more easily managed using software programs (Bowling, 2014). Coding is a technique of conceptualising research data and classifying them into categories by assigning a number to given answers (Bowling, 2014). Once the data have been coded, the descriptive statistic can be used to describe the study sample via mean (M), standard deviation (SD), frequency (N), and percentage (%). Quantitative research can be purely descriptive when it is used with the intent to measure attitudes, opinion, knowledge and behaviour (Bowling, 2014; Creswell, 2009).

4.3 Data collection instrument

4.3.1 The interview topic guide

The topic guide offers a tool to maintain the consistency of data collection and is seen as an instrument for steering the discussion in an interview (Arthur and Nazroo, 2003). It helps to ensure that central aspects of the research are covered systematically and with uniformity for the disclosure of details that are salient to each research respondent (Arthur and Nazroo, 2003).

An interview topic guide is usually generated from; the stated research objectives, existing relevant literature on the topic, discussion with the research team, and from conducting a pilot study (Arthur and Nazroo, 2003). In semi-structured interviews, a topic guide simply lists key topics or themes to be covered during the interview. A key feature of the topic guide is that the questions were interactive in nature, which means that the researcher used a range of probes and follow-up questions to achieve the depth of answers in terms of

explanation and exploration. This format allowed the researcher to explore all the factors that support interviewee's responses, for example, reasons, feelings, and opinions (Arthur and Nazroo, 2003). Generally speaking, a well-designed topic guide consists of short and clear questions that are designed to yield a full answer, and not to influence the answer itself (Arthur and Nazroo, 2003).

4.3.2 Study questionnaires and outcomes measures

As described in section (4.2.2.2), questionnaires are used in this study for collecting measurable outcomes from research respondents. Outcome measures and scales used for data collection are described below. Scales used for data collection are adopted from existing scales, which have been carefully developed and tested for validity, reliability, questions format, wording, and order effects.

4.3.2.1 Healthcare professionals' questionnaires

Questionnaires used to collect data from healthcare professionals (HCPs) consist from the following measurable scales:

- Preparation for decision-making scale
- End User Satisfaction instrument
- Acceptability scale

Preparation for decision-making scale

The preparation for decision-making scale (PrepDM scale) consists of 11 brief statements with a five-category Likert scale format ranging from 1 (Not at all) to 5 (A great deal). The PrepDM scale (practitioner version) was developed to assess a HCP's perception of how useful a decision aid intervention is in preparing patients to communicate with their HCPs and to make a health decision (Bennett et al., 2010; Graham and O'Connor, 1996). It addresses concepts of preparedness for decision making and predictors of preparedness

(Bennett et al., 2010; Graham and O'Connor, 1996). The PrepDM scale evolved over time as it was tested with different groups making health decisions (Bennett et al., 2010). Initially, the scale was used in a randomised controlled trial (RCT) of a decision aid for women considering hormone replacement therapy (HRT) during and after menopause (O'Connor et al., 2000). The scale showed high internal consistency (α = 0.92) and discriminated between the intervention and control study arms (O'Connor et al., 2000). A version of the scale was used in subsequent studies including; a pre–post evaluations of decision support interventions for women considering breast cancer prevention options (Stacey et al., 2003), and in men deciding on treatment for early-stage prostate cancer (Feldman-Stewart et al., 2004). The scale demonstrated high internal consistency (α coefficients: 0.94 and 0.86, respectively) and showed consistent item total correlations (Feldman-Stewart et al., 2004; Stacey et al., 2003). In Bennett et al., (2010) the α coefficients for internal consistency of the scale across the five patient groups ranged from 0.92 to 0.96 and Item-total correlation analysis were also high (0.75–0.81). In the current study, the Cronbach alpha coefficient was 0.94.

Satisfaction scale

Doll and Torkzadeh (1988) developed and validated an End-User Computing Satisfaction (EUCS) instrument. It includes five components: content, accuracy, format, ease of use, and timeliness. The instrument was regarded as comprehensive and includes 12-item (Xiao and Dasgupta, 2002). Based on Xiao and Dasgupta (2002) framework, research participants' satisfaction of the decision support tool was evaluated by using five success measures: content, accuracy, format, ease of use, and timeliness. The construct was developed with a five point Likert-type scale (1 = almost never; 2 = some of the time; 3 = about half of the time; 4 = most of the time; and 5 = almost always) (Xiao and Dasgupta, 2002). The scale was used in subsequent studies in pre–post evaluations of users'

satisfaction with decision support system (McHaney, Hightower and White, 1999). This study was found to have a high internal consistency of 0.938. This study's α (McHaney et al., 1999) compares favourably with an overall α of 0.92 in the original study (Doll and Torkzadeh, 1988). The instrument was widely accepted and adopted by other researchers. For example, McHaney and Cronan (1998) and McHaney and Cronan (2000) adopted it to examining computer simulation success and also demonstrated overall high internal consistency; α coefficients: 0.91 and 0.85, respectively. In the current study, the Cronbach alpha coefficient was 0.93.

Acceptability scale

This scale explores respondent's perceptions of whether the DST would be feasible to implement in a real-world clinic setting by asking questions about acceptability regarding the perceived usefulness and perceived ease of use, and overall suitability for decision making (O'Connor and Cranney, 1996). The practitioner version of the scale consists of 15 items and responses are reported using five-point Likert scale format ranging from 1 (strongly disagree) to 5 (strongly agree). The practitioner version of the scale was used in a study by Van der Steen et al., (2011) to measure physicians' and nurses' perceived acceptability of a Canadian family booklet for dementia and the scale found high internal consistency; Cronbach alpha coefficient was 0.93. In the current study, the Cronbach alpha coefficient was 0.847.

4.3.2.2 Patients' questionnaires

Questionnaires used to collect data employed the following measurable scales:

- Acceptability
- Preparation for decision making
- Patient decision conflict scale
- The control preferences scale

Acceptability questionnaire

This questionnaire explores respondent's perceptions of the decision aid. Acceptability of the decision aid was assessed in terms of; comprehensibility of components of the DA on a scale labelled by poor to excellent, length of presentation, the way the information was presented, amount of information, and balance using structured response categories (O'Connor and Cranney, 1996). The scale was commonly used to evaluate patients' perceived acceptability of a decision aid; O'Connor et al., (1998) used the acceptability questionnaire to measure women's acceptability of hormone replacement therapy decision aid, in a randomised controlled trial O'Connor et al., (1998) used the questionnaire to evaluate a DA for postmenopausal women considering long-term hormone therapy, and was also used in many other different studies to evaluate patients' perceived acceptability of PDAs designed for different conditions (Cranney et al., 2002; Drake et al., 1999; Fiset et al., 2000; Grant et al., 2001; Mitchell, Tetroe and O'Connor, 2001.).

Preparation for decision making scale

The preparation for decision making scale (PrepDM scale) consists of 10 brief statements with a five-category Likert scale format ranging from 1 (Not at all) to 5 (A great deal). The PrepDM scale (patient version) was developed to assess a patient's perception of how useful a decision aid was in preparing them to communicate during consultation and to make an informed decision (Garaham and O'Conner, 2010). It addresses concepts of preparedness for decision making and predictors of preparedness (Bennett et al., 2010; Graham and O'Connor, 1996). The PrepDM scale evolved over time as it was tested with different groups making health decisions (Bennett et al., 2010). The scale showed high internal consistency ranges from 0.92 to 0.96 (Bennett et al., 2010; O'Connor et al., 2000; Stacey et al., 2003). In the current study, the Cronbach alpha coefficient was 0.976.

Patient decision conflict scale

A decisional conflict scale (DCS) was developed using items derived from the decisional conflict construct; uncertainty, factors contributing to the uncertainty, and perceptions of effective decision making (O'Connor, 1995). The subscales evolved over time as the DCS was tested with different groups making health decisions (O'Connor, 1995). The decision conflict scale (patient version) consists of a series of statements measuring respondent's perceptions of modifiable factors contributing to uncertainty using the following subscales: values clarity subscale; support subscale; uncertainty subscale, and effective decision subscale (O'Connor, 1995). Question format in the patient version of decisional conflict scale was designed to suit patients with limited response skills (O'Connor, 1995). It is easier response format compared to the clinician statement format version. The scale consists of 10 items, each item consists of a brief statement with a three-category Likert scale format, items are given a score value of 0 = yes; 2 = unsure; 4 = No.

The DCS met acceptable standards of reliability and validity, is sensitive to change, and discriminates between those who make and those who delay decisions (Bunn and O'Connor, 1996; O'Connor, 1995 O'Connor, Tugwell and Wells, 1994). The test-retest correlation coefficient was 0.81(O'Connor, 1995). Internal consistency was high, with alpha coefficients ranging from 0.78 to 0.92 for the total scale and from 0.58 to 0.92 for the subscales (O'Connor, 1995; O'Connor, Pennie and Dales, 1996). In the current study, the Cronbach alpha coefficient was 0.521 for the total score and from 0.397 to 0.647 for the subscales.

The control preferences scale

The Control Preferences Scale (CPS) is a validated and widely used measure of patients' consultation preferences for treatment decision making (Degner et al., 1997). The original CPS consists of vignettes, each with a statement and a cartoon that portrays the five

different roles in the decision-making process (Degner et al., 1997). The CPS items include the following: (1) the doctor should make the decision alone, (2) the doctor should make the decision after discussion with the patient, (3) the doctor and patient should make the decision together, (4) the patient should make the decision after consultation with the doctor or (5) the patient alone should make the decision (Degner et al., 1997). The CPS is considered the most frequently used instrument of patient decision role preferences (Chewning et al., 2012).

4.4 Quality criteria for mixed methods research

Paradigmatic differences between quantitative and qualitative methods suggest that quality criteria shared by both methods may not be equally important to each method (Sale and Brazil, 2004). Criteria for judging the rigour of inquiries carried out within the qualitative and quantitative methods are well established and include such measures as internal and external validity, reliability and objectivity, where terms such as credibility, transferability, dependability and confirmability are used to critically appraise qualitative approach (Onwuegbuzie and Johnson, 2006).

Guba and Lincoln, (1994) used the term trustworthiness parallels to the term rigour in quantitative methods (Onwuegbuzie and Johnson, 2006). Sale and Brazil, (2004) expanded what Guba and Lincoln called trustworthiness and rigour to include further four quality criteria to apply to particular methods and paradigms:

- Truth value – refers to internal validity for quantitative methods versus credibility for qualitative methods
- Applicability – refers to external validity for quantitative methods versus transferability for qualitative methods

- Consistency – refers to reliability for quantitative methods versus dependability for qualitative methods;
- Neutrality – refers to objectivity for quantitative methods versus confirmability for qualitative methods.

Indeed, there is little agreement on how to achieve quality in mixed method research beyond the assumption that the concept of rigour in conducting mixed method research refers to the essential ingredients of quality criteria as defined by O'Cathain et al. (2008), includes:

- Justification of a mixed methods approach for the research question
- Description of mixed methods research design, including; purpose, priority, and sequence
- Description of research design for each method, including; sampling, data collection, analysis, and interpretation
- Description of integration of data in triangulation design
- Description of research limitations related to the mixed methods approach
- Discussion of the insights gained from mixed methods approach

4.5 Research methods

4.5.1 Research aims and objectives

The overall aim of the study was to evaluate the utility of the computerised decision support tool in anticoagulation management using a mixed methods approach.

The rationale for this aim originated from the researcher's review of the decision support system research literature on anticoagulation management (as was discussed in section 2.3

and 2.4). There seemed to be reasonable studies that concerned the impact of CDSSs on key decision points in anticoagulants prescribing decision. However, the heterogeneity of outcomes in these studies makes the synthesis of evidence challenging and creates difficulties in providing clear guidance on where CDSSs are likely to be most effective. None of which had explored HCPs' perspectives in depth on the utility of CDSS on anticoagulation decision-making process or decision quality. In addition, a review of the patient decision aids research literature on anticoagulation management found few published studies, none of which had explored patients' perspectives in depth on the impact of PDA on anticoagulation decision-making process or decision quality. Furthermore, none of which had explored perspectives of HCPs and their patients in the same study. Very little published research that concerned UK healthcare settings and practices were found, and qualitative studies are generally absent from all studies. This established a research interest in the evaluation of the DST in anticoagulation management from HCPs' and patients' perspectives.

To this point in the research, the researcher assumptions included that the DST and associated PDA would likely to be useful in supporting anticoagulation decision-making and decision quality, and this may have implications for clinical practice. The reason why a mixed-method approach was chosen to explore these interests was explained in section 4.1.1, the decision to use semi-structured interviews and questionnaires was explained in sections 4.2.1.1 and 4.2.2.2, and the rationale for using the broad principles of thematic framework approach as a practical approach was outlined in section 4.2.1.2. The process of recruitment and interviewing in all research stages of the study is discussed in detail in sections 4.5.3 and 4.5.4.

Stage one: Aims and objectives

The specific aim of the initial stage of the study was to explore the suboptimal determinants in the anticoagulation decision-making process using semi-structured qualitative interviews with a sample of HCPs who are involved in anticoagulation management in AF

The study objectives were to:

- Interview HCPs to explore and understand anticoagulation therapy decision making process
- Explore HCPs' experiences with anticoagulants decision making
- Prompt HCPs to reveal suboptimal determinants in the decision-making process
- Prompt HCPs to discuss strategies to address needs

The origins of the first stage of the study focused on identifying the suboptimal determinants in anticoagulation decision-making. This was supported by the literature since the evaluation of decision support tool is a complex intervention that requires an iterative process of evaluation (as was discussed in section 4.1.1). Evidence from ODSF study (discussed in section 4.1.3) indicated the need to identify suboptimal determinants in decision making before commencing the evaluation process. However, (discussed in section 1.1) there appeared to be little research that had explored HCPs' perspectives in-depth on the use of anticoagulants, especially in UK healthcare settings since NICE CG 180 launched in 2014 (e.g. Barra and Fynn, 2015; Cowan et al., 2013; Holt et al., 2013; Scowcroft et al., 2013). For this reason, HCPs were interviewed, which was a purposive sample to test these ideas and in doing so identify strategies that can help address

suboptimal determinants in the decision-making process. The process of recruitment and interviewing in this initial stage of the study is discussed in sections 4.5.3 and 4.5.4.

During the initial stage of the study the assumption that the DST would likely to be useful in supporting anticoagulation decision making and decision quality did not emerge from analysis of the data, but was supported by the literature, since quantitative studies (discussed in section 2.3) indicated that DSS for anticoagulation management could have potential for improving anticoagulation prescribing practice (e.g. Chatellier et al., 1998; Fitzmaurice et al., 1998; Pearson et al., 2009). However, (as discussed in sections 2.3) there appeared to be little research that had explored HCPs' perspectives in-depth on the potential utility of DSSs in supporting anticoagulant decision-making in clinical practice. To do this HCPs were introduced to the DST and interviewed after that. The process of recruitment and interviewing in this second stage of the study is discussed in sections 4.5.3 and 4.5.4.

Stage two: Aims and objectives

The specific aim of the second stage of the study was to conduct second interviews with the HCPs to evaluate the potential utility of the DST in anticoagulation decision-making process.

The study objectives were to:

- Explore HCPs' views of the potential utility of the DST in clinical practice
- Prompt HCPs to explore design features and functions of the DST
- Prompt HCPs to discuss the potential impact of implementing the DST into routine clinical workflows

- Investigate HCPs' potential concerns associated with the DST implementation in clinical practice
- Investigate the impact of the DST on preparing patients for decision making
- Understand the overall potential of the DST to address the suboptimal determinants in anticoagulation decision making
- Prompt HCPs to suggest recommendations for promoting more effective use
- Explore HCPs' perceived preparedness for decision making, acceptability, satisfaction of the DST using quantitative measures which were answered using pure descriptive statistics

Following the DST demonstration and pre-interventional evaluation stage, all interviewed HCPs were asked to implement the DST and associated PDA into routine clinical workflows and to invite at least two patients to partake in the DA evaluative study.

The origins of the third stage of the study focused on HCPs in the initial sample who implemented the decision support tool in routine clinical practice. Their perspectives on the utility of the DST in clinical practice were explored. Also, their perspectives on the usefulness of the tool may have been different to the other HCPs who had not implemented the DST into routine practice. The process of recruitment and interviewing in this third stage of the study is discussed in sections 4.5.3 and 4.5.4.

Stage three: Aims and objectives

The specific aim of the third stage of the study was to conduct semi-structures qualitative interviews with HCPs from initial stage who had/had not implemented the DST in routine

clinical practice so that these could be compared with their perspectives explored during second interviews.

The study objectives were to:

- Explore HCPs' experiences from implementing the DST into routine clinical workflows
- Explore HCPs views on the impact of implementing the DST on quality of the prescribing decision made
- Identify actual barriers with implementing the CDS tool in clinical practice
- Identify perceived barriers with implementing the CDS tool in clinical practice
- Examine the difference in HCPs responses between pre-and-post intervention evaluation

Stage four: Aims and objectives

The specific aim of the fourth stage of the study was to conduct semi-structured qualitative interviews with the patients after they experienced the DST during the consultation to explore their perspectives on the usefulness of DA for anticoagulation decision-making.

The study objectives were to:

- Explore patients' experiences of the utility of the DA in decision making
- Prompt patients to explore their views and perceptions about involvement in the decision-making process
- Prompt patients to discuss the impact of the DA on preparing patients for decision making
- Investigate patients' potential concerns associated with the DA implementation in clinical practice

- Explore patients' perceived preparedness for decision making using the DA, acceptability, and decision conflict using quantitative measures which were answered using pure descriptive statistics

The rationale for the fourth stage originated from assumptions that patients would view the PDA useful in anticoagulation decision-making. This was supported by the literature, since quantitative studies (discussed in section 2.4) indicated that AF patients perceived DA useful in improving understanding and perception of AF and treatment (e.g. Aliot et al., 2010; Lane et al., 2006; Lip et al., 2002). Besides, None of the reviewed studies seemed to have explored patients' perspectives on effects of decision aids on attributes of the decision and decision-making process in depth (as was discussed in section 2.4.4), although research that concerned different outcome measures (for example, satisfaction, knowledge, decision conflict) were found. This established a research interest in exploring patients' perspectives on the use of DA in improving anticoagulation decision making and decision quality.

Therefore, the patients who experienced the DST during the consultation were interviewed. The process of recruitment and interviewing in this fourth stage of the study is discussed in sections 4.5.3 and 4.5.4.

4.5.2 The work preceding conducting the study

Three key steps preceded this study:

1. Development, validation and endorsement of the DST as described in section 1.3

2. Patient and service user involvement

3. Ethical approval for conducting the research

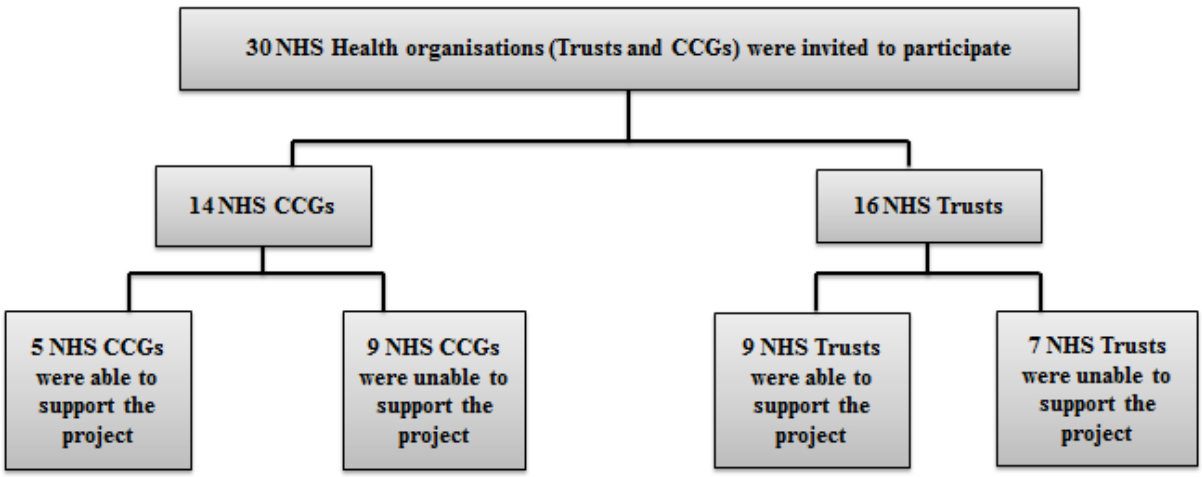
4.5.2.1 Potential research sites

Prior to applying for research ethics committee approvals, the research team identified potential research sites to implement the DST and conduct the project.

The selection criteria were the geographical distribution of research sites was made to include NHS Trusts and primary care clinical commissioning groups (CCGs) located within the west midlands area.

Having identified potential research sites, the research team agreed to send an introductory email to the research and development (R and D) department team, research lead and or potential research collaborator in the trust to allow these participating NHS organisations to focus their resources on assessing and confirming their capacity and capability to deliver the study. Figure (4.2) shows trusts and CCGs responses to the invitation to participate.

Figure 4. 2: Flow chart of health organisations response to participate



The study received R and D department approval from 14 NHS health organisations, of which, five primary care clinical commissioning groups (CCGs) and nine NHS Trusts. However, the study was conducted at 11 NHS health organisations, of which, three primary care clinical commissioning groups (CCGs) and eight NHS Trusts.

4.5.2.2 Patient and service user involvement

The Medical Research Council recommends identifying what changes are expected from the intervention, and how change is to be achieved. This can be done, for example, by interviewing with 'stakeholders', i.e. those targeted by the intervention, or involved in its delivery and evaluation that has already been developed and implemented (Craig et al., 2008).

Prior the study commencement, feedback was received regarding the study feasibility, design and process via a series of meetings with; atrial fibrillation patients, a general practitioner (GP) research facilitator at National Institute for Health Research (NIHR), a GP clinical research speciality lead for primary care at NIHR, locality support manager of the Clinical Commissioning Group (CCG), and the potential research local collaborators from potential NHS trusts.

Meetings with stakeholders from both primary and secondary care were conducted by the researcher (R.H.), the research principal investigator (S.C.), and the DST developer (S.T.). The meeting included the demonstration of the DST, answering their questions, and discussing the study protocol, research documents and recruitment process. These meetings were set up to provide advice on the best method to approach GPs from primary care practices and consultants, nurses and pharmacists from secondary care.

A meeting was also arranged with Patient and Public Involvement lead at Keele University to seek advice on early involvement of patients.

<u>Impact of the early involvement</u>

GPs and primary care development manager suggested advertising about the project in the weekly newsletter and attach a research flyer (attached as appendix three) for at least two

times so that GPs in the network know about the project and if they were interested they could contact the researcher directly.

The research directors who agreed to be interviewed at this stage explained to the researcher; how the anticoagulation service runs in the trust, referral process of patients between the primary and secondary settings, the best way to approach consultants, nurses, and pharmacists, how to initiate local dissemination strategy. They also advised on names with special interest with anticoagulation management and also advising on research materials and procedures.

For the benefit of patients and to maximize patients' recruitment rate, the researcher approached and contacted two patients from the public (by asking friends and colleagues) to discuss the research protocol in general, patient approaching and recruitment procedure, and to review and test patients' related documents and data collection tools. Two participants were approached in an informal one-to-one at their homes; a 37 and 74-year-old female patients who were diagnosed with AF and were taking warfarin. The researcher discussed the following sections: patient approaching and recruitment procedure, the interview venue and time allocated for the interview and completion of questionnaires, data collection tools, and other patient supporting documents, for example, patient information sheet, consent forms, invitation letter. All research documents were checked for simplicity, and ease of understanding, design and format. All documents were checked.

In response to the patients' comments, some questions' wording was changed. The patients also commented on the practical arrangements for recruitment by the researcher. For example, they advised giving patients a week in between the consultation visit and time to see the researcher. They also advised on offering patients the option to choose the place of the interview, whether at home or in the clinic.

4.5.2.3 Research Ethics Committee approval

The entire study was approved by NHS research ethics committee REC#14/LO/2053 on 18 November 2014. A copy of the ethics approval is included as appendix two.

Approval from each research site was subsequently sought and obtained. Following the REC requirements, annual progress reports and a completion of research form have been submitted.

The application for approval for the entire study was accompanied by the HCP Information Sheet, the HCP consent forms, HCP Information letter, the HCP interview guide and questionnaires, Patient Information Sheet, the Patient consent forms, the patient invitation letter, the patient interview guide and questionnaires. An example of a HCP Information Sheet is included as appendix four, and an example of a consent form is included as appendix five. The interview guide used in stage one is included as appendix six, the interview guide used in stage two is included as appendix seven, the interview guide used in stage three is included as appendix eight, and the questionnaire used in stage two is included as appendix nine. A letter that was sent to HCP to inform them about their patients' participation in the study is included as appendix ten.

An example of a Patient Information Sheet is included as appendix thirteen, and an example of a consent form is included as appendix fourteen. The interview guide used in stage four is included as appendix fifteen, and the questionnaire is included as appendix sixteen. The invitation letter that was sent to patients in stage four is included as appendix twelve and consent to contact form is included as appendix eleven.

4.5.3 Recruitment of participants

In the initial stage of the study, a sample of HCPs was recruited from the pre-defined NHS trusts and primary care CCGs in the west midlands area. The intention was to recruit a broadly representative sample of HCPs to explore anticoagulation decision making context and identify the suboptimal determinants in the decision-making process in depth. As was discussed in section 4.1.4, the sampling strategy used could be described as a purposive convenience sample. Purposive sample because HCPs were selected who shared characteristics that were believed to be most informative in achieving the objectives of the study (e.g. they are involved in anticoagulation therapy management in AF). Likewise, convenience sampling, because HCPs selected were those most willing to participate and accessible.

The criteria used in selecting HCPs were intended to be as inclusive as possible. As such, all HCPs who have specific experiences and roles in anticoagulation management in AF patients and were willing to give a detailed description of their personal experience were eligible to participate, provided that written consent was given. HCP participants were excluded if have not any specific experiences and interest in anticoagulation management in AF. No other exclusion criteria were applied.

All HCPs involved in the process of anticoagulants prescribing, monitoring, and consultation were invited to take part in the study. They were consultants and registrars (from haematology, cardiology, stroke, and acute medicine specialities), and non-medical independent prescribers; specialist nurses (from atrial fibrillation, stroke, and anticoagulation clinics) and pharmacists.

Using publicly available email address of the target HCPs, a list of contactable HCPs was prepared and included convenience sample selected purposively from secondary care NHS trusts agreed to support the project.

The researcher sent a standard invitation email to potential participants using the publicly available email address. The email text provided a brief description of the entire research, how and why they have been selected, by whom the research is being conducted, what it involves, and the researcher contact information. A reminder email was sent to any potential participants who have not responded after ten working days of the initial contact.

Healthcare professionals who replied by email expressing initial willingness to participate in the study were contacted again by replying to email to provide organisation's headed participant information sheet (an example is included as appendix four), attach the URL link of the decision support tool if they wished to try it before the interview, answer their questions if any, and were asked to arrange a location of the HCP's choice and a mutually convenient time for the interview. A reminder email was sent to any participant who has not responded after ten working days of the initial contact.

Study recruitment started on 13th of April 2016 and extended until 25th October 2016. This process of recruitment was successful in recruiting 47 HCPs to the study (over a period of six months).

As discussed in section 4.2.1.2, that in thematic framework approaches participants recruitment and interviews continue until no new themes emerge, at which point saturation is achieved. In this stage of the study by the time about forty-three interviews had been conducted no new themes appeared to be emerging that related to the topics in the interview guide, which was confirmed by the final four interviews. The decision to cease recruitment was made because it was felt that saturation had been achieved.

Invitation to take part in the study took place through emails from; the researcher directly, forwarded emails from invited HCPs, and the primary care network. Therefore, the researcher was not completely in control about how many hospital-based HCPs and GPs were invited by emails. However, the researcher directly contacted 186 HCPs from the nine NHS trusts who agreed to support the project. See figure (4.3) and table (4.1) for recruitment flow of hospital-based HCPs. Table (4.2) shows common responses from HCPs who declined to participate in the study.

General practitioner recruitment from primary care was initiated by sending project flyer and research information to the research manager at each participating primary care CCGs to go into the weekly newsletter of the CCGs' network. Research flyer is included as appendix three.

Figure 4. 3: Recruitment overview of hospital-based HCPs

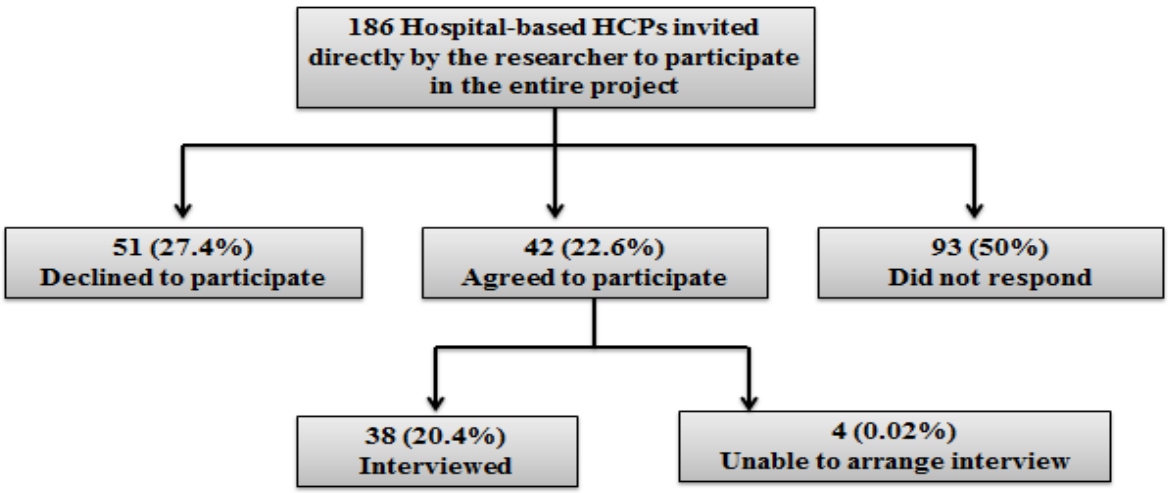


Table 4. 1: Healthcare professionals' recruitment

NHS trust agreed to participate	**Number of HCPs recruited**	**NHS primary care CCGs agreed to participate**		**Number of HCPs recruited**
NHS Foundation Trust Hospitals (1)	1	NHS CCG (1)	GP practice (1)	1
			GP practice (2)	2
			GP practice (3)	1
NHS Foundation Trust Hospitals (2)	1	NHS CCG (2)		1
NHS Foundation Trust Hospitals (3)	13	NHS CCG (3)		0
NHS Foundation Trust Hospitals (4)	1	NHS CCG (4)		0
NHS Foundation Trust Hospitals (5)	1	NHS CCG (5)	GP practice (1)	1
			GP practice (2)	1
			GP practice (3)	2
NHS Foundation Trust Hospitals (6)	2			
NHS Foundation Trust Hospitals (7)	17			
NHS Foundation Trust Hospitals (8)	0			
NHS Foundation Trust Hospitals (9)	2			
Total	38 hospital-based HCPs			9 from primary care

Table 4. 2: Example of replies from HCPs who declined to participate

Reasons provided by HCPs who declined to participate	
✓ Not interested ✓ Work on other researches ✓ Expecting maternity leave ✓ Work part time ✓ Very little to do with OACs prescribing ✓ Left the trust ✓ Retired ✓ Not area of prescribing ✓ Expecting to leave the trust ✓ Going on holiday	✓ Have established NOACs service ✓ Already have a clinic protocol and cannot change ✓ Need to discuss it with colleagues ✓ Just 'No' ✓ Unable to support ✓ Not involved in anticoagulant prescribing ✓ Busy ✓ Not for AF but for DVT and PE

The second stage of the study took place at the same time during study one. This means that HCPs were recruited to participate in stage one and stage two at the same time.

During the initial stage, the researcher was able to have an initial perception of the number of HCPs who were interested in implementing the DST into their routine workflow. Thirty-one HCPs initially agreed to implement the DST into their routine clinical workflows. Sixteen HCPs made their decision to drop out from the study at the end of the second stage. Figure (4.4) illustrates recruitment flow at this stage of the study

During the intervention period, the researcher sent a reminder email every week to all HCPs who initially agreed to implement the DST into routine care to prompt them to update the researcher on how the implementation is going, to provide quick feedback on experiences with patient recruitment and to identify any barriers associated with implementation.

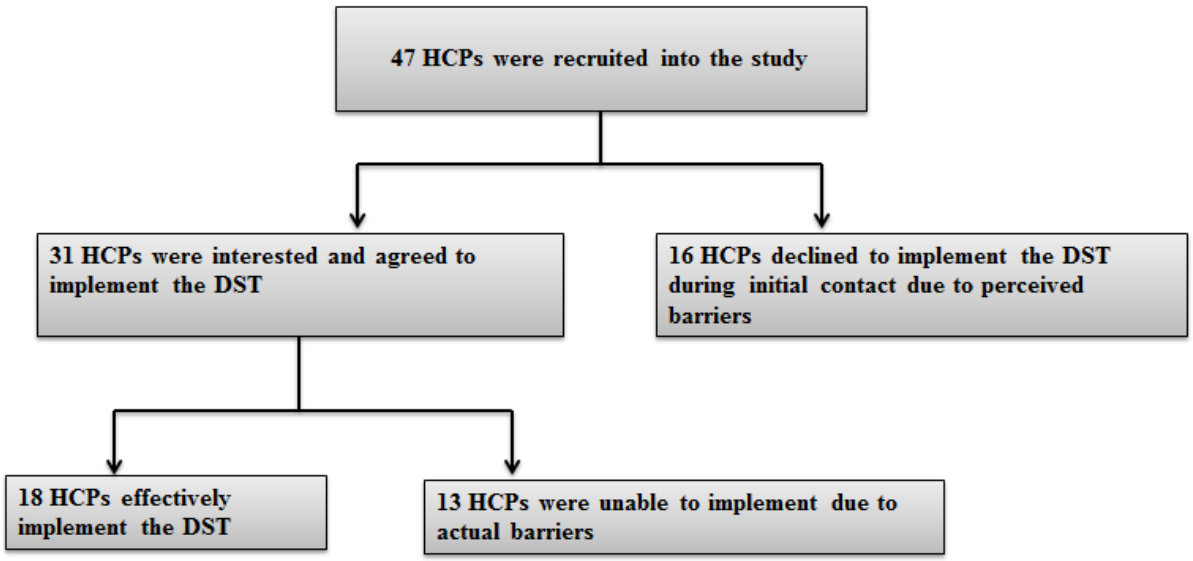
In the third stage of the study, the intention was to re-recruit HCPs from the initial stage of the study (which involved second interviews approximately eight weeks after the initial interview). These HCPs were selected on the basis of having been interviewed in the initial stage of the study, that they consented to be interviewed again, and expressed initial interest to implement the DST into routine clinical practice. No other inclusion or exclusion criteria were applied.

The process of re-recruiting the HCPs for the third stage of the study, started when the intervention period was over or earlier as appropriate. This indicated that of the thirty-one HCPs who were initially interested to implement the DST, only eighteen HCPs were able to implement the tool into routine practice. Table (4.2) shows common responses from HCPs who declined to participate in the study.

All HCPs who initially expressed their interest in implementing the DST into their routine care were contacted by email to invite them to participate in the third stage and were asked to arrange a location of their choice and a mutually convenient time for the interview (Either over the phone or face-to-face). A reminder email was sent to any participant who has not responded after ten working days.

Theoretical saturation at this stage of the study was recognised difficult because further recruitment of HCPs would have been impossible. Therefore, the researcher claimed premature saturation when no new themes appeared to be emerging that related to the topic which was confirmed by the final three interviews.

Figure 4. 4: Recruitment flow during implementation stage



As discussed in section 4.5.1, the fourth stage of the study focused on conducting interviews with patients who experienced the DST during the consultation.

All HCPs who agreed to implement the DST into routine practice were asked to identify patients and speak to them about the study. As such, a patient who had a consultation in which the PDA was used were eligible, unless, in the HCPs' opinion interviewing that patient might cause unnecessary extra stress to that patient.

Patients who met all the following criteria were eligible for the study:

- Adult (18 years of age)
- Mentally competent and able to consent for a study
- Diagnosed with non-valvular atrial fibrillation
- Taking or going to start any of OACs (warfarin, dabigatran, rivaroxaban, apixaban, or edoxaban) for non-valvular atrial fibrillation

- Have experienced the patient decision aid during consultation

Patients were excluded if they met any of the following:

- If patient is prescribed OAC for condition other than non-valvular AF
- Patients diagnosed with dementia, lack of capacity or fluctuating capacity or have cognitive impairment sufficient to hinder shared decision making will be excluded
- Patients who did not adequately understand verbal explanations or written information
- Patients were excluded if in the HCP opinion interviewing that patient may cause unnecessary extra stress to that patient

The decision regarding cognitive ability and loss of capacity, was judged with the help of HCPs who can access the potential participant's medical notes. The research team accessed no patient identifiable information. No other exclusion criteria were applied.

When a patient was considered suitable and mentally competent to consent for a study using 'consent to contact form' (included as appendix eleven) the HCP asked whether the patient was comfortable to be approached by the study researcher. If agreeable, the HCP provided a brief description of the study and provided the patient with the research information sheet to go through (included as appendix thirteen. If agreed, the HCP asked the patient to complete 'consent to contact form'. The HCP then send a scanned copy of the form to the researcher using personal email. When received, the researcher sent the research package to the patient's home address provided in the 'consent to contact form'. The research package includes; invitation letter (included as appendix twelve), patient information sheet (included as appendix thirteen), a reply slip and a pre-paid envelope. Patients were asked to arrange a location of the patient's choice and a mutually convenient

time for the interview. A pre-paid envelope was included so that patients who chose to participate could complete and return their consent forms. Patients who did reply were contacted by telephone to confirm a location and a mutually convenient time for the interview. Patients who did not reply were contacted by telephone after five working days from initial contact, and they were asked whether they were happy to participate, answer their questions, and arrange for the interview if agreeable. Patients who refused to participate were subsequently excluded from the study.

Study recruitment started on 18th of August 2016 and extended until 16th May 2017. This process of recruitment was successful in recruiting 17 patients to the study (over a period of nine months).

Figure 4. 5: Patients' recruitment flow chart

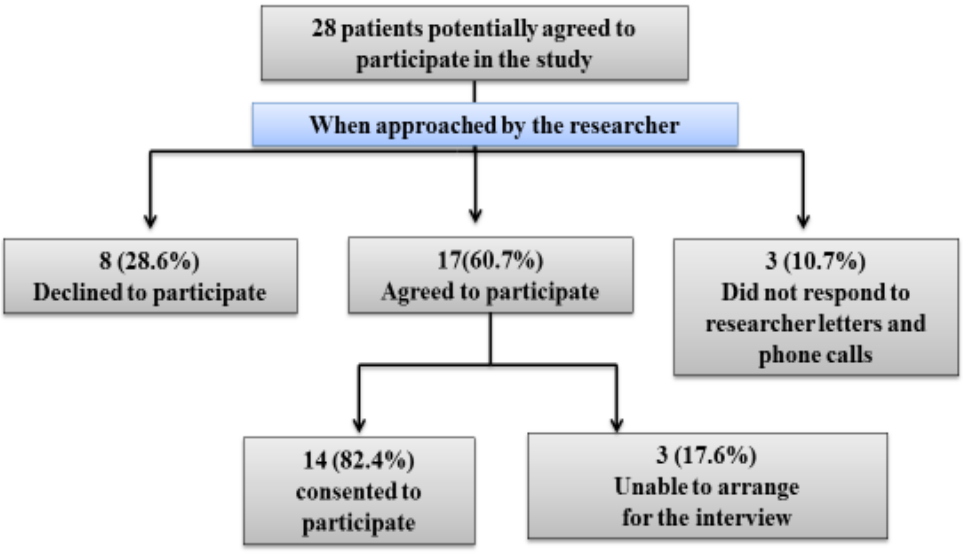


Table 4. 3: Patients' invitation and recruitment

Research site	HCP, research number	Number of patients initially consent to participate	Number of patients interviewed
NHS Foundation Trust Hospitals (3)	Haematologist, 1	2	0
	AM consultant, 3	0	0
	Senior cardiology registrar, 23	2	1
	IP-pharmacist, 2	0	0
NHS Foundation Trust Hospitals (7)	Stroke consultant, 8	4	2
	Stroke consultant, 12	0	0
	Stroke consultant, 40	2	0
	AM consultant, 33	4	3
	AM consultant, 37	0	0
	nurse,13	3	2
	nurse, 32	0	0
	IP-pharmacist, 35	2	0
NHS Foundation Trust Hospitals (2)	Haematologist, 44	0	0
NHS CCG Primary Care (3)	GP, 15	0	0
	GP, 17	1	0
	Nurse, 21	2	1
NHS CCG Primary Care (1)	GP, 45	5	4
	GP, 47	1	1

The decision to cease recruitment at this point was made on the basis that by the time ten or eleven interviews had been conducted no new themes appeared to be emerging that related to the topics in the interview guide, which was confirmed by the remaining three or four interviews. At this point, it was felt that saturation had been reached and HCPs were told not to recruit further patients into the study.

4.5.4 Data collection: The interviews

In the initial stage of the study audio-recorded, semi-structured interviews were conducted with forty-seven HCPs. The interviews took place face-to-face in HCPs' workplace at their convenience. The interview began with a brief statement in the form of summary points about the entire research objectives, why the research was being conducted, and an overview of the topic guide. The HCP was informed about the total duration of the interview and that it would be digitally recorded, their participation was voluntary and that they had a right to accept or refuse to take part or to withdraw from the study at any time. Participants were asked to sign a consent form for participating in the entire research before the interview started. Reconfirmation of consent to participate and consent for the use of quotes was obtained verbally at the end of the interview, supported by signing a consent form for the use of quotes. One copy was retained by the research participant, and one copy was retained for the research file. Participants were also assured about issues of confidentiality and anonymity during the research process and data analysis and reporting, as described in section 4.7.

As was discussed in section 4.3.1, the topics of interest that the researcher intended to cover in qualitative interviews were usually drafted into an interview topic guide before the interviews. The interview guide (included as appendix six) was developed to meet the aim of the initial stage of the study, which was to explore the suboptimal determinants in the

anticoagulation decision-making process. As discussed in section 4.1.1, evidence from the literature, (The ODSF study as discussed in section 4.1.3) was involved in initially forming the research interest that led to this aim, and these were included in the interview topic guide. The topic guide was formulated as HCPs' pathway for anticoagulation therapy decision making; HCPs' perceptions of patient involvement in the decision-making process; and barriers to delivering optimal anticoagulant management. Prompts and follow up questions were used as appropriate.

The topic on anticoagulation therapy decision-making covered how the prescribing decision was usually made, what factors did influence the prescribing decision, what communications aids did they use during the consultation, and what strategies did they use to support communication of information to patients. The topic on HCPs' perceptions of patient involvement in treatment decision covered whether patients were involved in treatment decision and HCPs were asked what their views about involving patients in the decision-making process. Questions about barriers influenced anticoagulation prescribing decision were included. Questions were also included about which of these barriers were related to; patients, HCPs, or healthcare system. Questions about strategies that they considered important to addressing barriers to suboptimal determinants in the decision-making process were included.

The interviews generally lasted approximately between 30 minutes to one hour. After each interview, the researcher reflected and made notes on how the interview had gone and important issues or themes that had emerged. These notes also included any relevant comments and suggestions made by interviewees after the audio recorder was switched off. The interviews were transcribed verbatim immediately after the interview (as described in section 4.6.1.1). Repeated listening and reading of the first four transcripts enabled the

researcher to become immersed in the data, allow assessment of how well the topic guide worked, and identify an unexpected topic for exploration in further interviews.

The HCPs' interview topic guides and questionnaires were reviewed before data collection commenced. The approved version of the interview guide was circulated to three research members of the Department of Medicines Optimisation at the school of pharmacy/Keele University to assess and review whether these questions allow potential participants to give full and coherent answers of what was required to meet research objectives. Minor adjustments were made in light of feedback received. No further amendments were made following this process, and all documents were considered a final version. This step applies to all other data collection documents used to conduct the study.

When stage one was completed, the researcher switched off the audio recorder and asked whether the HCP was comfortable to continue with stage two. For the majority of HCPs, stage one and two took place in the same interview. The interview began with a brief statement about what the second stage involves, and an overview of the topic guide and questionnaires. The HCP was informed about the duration of the interview and that it would be digitally recorded. Reconfirmation of consent to participate and consent for the use of quotes was obtained verbally at the end of the interview. The researcher used a personal laptop computer to present the DST and the associated PDA using vignette to demonstrate how it works and explore the different screens within the tool. The interviews generally lasted approximately 30 minutes, and this made the length of the whole interview approximately one hour in length.

In the second stage of the study audio-recorded, semi-structured interviews were conducted with the forty-seven HCPs from stage one. All interviews were conducted face-to-face at the HCPs' workplace. The interview topic guide for this stage (included as appendix

seven) was developed to meet the aim of the second stage of the study, which was to evaluate the potential utility of the DST in the anticoagulation decision-making process. The topic guide was formulated as HCPs' views of the potential utility of the DST in clinical practice; perceptions of the DST design features and functions; views of potential concerns associated with the DST implementation in clinical practice; and perceived barriers to implementation in clinical practice (this topic was used only with the sixteen HCPs who made the decision not to implement the DST into their routine practice).

The topic on HCPs' views of the potential utility of the DST included HCPs' perceptions of the potential of the DST to address the suboptimal determinants in anticoagulation decision making. It was intended to explore the impact of the DST on preparing patients for decision making and understand advantages of using the DST in clinical practice over their normal practice. HCPs were prompted to explain how the DST might support anticoagulation therapy prescribing practice. The topic on HCPs' perspectives on design features and functions intended to uncover specific interface design features that were important to improve users' acceptability and satisfaction of the DST. The topic guides included questions to explore how the DST might improve the level of patient involvement in the decision-making process. The topic on potential concerns associated with the implementation of the DST covered questions on what might hinder the implementation of the DST into routine clinical practice, whether these barriers related to the DST, HCPs, healthcare system or patients. Questions to explore possible recommendations for promoting more effective use were included. The topic on perceived barriers to implementation of the DST intended to investigate what were the barriers that might hinder the implementation of the DST, what barriers related to the DST, what barriers related to the healthcare system and what barriers related to HCPs.

Prompts and follow up questions were used as appropriate. All interviews were transcribed verbatim immediately after the interview. Repeated listening and reading of the first four transcripts enabled the researcher to become immersed in the data and identify an unexpected topic for exploration in further interviews.

As was discussed in sections 4.3.2 and 4.5.1, the researcher intended to collect measurable outcomes using self-administered questionnaires. The delivered questionnaires were printed clearly and professionally on the organisation's headed paper, included the name and address of research team and the participant's organisation, and were formatted so they were easy to read and comprehend. The front page of the questionnaires contained the project title, stage of the study, participant serial number, and included the label confidential. Instructions to participants were set clearly at the beginning, and the questionnaire content was given briefly in bullet points. A 'thank you' statement was given at the end of the front page and the end of the questionnaire. Questionnaires were similar for all HCPs. As was discussed in section 4.3.2.1, all measures selected for use were supported by a rational, and were adopted from existing measurement scales from published literature and have been carefully developed and tested for validity, reliability, questions format, wording, and order effects. Questionnaires were checked for completion at the end of the interview. The questionnaires are included as appendix nine.

In the third stage of the study audio-recorded, semi-structured third interviews were conducted with the thirty-one HCPs approximately eight weeks after the initial interviews. The interviews were conducted either face-to-face at the HCPs' workplace or over the phone as appropriate. The interviews generally lasted approximately 20 minutes. Phone interviews were conducted in the researcher's office in the school of pharmacy using the provided landline telephone. Face-to-face interviews were conducted in the HCPs' workplace. Interviews with HCPs whether face-to-face or over the phone began with a

brief statement about the interview purpose and an overview of the topic guide. HCPs were informed about the total duration of the interview and that it would be digitally recorded. Reconfirmation of consent to participate and use of quotes was obtained verbally at the beginning of the interview, and they were also re-assured about issues of confidentiality and anonymity during the research process, data analysis and reporting as described in section 4.7. Transcribing took place immediately after the interview.

As described in section 4.5.3, HCPs were encouraged to provide continuous feedback during the intervention period using personal emails. As discussed in section 4.2.1.1, email correspondence included written communication between the researcher and each HCP as a way of capturing HCPs' day-to-day experiences with implementing the DST in routine clinical practice.

The interview guide for this stage (included as appendix eight) was developed to meet the aim of the third stage of the study, which was to explore any changes in the HCPs' perspectives on utility of the DST in clinical practice, so that the findings could be compared with the previous findings of the study as indicated in section 4.5.1. As such, the topic guide was formulated as questions about HCPs feedback and experiences with implementing the DST into routine practice; detailed descriptions of the HCPs' experiences of the value the tool had for them and their patients. Questions to explore perceived and actual barriers and challenges to implementation were also included. Further details were sought to explore which of those barriers were related to patients, the healthcare system, or the HCPs. Interviews with HCPs who found it difficult to implement the DST in clinical practice were focused on questions related to perceived barriers that hindered the implementation. The interview topic guide included as appendix eight.

After each interview, the researcher reflected and made notes on how the interview had gone and important issues or themes that had emerged. These notes also included any relevant comments and suggestions made by interviewees after the audio recorder was switched off. The interviews were transcribed verbatim immediately after the interview (as described in section 4.6.1.1). Repeated listening and reading of the first four transcripts enabled the researcher to become immersed in the data, allow assessment of how well the topic guide worked, and identify an unexpected topic for exploration in further interviews. No technical problems occurred with the recorder.

As discussed in section 4.2.1.5, it is acknowledged that the identity of the researcher amongst other things is highly likely to affect the construction of the data (this is discussed further in section 9.2). Subsequently, the researcher introduced herself to HCPs as a researcher from the University rather than as a pharmacist.

In the fourth stage of the study audio-recorded, semi-structured interviews were conducted face-to-face with fourteen patients. Three of the fourteen interviews were conducted at the GP practice rather than at the patient's home, which was entirely the patient's choice. A room was used, that was the participating GP room where the consultation originally took place. This room was chosen because it was private (i.e. the interview would not be overheard or disturbed) and was the GP room that the patients were familiar with. The intention was to provide an environment that was as comfortable as could be achieved. Data collection for this stage began with a brief statement in the form of summary points about research aims and objectives and an overview of the topic guide and questionnaires. Patients were informed about the total duration of the interview and that it would be digitally recorded and advised that their participation was voluntary and that they had a right to accept or refuse to take part or to withdraw from the study. Moreover, patients were reminded that they could stop the interview at any time and were free to choose not to

answer any of the questions. Patients were asked to sign a consent form for participating in this study and consent for the use of quotes before the interview started. Reconfirmation of consent to participate and consent for the use of quotes was obtained verbally at the end of the interview. One copy was retained by the research participant, and one copy was retained for the research file. Patients were also assured about issues of confidentiality and anonymity during the research process and data analysis and reporting, as indicated in section 4.7.

As was discussed in section 4.3.1, the topics of interest that the researcher intended to cover in qualitative interviews were usually drafted into an interview topic guide before the interviews. The interview guide (included as appendix fifteen) was developed to meet the aim of this stage of the study, which was to explored patients' perspectives in-depth on the usefulness of DA for anticoagulation decision-making and decision quality so that these could be compared with the perspectives of the HCPs. The topic guide was formulated as perceptions of the impact of the DA to improve the decision-making process and decision quality; and barriers to using the DA in clinical practice. Prompts and follow up questions were used as appropriate.

The topic on their perspectives of the utility of the DA covered subsequent questions about the value of using the DA in clinical practice, whether they were satisfied with the decision-making process and decision made, how they were involved in the treatment decision and the impact this had on their decision. The topic on barriers to using the decision aid in clinical practice was mainly concerned with any concerns that patients might have and whether this was related to the DA's content or presentation.

As was discussed in sections 4.3.2.2 and 4.5.1, the researcher intended to collect measurable outcomes using self-administered questionnaires. The delivered questionnaires

were printed clearly and professionally on the organisation's headed paper, included the name and address of research team and the participant's organisation, and were formatted so they were easy to read and comprehend. The front page of the questionnaires contained the project title, stage of the study, participant serial number, and included the label confidential. Instructions to participants were set clearly at the beginning, and the questionnaire content was given briefly in bullet points. A 'thank you' statement was given at the end of the front page and the end of the questionnaire. As was discussed in section 4.3.2, all measures selected for use were supported by a rational, and were adopted from existing measurement scales from published literature and have been carefully developed and tested for validity, reliability, questions format, wording, and order effects. Questionnaires were checked for completion at the end of the interview. The questionnaires are included as appendix sixteen.

The interviews generally lasted approximately 45 minutes. After each interview, the researcher reflected and made notes on how the interview had gone and important issues or themes that had emerged. These notes also included any relevant comments and suggestions made by interviewees after the audio recorder was switched off. The interviews were transcribed verbatim immediately after the interview (as described in section 4.6.1.1). Repeated listening and reading of the first four transcripts enabled the researcher to; become immersed in the data, allow assessment of how well the topic guide worked, and identify an unexpected topic for exploration in further interviews. No technical problems occurred with the digital recorder during patients' interviews.

The patients' interview topic guide and questionnaires were reviewed before data collection commenced. The approved version of the interview guide was circulated to three research members of the Department of Medicines Optimisation at the school of pharmacy/Keele University to assess and review whether these questions allow potential

participants to give full and coherent answers of what was required to meet research objectives. No adjustments were made following this process, and all documents were considered a final version.

Following the fourth stage of the study, a letter was sent to the patient's HCPs to inform him/her about the patient's participation.

As discussed in section 4.2.1.5, it is acknowledged that the identity of the researcher amongst other things is highly likely to affect the construction of the data (this is discussed further in section 9.2). Subsequently, the researcher introduced herself to patients as a researcher from the University rather than as a pharmacist.

Before starting meeting patients in their homes, the researcher familiarised herself with Keele Lone Working Policy. Guidance and policy are available at Keele University web page https://www.keele.ac.uk/dohs/a2z/loneworking/.

4.6 Data analysis

4.6.1 Qualitative data analysis

Thematic framework analysis is an iterative, deductive process, which as discussed in section 4.2.1.2 allows the researcher to define categories at the start of the process and it enables inclusion of new themes that may emerge from the data and examine them using a process called constant comparison, in which each item is checked or compared with the rest of the data to establish analytical categories.

4.6.1.1 Data recording and transcription

The interviews were recorded with a digital recorder which could be listened to again to inform the data analysis process. Notes were taken during the interview as described in section 4.5.4. No technical difficulties were experienced.

The audio file was downloaded onto the university network onto password protected disk-space, and the file on the recorder was deleted. All interviews were transcribed by a transcribing company trusted to undertake regular work for the university. The audio files were sent to the transcribing company in an encrypted file (further detail is included as appendix seventeen).

The typed transcriptions were anonymised replacing any names with a number. The transcript was checked for accuracy by comparison with the recorded interview. The transcripts were stored safely on the university network, on a password encrypted laptop and the file names were also coded.

4.6.1.2 Thematic framework approach

The thematic framework analysis was used to classify, organise, and analyse data following the procedure described by Pope et al., (2000) and Ritchie and Lewis (2003).

The earliest step in data analysis in the framework approach was familiarisation with raw data by reading and re-reading the transcript to identify all the concepts and themes by which the data can be examined and compared. This step was carried out by drawing on prior concepts derived from the research aims and objectives of the study and by issues raised by research respondents that recur in the data.

At this stage, the researcher created a detailed index of the data. This step followed by applying the thematic framework to all the data in textual form by annotating the transcripts with numerical codes from the index. Then the researcher regrouped the data according to the appropriate part of the thematic framework to which they relate and forming charts. At this stage, the researcher ended with several charts for each theme with entries for several respondents supported by initial summaries of respondents' views.

Following production of the charts, the next stage in the analysis involved between-case comparison that aimed to identify the variety of experiences between respondents and explore whether typologies exist, looking for patterns within the data, common explanations or experiences between respondents (as discussed in section 4.2.1.2). For this study, typologies attempted to identify any group of HCPs who had similar experiences and attitudes of the anticoagulation decision-making process and to determine whether different typologies in each group of a profession than there were in others. To apply this concept to current data analysis, the data were grouped by different profession of participating HCPs and frequencies of different experiences were sought. Patterns within the data were then examined to identify any factors that might predict outcomes, such as the number of years of experiences in the field that may predict the way decision-making process. Once these factors had been examined, a within-case analysis was carried out to consider patterns within the data by investigating links between themes. For example, a within-case analysis may demonstrate that HCPs who have many years of experiences in their field also may find anticoagulation decision easy to make or tend to adopt a paternalistic mode of consultation with patients. Applying these techniques to data can give a structured approach to data extraction, grouping and analysis. The data and the analytical categories were discussed with the research supervisors.

As discussed in section 4.2.1.3, the decision was made to use manual analysis of qualitative findings throughout the entire project. Transcripts were printed, and the researcher highlighted passages of text using coloured highlighter pens that were examples of themes and cross-referencing these to similar passages from other transcripts to begin to develop a detailed index of the data. This step was followed by applying the thematic framework to all the data in textual form by annotating the transcripts with numerical codes from the index. Using an excel sheet, the researcher regrouped the data according to

the appropriate part of the thematic framework to which they relate and forming charts. At this stage, the researcher ended with several charts for each theme with entries for several respondents supported by initial summaries of respondents' views. Email feedback data was treated in a similar way to data obtained from face-to-face interviews. The email text was copied and pasted directly into a new file for analysis and thematic analysis of HCPs' responses was undertaken as described earlier.

In addition to the notes made after each interview, as described in section 4.5.4, the researcher kept a journal of reflections and thoughts about interpretations of the data, which included diagrams of possible relationships between emerging categories to guide or reflect the analysis. This was found to be a highly useful way of recording thoughts that could be referred to later when reflecting on new data or new ideas.

4.6.1.3 Presentation of results

The results from qualitative findings were presented using frequency of views by using general terms to indicate a dominance of views for each theme or concept (Ritchie and Lewis, 2003). This choice was made because the sampling strategy did not aim to identify a statistically representative sample and it may be misleading to express frequencies of responses as there is no indication as to how these numbers should be interpreted (Ritchie and Lewis, 2003).

4.6.2 Quantitative data processing and analysis

Questionnaires were anonymised replacing any names of people, or anything else potentially identifiable, with a research number. Questionnaires were checked for completion immediately during the interviews. The SPSS software program was downloaded on the university network and a password encrypted laptop, and the output documents from analysis were saved on password protected files.

In preparation for analysis, quantitative data was coded to reduce large quantities of information into a form that was more easily managed using software programs. Coding is a technique of conceptualising research data and classifying them into categories by assigning a number to given answers (as described in section 4.2.2.4).

For straightforward analyses, all descriptive statistics were computed using the Statistical Package for the Social Sciences (SPSS, version 24). Once the data have been coded, the descriptive statistic was used to describe the study sample via mean (M), standard deviation (SD), frequency (N), and percentage (%).

Descriptive statistics were sufficient to answer the current research questions. As discussed in section 4.2.2.4, quantitative research can be purely descriptive when it is used with the intent to measure attitudes, opinion, knowledge and behaviour. In this study, quantitative data was collected only at baseline, and the researcher did not collect quantitative data after the DST was implemented in clinical practice, so could not apply any tests of significance or correlation statistics.

4.7 Confidentiality

In the interests of all research participants' confidentiality, audio-recorded and completed consent forms, reply slips, and questionnaires were kept in a locked cupboard to which only the researcher and the supervisory team had access, and only the researcher knew the identity of the research participants. Similarly, electronic data containing personally identifiable information were stored only on password protected media that only the researcher had access to. Interviews were conducted in a private location if not in the patient's home (in the case of interviewing patients). Care has been taken to ensure that information has not been included in reports, publications or this thesis that might allow any patients, HCPs, GP practice or hospitals to be identified. All of the participants were

informed in the Participant Information Sheet that they read before giving their consent that these measures would be adhered to. These measures were adhered to because participants' confidentiality was considered to be a key priority throughout the study.

4.8 Chapter summary

This chapter describes the choice of mixed-methods approach to this study. A qualitative approach was chosen to providing the understanding by giving data that provides a deeper and multi-faceted insight into some aspects of the intervention, while quantitative methods were chosen to providing insight into other aspects of the intervention and explanation aimed at generalisation. Semi-structured interviews were used because this technique provides a detailed investigation of participants' accounts. The study drew on the broad principles of thematic framework approach as a practical approach to data analysis. Questionnaires were used because this method provides a numeric description of trends, attitudes, experiences, and views of a population by studying a sample of that population.

The overall aim of the study was to explore HCPs and patients' perspectives on the utility of the DST and associated PDA in anticoagulation management using a mixed-method approach. This involved a purposive sample of HCPs and patients who shared characteristics that were believed to be most informative in achieving the objectives of the study and were willing to participate in the study.

It has been argued that there is little agreement on how to achieve quality in mixed method research beyond the requirement that it should take a systematic, reflective and transparent approach to research design, methods of data collection, analysis, and interpretation of the data. A reflexive approach to this was taken, which is why the detailed discussion has been provided about the aims of the study, how participants were selected and recruited, how interviews were conducted and how data was recorded and analysed. Analysis of research

findings is now presented in the following four chapters, beginning with the initial stage interview data on HCPs' perspectives on suboptimal determinants in anticoagulation decision making.

Chapter 5: Healthcare professionals' perspectives on the barriers in anticoagulant prescribing decision: Analysis of initial interviews

The aim of the initial stage of the study (as discussed in section 4.5.1) was to conduct semi-structured qualitative interviews with a purposive sample of HCPs who are involved in anticoagulation management in AF to explore their perspectives on the suboptimal determinants in the anticoagulation decision-making process. For the purpose of this study, as discussed in section 4.5.1, forty-seven HCPs were recruited into the study. The aim of this chapter is to discuss the analysis of the data from the initial stage interviews that concerns HCP's perspectives on the barriers in the anticoagulant prescribing decision.

Demographic information about the HCPs is included in section 5.1. HCPs' pathway for anticoagulation therapy decision-making process is discussed in section 5.2, section 5.3 concerns their interpretation of factors that motivate patients to accept anticoagulation therapy and section 5.4 discusses their interpretation of factors that cause patients to refuse anticoagulation therapy. HCPs' perspectives on barriers to delivering optimal anticoagulation therapy decision-making are discussed in section 5.5, and section 5.6 presents strategies to optimise anticoagulants prescribing decision. The main findings from the initial interview stage of the study are discussed in section 5.7.

5.1 Healthcare professional demographics

Demographic information about the HCPs is summarised in table 5.1.

Table 5. 1: Demographic characteristics of HCPs

Characteristics	**N (%)**
Gender N=47	
Male	30 (63.8)
Female	17 (36.2)
Age group (mean= 46.13, SD= 9.37)	
≤39 Yrs.	12 (25.5)
40-46 Yrs.	12 (25.5)
47-54 Yrs.	12 (25.5)
≥55 Yrs.	11 (23.4)
Healthcare HCP N=47	
Consultants and registrars, of which:	28 (59.6)
Cardiology consultants and registrars	7 (14.9)
Stroke consultants	9 (19.1)
Acute medicine consultants and registrars	8 (17)
Haematology consultants and registrars	4 (8.5)
General practitioners	8 (17)
Non-medical independent prescribers	11 (23.4)
Nurses	5 (10.6)
Independent prescribing (IP) pharmacists	6 (12.8)
Experiences in their field (mean=9.43, SD=7.9)	
≤3 Yrs.	12 (25.5)
4-7 Yrs.	12 (25.5)
8-14 Yrs.	12 (25.5)
≥15 Yrs.	11 (23.4)

Forty-seven HCPs participated in this stage of the project. The sample was diverse in terms of participants' age, profession, speciality background, and experiences in the field. A descriptive analysis of the sample revealed that of the 47 HCPs, 30 (63.8%) were male and 17 (36.2%) were female. The sample had a mean age of 46.13 years (SD= 9.37), where about half of the sample (51%) were in the age range between 40 and 54 years. More than half of the sample constituted of hospital-based consultants and registrars (N=28, 59.6 %), GPs represent 17% (N=8) of the sample, and non-medical independent prescribers (specialist nurses and pharmacists) represent only 23.4% of the sample (N=11). On average, research participants had 9.43 (SD= 7.9) years of experiences in their field of speciality. Approximately half of the sample (N=24, 51%) have been specialised in the field between 4-14 years, 12 (25.5%) had three years or less of experiences in the field, and only 11 (23.4%) had more than 15 years of experiences in their field.

5.2 Healthcare professionals' pathway for anticoagulation therapy decision-making

This section focuses on exploring the decision-making process about anticoagulants for preventing AF-related stroke. Interview findings revealed that the majority of HCPs tended to break the consultation into two parts with a different focus.

Initially, HCPs tended to adopt a patient-focused education style aspiring to increase patients' knowledge and awareness of AF and AF-related stroke risks to improve patient's adherence to treatment. Each HCP placed a different emphasis on the amount and type of information given to patients and used a variety of communication aids.

During the second part of the consultation, HCPs focused on prescribing decision making using various communication styles with the emphasis on increasing patients' compliance to treatment. These two different emphases- patient-focused education and the decision of which agent to prescribe - were the main themes that structure this overarching theme.

5.2.1 Patient-focused education and information needs

This theme focused on exploring the various amount and type of information used to increase patients' knowledge and awareness about AF and anticoagulation therapy. All interviewed HCPs strongly believed that the key to ensuring optimal anticoagulation management was getting the patient to understand AF and AF-related stroke risks. HCPs from different speciality had different views as to the various type of information that they believed patients should know about. For example, cardiologists were very comprehensive in providing information about AF including a comprehensive assessment of patients' stroke risk and bleeding risk compared to HCPs from other specialities. Cardiologists tended to start the consultation with explaining the pathology of AF and its effect on heart normal rhythm, detailing the mechanism of clot formation, and then discussing both stroke and bleeding risks. Compared to cardiologists, HCPs from other specialities usually started the consultation with explaining the pathology of AF and they usually only consider stroke risk assessment using the CHA_2DS_2-VASc score in their own decision about anticoagulant therapy.

Overall, all HCPs believed that patient education and understanding were the important determinant to patient compliance and adherence to treatment recommendations. In addition to using simple terms and everyday language, some HCPs used additional communication aids in supporting communication of information; which ranged from providing written material and leaflets and using diagrams and graphs. All interviewed HCPs revealed that they tended to reassure patients about the perceived benefits of anticoagulation therapy.

Amongst the interviewed HCPs, few of them supported the idea that prior to presenting at the clinic, patients should be given materials to inform them about AF and explain the

associated stroke risk and provide information about all available treatment options, so that they can ask more pertinent questions. While others preferred that patients came to the consultation knowing nothing, so that, they can convince patients to comply with the treatment.

The followings are samples from different speciality consultants showing the flow of the consultation using the different type of information and communication aids.

For example, a cardiologist pointed the importance to start the consultation with patient education about AF and AF-related stroke risks in preparation to discuss anticoagulant treatment.

"Well, first of all they have to understand the pathology of the condition and why there is concern that they may need anticoagulation, and I think they need to just make a decision as to whether they are willing or not to accept to go on anticoagulant treatment having understood that there is some risk, increased risk of bleeding" Cardiologist 16

Another cardiologist presented the information in a graphic-based format and by using everyday language, to explain in detail what AF meant and the mechanism of having a stroke. After that, he then discussed in detail the risk of bleedings to decide whether the benefits of anticoagulation were better than the risks of being anticoagulated.

"Normally first explain why does atrial fibrillation give you a higher risk of thrombosis formation in the left atrium or the facial appendage and draw a picture usually to show them what the problem is and explain that this then connects the systemic circulation which means it would be a potential risk and I'll explain that the risk is affected by a number of factors and so depending on what those factors are we have to decide whether the benefits of anticoagulation are better than the risks of being anticoagulated and I

explain the risk of bleeding and that's probably one of the most important things that patients want to avoid…."Cardiologist 20

On the other hand, however, stroke consultants indicated that they usually only consider stroke risk assessment, and stressed the importance of increasing patients' awareness to stroke risks and its subsequent impact on patients' lives. Also, they spoke about patient reassurance through talking about the importance of anticoagulation therapy in reducing stroke risks associated with AF.

"*So they need to understand the risk of having a stroke, or what we're talking about, ischemic stroke, and I suppose the impact on quality of life, or the disability that comes with that, and the importance of prevention, and to counsel people about the importance of anticoagulation." Stroke consultant 11*

The following example relates to another stroke consultant who only considered stroke risk assessment using the latest scoring tool (CHA_2DS_2-VASC) and with particular emphasis on presenting and explaining individualised annual stroke risk percentages, and then he reassured his patients by quoting evidence from current national and international guidelines on the benefit from anticoagulants.

"I usually use the CHA_2DS_2-VASC score, which I calculate in front of the patients, show them and tell them this is their annual risk of stroke, and help them guide through the process along with explaining to them the current, NICE [National Institute for Health and Care Excellence] guidelines along with the European guidelines, on when to recommend – when anticoagulation is recommended." Stroke consultant 19

Moreover, a specialist nurse did not even use CHA_2DS_2-VASc and was focused on presenting the information to patients in diagram-based and graphic formats to explain how

the clot is formed and travelled in preparation to convince her patients for the need to start anticoagulation therapy.

"… I also use diagrams. So I've got diagrams of clots travelling to the head or how the clot mechanism works in the system ……so I use that as an aid for them to decide what they want." nurse 24

Like the nurse specialist, a haematology consultant revealed that during consultation he tended to focus on increasing patient knowledge and awareness of AF by using information that is simple to understand and presented in different format. Indeed, he regarded verbal communication is a commonly accepted communication method, but the use of various communication aids, for example, written leaflet or video have added value to the consultation. Moreover, he considered delivering effective education to patients necessary because this would give patients kind of reassurance and convince patients to comply with the treatment.

"I think it should be kind of, in a simple written format, and information given to them, that this is what atrial fibrillation means, what does it do to the heart in terms, of clot formation, but they need to understand it in simple terms, and it should be given to them in written format and maybe in audio format or video or whatever and that they also understand what the blood thinning medicine can do and to what extent it can prevent and if the benefits better than the risks. You need information and evidence and a resource for that to help them…, so we can try to convince [patients] that this is going to be definitely prevented by 30% or 40%, I think that will convince him." Haematology consultant 1

General practitioners (GPs) tended to break the consultation into more than one appointment. During the first appointment, they tended to provide clear and simple information to explain AF and introduce anticoagulation therapy. This was supported by

providing written material to go through at home. GPs acknowledged that this had helped patients to absorb better the information delivered during the first appointment, hence, encourage patients to be better involved in the discussion about treatment choice, ask more prominent questions, and look up for further information.

"I usually break up the consultation into more than one appointment, because the first consultation I usually spend explaining what AF is. So they have an understanding of what it is. And then I explain that there are different management options, and then I will give them some information on things like anticoagulation, and then ask them to come back and make another appointment to then take it further…" GP 15

Many HCPs agreed that the key to successful patient education was to provide patients with clear and right information that is essential to improve patient compliance.

"…. So, I think it's really important that everything is explained to them about why they're taking it because if they don't realise the importance of taking it, they're not going to be compliant with it." nurse 13

Furthermore, a stroke consultant seemed to have assumed that giving patients the right fact and information using verbal communication was enough for the patient to understand what they need to know about AF and associated risks.

"I mean you just have to give the facts…and giving the right sort of information and right sort of facts and then they will grasp it." Stroke consultant, 12

Analysis of the interviews found that there were similarities in what HCPs thought about the amount of information they give to patients during consultation. They tended to provide information that is likely to be tailored to the patient's age and education level. For instance, a stroke consultant pointed out that older patient's demand less information

compared to younger patients who need more information to weigh up the evidence and then come to a sensible decision.

"Again it is quite variable, from my experience there would be a group of patients who will tell us 'You know best, and I'm happy to follow whatever you suggest.' The others especially in the relatively younger age group would want to weigh the risk and benefits of the evidence, and then come to a sensible conclusion at the end of the day." Stroke consultant 19

Other HCPs indicated that patient education level and awareness would facilitate the discussion.

"If the patients know, for example, what their risk is and if they know that atrial fibrillation is a risk of a stroke…So makes it possibly easier to go through the whole consultation about the oral anticoagulation." Senior cardiology registrar 22

Comparably, a haematology registrar regarded patients who came prepared with sufficient knowledge, may ask more pertinent questions compared to patients who have not.

"*I think it depends completely on the patient. Certainly, the patients who have read up around the subject may ask more pertinent questions compared to the patients who haven't." Haematology registrar 42*

A cardiology registrar, however, expressed opposite views in this regard. Although he valued patients who came prepared about the disease and its stroke related risk, but he preferred patients who came blank as a clean slate and knew nothing about the condition.

"If the patient had a bit of positive information about the condition … then it's easy. Also, I prefer patients who don't know anything about their condition because then it's a clean

slate and you just tell them everything from the start, and they understand…" Senior cardiology registrar 23

5.2.2 Anticoagulants prescribing decision-making process

This theme represents the second phase of the consultation with a clear shift in paradigm. During this stage, all HCPs focus was shifted from patient education about AF and AF-related stroke risks into discussing management options and deciding on the choice of anticoagulants aspiring for patient compliance and adherence.

HCP-patient interaction during this stage of consultation was broadly described as; providing patients with information about available therapeutic options, explaining risks and benefits associated with each option, and asking for patients' opinion on possible treatment choice, should they wish so. Overall, the majority of HCPs indicated that paternalism could be unavoidable. For instance, not every patient wanted to participate in decision making; however, not every HCP aspired to involve patients in the treatment decision, due to characteristics of patients; which basically reflect socio-demographic variables, linked to patient age, education level, language, and health status in terms of capacity and capability. Most HCPs mentioned patient health care need, whether the patient is well enough to have a clinic-based consultation or to be ill and hospitalised. On the other hand, all HCPs appeared to have assumed that the patient-HCPs relationship is characterised by trust, and patients prefer to delegate the authority to HCPs to make treatment decision on their behalf. Local practice/hospital protocol was another factor that would impact the treatment choice decision as told by few respondents.

5.2.2.1 Paternalistic model

Analysis of the interviews found that almost all HCPs tended to present the patient with selected or minimum information about treatment options that encourage the patient to comply with the treatment choice the HCP considered best. In that, they seemed to have assumed that there were shared elements for determining what is in the patients' best interest, yet limited patient participation.

For instance, when HCPs felt, they were under time pressure the paternalistic model seemed to be the default, as illustrated by the cardiology registrar:

"There is a minor involvement of the patient which is mainly asking them how many tablets they want to take mainly…It's difficult because we're talking about a decision that needs to be taken in ten minutes…It's mainly based on my decision and what I will explain to the patient…to be honest, we're not encouraging patients about the decision of the anticoagulant..." Senior cardiology registrar 22

There were similarities in opinions among all HCPs that in ward settings and other particular clinical environments where discussion of treatment decision with patients seemed to be difficult, the paternalistic model guided communication and decision making, as indicated below:

"Well, thinking about it purely from a secondary care perspective …So the patients are unwell, they're in hospital … There are a whole group of people standing around you are telling you, 'This is what you need to do. This is what we're going to do to you.' …It is not a good environment to make decisions like that …" IP pharmacist 27

The following acute medicine consultant provided examples of how clinical environment would impact on communication and decision-making approach.

"It depends on whether I'm on the acute medical unit or on the ambulatory emergency care unit. On the AMU, we tend to have a bit more time because they're inpatients…AEC [ambulatory emergency care], because it's a bit quicker and more turnovers, we often go quickly through things with the patient…" AM consultant 37

The following GP was aware of the extent to which her role was paternalist, and she expressed trust in her knowledge and experiences derived from education in matters of medicine.

"*…They will have a discussion… and, you know, it's my opinion. I guess that's a bit of an arrogant thing to say but, you know, the reason I'm here is because I'm educated in matters of medicine…I think I'm giving patients the best possible advice..." GP 4*

However, another GP in direct contrast to the paternalist approach, she insisted on involving her patients and sharing the treatment decision with them. She understood that if she wanted to enable her patients to be involved, she had to use simple information and flexible methods.

"*I always involve patients in every decision– that is made. It's not down to me. It's down to the patient. So, it has to be kept really, really simple … very basic, and then try and help them come to their own decision through that." GP 15*

Almost half of respondents revealed that patients tended to feel overwhelmed by the information given and found it uncomfortable to the onus to be put on them, to make a decision. In HCPs understanding, this counts as unavoidable paternalistic.

"I think the majority of patients in my experience would prefer the doctor to make the decision yes. I think some find it difficult to weigh up all the information or even understand it, and some patients find it uncomfortable to the onus to be put on them, to make a decision in the first place, they think that's the doctor's job." AM consultant 10

Similarly, a stroke consultant reinforced the previous point made by the AM consultant, in that, some patients might experience uncomfortable feeling from being involved in treatment decision making.

"Again, that kind of consultation depends on patient preference, and there are still a lot of people who would be overwhelmed by that and feel unwilling in a way, or not confident enough to make decisions for themselves…so some people prefer the paternalistic approach of the doctor …even if they have the capacity to make the decision but just choose not to..." Stroke consultant 11

In this context, all HCPs revealed that elderly patients often expressed trust in their healthcare provider to do the best for them, and preferred to delegate the treatment decision making authority to their healthcare provider, the example from cardiology registrar:

"…very elderly populations, usually in the 70s or 80s, and usually they trust the doctors, and they would prefer us to make the decision that would be in their best interest. So if that's what the patient wants." Senior cardiology registrar 30

Majority of HCPs revealed that due to factors related to an availability of formulary or due to general trend within the practice to prescribe one agent over the other, they tended to present patients with a selected or minimum amount of information about treatment options, as illustrated below:

"…The choice of the direct oral anticoagulant is often bound by the hospital, and so they don't have everything [all available options] formulary. You can't offer them everything…" Haematology registrar 42

"Yes, there is a trend because it goes by our formulary; More or less we follow the drug formulary." GP 46

Nevertheless, few HCPs referred to adopting shared decision-making approach to decide on the treatment choice. For instance, the following specialist nurse expressed her understanding of sharing the treatment decision and indicated that she tended to involve all parties in all stages of the treatment decision-making process; from consultant to patients, down to family and carers.

"to me, means having everybody involved in the process from the consultant down to [the] patient, down to family and carers..." nurse 13

This specialist nurse alternatively intended to use the phrase, joint decision, to refer to HCP-patient interaction to elucidate patient's values and to help the patient select the treatment choice that realises these values.

"...My role in making the decision is to provide the patient with as much information on their options as I can. So, as I've said, I talk to them at great length about what Warfarin is and how it's managed. I talk to them about NOACs, what they are and how they are managed and try to make a joint decision with the patient..." nurse 13

The following stroke consultant described in fine details his approach to deciding on the treatment choice with his patients. Where he and the patient reveal treatment preferences and both agree on the treatment choice, as indicated below:

"I say, from the guidelines, 'We've got blood thinning agents. We've got Warfarin. We've got other newer agents' and ask what they want. Do they want something that needs monitoring, something that doesn't need monitoring, whether they want once a day or whether they want twice a day? I tell them about the adverse effects, and then we all decide and sit and make a decision." Stroke consultant 12

5.2.2.2 Healthcare professionals' perceptions of anticoagulation prescribing decision

While all HCPs could cite cases where the decision of whether or not to anticoagulate was not difficult for them to make, all of the HCPs mentioned instances as being difficult when it came to deciding which specific agent to choose. The quotes used, represent a wide range of opinion about how difficult the prescribing decision was in real-world practice. Respondents used different phrases to describe their personal experiences. For example, cardiology and stroke specialist HCPs who had many years of experiences in the field and come across the decision many times thought the decision not difficult at all.

"Personally I am very knowledgeable of the field. I think I'm okay." Cardiologist 16

"I don't find it difficult at all." Stroke consultant 40

A cardiology specialist contrasted the view from other cardiology colleagues by saying: it is a not difficult decision for him, but he declared that the process included could be difficult because it is time-consuming.

"…I mean it's not a difficult decision, but you have to gather all the information – all the available information [evidence] about the patient and then, think about it and then make a decision and then communicate and discuss it. So the process takes time." Cardiology specialist 18

On the other hand, all HCPs from acute medicine and haematology specialities consistently reported that the prescribing decision and communicating the treatment decision to patients were difficult for them, as expressed below:

"It is a difficult area …so these decisions are not easy to make for doctor or patient." AM consultant 10

The following haematologist acknowledged that the decision was difficult because it should be individualised for each patient.

"I think generally it's not that difficult because the physician will understand the benefits and risks, but the decisions are individualised, so if you think this patient yes, [he]'ll benefit from this [the other patient will not]…" Haematology consultant 1

"It's quite complex but the more you do it, the easier it becomes…" AM consultant 37

Although stroke consultants revealed that the decision is easy for them to make, few reported that the decision could be challenging, specifically, when they are presented with frail patients and have got a high risk of bleeding, as reflected below:

"I've never felt that it is difficult to make a decision. Sometimes it can be challenging, especially people with a bleeding risk and frail patients…" Stroke consultant 34

5.3 Patient motivation to accept anticoagulation decision

When interviewees were asked, "what motivated your patients to accept the decision for anticoagulation therapy?" The responses simply revealed the potential impact of increasing patients' awareness and knowledge on patients' attitudes about anticoagulation therapy. HCPs emphasised the link between patient awareness about their risk of having a stroke and willingness to accept the decision to start anticoagulation therapy.

"*Their understanding that this drug is going to reduce their risk of getting a stroke. That is definitely the most motivating factor, I think. They feel that they will be safer with this drug than without." Stroke consultant 43*

Compared to most HCPs who tended to use knowledge and information to help patients in the decision-making process around anticoagulation therapy, few HCPs who see patients in ward-setting tended to use real-world examples of patients with devastating stroke, in order

to convince patients to accept anticoagulation therapy, as indicated by a stroke consultant who used a GP practice as an example of why GPs occasionally meets with resistance.

"I say, 'You are sitting here, and I don't want you to come to this [site] like this, so that's why I'm giving you the tablet, to prevent a stroke.' So they understand when I talk from my side and what I'm seeing. When the GPs talk from their side, sometimes it may not be very convincing..." Stroke consultant 34

5.4 Patient's refusal to accept anticoagulant therapy

Healthcare professionals revealed several explanations for patient's tendency to refuse treatment. Refusal of anticoagulation was mainly attributed to three interrelated factors; (1) patient-related factors, (2) treatment-related factors, and (3) condition-related factors.

5.4.1 Patient-related factors

The first factor the interviewed HCPs revealed was patient-related, such as; patients' health literacy, education, perceptions of AF-related risk of stroke, understanding of medical facts and risk percentages, and expectations of perceived benefits of anticoagulant.

All healthcare professionals were consistent in the descriptions of patients' attitudes presented to them. For example, acute medicine consultant spoke about patients' inability to quantify the risk and benefits from anticoagulants therapy because they can't comprehend enough, and they can't digest the amount of information given in the short space of time during clinical encounters.

"I don't think it's easy for them, ...I think if I just summarise, I would say their inability to quantify the risk and benefit because I don't think they can; one, they can't comprehend enough, two, I don't think the information that you give them in that short space of time is enough for them to actually make decision..." AM consultant 31

Again, a haematologist mentioned patient education and understanding levels were relating to difficulties during the consultation and specifically when it came to deciding on which agent to prescribe.

"*So I think it's difficult for them to sometimes weigh up that judgment themselves, especially if they may not have the understanding…" Haematology registrar 42*

An acute medicine consultant revealed that patients' involvement in the treatment decision was seen rather difficult. The availability of many options each with different advantages and disadvantages were found to contribute to patients' confusion.

"I think sometimes it's a matter of too many choices, too many things to consider…when faced with a multitude of advantages and disadvantages they find it difficult to weigh up…they seem confused by the fact of having to make a choice in the first place. Some people get confused by the more information you give them …" AM consultant 10

Furthermore, most HCPs talked about two scenarios; young and old patients with different reasons for refusing that appeared to be attributed to poor perceptions of AF-related stroke risk and expectations of perceived benefits from anticoagulants, an example from stroke consultant:

"*There are two types of patients. One is very young patients; they're not on any tablets and have just found out to be in AF. Convincing them that they're going to have a stroke and need a tablet can sometimes be difficult because they don't want to take any tablets. Some patients say, 'I don't want any tablets; I don't have any problem.' So to convince them can sometimes be challenging. At the other end of the spectrum are very old and frail patients in their nineties. They say, 'I've had a good life; I don't want any more tablets; I'm fine.' So to convince them is at the two ends and can be difficult sometimes". Stroke consultant 34*

HCPs provided examples from their experiences of how patients' health literacy and understanding of medical facts and risks percentages might have an impact on patients' decisions to accept anticoagulants, as stated below:

"The second is patients who feel that, 'I'm fine. You will say all these things to me but an annual risk of 1.9% or 2.4% for instance. 'I don't feel it's a palpable risk…'" Haematology consultant 44

"…with some patients, it's very difficult to get them to understand the risks of atrial fibrillation and actually, what a stroke is and how severe an AF related stroke is. So I think it's patient education…" nurse 13

Among interviewed HCPs, a GP tended to refer to anticoagulation therapy as preventive therapy, and in this case, he found it was difficult for patients to understand the probability associated with risk-benefit ratio; hence, patients decided not to take a tablet for life to prevent things that might happen but might not happen.

"…I think preventative medicine, in general, is quite tricky for patients that they are doing something just in case something happens that might not happen anyway, it's hard to make that balance of probability is difficult for patients to understand, I think." GP 17

Unnecessary fear from bleeding with anticoagulant was another reason for refusing, that is merely linked to patients' poor expectations of perceived benefits from anticoagulants, as told by most HCPs. Examples provided:

"Well, some people are still doubtful about the bleeding risk, they're not sure …" Stroke consultant 14

"Well if they're very scared about bleeds some patients have concern about road traffic accidents and injuries relating to that would cause haemorrhage and their ability to

survive that and again you just say well, the statistics include people having road accidents and they still say you're better off on anticoagulants, so that's taken into account in making the decision." Cardiologist 20

5.4.2 Treatment-related factors

Treatment-related factors were perceived to influence patients' decision to accept or refuse treatment. Mainly was justified by the fact that some patients just didn't like to take any tablets at all, or take a tablet for life, as illustrated below:

"Whether they like to take tablets at all, some don't like to take tablets whatever they are…" Stroke consultant 8

"…It's just the idea of taking long-term medication. [it] is difficult for some people..." Stroke consultant 11

5.4.3 Disease-related factors

Healthcare professionals reported that lack of symptoms (for example asymptomatic AF) and severity of symptoms (for example, having a minor stroke or having a TIA that completely resolved) contributed to patients' denial of their condition and an underestimation of their perceived stroke-related risks and benefits gained from treatment.

"I think it's just...a bit of denial within themselves because you will have patients who have had either a minor stroke or a TIA and they're completely resolved. They do not want to go on anticoagulation for the rest of their life. Those patients do get into a bit of a denial…" Stroke consultant 38

In this regards, the majority of HCPs indicated that treating asymptomatic patients to prevent the possible occurrence of stroke years later presented an even greater challenge for them, as reflected below:

"…especially if they've been asymptomatic, sometimes it can be a bit harder to make them accept it [anticoagulation therapy]." AM consultant 37

5.5 Barriers to optimal anticoagulation therapy decision making

This section outlines the key barriers to delivering an optimal prescribing decision in clinical practice. Healthcare professionals revealed several determinants in the decision-making process suboptimal. They were related to; communication of the decision to patients, and optimal use of anticoagulants.

5.5.1 The experienced barriers to effective communication and patient education

The findings from the initial stage of the study suggested similarities between HCPs' perspectives on barriers pertaining to effective communication and patient education. Specifically, patient's lack of interest and other nonclinical characteristics were factors influencing the communication of information during a consultation. More commonly, barriers relating to healthcare system were identified: lack of time; and lack of patient-specific education resources.

5.5.1.1 Barriers pertaining to the patient

Patient-related factors such as patient interest and patient nonclinical characteristics were consistently identified to influencing patients' seeking and exchanging of information.

A stroke consultant started the consultation by assessing; individual patients' desire to receiving information, patients' understanding, and patients' education level in preparation for discussion and treatment decision making.

"You kind of get the hint when you speak to somebody at the beginning of the [consultation] what sort of a patient they are, their understanding, their level of education

so you kind of guess about their need to know more, [and] how much they need to know more." Stroke consultant 14

Lack of interest

All HCPs consistently reported that they found many of their patients preferred to leave final treatment decisions up to them and not to receive information about their condition and treatment options.

"From [my] experience there would be a group of patients who will tell us 'You know best, and, I'm happy to follow whatever you suggest'…" Stroke consultant 19

The following stroke consultant referred to patients ambitions as an indication of patients' desire for information seeking or information receptive.

"That is patients' literacy and patients' knowledge about things and ambitions. They don't want to know many things. So, it's mainly the patient factor that is the main factor." Stroke consultant 34

Among HCPs, a haematology consultant spoke about patients' unwillingness to receive information and being involved in the final treatment decision.

"Unwillingness from the patient to have information and make an informed decision; we've got many patients who will say that you decide and [just] do it…." Haematology consultant 1

Patient nonclinical characteristics

Patient low education level, lack of understanding about AF and AF-related stroke risks, old age, and language barrier have been identified consistently as the suboptimal determinants in the decision-making process.

"Patient education, the language barrier, you simply cannot communicate, it can be age because older patients find it more difficult to engage sometimes with decisions…" AM consultant 10

For other HCPs, it was more about lack of awareness and lack of understanding of their condition and what is happening to them.

"…So sometimes, for whatever reason, it can just be so difficult to get a patient to understand what's happening to them." nurse 13

A haematology consultant believed that the inability of patients to understand and handle information was linked to the use of scientific language, statistic expressions, and medical jargon.

"*I think it's mostly lack of understanding, and it's hard because it's scientific if you use scientific terms and talk about you know, statistical things with them, so I think it's difficult for them to understand that, so I think [the] difficulty in understanding medical jargon…" Haematology consultant 1*

5.5.1.2 Barriers pertaining to the healthcare system

Across both healthcare settings, time was one of the most deficient resources in hospitals and GP practices. Most HCPs spoke about lack of education resources and lack of patient specific tools. A lack of suitable environment in hospitals particularly during ward clinical rounds resulted in the poor doctor-patient communication of the treatment decision.

Time

The findings from the initial stage of the study revealed that the length of consultations varied widely between practices and clinics. Compared to hospital-based doctors, GPs consultation lengths were typically last for 10 minutes, and they made an effort to keep to

time, so they tended to break the consultation into more than one appointment. The first consultation required to explain the condition, management options, and give patients written material about anticoagulants to read and then come back for another appointment to take it further.

"I usually break up the consultation into more than one appointment, because the first consultation I usually spend explaining what AF is. So they have an understanding of what it is. And then I explain that there are different management options, and then I will give them some information on things like anticoagulation, and then ask them to make – and then ask them to come back and make another appointment to then take it further, because there's not enough time to do it in one appointment. It's impossible [for] a 10-minute appointment." GP 4

On the other hand, hospital-based doctors worked with 15 to 20 minutes appointments which were perceived to be too short for them to provide a high quality of care for patients. They all acknowledged that dealing with AF and the discussion around anticoagulant management typically required longer time. They revealed that they usually tended to refer patients to the anticoagulation clinic because nurses have a longer time to spend with patients.

"As I say, time is the most important thing. We don't have, generally, more than 15-20 minutes…so to help with that, we have always referred those patients to the Anticoagulation Clinic which we have got. They will go back with the patient and make sure that they have understood everything…" Stroke consultant 40

All HCP spoke about the effect of consultation time on the content of the discussion during decision making. HCPs generally did experience time to be a limiting factor in providing effective consultation for patients. The majority of HCPs reasoned that if more time were

available to them, they would explain everything to patients in a way that patients understand. As illustrated in the examples below:

"Most important thing is time. If you have enough time to spend with the patient you can explain all these things to them in a means – in a way that they understand and improve their involvement as well and make it easier for both yourself to make the decision in consensus." senior cardiology registrar 30

"It's difficult because we're talking about a decision that needs to be taken in ten minutes…It's mainly based on my decision and what I will explain to the patient." Senior cardiology registrar 22

Nevertheless, all of the specialist nurses who were interviewed tended to be quite relaxed about consultation time, and did not regard time as a barrier to providing counselling for their patients, and were confident in their ability to provide individualised counselling and support for their patients. A nurse stated:

"…I spend about between 20 and 30 minutes with each of my patients. I feel like I've given them enough information about the risks and I feel like I've given them enough information about the medication …" nurse 13

Clinical environment

All hospital-based HCPs explicitly referred to the clinical setting, specifically, inpatient setting, as constituting to the problem. Given time as a scarce resource in the in-patient settings, all HCPs believed that the inpatient environment was an inappropriate clinical setting to provide counselling and support for patients, due to; lack of time during clinician ward rounds and the clinical environment.

"I think generally speaking for an inpatient ward, the fact that we have so little time with our patients on the ward...and we have to make all these complex decisions in a short period of time, often in an environment or setting that doesn't lend itself to provide this information..." IP pharmacist 36

Acute medicine consultants who worked in two departments- an ambulatory emergency care unit and an acute medical unit provided a comparison of the clinical environment for both settings. They revealed that the nature of communication and patient counselling provided in the ambulatory emergency care unit was limited to informing patients about the treatment choice because it is characterised by a quick turn-over. While in the acute medical unit, doctors tended to have more time compared to the previous setting to focus on patient education and communication of the prescribing decision, as illustrated below.

"It depends on whether I'm on the acute medical unit, or on the AEC [ambulatory emergency care]. On the AMU [acute medical unit], we tend to have a bit more time because they're inpatients. So often we'll ask either the pharmacists or a member of the anticoagulation team to actually talk to the patient...[The] AEC [ambulatory emergency care], because it's a bit quicker and more turnover, we often go quickly through things with the patient…" AM consultant 37

<u>Lack of patient specific education resources</u>

Furthermore, it seemed that all HCPs from both healthcare settings used standard drug information leaflet produced by drug companies and printed material in addition to verbal communication. And that there was a lack of patient specific educational resources. As illustrated in the example below:

"…The majority of the interaction is a verbal discussion, supported by – I suppose we do have documentations, leaflets produced by the companies that produce the anticoagulant

agents, I suppose as well as the standard anticoagulation booklets and information sheets…" Stroke consultant 11

There seemed to be similarities between HCPs perceptions of the usefulness gained from using information leaflet with patients. They talked about its usefulness in improving patients' understanding of their condition, and to prompt patients to ask questions at the follow-up visit.

"*I think leaflets are very useful for the patients…" Stroke consultant 34*

"…. so the resources, allowing them to ask questions, you know, at the next visit cause they might see something in there that they want to ask more about really." GP 7

All HCPs assumed that the success of patient information leaflet is dependent on whether or not the patient is interested to read it and the ability of the patient to understand it. A GP said that patients would not read given material if it is too long and wordy.

"*A lot of people you give information they won't read it. They'll say, 'Thank you' but, you know, they'll look at three pages of A4, and they'll go, It looks a lot of writing and reading…." GP 4*

Of increasing importance to HCPs is patient understanding of the material. An example was given by a haematology registrar of patients who had been given an information leaflet, read it but then get completely the wrong message out of it.

"I think it depends on whether the patient has understood it. They might have read up on it but then got the completely wrong end of the stick, so it's actually a much more difficult conversation because they've read up on it and not taken the right points out of it that you wanted them to." Haematology registrar 42

A GP suggested that limited patient' capacity either from language or through intellect might limit the use of information leaflets. As indicated below:

"So I don't – the difficulty that we have in this practice is that …our patients don't have the capacity, either from language or through intellect, they can't always understand all this information. So they have to rely on us to give that verbal." GP 15

Another GP emphasised that all current resources used to support their patients are standard, lengthy, wordy, and could be confusing to patients, she mentioned the paper version of the NICE patient decision aid as an example.

"Well, I used to use the NICE decision-making as they've got a lot longer recently…..so if you print it out its 30 pages or something and all the ones that aren't relevant to them come out as well, and it's difficult, and then they get confused with too much paperwork." GP 17

5.5.2 The experienced barriers to optimal use of anticoagulants

The barriers to optimal use of anticoagulants can be summarised under three main sub-themes: (1) barriers pertaining to HCPs, the most pertinent of which were HCPs' concerns about bleeding, and limited knowledge and practical experiences in the field; (2) barriers related to healthcare system; and (3) external barriers influencing the prescribing decision

5.5.2.1 Barriers pertaining to the healthcare professionals

Healthcare professionals' concerns about bleeding

Interview findings revealed that HCPs were unlikely to decide to prescribe anticoagulant if they expect harm from it. Analysis revealed similarities in barriers to prescribing anticoagulants, as perceived by all respondents. They were; HCPs' perceptions of the benefit versus the risk of anticoagulation therapy, HCPs' concerns about or perceptions of

possible contraindications to anticoagulation therapy (including a history of bleeding, active bleeding, very elderly, liver disease, kidney disease, and risks of falls) and clinical uncertainty. As shown in the examples:

"*Well, a patient who has a risk or has been falling quite often in the past, and who have got a considerable risk of bleeding or if a patient has got a significant renal disease, chronic kidney disease, or has shown any bleeding. Those are the patients who I'm not likely to start on it." Stroke consultant 43*

"I weigh up more seriously the risks and the benefits, cause if there's a perception that the risk of the NOACs or warfarin is higher in that patient, as in their risk of bleeding because they are perhaps somebody that is having frequent serious falls. I mean, I know they're not sort of contraindications, they're sort of relative cautions really, but, I dunno, I worry more about the risks than I do of the perceived benefits, if that makes sense" GP 7

Furthermore, for most consultants, increasing age per se was associated with a reduction in the likelihood of being prescribed anticoagulants mainly because of the perception that there is an increasing risk of bleeding in elderly people due to a decrease in cognitive function (feeling confused) and increased likelihood of falls.

"The very elderly people who are confused and falling down and the risk [are] immense for them, so it's not an easy decision to make, to anti-coagulate." AM consultant 31

An acute medicine consultant revealed that he usually tended to prescribe a lower dose of anticoagulant to avoid higher bleeding risk with higher doses, regardless of the patient stroke risk.

"I think you just [tended] to prescribe a lower dose a lot more than would be necessary, because you are thinking that while a lower dose has no real bleeding risk, a higher dose

may have a higher bleeding risk, now whether that would provide 100% protection as a normal dose is something that we have to see going forward." AM consultant 31

Few HCPs assumed that compared to their fear of bleeding risk with anticoagulants, patients were often willing to accept the risk of bleeding for an associated reduction in the risk of disabling stroke, as illustrated below:

"I think when you explain to patients that their risk of stroke is high, most people are happy to accept an anticoagulant because they want to avoid a stroke at all costs and often would be happy to accept the risk of bleeding to avoid a disabling stroke related to AF." IP pharmacist 36

"The motivation is to prevent stroke. Once I explain the problems with stroke and a big stroke causing the disabilities and mortalities, they're happy to go for anticoagulation despite the risk of having a bleed..." Stroke consultant 34

"...And so you have to say, 'Well, I can't guarantee, but this is what we're trying to achieve [with] 50% having a stroke.' And people will say, 'Well, a stroke's pretty devastating. So 50% reduction is pretty good, okay. I might have a bleeding, but I'd rather take a chance at not having a stroke, you know…' And most people are pretty - if you say stroke people are pretty - they know what a stroke is [yeah] and they kind of - that can be a lot of motivational content when you're talking about strokes and avoiding them really." GP 4

Lack of knowledge

Interview findings revealed that cardiologists, and to some extent stroke consultants seemed to be aware of all available national and international guidelines for AF management and were careful to familiarise themselves with all the evidence and knowledge about AF and anticoagulant management. As indicated in the examples below:

"Well personally because I've been a prescriber and a trialist, I pretty much know all the trials back to front..." Cardiologist 9

"The Clinic that we work in is dedicated as an Atrial Fibrillation Clinic. In order to start working in this Clinic, you need to know all the guidelines. You need to know almost everything about the NOACs…." Senior cardiology registrar 22

"...I help them guide through the process along with explaining to them the current, NICE guidelines along with the European guidelines, on when to recommend – when anticoagulation is recommended." Stroke consultant 19

Compared to cardiologists, GPs, acute medicine, and haematology consultants gave the impression of lack of familiarity with best practice recommendations and education around anticoagulant that contributed to their feelings of uncertainty and not having the confidence about which agent to prescribe, as indicated in the examples below:

"Well, it could be that you're just not quite sure whether the risk-benefit balance is favourable or not…and you're kind of a little bit ambivalent in terms of [which one to prescribe], 'I'm a little bit unsure about this,' ... I think it's just basically lack of knowledge, you know, being unsure and not having the confidence of doing something, you know…It's medical education and confidence, really." GP 4

"....you may feel not confident of prescribing it [the new oral anticoagulants] ...The difficulty is if you are not sure which anticoagulant would be best for the patient because it's very difficult to know at the beginning whether this will be good or that will be good, so you are taking a bit of a gamble,.....So you look at various things, what the guidance says, but you may not necessarily get it right straight away." Haematology consultant 1

Compared to cardiologist and stroke consultants, other HCPs indicated that availability, as of now, of four new treatment alternatives to warfarin, had expanded the options available

to them, but then, had introduced uncertainty among them when they attempted to prescribe the most appropriate agent. Acute medicine and haematology consultants indicated that the decision to prescribe warfarin was not a problem, compared to the decision to prescribe the new oral anticoagulants, as the acute medicine consultant stated:

"Yes, especially in the beginning when these new drugs came out, it was quite [difficult]…so you tended to remain with what you knew better like, you know, with Warfarin you've been using that for many, many years…" AM consultant 33

"…with warfarin it's not a big problem, it's mainly the newer anticoagulants that you know, … sometimes we are not sure which one is the best one in certain situations, you know …. so we're not always sure because you have to keep up to date with that knowledge and know it …. so at the back of the mind there is always a slight hesitation in prescribing them…." AM consultant 33

In addition to lack of knowledge and education among prescribers, there seemed further barriers related to lack of clear evidence-based information from guidelines, in particular, the lack of clear guidelines for complex anticoagulation issues: such as anticoagulation in the frail and restarting anticoagulation after a bleed. For instance, almost all stroke consultants gave examples of complex issues, which were not unusual in clinical practice, where they could not find any evidence from guidelines (e.g., the off-license use of anticoagulants) to support prescribing decisions.

"It tells me nothing about what I should do about a man that's had a haemorrhagic stroke last year, who I now see in the clinic and has got atrial fibrillation, or the patient that was on warfarin already and had a bleed despite therapeutic warfarin and they're coming back now a year later to see me, what am I meant to be recommending to them? And these are the situations or, for instance, off-licence use of the agents, you know, whether there's any

evidence to support off-licence use in people where we think there are strong concerns about people complying with warfarin or being concordant with warfarin say when they have a metallic heart valve. And these are not rare instances; there's always…unfortunately, I think there's very little support…" Stroke consultant 11

Healthcare professionals questioned the applicability of evidence from trial data to a non-study real world prescribing population, which may limit the applicability of guidelines in practice. A stroke consultant argued that it is not possible to see patients with no health problem other than AF, and who would be comparable with patients from clinical trials.

"…but it's also understanding the applicability of that to a non-study real world prescribing population, which again, if you look at the kind of people that we see now more and more, it's frail elderly people who one would almost guarantee were not going to be the kind of people that would be in a clinical trial…." Stroke consultant 11

Few HCPs considered that NICE guidelines are not being routinely updated and clinicians are left with no national guidelines to follow which would recommend the evidence-based best practice.

"… obviously we are following NICE, but they don't cover some of the aspects…" IP pharmacist 2

"……We'd use the guidelines from the European Society [of cardiology guidelines] because unfortunately NICE, they're not as up to date." AM consultant 41

Lack of support strategies: Hospital-based HCPs versus GPs

All hospital-based HCPs declared that they sought hospital colleagues' advice and discussion when the decision became complex, for example, they cited multi-disciplinary team (MDT) as the primary source of support on complex anticoagulation issues and

therefore have more opportunities to meet other colleagues who may offer prescribing advice.

"…At the end, the professional is sitting two doors next to you, so you can always go and ask." Senior Cardiology registrar 22

"I ask for assistance for patients who are very complex. So, a patient who may have had histories of subdural haematomas or history of quite [a] severe GI bleeds and then I have a consultant, where we have a multi-disciplinary team meeting, and we take that patient into that MDT [multi-disciplinary team] to make a safe decision on what's the best course of management for them." nurse 13

Other HCPs frequently mentioned easily approachable informal contact, especially about having the opportunity to seek advice on a particular patient case.

"…So sometimes, I have to seek feedback from my cardiology colleagues..." Haematology consultant 44

"There are cases that are not written in the book or not written in the paper; they are not straightforward as in guidelines can't answer these questions on these patients……These difficult cases we have MDTs every week so these sort of cases we discuss in the MDT, so that has other stroke consultants, so we get ideas from everybody else." Stroke consultant 14

Unlike hospital-based HCPs who are better supported either by the availability of dedicated clinic (for example AF clinic or anticoagulation clinics) or meetings with other colleagues who can offer advice and support, GPs were less supported and had fewer resources in comparison to secondary care HCPs. One senior cardiology registrar acknowledged the importance of knowledge and education to support the prescribing decision and appeared to have assumed that GPs particularly are reluctant to prescribe and

hence have a great tendency to pass the prescribing decision to hospital-based doctors. As illustrated in the examples below:

"*I suppose most of the time if someone is not well-versed to the different kinds of oral anticoagulant and they may have reluctance. For example, in the GP practice, most GPs would be reluctant to start [the] patient on oral anticoagulant unless he's been referred to secondary care. That's the most important thing…" Senior cardiology registrar 30*

5.5.2.2 Barriers pertaining to the healthcare system

Inadequate information exchange

Few HCPs indicated that lack of information about patients (e.g. information about first attack AF, and blood records), incomplete information (e.g. patient comes from nursing home, and they don't have the paper work with them) and loss of information (e.g. patients coming from different health economy) as barriers to effective communication of information about patients which may influence prescribing decisions. The above factors are reflected in the comments listed below.

"Lack of data mainly and the data isn't available, and that's why it's a problem, so the data on the first attack AF isn't available…" Cardiologist 20

"On 20% of cases, we do have difficulties because we're not given the information, or I don't have enough evidence……If somebody comes from a nursing home and they don't have the paperwork with them, so I have to read the packets and what's the medication blah, blah, blah." Haematology consultant 44

Breakdown in communication between clinicians and healthcare setting was consistent with healthcare system-related barrier. In this regard, most HCPs also mentioned that inadequate information exchange due to ineffective communication between both

healthcare settings, particularly, information related to laboratory tests was perceived as a barrier to warfarin management.

"… What we don't have is access to the GP blood records necessarily. So, if you're from a different health economy or even this health economy but just outside of our GP catchment a little bit, you might then can't access [patients] previous INR, …." IP pharmacist 27

Bureaucracy in prescription

Among all interviewed HCPs, a haematologist considered the bureaucracy necessary to generate a prescription as a limitation to accessing all the available anticoagulant choices. Although all anticoagulants were approved by the trust medicine committee, HCPs were still required to complete drug-related forms and get it approved by somebody in the trust.

"…bureaucracy in prescriptions and you know, you have to get it approved by a, b, c, and d before you can prescribe it and that's another thing… For example, in some drugs, we have to fill in a form, although it is approved but you still have to fill in a form, so that somebody else says yes and then you can use it, so these are barriers." Haematology consultant 1

5.5.2.3 External barriers influencing the prescribing decision

Availability of drug formularies and cost

Majority of HCPs considered other reasons that would influence their decision to prescribe anticoagulants. For example, factors like drug formularies and cost were appeared to influence the prescribing decision.

The following AM consultant appeared to have assumed that cost might inform the treatment choice, but might not impose a barrier to prescribe the more expensive agent when it is proven to be better than warfarin.

"Well the financial issue is still prominent, that warfarin is meant to be the first line when you prescribe it, and then there has to be a clinical reason to choose NOACs over warfarin, so that has to be apparent that it is better than warfarin, there's an advantage to the patient." AM 10

Few respondents talked specifically about considering the availability of drug formularies when choosing from the available options. For this haematology registrar, a formulary restriction seemed to have limited the choices available to patients. A GP reported a similar issue, as illustrated below:

"…The choice of the direct oral anticoagulant is often bound by the hospital, and so they don't have everything formulary. You can't offer them everything, but often the first choice is rivaroxaban." Haematology registrar 42

"There is a trend [in prescribing] because it goes by our formulary, isn't it? More or less we follow the drug formulary as a good practice" GP 46

Influences of pharmaceutical companies

Only one pharmacist seemed to have assumed that providing rebates from pharmaceutical companies for specific agents, might persuade physicians to prescribe their brand. The pharmacist stated:

"… I mean NICE talks about all agents being an option but going forward you may find that certain pharma companies might do different deals with certain health economies around cost…Yeah, local policies and local health economy having rebates..." IP pharmacist 29

5.6 Potential strategies to optimise anticoagulation therapy decision-making process

Healthcare professionals in this study were asked to identify suboptimal determinants in the anticoagulation decision-making process and to suggest strategies and recommendations, to address their needs. Responses showed that there were no differences between HCP speciality background or setting and their proposed recommendations for improvement.

The strategies suggested by HCPs to achieve optimal anticoagulants prescribing were categorised along a continuum of processes in the decision-making process.

5.6.1 Recommendations to address barriers related to communication and patient education

5.6.1.1 Develop patient-specific information material and resources

Overall, there seemed a general sense of the need for individualised patient information material that is simple to understand, easy to read, available in different languages, and includes multimedia materials and various interactive formats, for example, YouTube videos in a variety of languages.

"…we need written information which is in a concise format for the patients, so [we] need proper patient information sheets, whether it is, you know, electronic or whether it is written, [we] may need it in different languages…." Haematology consultant 1

"I think having a printout leaflet for the patient in their language …that would be great because we do have to and also it has to be a potentially in big size because many of the patients are older and find it difficult to read, or the alternative is to have videos in a variety of languages…so if there were YouTube videos in a variety of languages explaining why drug was chosen over another drug that would be tremendously useful and I think that

would be a better tool for patients. The paper is great but perhaps paper with links to videos…" Cardiologist 9

Likewise, a GP highlighted the need to provide broader information via other modalities, for example, NHS YouTube channel given its effectiveness in other areas of medicine and the opportunity to get the whole family involved in the education.

"A YouTube health channel would be great. An NHS YouTube channel, with all the kind of conditions that you might - and patients can look, and they can have little tutorials about conditions. That would be fantastic, you know. Not a lot of our patients have computers, but a lot of them do have smartphones, and the family can have a look at things, really. And if it was NHS led I think they could be quite useful." GP 4

5.6.2 Recommendations to address barriers related to prescribing of anticoagulants

5.6.2.1 Provide training sessions for practice nurse and GPs

Most GPs suggested that providing education and training to GPs and nurses in anticoagulation might have the potential to increase their knowledge, and hence confidence in the anticoagulants prescribing.

"I think it would help if everyone in the team were trained to the same level, so it would help if all the nurses had a very good working knowledge of AF. As well as all the doctors to have a good working knowledge as well, so it would help for everyone to be on the same level of knowledge, and everyone to be doing the same thing as well, perhaps, so that everyone has standardised care." GP 15

"….. just further education about the big impact of NOACs and warfarin on reducing stroke risk, and also not fearing warfarin and NOACs …"GP 7

5.6.2.2 Hope from forthcoming clinical trials

Cardiology consultants were hoping to bridge the evidence gap between clinical studies and real-world experience on anticoagulation prescribing in complex anticoagulation issues.

"*The good thing about the clinical trials there is we have a clinical trial virtually for every patient, so we know which drugs tend to be better in the older patients and the younger, those that have abnormal renal function, those that don't, those with lower body weight, so we're getting more data and more clinical trials although it will be two to three years and we'll get increasing data." Cardiologist 9*

5.6.2.3 Provide decision support tools

Majority of HCPs seemed to have assumed that, in principle, the use of decision support tools would be useful and could potentially support their prescribing decision and improve communication of the decision to patients. Talking to HCPs revealed that they were keen to suggest the features of a decision support tool that were assumed to support their needs and fill in the gap in current practice.

For example, a stroke consultant was clear about the features of support tool he wanted for his practice, the one which is quick, evidence-based, accessible, and provide a printout material for the patient.

"I think any sort of computerised programme is good, as far as it's quick, it's robust, we have a connection, you can print it out, and you can give it to the patient, and they have something documented…" Stroke consultant 12

Also, a haematologist gave an example of decision support tool which allows HCPs to feed in patient's health information and then comes up with a treatment recommendation and the rationale behind it.

"Yeah, I think [we] probably needs some tool to decide on which one will be beneficial to that patient, so you have a bit of a tool, you fill in the kind of, questionnaire or pro forma for that patient, that he's got a, b, c, d and that if you give him this drug then this is how he's going to be and you just get a score…" Haematology consultant 1

There were similarities in what HCPs perceived of the benefits gained from using decision support tools in clinical practice. For example, a pharmacist appreciated a tool to ensure that every patient is getting the same level of care.

"Again, like a check list or kind of tool obviously means that every patient is getting the same consultation tailored, but you're not accidentally missing something out because you've forgotten to mention that thing so I suppose that would ensure every patient gets the same access to [knowledge]" IP pharmacist 35

A GP said that where confidence is lacking, decision tools would always help provide the edge in being confident that the decision was the correct one.

"…I think a decision tool would always be helpful to give you the edge in being confident that your decision was the correct one…" GP 4

Moreover, HCPs highlighted the need for support tools, which are designed to provide good quality up-to-date information, easy to understand without the use of medical jargon, generate personalised written information, and use fewer words but more graphics.

"…Just providing good quality up-to-date information that's easy for them [patients] to understand, you know, without jargon…… I think the computer tools that then generate a

paper that they can take away, look at. I like things that have their name on that makes it more relevant to the patient. They're less likely to sort of put it in the bin." GP 7

"Most important is fewer words, more graphics. Patients love to see diagrams and graphics..." Senior cardiology registrar 30

A cardiologist seemed to have assumed that a decision support tool that uses a pictorial presentation to demonstrate patient-specific stroke and bleeding risk scores very helpful and very easy to explain to patients, hence support the communication of risk scores and facilitate the decision-making process.

"Yes. the pictorial presentation of risks and risk reduction, both for stroke and for bleeding, and I think some sort of handy, flip chart or something that you can use for CHADS VAS, one, two, three, four, five, six and HAS BLED would be very helpful and it would be something that, either in an app or that would be very easy to demonstrate." Cardiologist 16

Likewise, a GP described the use of pictorial representation by HCPs to support patients making decisions as a very useful model, which could enable HCPs to show patients the change in risk scores with and without anticoagulants, and was proved to be successful with other conditions and specifically, with statins prescribing.

"Pictorial decision is the only thing I'm really interested in. And we use it sometimes with statins, and we have the QRISK®2 [cardiovascular disease risk calculator] and things along those lines…So that's a very useful model and that you can actually alter the figures with and without and it gives you the numbers." GP 4

5.7 Discussion

This study aimed to understand the context of anticoagulants decision making and to identify which determinants in the decision-making process were suboptimal. This study employed a qualitative approach to gain multiple perspectives into the barriers to the optimal anticoagulant prescribing decision. Interview findings highlighted that determinants in the decision-making process around anticoagulation therapy were suboptimal and uncertain.

The purpose of this section is to discuss the main findings from the initial interview stage of the study. Consideration is then given to how these findings relate to the literature, especially the literature on barriers to anticoagulation therapy uptake in clinical practice that was discussed in chapter one (sections 5.7.1, 5.7.2, and 5.7.3). Finally, Key points are summarised in the final section of the chapter.

5.7.1 Barriers pertaining to the healthcare professional

5.7.1.1 Healthcare professionals' fear of bleeding risk

Healthcare professionals in this study revealed that elderly patients with AF were frequently not given anticoagulation therapy based on a high perceived potential risk of falls and bleeding risk. For some HCPs increasing age per se was associated with a reduction in the likelihood of being prescribed anticoagulants mainly because of the perception that there is an increased risk of bleeding in elderly people due to a decrease in cognitive function (feeling confused) and increased likelihood of falls. Likewise, a systematic review of the use of warfarin in elderly patients with AF found that having a significant risk of bleeding or a history of bleeding was seen the most cited reason not to anticoagulate, and physicians were less likely to anticoagulate patients over 70 even if the patient has no contraindications to warfarin (Pugh et al., 2011). By contrast, a prospective

cohort studied the risk of major bleeding from falls in elderly patients (at least 65 years of age) who were on oral anticoagulants for AF and concluded that being at risk of falls is not a valid reason to avoid oral anticoagulants in medical patients (Donzé et al., 2012). The use of risk–benefit analyses in a study by Garwood and Corbett, (2008) to assess the use of anticoagulant in elderly patients with AF revealed that despite risks associated with warfarin, its benefits outweigh its risks even in patients, who fall, and therefore warfarin should be used, rather than aspirin or no therapy (Garwood and Corbett, 2008). One could argue that HCPs in our study adopted similar attitudes to the Australian family physician in Gattellari et al., (2008) in that, they were less likely to prescribe anticoagulants for patient experiences of bleeding due to their fear of further bleeding events (Gattellari et al., 2008).

Randomised studies assessing the efficacy and safety of the NOACs, such as, dabigatran (Connolly et al., 2009), rivaroxaban (Patel et al., 2011), apixaban (Granger et al., 2011), and edoxaban (Giugliano et al., 2013) suggested better efficacy and safety (a lower risk of bleeding) profile compared to warfarin. In this context, a real-world data on physician attitudes toward and values related to the use of NOACs in stroke prevention revealed that physicians were more likely to select an attribute profile reflective of the new agents (apixaban, rivaroxaban, and dabigatran) over warfarin with the risk of major bleeding as the highest rated attribute (Andrade et al., 2016). However, real-world prescriptions do not necessarily reflect these values, which suggested other factors could influence physician decision-making around anticoagulation therapy (Andrade et al., 2016).

Conversely, HCPs from this study revealed that their patients were often willing to accept the risk of bleeding for an associated reduction in the risk of disabling stroke. Similar findings were found in the study of Devereaux and colleagues who concluded that patients placed more value on the avoidance of AF-related stroke and less value on the avoidance of bleeding than did physicians (Devereaux et al., 2001).

5.7.1.2 Understanding the concept of net clinical benefit

Interview findings revealed that real-world implementation of patients' comprehensive assessment was not ideal. Compared with stroke risk score (CHA_2DS_2-VASc), bleeding risk score (HAS-BLED) was rarely used by non-cardiology HCPs. Moreover, few HCPs did not even use CHA_2DS_2-VASc in clinical practice. In agreement with our findings, qualitative interviews with HCPs from Wang and Bajorek (2016) study revealed that comprehensive assessment of patients' stroke risk and bleeding risk were not routinely undertaken in clinical practice.

Although most HCPs in this study emphasised the importance of assessment of risk versus benefit when deciding which specific agent to prescribe, only a few of them were able to quantify the net clinical benefit of anticoagulants and integrate this concept within patients' characteristics to decide which specific agent to prescribe. Instead, they focused primarily on the risk of having a stroke, in particular, ischemic stroke. Thus, it was clear from our findings that, when selecting an anticoagulant, assessment of risk versus benefit was not often considered in clinical practice.

The concept of net clinical benefit has been used to quantify the balance between stroke and bleeding risks of oral anticoagulant therapy (Banerjee et al., 2012; Olesen et al., 2012; Singer et al., 2009). Singer and colleagues (2009) found that net clinical benefit of anticoagulation rose steadily with age and was greatest in patients with AF whose age was 85 years and older, and that this benefit persisted even when intracranial haemorrhage was given a severity weighting factor up to double that of ischemic stroke (Singer et al., 2009). These findings highlighted the importance of effective stroke prevention despite the elevated bleeding risk, particularly in the elderly, for whom anticoagulation therapy was often not offered for fear of bleeding (Singer et al., 2009). Furthermore, evidence from 'real world' data (The Danish National Patient Registry on patients with nonvalvular AF

between 1997–2008) revealed that when the risk of bleeding and stroke are both high, all three new OACs (dabigatran, rivaroxaban and apixaban) demonstrated a greater net clinical benefit compared with warfarin. The authors also found that the net clinical benefit was higher in patients with a high HAS-BLED score ≥3 with any anticoagulant (whether warfarin or a new agent) given that higher bleeding risk patients would also be at high ischemic stroke risk (Banerjee1 et al., 2012).

5.7.1.3 Knowledge and adherence to current atrial fibrillation management guidelines

Interview findings identified key reasons for the suboptimal implementation of the national and international guidelines (2012 focused update of the ESC Guidelines; NICE guidance, 2014; and NICE TAG 355 Edoxaban, 2015).

Findings of this study revealed that HCPs' knowledge about current national and international AF treatment guidelines affected their likelihood of prescribing anticoagulants. While HCPs from stroke and cardiology specialists expressed their awareness of all available guidelines and using those successfully to deliver evidence-based best practice, GPs, acute medicine and haematology specialists showed lack of familiarity with best practice recommendations and expressed uncertainties about which agent to prescribe. These inter-speciality differences in knowledge and adherence to AF management guidelines were identified in previous studies (Lip et al., 1996; Turakhia et al., 2013). Knowledge and adherence to AF management guidelines seemed to influence primary care and speciality physician anticoagulant prescription rates differently (Hess et al., 2014).

In understanding the reasons for lack of knowledge and adherence to AF management guidelines, HCPs' perceptions of current guidelines were important. They highlighted three main reasons; they were; lack of clear evidence-based information for complex

anticoagulation issues, the applicability of evidence from trial data to a non-study real world prescribing population, and they felt guidelines were not up-to-date. Previous studies reported many factors influencing the HCPs' decision to comply with recommendations from AF management guidelines (Alonso-Coello et al., 2008; Deplanque et al., 2004; Peterson et al., 2002). For example, In Peterson et al., (2002), GPs and cardiologists were reluctant to follow recommendations from AF management guidelines due to lack of confidence in the evidence from guidelines.

Healthcare professionals from this study argued that actual deficiencies in guidelines and information gap were the main reasons to explain their attitudes, in particular, on data gap with NOACs. Similar findings were reported by Lipman and colleagues (2004), who found that GPs considered that the information provided in guidelines and research did not always clarify their doubts (Lipman et al., 2004), and that data gaps with the NOACs were the key barrier to compliance to current guidelines (Nieuwlaat et al., 2006; Camm et al., 2015).

Healthcare professionals in this study argued, as have others (Camm et al., 2015; Javaid, 2016), the applicability of evidence from trial data to a non-study real world prescribing population because of differences in patient baseline characteristics, which may limit the applicability of guidelines in practice (Camm et al., 2015; Javaid, 2016). In one study (Alonso-Coello et al., 2008); physicians stated that they often gave more weight to their own experiences than to research findings and guidelines recommendations.

Off-label prescription of the new agents was another concern raised by study participants. They indicated that in certain clinical situations the off-label use of NOACs seems a reasonable alternative, for example, in complex anticoagulation issues and restarting anticoagulants after a bleed, and for a patient that was on warfarin already and had a bleed

despite therapeutic INR. The literature does not support the off-label use of NOACs, even when it seems a reasonable alternative, as it may unnecessarily increase the risk of major bleeding, and the benefit is uncertain (Molina and Selim, 2014). In a study to assess the frequency of off-label NOAC doses among AF patients and the associations between off-label dose therapy and clinical outcomes in the United States (U.S.) practice (Steinberg et al., 2016). Findings revealed that off-label doses (under-dosing or overdosing) was reported in approximately 1 in 8 patients, and was proven to be associated with worse clinical outcomes (Steinberg et al., 2016).

Healthcare professionals from this study also criticised NICE clinical guidelines; they felt that they were sometimes out of date, as there is a time lapse between new evidence emerging or a new agent became approved by international guidelines and the time it became approved by local guidelines. Even if guidelines were up to date, it did not guarantee to provide answers to data gaps with the NOACs and other specific areas within anticoagulation management issues. Similar criticism of the new ESC guidelines was reported by Camm and colleagues (2015).

Healthcare professionals' perceptions of decision making of which anticoagulant to prescribe have been reported complex (LaHaye et al., 2012; Wang and Bajorek, 2016). In this study, cardiology and stroke consultants' prescribing decisions were consistent with national and international guidelines (2012 focused update of the ESC Guidelines; NICE guidance, 2014; and NICE TAG 355 Edoxaban, 2015). However, HCPs from other speciality did not link their prescribing practice to recommendations from current guidelines and revealed a reluctance to prescribe NOACs to patients. Similar to findings from the previous study (Camm et al., 2015), this study identified inter-speciality differences in NOAC prescriptions rate between cardiology and stroke consultants on the one hand, and GPs, AM and haematology consultants on the other. While cardiology and

stroke consultants were comfortable and confident with the NOAC prescribing, HCPs from another speciality were more cautious and hesitant. Healthcare professionals' field of speciality and experiences in the prescription of anticoagulant might explain this difference. Similarly, studies have shown that differences in the prescription of anticoagulant were related to inter-speciality differences among prescribers (Lip et al., 1996; Vassilikos et al., 2010; Wang and Bajorek, 2016). In that cardiologist were more likely to prescribe appropriate anticoagulants for stroke prevention in AF patients than were other speciality consultants and GPs (Lip et al., 1996; Vassilikos et al., 2010; Wang and Bajorek, 2016). Moreover, findings from the literature indicated that such variation in anticoagulant prescribing could lead to a range of patient outcomes, with better benefits achieved when anticoagulant prescribing became consistent with guidelines (Lip et al., 2015).

Our finding may partially explain the under-use of NOACs according to latest data from EORP-AF Pilot Registry data which reported that oral anticoagulant use has increased, but NOAC use was still low (Lip et al., 2014).

A number of registries are under way that will provide real life longitudinal data on use, uptake and safety of OACs, including NOACs, such as GARFIELD-AF, ROSE (Rivaroxaban), and the GLORIA™-AF Registry Program. These studies aimed to offer reassurance to UK practitioners, particularly around safety and bleeding profiles (Gorogo, 2014).

5.7.2 Barriers pertaining to the patient

5.7.2.1 Knowledge and perceptions

Healthcare professionals perceived patient's lack of knowledge and poor perception of AF as a main concern influencing patients' decision to accept treatment with an

anticoagulant. Also, they reported that they felt that knowledge and understanding were worse in the elderly patient than younger. Similar findings were reported in previous studies by Bajorek et al., (2009) and Dantas et al., (2004). One of the factors that may explain lack of understanding associated with elderly was low educational level (Madrid et al., 2016).

The HCPs interviewed were more likely to relate patients' motivation to accept treatment with anticoagulants with patients' perceptions of stroke and understanding of risks and benefits associated with treatment. Previous studies emphasised the role of patient knowledge in successful anticoagulation treatment, and that eliciting patients' knowledge was seen necessary to address patient-level barriers (Alonso-Coello et al., 2008; Dalmau et al., 2017; Decker et al., 2012). These findings suggested that patients' poor health literacy may contribute to reasons for underuse of anticoagulation therapy in clinical practice (Wilke et al., 2012; Wilke et al., 2015).

Similarly, the HCPs interviewed indicated that patients that presented with decreased knowledge and poor perceptions of AF and AF-related stroke risks, generally, had lower compliance with therapy. This reflects the work of Arnsten et al., (1997) which reported that patients tended to adhere with anticoagulant when they perceived a risk of stroke or when they had a better understanding of benefits of anticoagulant.

Healthcare professionals in this study reported some instances of patients who refused treatment with anticoagulants mainly because of their expectations of perceived benefits of anticoagulant. These findings were in keeping with the literature on patient attitude towards oral anticoagulant therapy (Dalmau et al., 2017; LaHaye et al., 2014; Lane and Lip, 2014; Potpara et al., 2015), which can be addressed by further education and explanation of the benefits of treatment and possible consequences of inaction (Lane and

Lip, 2014). Healthcare professionals in this study commonly agreed that the provision of such information to patients was inadequate, including the use of standard drug information leaflets and pharmaceutical company leaflets, and they felt that existing written leaflets were not tailored to meet individual patient's needs. Bajorek et al., (2007), recognised the importance of providing adequate and sufficient information to patients using written leaflets to reinforce patient education.

The main risk of therapy that HCPs believed concerned their patients was bleeding. However, they indicated that patients were willing to accept bleeding risks for a decrease in the probability of experiencing a stroke. These findings confirmed previous work on AF patients' perceptions of stroke and bleeding outcomes which clearly demonstrated that patients viewed a minor stroke worse than major bleeding (Alonso-Coello et al., 2008; Devereaux et al., 2001; LaHay et al., 2014). A survey incorporating physician and patient questionnaires was undertaken to better understand physicians' and patients' knowledge, perceptions, and attitudes to AF (Aliot et al., 2010). Results indicated there was a tendency for physicians to underestimate their patients' understanding of the benefits of AF treatments and to overestimate patients' knowledge about treatment complications (Aliot et al., 2010). However, in the same study real-world data from patients showed that there was a relatively high level of patient knowledge of the benefits of medication and their side effects, and of possible complications of AF (Aliot et al., 2010). The results highlighted that there was a potential gap between the realities and physicians' perceptions of patients' attitude and understanding of AF and anticoagulation therapy (Aliot et al., 2010).

Another, interesting finding of our study was the fact that the majority of HCPs stated that they practised shared decision-making, in that they provided information and fact to patients, but still wanted to take the lead responsibility to make the treatment decision. They stated that most of their patients with AF were of the old-age population or presented

with limited learning capabilities, and preferred to delegate the treatment choice to their HCPs. Our findings suggested that shared decision–making is not really taking place in clinical practice. A similar discrepancy in HCPs perceptions about their decision-making style was reported in Borg et al., (2012) and in a systematic review by Dalmau et al., (2017).

5.7.3 External factors impacting optimal prescribing

5.7.3.1 Influence of pharmaceutical company

In this study, cost of the NOACs was not mentioned by research respondents as an issue influencing their decision to choose any agent when it was proven to be best for the patient. The literature reported mixed influences of cost on HCPs' decision making (Barra and Fynn, 2014; Jones et al., 2001; Mason, 2008; Schumock et al., 2004). While HCPs in Barra and Fynn, (2014) study revealed that the high cost of the new oral anticoagulants was seen as a potential barrier to prescribing them, several studies were consistent with findings from our study, which concluded that cost relative to existing treatments was a consideration for prescribers but was not a major issue (Jones et al., 2001; Mason, 2008; Schumock et al., 2004). Many researchers have published cost-effectiveness models of the novel anticoagulants for stroke prevention in AF (SPAF) (Limone et al., 2013). These models suggested that the NOACs are cost-effective, but did not provide adequate data for head-to-head comparison of the individual agents. This made it difficult to determine the most cost-effective agent (Javaid, 2016; Limone et al., 2013).

A pharmacist from this research revealed that receiving rebates from pharmaceutical companies was perceived as an issue affecting HCPs prescribing practice.

This influence might be explained because the pharmaceutical companies of the different novel agents can influence the policy recommendations set by the local Medicine

Management Committees (MMCs) for primary and secondary care by providing rebates of a specific agent to persuade the MMCs to enforce prescribers to prescribe their brand (Gorog, 2014). One could conclude that the pharmaceutical companies of the different novel agents have the potential to influence the prescribing practice among healthcare settings which adopted a cost-cutting policy. This may explain the variation in local prescribing guidelines for NOACs between the different health economies.

5.7.3.2 Administrative obstacles

In this study, bureaucracy in medicines authorisation was perceived as an issue in clinical practice, which limited HCPs flexibility in prescribing preferred anticoagulant. Healthcare professionals from previous studies revealed that the administrative hurdles associated with prescription of NOACs, for example, the need to complete paperwork and provide justification of the clinical decision, were more likely to impose an additional barrier to NOAC prescribing in clinical practice (Camm et al., 2015).

5.7.4 Conclusion

This study explored HCPs' perspectives on barriers to anticoagulation therapy decision making in clinical practice. These findings add to the literature by suggesting that HCPs' perceptions of anticoagulants prescribing decision may be more complex than previously reported. In particular, the findings suggest that HCPs continue to under-estimate the net clinical benefit of anticoagulants, in contrast to what has previously been found in quantitative studies. The implications of these findings include the need for HCPs to recognise; the importance of conducting a comprehensive risk assessment for AF patients', and to prioritise effective stroke prevention strategy despite the elevated bleeding risk.

Furthermore, the findings suggest that AF patients are not receiving tailored information to meet individual needs and that they depend mainly on the information delivered verbally

by their healthcare providers, in contrast to what has previously been found in qualitative studies. The implications of these findings include the need for educational intervention, in terms of providing training and education session to HCPs, in particular, for GPs.

Decision support tools, however, were assumed to help to overcome these barriers, and further data from forthcoming trials may also help to close the knowledge gap in the literature.

The analysis of the data concerning these HCPs' perspectives on the decision support tool for anticoagulation therapy will now be discussed.

Chapter 6: Healthcare professionals' perspectives on the potential utility of the Decision Support Tool: Analysis of initial interviews

This aim of this chapter is to discuss the analysis of the data from the initial stage that concerns the pre-interventional evaluation of the DST to collate evidence on its potential usefulness in anticoagulation management. For the purpose of this study, as discussed in section 4.5.1, both qualitative and quantitative research approaches were employed concurrently.

Healthcare professionals' perspectives and views on the features and functions of the DST are discussed in sections 6.1 and 6.2. The perceived value and concerns from implementing the DST into routine clinical practice are discussed in sections 6.3 and 6.4. Initial views and satisfaction with using the DST in anticoagulants prescribing decision are presented in sections 6.5 and 6.6. HCPs' recommendations for promoting more effective use of the DST are discussed in section 6.7. The quantitative measures used to evaluate user acceptability, satisfaction, and the tool potential to prepare patients for informed discussion are discussed in section 6.8. Discussion of how these findings relate to the literature is presented in section 6.9.

6.1 Features of the decision support tool and associated patient decision aid

This theme focuses on exploring the features of the DST and associated PDA that were important to anticoagulation therapy prescribing decision context. Four main features were identified; general features, features related to content, features related to interaction and features related to communication.

6.1.1 General features

The Keele Anticoagulation Therapy Decision Support Tool was designed as a computer-based resource that is accessible directly from the following URL: http://www.anticoagulation-dst.co.uk/home. The majority of HCPs considered this method of delivery of the DST advantageous to their practice as it was readily accessible, available, and easy to activate at the time they need it.

"It's available online free…, which is readily accessible..." AM consultant 41

"Having it available, so if I put it on my iPhone, I could activate it every time I need it." Stroke consultant 8

As reflected by HCPs, there was some foreseen usefulness from using computer-based decision support tool in clinical practice. For example, a cardiologist explained that with computer-based, internet-based decision support tool, it was easy to have quick access to hyperlinks embedded within the tool compared to paper-based decision support tool.

"In a way, a computer is more efficient than reading a leaflet because the leaflet doesn't have the hyperlinks, so I think the hyperlinks. For people who use a computer can be very useful..." Cardiologist 20

Another cardiologist felt that using a computer-based programme would be more reliable than his practice because computer led resources always tend to follow the same thing each time and are not going to miss any step in the decision-making process.

"I suspect because this is computerised it would be more reliable than me in the end…I think there will be times when, for example, I might not have taken the patient's weight into account, … So, this is actually a bit more reliable because it always does the same thing,

as computer programmes do. It's not going to miss anything. Yes, step by step" Cardiologist 16

The decision support tool and associated PDA were repeatedly found by most respondents as a quick resource. In fact, HCPs perceived some features and functions within the tool essential to speed up the whole decision-making process.

In this sense, a cardiology registrar seemed to have assumed that it can be just flip the screen over to go through the decision support tool.

"...So, I can just flip the screen over; the patient will be able to see what I'm describing to them ..." Senior cardiology registrar 30

Among those respondents, most believed that speed can be achieved once they get familiar with it and know how to use it their way.

"...it would have fitted quite nicely... it would be getting used to the tool and knowing to work it quite quickly ... because if you play with it more and more, you get used to it." nurse 13

"...obviously if you know how to use it you know your way around it it's going to be very quick..." GP 15

A specialist nurse valued the ability to access information leaflets and the ease to get them printed out which in her opinion can speed up the decision-making process and the whole consultation.

"I think it would improve it really and I think some of the things on there, such as the hyperlinks to certain information leaflets; you can spend time struggling for those and trying to print them off because we obviously don't stock everything... If you could just quickly click on a link and print it off, that's much better." nurse 13

Likewise, a cardiology registrar valued the availability of hyperlinks to useful information leaflets, which took him a click on the print button to get it. A screenshot to show links to patient information leaflets in chapter one, figure 1.24.

"And with all the links that [tool] have provided I can go – quickly go online to look for that information, and click on 'print' button and print it out for them and my adjoining printer. So, all this helps" Senior cardiology registrar 30

In the GP opinion, the use of the DST in practice can be quicker compared to her routine practice, because it covers all the information and steps to make and communicate the prescribing decision.

"It's all in one place, so that's good and all the information's there together, so that'll be really helpful, and it looks like it's a bit quicker to use..." GP 17

6.1.2 Features related to content

The first and the most important feature, HCPs were careful to talk about was the information provided by the DST. Participants were asked to talk about the content of the tool and how they judge the kind of information provided, methods of information delivery, and presentation.

Overall, all HCPs indicated that the information and evidence presented by the DST seemed sufficient to satisfy their needs and patients' information needs as well, as shown below:

"Appropriate and very detailed. So, it's enough. More than enough." Cardiology specialist 18

"… The tool provides all the necessary information… It's adequate to satisfy the patient and the clinician in the decision-making." AM consultant 28

A GP revealed that the information provided by the tool was a balance between very comprehensive and being efficient. Other HCPs used the phrase just the right information that they want to look for.

"...I think it's a balance between being very comprehensive and being efficient..." GP 15

"I think it's just the right amount" Senior cardiology registrar 30

The majority continued to describe the kind of information provided by the tool. They all described the tool content to include information about atrial fibrillation, treatment options, and include enough information about benefits and risks of treatment, as illustrated below:

"...the information regarding atrial fibrillation, the risk of bleeding, the risk of stroke, I think they are good pieces of information." AM consultant 28

"...all the available options are there, and it will jog your memory as to what to discuss with them [patients]..." nurse 39

All HCPs found the patient decision aid was the most useful part for patients in terms of the types and topics of information covered as shown in the screenshot from the PDA, in chapter one, figure 1.19.

"... Obviously, you've got the extra option part here, which is part of the patient's decision tool. I think that's probably going to be the most important part for the patient. It really does go into everything that they've spoken to me about what they've been mostly worried about. Yeah, I think that section will be really helpful for the patient." AM consultant 37

"... the fact it's all there, I think is useful. I'd say the patient decision aid is a useful bit to show....as a comprehensive resource for information....., it's all there." AM consultant 3

There appeared similarities in what HCPs assumed useful of the tool to bring all the information they need to make an appropriate prescribing decision and that they don't need

to seek information from alternative resources. In particular, they gave the example of quick access to NICE clinical guidelines as illustrated in chapter one, figure 1.4, drug interaction checker (figure 1.16), and various other aspects of the tool.

"The information that's provided on the tool is quite good, and it is extremely helpful, especially to professionals who don't do this on a day-to-day basis. And what I particularly liked is the references [the links] that were provided and the easy click, especially to NICE [clinical guidelines], as well as drug interactions and various other aspects of the tool, and that was available." Stroke consultant 19

All respondents indicated that pop up alert boxes and reminders that pop up as they go through the tool would be useful to support their prescribing decision. For example, a GP pointed to the Adverse Events alert box which reminds HCP to complete the yellow card. Screenshot of the alert box is illustrated in chapter one, figure 1.14.

"*…I like the fact that it draws in different doses for different problems, so it's good. I like the way that the yellow card prompt came up as well. It was clever." GP 7*

In this regard, a haematology registrar referred to these alert messages and information boxes as necessary to enforce everything that prescribers should be thinking about and more likely should follow.

"…It involves forcing the physician to think about their renal function and their bleeding risk and their interaction with other medication. It kind of enforces everything that they should be thinking about, so I think it's helpful in that way." Haematology registrar 42

Research participants were also prompted to comment on the presentation of the stroke and bleeding risks calculator. They all liked the design, format, and ease of use, Screenshots available at chapter one, figure 1.10.

"It's all there. It's clear, you can't miss it, and it shows you all of it together…So, it's all on one page. No clicking forwards and backwards with it." AM consultant 3

"I think it's very useful. It covers everything, so everything's in one place, so you've got ...the CHA_2DS_2-VASc score, the HAS-BLED. It's all in one place, and it's all calculated for you, which is very nice." IP pharmacist 2

Research respondents also talked about the usefulness of graphics to present benefits and effects of anticoagulants. In this regard, all HCPs felt that the use of graphical representation would help to present the information in ways that allowed patients to understand key messages and make comparison between options by switching between 'No Treatment' and 'Anticoagulant' options to see the benefits/risks graphs, and the ability to switch between different formats, for example, Cates plots or bar charts. Figures 1.22, 1.23 and 1.24 illustrate the tool output.

"Well, I think that graphical representation of the risk, the number of people that would have a stroke with and without anticoagulation versus the bleeding risks…which again would be useful representations to put to patients in the discussions." Stroke consultant 11

"…So, they can understand it very clearly in different ways. So, that's fine…"AM consultant 5

The majority of HCPs reported that providing information to patients in three different formats; verbal, visual, and written materials would have a significant influence upon subsequent recall of information.

"…I think the little, happy faces and the risks is a really nice visual tool that patients like and helps them to understand quite quickly. People learn differently and take in information differently. You've got the visual one there, you've got the written word, and you've got the verbal communication, so that's all really good for the patient…." Nurse 21

The following prescribing pharmacist explained the impact of using a variety of communication aids on patients' ability to pay attention to and absorb key messages, and recall of information.

"The faces. I thought that was really useful because I think a lot of the time, even if you give patients lots of words or you speak to them, …they don't remember it but if you can have a visual, it's more likely to be remembered and also because it's colourful. It's very easy to look at the faces and see the red ones or the green ones, so that's more likely to stick than verbal or just words, I think." IP pharmacist 26

All research respondents indicated that the tool provided a step-by-step approach to thinking about the prescribing decision and discussing the various queries the patient may have during the decision-making process. It was seen as prompt in the way it is structured and organised by providing consistent steps during communication with every patient, so HCPs would not overlook any step. As indicated below:

"It's a very good prompt, and it would prompt us, to let the patient know everything they need to know and for the patient to tell us anything they need to tell us and keep everything at the forefront of what we need to be doing with those patients with AF and medication." Nurse 21

"It's a step by step, so every patient gets the same quality of consultation…Again I think it's a tool that makes sure you don't overlook something, that you always follow the same steps consistently…" IP pharmacist 35

"It's more structured, and I'm less likely to miss something out. It also reminds you of certain things, such as renal function, which may be in your mind at the beginning but as the consultation goes on you may forget…it is more organised and more structured and visual." AM consultant 37

All research participants acknowledged that the DST and associated PDA seemed to contain high-quality information that was from the most recent clinical trials, the most up-to-date evidence based research studies, and was supported by NICE. They also indicated that the evidence seemed to be balanced, complete, accurate, unbiased and robust. Comments were given after exploring the references page shown in chapter one, figure 1.3.

"…So, it looked like it was high quality and the most up-to-date evidence that was available for the area." AM consultant 37

"…It's balanced and obviously based on guidelines, so it's evidence-based, yes… It's accurate…" Cardiologist 16

"The quality provided is actually pretty good. It's fair as well. It's not biased." Senior cardiology registrar 30

"…The evidence presented is quite robust…" Stroke consultant 19

"And it's regularly updated …. and it is supported by the NICE" Stroke consultant 43

To that end, research participants indicated that the PDA provided information that was structured, clear, concise, and flowed in a more logical and simple way.

"[It] can provide information in a more logical and simple way, which helps the patient to understand in a simple term and simple way …" AM consultant 28

"I think it's clear. It's pretty concise, and it flows quite logically." AM consultant 3

"I think it's quite a good one I liked it, it is quite straightforward, easily understand, even a lay person can understand." Stroke consultant 14

6.1.3 Features related to interaction

Interviews revealed two main features related to user-system interaction, of which; aspects related to user interface design, and aspects related to savings associated with using the tool.

Research respondents considered the decision support tool interface as user-friendly and very nicely designed tool. The following quotes list interface-design features as described by research respondents during the tool demonstration phase, in that:

- The tool was organised and nicely designed. Figures 1.1 and 1.7, illustrate the DST homepage design and layout

"It's more organised, and it's more descriptive. It's more in depth." nurse 24

"It's a very nicely designed tool…" Stroke consultant 11

- The screen layout was easy to understand and use.

"It's very nicely laid out…the pages [are] not crowded…" Stroke consultant 11

- The use of colour and big sized-font in a way that enhances the overall appearance of the tool.

"…the font is a nice big size, it [has] a nice colour scheme…" Stroke consultant 11

- It was concise and clear

"I think it's clear. It's pretty concise, and it flows quite logically." AM consultant 3

- The use of dropdown menus and tick boxes to feed in patient's health information. Figures 1.10 and 1.12 show the tool design

"…The dropdown menus were good…" AM consultant 37

"It's very good. It seems user-friendly and it – at the moment it seems to be ticking boxes…. It's still quite concise…" nurse 32

- It included reasonable amount of information and the use of hidden screens for detailed information

"I think it includes a reasonable amount of information…" Stroke consultant 19

"…All the information is in the background; it's not in your face when you click on…" Nurse 21

On the whole, all HCPs were comfortable with the system interface design; hence, they suggested that interaction with the system should be simple, easy to learn and navigate.

"…I find it very easy to follow…" Stroke consultant 11

"…It flows really easily..." GP 46

"…It seemed quite easy to navigate around…" GP 7

"…[It] looks, quite user-friendly and helpful." GP 17

The second feature related to interaction was the documentation function. In this regard, most HCPs referred to the Referral screen embedded in the tool and ability to print out the whole screens as a PDF document and attach it to patient medical record. In HCPs' opinion, this would save their time during the consultation, in that they will not need to write in the patient notes after consultation or write a letter to the GP. Screenshot of Referral screen available at chapter one, figure 1.25.

"…the fact that you've got an end result that you can then file in the patient notes as well so that you've actually saved time, I think, in the long run, rather than having to write everything down individually." AM consultant 3

"…I suppose you can print out the assessment and put it in the notes as part of the documentation. Because, I suppose, again, what we're tending to do then is then document the discussion in the notes… then we have to dictate a letter for the GP and copy it to the patient…So, it helps from an administrative point of view… it saves writing time, Reception time...then it might save paper and save filing time for all sorts of reception staff …Well, I suppose potentially..." Stroke consultant 11

6.1.4 Features related to communication

All HCPs valued the ability of the tool to support communication of treatment decision to patients. For example, they pointed to Treatment Recommendation screen that could be used to justify the treatment decision made. Example of the treatment recommendation screen is shown in chapter one, figure 1.18.

"It was the recommendation screen and the fact that I can show them this and say, you know, give it to them in more structured. I think that's the most useful thing." AM consultant 3

All HCPs regarded the PDA a useful part to support communication of the treatment decision. In particular, the section about How you feel about the options screen (shown in figure 1.21 from chapter one), which could be used to help HCPs to explore patients' values and preferences of the treatment decision and discuss the various queries the patient may have.

"…The screen when you ask to find how important the dose, the monitoring, find what is and is not important. AM consultant 5

"Obviously you've got the extra option part here, which is part of the patient's decision tool. I think that's probably going to be the most important part for the patient. It really

does go into everything…I think that section [Participant was pointing to screen shown in figure 1.21] *will be really helpful for the patient." AM consultant 37*

6.2 Functions of the decision support tool and associated patient decision aid

This theme emerged after prompting HCPs to talk about the value the DST would have for them and their patients in preparation for decision making.

In summary, all HCPs appeared to have assumed that the tool was a comprehensive and efficient source of information, in that; it provided information in an objective and unbiased way. Also, they seemed to have assumed that the tool would be useful to explicitly assist in clarifying patient's preferences. They added that the use of graphics in combination with other screens, for example, more information about treatment options screen and how you feel about the options screen, would help them in guiding patients step-by-step through all available choices to weigh or narrow their options. They also suggested that the use of interactive visual demonstrations of benefits and effects of anticoagulants and the ability to give out leaflets and information material would support patients' understanding of verbal information, therefore enhancing information communication and recall. Moreover, all research respondents indicated that the decision support tool had potential to promote shared decision making with HCP and patient together.

6.2.1 Providing information and clarifying preferences

Healthcare professionals said that the tool is a step in the right direction to improve clinical care for patients by providing accurate, evidence-based, balanced, and understandable information.

"…I think it's a step in the right direction…" AM consultant 10

"It looks quite comprehensive. It seems to have everything that you'd need there" GP 17

"The tool helps in decision-making and…to share information [with] the patient, about the risk and benefit, and you can provide information in a more logical and simple way, which helps them to understand..." AM consultant 28

All HCPs liked the way information is presented in the decision aid to explain several things that were important for patients to decide about whether or not to take anticoagulation therapy to reduce the risk of stroke and which one to take.

"…the information regarding atrial fibrillation, the risk of bleeding, the risk of stroke, I think they are good pieces of information." AM consultant 28

"…all the available options are there…to discuss with them [patients]…." nurse 39

Research respondents were quick to explain the importance of giving patients information leaflet on their condition and treatment. For instance, a prescribing pharmacist identified these as an important and useful resource for enhancing patients' understanding and retention of information, because they are having something documented to refer to when they needed it.

"… patients can then go away and look back on what you've said because you've given them the printout. I think their understanding will possibly be the same at that time, but their future understanding will be better... because what they understand at that time may be lost if they haven't got something to refer to when they go home. The retention of that information will be better, I think." IP pharmacist 26

Moreover, this prescribing pharmacist appeared to assume that the leaflets would be a good prompt for patients by encouraging patients to raise pertinent questions and feel more

confident to communicate with a pharmacist or their GP seeking a further explanation about a specific point.

"…I think some of the information that you can print off for the patient seems to be quite useful because…they may not be able to speak to me again, but they may be able to speak to the pharmacist or take to their GP and say, 'I was given this. I didn't think of this at the time, but can you answer me this?' So, they've got something concrete, yeah." IP pharmacist 26

The following AM consultant highlighted the added value of providing written information to patients, in terms of preparing patients for follow up visits, so that patients can come prepared. This would potentially facilitate the discussion and speed up the consultation.

"…Potentially they could even look at this before the consultation and then have an idea of what they want before they even come and see you. So, they come prepared... So, it might even potentially speed up the consultation…" AM consultant 37

Moreover, there was a high level of consistency of comments for the usefulness of visual aids to facilitate patient education and recall of information. HCPs indicated that graphic representations are helpful additions to the information material within the tool to improving patients' understanding, and recall, especially when they are presented along with verbal information.

"… It's more likely to be remembered and also more likely to stick than verbal or just words" IP pharmacist 26

There was steadiness in opinion among HCPs that two screens were assumed important to support the decision-making process; 'More information about treatment options' screen and 'How you feel about the options' screen. They were considered useful to help patients

to get unbiased information about available treatment options and to clarify patient values and preferences. A screenshot of the screens at figures 1.20 and 1.21 from chapter one

"… [the section which asks questions] about problems with what foods I can and can't eat and whether I need to have my blood checked regularly. All those sorts of things are right there. So, I think that will help them clarify things…When they're trying to come up with a decision for what's best for [them] to take." AM consultant 37

"…So that's fine. And when maybe the other screen when you ask to find how important the dose, the monitoring, find what is and is not important." AM consultant 5

6.2.2 Promoting shared decision making

Evaluating the tool from a HCP-centred perspective revealed that patient involvement in the prescribing decision could be enhanced by the use of the tool in clinical practice.

The majority of HCPs indicated that the DST could help improve the decision-making process and decision quality by promoting shared decision making, in that patients can make their own informed choice of which option to take.

"I think it would clearly help, in terms of making a shared decision and making an informed decision from the patient's point of view. I think [it] facilitates the discussion. Also, it would be allowing the patient to come to an informed decision…" AM consultant 37

Research respondents tended to explain how the tool would facilitate the shared decision-making approach, in that, it can help patients be actively involved in each step of the process, and can see that the treatment recommendation is tailored to them. As a result, patients feel they have made an informed choice.

"…it gives the patient an opportunity to see that they're involved in their own decision making, and it gives them an idea of what goes into that decision making…"AM consultant 37

"…definitely heavy involvement for the patients…obviously a lot of sharing decision elements with the patients, so I think that's probably its biggest impact." IP pharmacist 35

"I think that's where it really lends itself because obviously, the patient can sit alongside the prescriber and…by sharing information about themselves, they can see that the treatment that's being recommended has been tailored to them, so it would help them feel that they've been really involved in choosing the correct agent for themselves." IP pharmacist 29

An acute medicine consultant suggested that patients' involvement in the decision-making process would increase patients' confidence in treatment decision outcomes and can impact adherence to treatment. As stated:

"Well, it will probably give more confidence to the patient…because they are better informed, it would make adherence better." AM consultant 5

6.3 Perceived value from implementing the decision support tool into routine clinical practice

6.3.1 Help HCPs to structure and standardise their practice

Most HCPs viewed the use of the DST in the decision-making process in routine clinical practice advantageous over their usual practice, partly, because this kind of decision support intervention was seen rather more structured, more organised and that they were less likely to overlook anything during the decision-making process.

"I guess the advantage is that you are never gonna [going] forget an important area, so that's an advantage, and the other advantage is that all the information is in one place." GP 15

"…it's more organised and more structured..." AM consultant 37

The following prescribing pharmacist described his usual practice as free-flowing flexible discussion, which put him at risk to miss things out from his discussion; hence, this would impact the quality of the informed decision the patient going to consider.

"I think by using this tool you're more likely to cover all the areas more consistently than having a more free-flowing flexible discussion, where there's a risk maybe that you don't talk about HAS-BLED scores and addressing the need to reduce the HAS-BLED score. I think if you have a more flexible discussion there's a risk that you'll miss things out from your discussion, so perhaps the patient isn't able to make a truly informed decision." IP pharmacist 36

Acute medicine consultant suggested that if all HCPs used this tool regularly, this would standardise practice at the level of both the individual and the whole trust.

"The tool helps in decision making and… it will also standardise the practice for everyone." AM consultant 28

6.3.2 Help provide Healthcare professionals with information and resources that are relevant to the topic

All HCPs valued the ability of the tool to provide links to relevant content in online information resources. They also highlighted the important role of the information button to help them to resolve many of their information needs and allow them to find answers to their medication-related questions more quickly. Particularly, those related to links to

Summary of Product Characteristics (SPC), British National Formulary (BNF), NICE clinical guidelines, and drug interaction checker, as illustrated in figures 1.3 and 1.26 from chapter one.

The majority of research respondents felt that, in principle, the tool provided them with all the evidence-based information, risk/benefit assessment scores, and resources that are most likely to be relevant to all aspects of decision making.

"The information that's provided on the tool is quite good, and it is extremely helpful, especially to professionals who don't do this on a day-to-day basis. and what I particularly liked is the references that were provided and the easy click, especially to NICE, as well as drug interactions and various other aspects of the tool, and that was available." Stroke consultant 19

Most HCPs commented on the background screens or hidden screens, in that, these screens were considered detailed, easy to access and pick through the relevant information and that are directed to specific content. Example of hidden screen is provided in figures 1.15 and 1.16 from chapter one.

"I think some of the back-slides, so there's quite a lot of information, but I think that's important that it's there…if you wanna [want] go and look for more information than you can get it, and then – and it's sort of easy, and it seemed reasonably easy to sort of pick through the relevant bits really." Haematologist 6

An acute medicine consultant commented that the *'i'* buttons can be used to promote learning for many HCPs, in that, it can help to resolve many of information needs, especially those related to knowledge gaps.

"Yeah, very good, everything is in there, again it, the information provided lends itself more to someone who is learning about something rather than just using it, so, you know

you click on the 'i' and it gives you a whole page, two pages of stuff which you will read, I think it will be a useful thing generally for people to learn about" AM consultant 31

All HCPs indicated that the tool could be a valuable resource for learning, providing education opportunities, and useful for helping them to be aware of the evidence, adhere to clinical guidelines and make an appropriate and safe decision. This was evident because the tool can provide detailed information about options, the benefits and harms of each option, and narrows down the options to which agent they can use. As reflected below:

"You've got everything. You've got all the guidelines there. You've got CHA_2DS_2 /VASc, HAS-BLED. You've got the factors that influence the decision between Warfarin and NOACs. So, it's quite good…" Senior cardiology registrar 22

"…all of the information that you need to know to make the right decision for the oral anticoagulation. I think that has everything in there and it would be great." Senior Cardiology registrar 22

"I think it's a really good tool especially for those who don't know much about guidelines and dosing..." Senior cardiology registrar 23

Most HCPs indicated that the DST was useful because it helped to narrow down to which agents to recommend. Example below:

"I think it's very useful because it helps us narrow down which agents they can use and what are precautions that we need to take care of when coming to using those agents. So, I think it's extremely useful in that case." Senior cardiology registrar 30

For HCPs who expressed fear from bleeding risk with OACs, and over-estimated bleeding risks with some patients, they valued the ability of the DST to quantify bleeding and stroke risk scores and draw attention to interaction and dose consideration. A GP stated:

"I think probably because we over-estimate the danger of bleeding with warfarin and NOACs, so I think it will probably quantify that much better with regular use of HAS-BLED and I like the fact that it's draws in interactions and it draws in different doses for different problems, so it's good. I like the way that the yellow card prompt came up as well. It was clever." GP 7

Even though many respondents reacted positively to the pivotal role of the tool in improving the quality of the decision-making process, there was a general sense of concern about its usefulness for experienced healthcare professionals with many years of experience in the field. This trend was obvious among stroke and cardiology consultants who made the similar decision many times every day.

"…it's useful then for people that haven't got that much experience or need that extra guidance …" Stroke consultant 11

"… I'm doing it all the time as my main subject, so every clinic I'm seeing three patients with it, so it's not really something I have to look up each time but if atrial fibrillation is just a small part of my practice then it would be useful and just to remind me of what the various factors are..." Cardiologist 20

6.3.3 Encourage the implementation of shared decision-making approach

All respondents agreed that this tool has the potential to promote shared decision-making for the HCP and patient.

"…it's a useful consultation tool because the patient's sitting there, it's graphic, so, you know, it's reinforcing a verbal message as well… it will just bring in robust evidence, and the accurate facts and figures to patients…I think it should allow the patient to have all the information they need."" GP 7

"…the tool helps in decision making and shared decision making…" AM consultant 28

The majority of respondents felt that, in principle, the tool would enable them to explain to patients in simple term and understandable way of what is AF, what are the risks associated with AF, and what are the benefits from therapy, which otherwise would be quite difficult for most patients to understand.

"I think it would clearly help, in terms of making a shared decision and making an informed decision from the patient's point of view…also it would be allowing the patient to come to an informed decision. So yes, I do believe it would help…. I think it helps to visually explain what we mean by a risk of stroke of so many percentages per year, which I think otherwise would be quite difficult for most patients to understand. So, I do think it's a good tool." IP pharmacist 36

Overall, participants valued the tool for its ability to empower patients in the decision-making process and increase the overall care of patients. Example provided:

"I think it will increase the overall care of the patient. It will improve prescribing. It will empower the patient in the decision-making." AM consultant 28

6.3.4 Help healthcare professionals to improve their prescribing practice

Healthcare professionals revealed that the use of the DST in anticoagulation decision-making process would have the potential to improve their prescribing practice, as indicated below:

For example, a stroke consultant seemed to have assumed that compared to his usual decision-making approach, the use of this tool might help in reducing the number of decisions which are not right. He stated:

"In normal practice, a lot of times we depend upon what we think and believe which may not be right…I think this tool will be instrumental in reducing the number of decisions which are not right" Stroke consultant 43

An AM consultant suggested that one of the potential advantages of implementing the DST in clinical practice is to reduce the opportunity of making a biased prescribing decision.

"I think it's a good tool and rather than being bias by certain people coming in and asking us [to prescribe specific agent] … this is better…" AM consultant 41

The majority of HCPs indicated that using the DST in the decision-making process can help in applying a comprehensive assessment of patient before they consider treatment decision. In particular, assessment of patient's bleeding risk, stroke risk, renal function, drug interaction, and patient's weight. As reflected below:

"…It [the tool] involves forcing the physician to think about their renal function and their bleeding risk and their interaction with other medication. It kind of enforces everything that they should be thinking about, so I think it's helpful in that way." Haematology registrar 42

"…Again, I think it's a tool which makes sure you don't overlook something, that you always follow the same steps consistently, you might find oh I forgot about the fact that the patient was 50 kilos" IP pharmacist 35

"Well I think, sometimes when we make a decision we don't look at all the contra-indications for example, but if they're all right there in front of you then you know, you'd probably think more about those things, so it might be the case that it might make us think more about things." AM consultant 33

The following nurse pointed that it is a very safe tool because it is based on evidence-based best practice.

"...we've got the best evidence available, and that's based on the best evidence there is at the moment. That is a very safe tool as far as I'm concerned, and that's best practice…" Nurse 21

6.4 Perceived concerns from implementing the DST into routine practice

Participants were also asked a series of questions to elicit their opinions of the potential concerns from implementing the DST into routine clinical practice. Potential concerns were; (1) time pressure, (2) confidentiality, (3) over-reliance and transfer of power to decision support tools, (4) concerns regarding a patient-HCP relationship, and (5) information overload.

6.4.1 Time pressure

Most HCPs perceived time pressure during the consultation as a potential concern from implementing the DST into routine clinical practice. Example provided:

"Because going through this tool might take time. Sometimes I do a ten to 15-minute consultation in the clinics, so going through the tool can be a little bit cumbersome. So, time can be a barrier." Stroke consultant 34

Even though time pressure during consultation was perceived as a potential concern, HCPs indicated that they should accept the fact that using the tool in practice would impose extra time, because it is detailed and comprehensive, and the fact that they cannot ignore any piece of information, because of the nature of the decision that needs to be made.

"The disadvantage, it's the time, but we have to accept that it takes time, because it's a good tool, it's detailed, it takes time. You can't ignore a piece of information to make it

smaller, if you would like a big thing [comprehensive] then [it takes time], you have to go through it, [it] takes time, yeah. It's not a two seconds decision to make." Cardiology specialist 18

In a GP opinion, the issue was not inherent to the DST itself, but it is the nature of the decision that needs to be made.

"I don't think it's the tool that's making it take longer. I think it's a long discussion to have anyway." GP 15

A further comment came from AM consultant, who felt that the tool would make his consultation time longer but that because he needed to go step-by-step through the decision, compared to his practice, where he just skipped many steps and tended to discuss very few things with patients.

"It might take longer because you'll be explaining a lot of things and ...So if you don't use the tool you've been using, you'd be explaining to them only a few points which you think are very important. So yes, it may take longer." AM consultant 5

Additional comments from HCPs clarified reasons behind their concerns from the potential increase in consultation time with using the DST. For example, most of them indicated that sharing the decision-making process with patients may raise a couple of more questions by the patient. As indicated below:

"it shouldn't take any longer, but it may raise a couple more questions. The things that they can't see words, they don't understand. So, it might make the consultation longer…" AM consultant 3

"…but the thing is they'll ask all sorts of questions, and they'll be a lot of discussion about it so that's where it will take more than ten minutes." GP 17

Other HCPs talked about technical aspects and information technology, rather than any inherent attributes of the tool. As reflected below:

"The trade-off might be that it's more quality but obviously a bit more time consuming and that may well just be the simple things of having to get the right equipment ready, all set up and running, so it possibly could be a bit time consuming probably from the technical aspect of it rather than the clinical aspect." IP pharmacist 35

The majority of HCPs indicated that the DST was the right thing to have for anticoagulant decision making, and they were keen to provide suggestions of what can be done to make it easier for other HCPs to use it. As listed below:

Speciality clinic: many have suggested that this tool would perfectly fit in speciality clinics because they have 20 minutes for each patient.

"You'd have to have a separate Clinic for it…" Stroke consultant 12

"…I'm very lucky, that I get 20 minutes …" nurse 13

Getting used to it: others thought that the more they use the tool, the better they get used to it

"I think, with time, it will be useful…. Yes, when you get used to it, it's quicker" Stroke consultant 43

Be prepared for next patient: A specialist nurse felt that in her practice, she has the opportunity to prepare herself for next patient, so she can set up the computer and go through few details before the patient appears in front of the clinic door.

"…because I tend to read through my patients before I see them, so I've got a bit of a background going on. It perhaps would be good to go through it prior to seeing the patient and having that decision support tool already up and running…" nurse 13

Two-stage approach: all GPs suggested a two-stage approach to use the DST, which appeared to match how they usually break the consultation into two parts. As illustrated below:

"…So, you kind, of do need a two-staged approach where in between the first and second consultation there's adequate information that's given out." GP 15

One-stage approach with the use of paper format and leaflets: Few HCPs assumed that if HCPs use the paper version of the tool to discuss and share the decision-making process with the patient, then it would be more likely, that using the DST will not make the consultation time longer.

"If you can provide all the relevant information in the paper format as well… you can discuss and share the information and make a decision and provide the rest of the information in the paper format" AM consultant 28

All HCPs assumed that using the DST and associated PDA during decision-making process may take between 10 and 20 minutes.

"I think it's going to take at least 15 minutes to work your way through this if not longer." Stroke consultant 8

"I need to have ten minutes to do it properly and probably 15 minutes to print it out, save it and give the information." Stroke consultant 12

"*…if you go through the whole thing you may need to spend at least about 20 minutes per patient which sometimes can be difficult, that's the main issue." AM consultant 41*

6.4.2 Confidentiality

Few HCPs expressed their concerns regarding confidentiality status because they were entering patients' name and date of birth into an external electronic system. They were

reassured by referring to storing of patient details screen. As illustrated in figure 1.9 from chapter one

"Well, I think the first thing we were talking about, is always on any external website or web link then every trust and NHS body is going to be concerned about the confidentiality of the information and would want reassurance that personally identifiable data isn't being transmitted to a database for any purpose that isn't agreed and approved beforehand…" Stroke consultant 11

"Probably, I'm always a little anxious about putting patient information data on a system that's outside of our own, even though maybe it won't go beyond the computer." GP 7

An AM consultant assumed that this might be patients' concerns as well.

"…they [patient] may not be keen on having their details put into a website nationally…." AM consultant 37

6.4.3 Over-reliance and transfer of power to decision support tools

Only one respondent held a strong view against using the decision support tool in practice. In probing, more deeply into his resistance to recommending the use of decision support tool in practice, it became apparent that his reluctance was toward the use of any kind of decision support tool. As such, he remained a deviant case on this point.

- Potential 'deskilling' effect

"…I think in the long term that might deskill some of our clinicians and prescribers from having complex and informed discussions with patients." IP pharmacist 36

- Promote over-reliance on software; limit clinicians' freedom and flexibility in decision making

"…What you will have though is a move to have a decision support system for COPD; a decision support system for diabetes; a decision support system for anticoagulation. The risk when you have so many tools based complex discussions is that you replace good physician practice and perhaps a more flexible discussion with the patient, to determine whether they want to have an informed decision or whether they want the doctor to make the decision for them and how involved do they want to be in their care…" IP pharmacist 36

"…Maybe we're fragmenting too many decisions down and relying overly on computerised decision support tools…" IP pharmacist 36

- Can be perceived as a threat to clinical judgment

"…I think the risk is that you rely on the tool to replace your underlying understanding of the issues…" IP pharmacist 36

- Can be perceived as a threat to clinician desire for learning

"…Where maybe it's an underlying knowledge and understanding issue that's preventing people having an informed decision…So then you don't go away and find out more about the HAS-BLED score or a CHA_2DS_2-VASc score because the computer does that all for you…" IP pharmacist 36

6.4.4 Concerns regarding patient-healthcare professional relationship

Healthcare professionals were specifically asked whether using this tool during patient encounters would affect the relationship with their patients. Responses were mixed, but there was a general sense that using the tool would effectively enhance the relationship, making it a stronger relationship. This was potentially in part due to the potential for

improving communication with patients by giving them more information and involving them in decisions regarding their health.

"I suppose if you've got a situation where you're improving communication with the patient by giving them more information then yeah potentially that's of benefit to the patient-practitioner relationship." IP pharmacist 27

"It can improve our relationship with the patient." Stroke consultant 43

Contrary to the potential positive impact on the patient-HCP relationship, few HCPs expressed their concerns regarding patients' potential attitudes towards their healthcare provider when they used a computer to decide on treatment. This view was common between cardiologists and some of the stroke consultants, who felt that patient may view them as incompetent if they use a decision support tool during the consultation.

"I think it would, that the doctor isn't really competent if they need to use a tool…because they think that the physician maybe doesn't know the answer…" Cardiologist 20

"I don't think it should affect, but I can see it as... most patients would... I don't want them to feel or think, 'Oh, this doctor doesn't know what he's doing, and he's relying on the computer to make a decision'..." Stroke consultant 38

A haematology registrar said that using the tool should not have an adverse impact on patients' attitude towards their clinician. Given this, she suggested that it might change the dynamics of the doctor-patient interaction in that both are looking at a screen and are not looking at each other.

"It does change the dynamics of the doctor-patient consultation because it'll be more like you're talking to the computer rather than the patient… changing the way that you're

consulting the patient, in that the two of you are looking at a screen and you're not looking at each other." Haematology registrar 42

Additionally, A stroke consultant considered eye contact with patients during the clinical encounter is necessary for building a good face-to-face communication with patients, and he seemed to have assumed that using the DST might be a concern for some patients.

"Not in particular, and again it will depend on a person's nature, as I said to you. There are a lot of patients who would prefer a face-to-face consultation with eye contact rather than the physician sitting in front of them and solely relying and focusing on the computer. That may not go down very well in a certain group of patients." Stroke consultant 19

6.4.5 Information overload

Few HCPs felt that the amount of information presented to patients was a bit too much, and patients may feel confused. As shown in the example below:

"From a physician's point of view, that's fine, but from a patient's point of view, I think it's a bit too much information loaded." Stroke consultant 38

An AM consultant explained that the main reasons for the potential for patients' confusion were that because patients are new to the topic and HCPs are giving away so much information patients can only process a limited amount.

"…because they're new to this NOACs and everything, and you're giving so much information in a short period of time, so there is a possibility that it may be difficult for them to be honest." AM consultant 41

Those HCPs were keen to provide suggestions to deal effectively with information overload during the consultation. For example, the following consultant suggested that

introducing the tool to patients before running the program, and explaining what they expect from it, would help patients to understand better.

"... so, before you use it you have to take a guided tour to the patient first so that he understands what you are trying to say." AM consultant 5

Another consultant suggested to control the amount of verbal communication and to give patients a printout material to read.

"... the question is would the patients get information overload, and I think the key you need to control the amount of information the patients get to the key messages…You can give them a printout" Cardiologist 9

6.5 Professionals' initial satisfaction

Up to this point during the interview, all participants were asked about initial satisfaction with using the DST in the decision-making process. Thirty-eight professionals were satisfied. However, nine were comfortable with the tool but said that they were not sure until they tried it out. As reflected below:

"Very satisfied" AM consultant 41

"I would say I'm fairly satisfied with it. I've not used it enough, but at the moment I'd say I'm fairly satisfied…" AM consultant 37

"You know, that's difficult to say unless you practically use it." Haematologist 1

A GP gave it a score seven out of ten. She explained that the score could be pushed to ten if the tool were streamlined and embedded in EMIS web, which then would make her satisfied.

"I would say I was – on a scale of 1 to 10 of 10 being extremely satisfied; I'd say I was probably about a 7. And, you know, again if it were streamlined a bit more it would

probably be pushed up to a 10. And what would actually really push it up to a 10 was that if it were a combination of streamlined and embedded into EMIS web at the same time, and then all you need – cause once it's embedded in EMIS web all you need is a click of a button for the CHADS – one click for the CHADS-VASC to come up, because it automatically does it, and we'd like that with HAS-BLED, so that would definitely make me satisfied, yeah." GP 15

6.6 Overall view on the current decision support tool

All respondents were asked to summarise the decision support tool and associated PDA as its now. All HCPs seemed to consider the DST novel, user-friendly, and promising, as indicated below:

"This is something which I think is quite novel, and it is a good thing to have..." Stroke consultant 19

"It looks like it's a very thorough, well-informed…" GP 7

"Promising, seems quite clear, again structured and definitely heavy involvement for the patients." IP pharmacist 35

"It's very good. It seems user-friendly…" nurse 32

"… it has potential." AM consultant 10

"I think it looks very good and very promising. I'm very impressed with this as a tool. It's simple and easy, in that it's straightforward to use" AM consultant 37

6.7 Recommendations for promoting more effective use

This section presents strategies for improving the tool design and potential dissemination. Most of the strategies were drawn from respondents on the decision support tool, however,

were related to the tool dissemination. While the majority of HCPs were satisfied with the tool content and format, a few suggested information that could be included.

6.7.1 Strategies for promoting the tool widespread dissemination

6.7.1.1 Promoting awareness of the tool availability

Since the majority of interviewed HCPs were unaware of the availability of 'Keele anticoagulation therapy decision support tool', most participating HCPs suggested promotional strategies to let potential users know about the tool through effective and targeted strategies. As illustrated in the examples below:

- *"…advertising through the trust network…" AM consultant 5*
- *"…internal communications, such as lunch-time meeting, or clinical meeting…" Stroke consultant 8*
- *"…direct-to-colleague communication about the tool usefulness…" Haematologist 1*
- *"…local teaching sessions for GPs, or an online module…" GP 7*

6.7.1.2 Targeting appropriate users and healthcare setting

Obviously, because not all anticoagulant clinics are consultant-led, HCPs suggested integrating the tool within:

Nurse-led clinic

"It helps to establish the nurse-led clinic… it can be [yes, done by the nurse] and this tool can support the nurses in decision-making." AM consultant 28

"We've got nurses working in the anticoagulation clinic so these sorts of conversations are mainly held between nurses and patients, so I could see them using the tool." Stroke consultant 8

Pharmacist-led clinic

"Well, cause obviously not all anticoagulant clinics are doctor-led, so I think, you know, we've got a pharmacy-led, and I do think it wouldn't be unhelpful..." Haematologist 6

GP-Practice

For instance, a specialist nurse spoke from her experience and declared that this tool would really help GPs in deciding to prescribe OACs to patients because there is usually a big time lapse between a GP appointment and referral to secondary care. This time lapse puts patients at high risk of having a stroke before being seen by hospital-based doctors.

"I think it would be very useful for anybody… especially GPs…For Primary Care, this would really aid them in making a decision to anti-coagulate patients because there's always a big-time lapse between a GP seeing a patient, then a referral being made into Secondary Care. So that risk of stroke is huge…I think if patients can be anticoagulated quicker in primary care. It would be so useful and safer." nurse 13

"Well, I think it's good for a Primary Care physician who's got an anticoagulation interest." Haematologist 44

"I think it's absolutely ideal for GPs, [and] non-GPs. Yeah. I think it's geared towards nurses and pharmacists..." GP 15

Most HCPs explicitly referred to the potential usefulness of the tool for GPs in primary care. They indicated that using the tool by GPs will help them to take the lead responsibility for the first prescription of anticoagulants. For example, stroke consultants suggested that implementing the DST in primary care would certainly assist GPs in the appropriate prescribing of NOACs, and give them better guidance and confidence through the prescribing decision.

"Certainly, there is scope for using this tool, perhaps in primary care where colleagues probably are less experienced in prescribing anticoagulants that may be something to help, boost their confidence and get a better idea about prescribing NOACs…" Stroke consultant 19

"I think if you implemented this in GP practices they would be very happy to use this tool to decide on what anticoagulation, especially in a primary care setting." Stroke consultant 34

"My GPs colleagues who are not much used to anti-coagulate patients; I think for that kind of people who are doing this day in and day out it will be very, very useful for them." Stroke consultant 38

Moreover, a prescribing pharmacist suggested that this tool would be useful for HCPs who are not familiar with the prescribing of NOACs.

"I think because I see so many mistakes with NOACs (not so much with Warfarin) and it's only because people don't know the various options that are out there and particularly as NOACs become more generalised and you see more of it in Primary Care, I think it will be useful, particularly for those who are using it and are unfamiliar with the prescribing of NOACs." IP pharmacist 26

6.7.1.3 Promoting the tool availability

Healthcare professionals were keen to suggest additional strategies that would motivate them and other colleagues to implement the tool in their routine practice. Strategies are listed below:

Obtain organisation approvals

"I think integration within the clinical system will be really useful, yeah." GP 7

"Integrated and encrypted, yeah." Senior cardiology registrar 30

Trust approvals

"So, if it is approved by the Trust, if it is integrated, so we are more than happy to use it. So, it's within the policy" IP pharmacist 2

IT department approval

The following AM consultant suggested that they also appreciate approval from IT department to agree for the link to be on the trust guidance system.

"I think the most important thing is we need to get the IT department to agree for the link to be on our guidance system that will be the most important." AM consultant 41

Drugs and Therapeutics Committee approval

"I imagine it would have to go through the Drugs and Therapeutics Committee here and if they were happy, then as a decision aid, it would be fine…I guess they would just be saying, 'Yes, we would validate the information', yeah." AM consultant 3

Integrated into the EMIS

"If it could be linked to EMIS, that sounds really good, or if it's linked to an EMIS number that sounds better…where potentially it could extract the information from EMIS…that's really useful." GP 7

Get it approved by the health economy

A prescribing pharmacist suggested that the tool need to be approved by the whole health economy, so this in return may produce consistent prescribing practice among hospitals and primary care practices involved.

"I think you need to make sure that all the health economy like the proxy CG and the hospital and everybody is all signed up to using it consistently across a health economy or a region…" Stroke IP pharmacist 29

Patient feedback and approval

Few HCPs suggested patients' involvement in the decision to implement the DST into routine clinical practice is necessary to stimulate trust approval of the tool, as evidenced below:

"Well…If it is proved that the patients like this kind of format and if they come in overwhelmingly saying, 'Yes, we like this', then we should go ahead…That probably is the biggest factor to approve or confirm whether we need to go ahead…" Stroke consultant 38

6.7.2 Strategies to promote the tool design and content

The initial evaluation of the DST by potential users provided insights into additional content and features to satisfy their real need to make better decisions. As listed below:

Drug interaction checkers

Prescribing pharmacists suggested including Stockley's drug interaction checkers www.medicinescomplete.com

"So, I think the interaction checker needs to be one not based in the United States, but needs to be based via the Stockley's drug interaction checker via medicinescomplete.com" Cardiology IP pharmacist 36

Renal function test

Most HCPs from both secondary and primary care suggested adding a link to Creatinine clearance formula because usually, they calculate it manually.

"You could probably put a formula in there. So [you] tick the link to calculate creatinine clearance, yeah" GP 45

Informal contact with HCPs other than those who participated in this evaluative study suggested including the following:

- Alert reminder to assess patient's risk of fall
- Alert reminder to find if the patient use tablet dispenser (e.g. Medidos, dosette box) for administration
- Help line (as shown in figure 1.5 from chapter one)

"I mean if there's a helpline on there. Oh...There's a helpline if I got stuck... Right..." nurse 24.

In the context of improving the tool design, it was found that all HCPs were satisfied by the tool format, presentation and design. However, only a few HCPs 6/47 (approximately 13%), suggested a strategy or design feature to present information in a way that allows easy access to certain items without the need to go through the whole tool.

De-coupling the screens

Few HCPs indicated that different clinical settings or different patients' needs might find different information relevant. For example, rather than simply going through the pages to get to the PDA, they suggested breaking the decision support tool and associated patient decision aid into two discrete components. As illustrated below:

"That's what I mean; you could de-couple it so that they're all separates, which is what I thought. But then the problem with that is you don't have the information running through. So when you're putting in the patient's age or weight or whatever, if they're all uncoupled then it might not be quite an accurate answer. But if it were decoupled it would

actually be beneficial. That way you could just let the patient use their patient decision aid bit, or if you just wanted to use the CHADS-VASC and HAS-BLED, then you could just use that bit. So, I think that's the number one change I would make with it." AM consultant 37

6.8 Quantitative Findings

This section presents the data gathered from questionnaires given to all research respondents after conducting the semi-structured interviews. The questionnaire consisted of four parts; demographic section, preparation for decision-making scale, acceptability scale, and End-User Computing Satisfaction (EUCS) Instrument (attached as appendix nine). Data analysis was mainly descriptive statistics to describe the sample via mean (M), standard deviation (SD), and percentage (%). At this stage of the research, descriptive statistics were sufficiently suitable to exploring health professional's perspectives on the utility, satisfaction, and acceptability of the decision support tool and associated patient decision aid. Data was gathered from all 47 respondents.

All descriptive statistics were computed using the Statistical Package for the Social Sciences (IBM® SPSS®, version 24, using a personal computer).

6.8.1 Preparation for decision making

In this study, the PrepDM scale enabled research participants to initially assess the potential usefulness of patient decision aid in preparing patients to communicate during the consultation and to make an informed decision (as discussed in section 4.3.2.1).

The mean score across all items was more than 3 with a possible range of 1 (not useful) to 5 (very useful). The only exception was a mean score of 3 and less for the practitioners' ratings of the potential effect of the DST might have on time spent during the consultation visit and on patient–physician relationship as illustrated in table (6.1)

Table 6. 1: Mean score of all items of the Prep-DM scale

PrepDM Statements No.	Prep DM 1	Prep DM 2	Prep DM 3	Prep DM 4	Prep DM 5	Prep DM 6	Prep DM 7	Prep DM 8	Prep DM 9	Prep DM 10	Prep DM 11
Mean (SD)	4.02 (0.897)	3.77 (1.047)	3.30 (1.214)	3.96 (0.908)	3.87 (1.096)	3.79 (0.907)	3.83 (1.090)	3.32 (1.181)	2.85 (1.367)	3.02 (1.310)	3.45 (1.176)
Minimum	2	1	1	2	1	1	1	1	1	1	1
Maximum	5	5	5	5	5	5	5	5	5	5	5

Table 6. 2: Professionals responses to all items from Prep-DM scale

To what extent does the use of the patient decision aid (PDA) by your patient	A great deal /Quite a bit	
	N	(%)
1. help [patient] to fully understand the risks and benefits of anticoagulation therapy	33	70.2
2. Help [patient] identify the importance [patient] places on the risks and benefits of anticoagulation therapy	30	63.9
3. Prepare [patient] for the follow-up consultation visit	22	46.8
4. help [patient] be as involved in the decision-making process as [patient] desired	33	70.2
5. help [patient] to make a more informed decision	33	70.2
6. Help you to understand the issues more fully that are most important to [patient]	34	72.3
7. Help you tailor your counselling to [patient] preference for decision participation	33	70.2
8. Facilitate the follow-up consultation visit	23	48.9
9. Affect the patient –physician relationship	13	27.6
10. Improved the way time was spent during the follow-up consultation visit	19	40.4
11. Improved the quality of the consultation visit	26	55.3

PrepDM scores at this stage of the project suggested that the patient decision aid had potential as a tool in preparing patients to communicate with their practitioner about their treatment decisions. As illustrated in table (6.2), responses were grouped into categories to give meaning to HCPs' responses. More than 70% of respondents perceived the decision aid helpful for patients to understand risks and benefits of treatment options fully, be involved in the decision process, and enable patients to make more informed decision. Similarly, more than 70% of respondents agreed that the tool would have the potential to

help HCPs to explore patient needs and tailor the consultation to meet patient preferences. Respondents expressed diverging views on the statement of whether the tool would improve the way time was spent during consultation; 19 respondents (40%) thought that implementing the DST into routine clinical practice may improve the way time would be spent during the consultation. One-third of respondents expressed their concerns that using the tool during consultation would negatively affect their relationship with their patients. Overall, over half of respondents would have thought that using the tool in practice would improve the quality of the consultation.

6.8.2 End-User Computing Satisfaction

Healthcare professionals' satisfaction with the decision support tool was evaluated by using five success measures: content, accuracy, format, ease of use, and timeliness. The construct was developed with a five-point Likert-type scale (1 = almost never; 2 = some of the time; 3 = about half of the time; 4 = most of the time; and 5 = almost always) (discussed in section 4.3.2.1). As illustrated in table (6.3), four measures were used for evaluating the tool content: precision of information, comprehensiveness, the sufficiency of information, and information that meets their needs. Two measures were used for evaluating the tool accuracy: accuracy of information and satisfaction with information accuracy. An additional two measures were used for evaluating the tool format: usefulness of the output format and clarity of information. Two further measures were used to rate the ease of use of the tool design-interface. Finally, two measures were used to evaluate information quality: timeliness and up-to-datedness.

As illustrated in tables (6.3) and (6.4), positive responses (most of the time and almost always) were grouped to show respondents satisfaction with all sub-scale measures. Specifically, the highest positive responses were given to; satisfaction with the tool format

(sub-scale mean 4.11, and 81.9% of respondents agreed to this success measure), followed by accuracy of the information (sub-scale mean 3.9, and 76.6 % of respondents agreed to this success measure), information timeliness (sub-scale mean 4.06, and 75.55% of respondents agreed to this success measure), information content (sub-scale mean 3.87, and 72.88 of respondents agreed to this success measure) and ease of use of tool (sub-score mean 3.96, and 72.4%) in order. Compared with the majority of success measures, however, two questions, one from content subscale and one from timeliness subscale received the least positive responses (most of the time and almost always) from research participants. Only 61.7% and 63.8% of respondents answered with either 'most of the time' or 'almost always' when asked about the usefulness of information output and timeliness to information need respectively.

In conclusion, HCPs' responses were consistent across all satisfaction success measures. Good responses to success measures from End-User Computing Satisfaction instrument supported participants' responses from qualitative responses on the tool's potential usefulness.

Table 6. 3: End-User Computing Satisfaction mean, minimum and maximum

Instrument questions	Cont 1	Cont 2	Cont 3	Cont 4	Accu 1	Accu 2	Form 1	Form2	Eas1	Eas2	Tim1	Tim 2
Mean (SD)	3.77 (0.813)	3.85 (1.021)	3.66 (1.089)	4.19 (0.851)	3.91 (0.929)	3.89 (0.914)	4.02 (0.921)	4.19 (0.876)	3.96 (0.908)	3.96 (0.908)	3.89 (0.983)	4.23 (0.865)
Minimum	2	1	1	1	1	1	1	1	1	1	2	1
Maximum	5	5	5	5	5	5	5	5	5	5	5	5
Average mean	3.87				3.90		4.11		3.96		4.06	

Table 6. 4: Professionals responses to all items from End-User Computing Satisfaction scale

	Most of the time/Almost always		
	N	%	Mean %
1. Does the tool provide the precise information you need?	33	70.2	
2. Does the information content meet your needs?	34	72.4	**Content**
3. Does the system provide reports that seem to be just about exactly what you need?	29	61.7	72.88
4. Does the system provide sufficient information?	41	87.2	
5. Is the system accurate?	36	76.6	**Accuracy**
6. Are you satisfied with the accuracy of the system?	36	76.6	76.6
7. Do you think the output is presented in a useful format?	37	78.7	**Format**
8. Is the information clear?	40	85.1	81.9
9. Is the system user friendly?	34	72.4	**Ease of use**
10. Is the system easy to use?	34	72.4	72.4
11. Do you get the information you need in time?	30	63.8	**Timeliness**
12. Does the system provide up-to-date information?	41	87.3	75.55

6.8.3 Acceptability

The acceptability questionnaire designed by the Ottawa Decision Support Group (ODS) was identified as appropriate to explore HCPs' acceptability of the decision support tool and feasibility of its implementation into routine clinical practice (discussed in section 4.3.2.1).

All interviewed HCPs were asked whether the decision aid would be feasible to implement in a real-world clinic setting by asking questions about acceptability in terms of perceived usefulness and perceived ease of use. Respondents were asked to rate each statement using the Likert scale, a rating of '1' means, that respondent 'strongly disagree', while a '5' indicates, that respondent 'strongly agree' to statements. Participants who responded by positive (agree and strongly agree) responses regarding the acceptability of the decision

support tool are summarised in table 6.5. Table 6.6 provides an overview of mean value to each statement from acceptability questionnaire.

Table 6. 5: Acceptability scale mean, minimum and maximum

Accept-scale statement	A1	A2	A3	A4	A5	A6	A7	A8	A9	A10	A11	A12	A13	A14	A15
Mean (SD)	3.68 (0.889)	4.11 (0.477)	3.83 (0.789)	4.15 (0.691)	3.53 (1.100)	4.09 (0.905)	3.70 (1.020)	2.60 (1.228)	3.72 (0.852)	3.79 (0.657)	3.77 (0.786)	3.74 (0.607)	3.79 (0.907)	3.30 (1.082)	3.68 (0.980)
Minimum	1	3	2	2	1	1	1	1	1	2	1	2	1	1	1
Maximum	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5

Table 6. 6: Healthcare professionals' responses to all items from Acceptability scale

In general,	Agree/ Strongly agree	
	N	%
1. It will be easy for me to use	32	68.1
2. It is easy for me to understand	44	93.6
3. It will be easy for me to experiment with using the strategy before making a final decision to adopt it	34	72.3
4. The results of using the strategy will be easy to see	41	87.2
5. Using this strategy is better than how I usually go about helping patients decide about their anticoagulant treatment	25	53.2
6. This strategy is compatible with the way I think things should be done	39	82.9
7. The use of this strategy is a more cost effective than my usual approach to helping patients decide about anticoagulation therapy	31	66
8. Compared with my usual approach, this strategy will result in my patients making more informed decisions	13	27.7
9. Using this strategy will save me time	31	66
10. This strategy is a reliable method of helping patients make decisions about anticoagulant treatment	33	70.2
11. Pieces or components of the tool can be used by themselves	33	70.2
12. This type of strategy is suitable for helping patients make value laden choices	33	70.2
13. This strategy complements my usual approach	36	76.6
14. Using this tool does not involve making major changes to the way I usually do things	25	53.2
15. There is a high probability that using this strategy may cause/result in more benefit than harm	31	65.9

The majority of respondents felt that the decision support tool was acceptable: 93.6% felt that it was easy for them to understand, (87.2%) felt that it was easy to see, and (82.9%) perceived the tool was compatible with the way things should be done. In this sense, more than three-quarter of respondents said that the tool complemented their usual approach.

More than 70% of respondents indicated that the tool was a reliable approach for helping patients making a value-laden decision. But only 27.7% of respondents (Total mean score was 2.6) indicated that, compared to their usual approach, this tool would result in patients making more informed decisions, and only half of respondents felt that using this decision support tool would be better than how usually they go about helping the patient decide about their treatment. As seen in table 6.8, 66% of respondents felt that using the tool will save them time.

Overall participants' responses indicated that they regarded the decision support tool as rather useful and easy to use. Nevertheless, the low overall ratings for some items when they were asked to compare the decision support tool approach with their usual approach showed that the acceptance was not high. The usefulness and ease-of-use statements received the highest possible positive responses in the range between approximately 70% and 90% of research participants.

Finally, participants were asked if they would recommend the decision support tool to others; the responses were ranked on a scale from '0' (not at all likely) to '10' (extremely likely). Responses were grouped, and the majority of forty-one respondents (87.23%) had a positive attitude toward the tool in general and would recommend the use of the tool to others, and replied between seven and ten, yet, only three participants (6.3%) replied between two and four.

6.9 Discussion

This study aimed to explore HCPs' perspectives on the potential utility of the DST in the anticoagulation decision-making process. This study employed a mixed-method approach to exactly understand respondents' views of the main features and interrelated functions that were necessary to help HCPs from different speciality and healthcare settings in the prescribing decision in clinical practice. Interview findings highlighted that the tool was designed to meet the decision context, in that, its format, design, and content all met HCPs' needs and perceived patients' needs.

The purpose of this section is to discuss the main findings from the initial interview stage of the study. Consideration is then given to how these findings relate to the literature, especially the literature on barriers and facilitators to implementing the DSSs in clinical practice that was discussed in chapter two (sections 6.9.1 and 6.92). Finally, Key points are summarised in the final section of the chapter.

6.9.1 Perceptions of the design features of the decision support tool

6.9.1.1 General design feature

The pre-intervention evaluation of the DST revealed design features that were essential to enhance the tool acceptability and user satisfaction. The healthcare professionals in this study reported on interface design and features that were in agreement with previous studies on acceptance of DSSs at the point of care (Bright et al., 2012; Gadd et al., 1998; Nygren et al., 1992; Tang et al., 1991; Wiedenbeck, 1999). Findings from this study indicated that the provision of the DST using computer and accessible from the internet would succeed in providing HCPs with support at the point of care. Compared to paper-format decision support tools, computer-based tools were more likely to succeed in providing support at the time and location of decision making (Bates et al., 2003;

Kawamoto et al., 2005). HCPs in this study perceived that the tool design and features have potential to speed up the consultation and improve the way time would be spent during the patient encounter. Evidence supporting these findings comes from studies evaluating user satisfaction with computerised physician order entry (Bates et al., 2003; Lee et al., 1996; Overhage et al., 2001). In these studies, the authors found that the primary determinant of physician satisfaction with information systems was speed (Bates et al., 2003; Lee et al., 1996; Overhage et al., 2001). The authors concluded that DSSs that have presented features and functionalities to speed up the consultation and facilitate the decision-making process is worth taking (Bates et al., 2003; Lee et al., 1996; Overhage et al., 2001).

6.9.1.2 Features related to communication and interaction

In this study, HCPs revealed that using visual aids to present given change in risk/benefit with versus without treatment necessary to facilitate communication during the consultation and to make an informed decision. Using graphical techniques, for example, pictographs to present individualised risks of stroke and bleeding was found to facilitate shared decision making with patients (Hawley et al., 2008; Man-Son-Hing et al., 1999; Tait et al., 2010; Zikmund-Fisher et al., 2008). The authors revealed that using pictographs helped all patients regardless of education and understanding levels to better comprehend risk information than statistical and verbal information alone (Hawley et al., 2008; Tait et al., 2010).

Interview data demonstrated the potential of the DST to resolve HCPs' information needs, especially those related to their knowledge gaps. Several studies demonstrated similar findings, in that, DSS users were able to answer their questions quickly; simply, by making information accessible to clinicians at the time, they need it, which in return positively affected patient care decisions (Magrabi et al., 2005; Westbrook, Coiera and Gosling,

2005). In addition to the tool ability to fulfil the obvious information needs that arise at the point of care, HCPs indicated that the DST had potential as a prompt to provide information that needed to be discussed with patients and considered in the treatment decisions, for example, patient weight and renal function when choosing the specific anticoagulant. The literature referred to this function as “latent need” (Bates et al., 2003; Chertow et al., 2001; Overhage et al., 1997). Effective decision support system was found to have the capability to anticipate the ‘‘latent needs’’ of clinicians (Bates et al., 2003). Another common feature valued by respondents was the ability of the tool to provide professionals with treatment recommendations that were supported with reasoning and important management consideration. Decision support systems that provide treatment recommendation rather than an assessment of patients were more likely to succeed in clinical practice (Kawamoto et al., 2005).

Research participants identified the ability of the tool to view and print patient-centred education material and information leaflets as useful. Gadd et al., (1998), highlighted similar feature that was found to improve perceived usability and motivate use. Finally, this study demonstrated the potential value of using the DST as an encounter documentation tool, that, it could perform tasks currently consuming additional clinician time. Encounter documentation feature was found to be most valuable to allow physicians to; record important information, process appropriate course of care, and was viewed as an incentive that could sustain physicians' interest in using the system (Gadd et al., 1998).

6.9.2 Perceived concerns related to the use of the decision support tool

Findings from interviews revealed that time pressure was the most often cited concern to implementing the DST in clinical practice. The majority of HCPs indicated that compared to their usual approach, more time would be needed to use the tool in the routine clinical

workflow. On the other hand, data from the acceptability scale showed that (66%) of respondents agreed/strongly agreed that using this tool could save time during clinical practice. Based on HCPs' responses from interview data, one can argue that using the prescriber part of the DST would have the potential to improve the way time would be spent during the clinical encounter, in that, it will save HCPs' time from searching information needed to make clinical decisions. Using the PDA was perceived as too time-consuming to be used during clinical encounter realistically.

Previous studies on PDAs, commonly cited perceived lack of time as a barrier to the use of PDAs in the clinical setting (Harrison et al., 2009; O'Connor et al., 2007; O'Donnell et al., 2006; Wittmann-Price et al., 2009). The literature is inconsistent as to the effect of decision support systems on time efficiency of clinicians (Chaudhry et al., 2006; Poissant et al., 2005), and in a study by Chaudhry and colleagues (2006) revealed that time requirement decreases as practitioners get used to the DSS.

Interview findings revealed that the provision of standalone decision support tool was perceived as a concern for successful implementation of the tool in both primary and secondary care. Research respondents suggested that integration of the tool into the clinical health system, e.g. EMIS, would more likely to enhance the tool uptake by GPs. These findings were in agreement with studies reported that compared to standalone systems, integrated decision support systems were more likely to succeed in clinical practice (Eckman et al., 2016; Kawamoto et al., 2005; Garg et al., 2005; Mollon et al., 2009).

Research respondents felt that the use of DST during the consultation would interfere with the doctor-patient relationship. In this regard, the literature reported mixed effect from using DSSs on doctor-patient communication. Harrison and colleagues studied the views of colorectal surgeons toward decision support tool use with patients and found that the use

of decision support tools during the consultation would interfere with the doctor-patient relationship (Harrison et al., 2009). For instance, in a study by Varonena et al. (2008) revealed that physicians' main worries from using DSS concerned effects on communication during the consultation (Varonena et al., 2008). However, in a study to explore the impact of computer use by GPs on doctor-patient communication in the Australian general practice, findings revealed, that patients tended to have positive attitudes towards the use of computers by their GPs during consultation, and commented that doctor-patient communication and the doctor-patient relationship were not affected, rather, contributed to quality of care and satisfaction with the consultation (Callen et al., 2005). Moreover, several previous studies found that using computers during consultation did not adversely affect doctor-patient communication during the consultation (Bomba & de Silva 2001; Bomba & Land 2003; Chan & McGlade 2003).

Whilst nearly most respondents were concerned about time pressure, only one respondent was concerned about the risk of potential deskilling of clinicians and over-reliance on software in decision making. This does not mean that later was a less important issue than time, only that it was less frequently measured or discussed in the literature. Flynn and McGuinness, (2011), conducted a survey study to explore clinicians' perceptions and attitudes to the introduction of decision aids into their clinical practice. They found that clinicians participated in the study perceived using decision aids potentially could result in the deskilling of HCPs' own information-seeking skills (Flynn and McGuinness, 2011). A similar threat to clinician skills was reported by Varonena et al., (2008).

Healthcare professionals' responses to question five from the 'acceptability scale' revealed that about half of respondents (53.2%) indicated that using the DA would be better than how they usually go about helping patients decide about their anticoagulant treatment. Approximately half (27.7%) of those who agreed to the statement in question five,

indicated that compared with usual approach, this tool would result in patients making more informed decisions (As illustrated in table 6.6). HCPs' attitude can be explained due to; adoption of a paternalistic mode of communication in consultation, HCPs' resistance to changing established workflow routines, and HCPs' perceptions that the DA might not be appropriate or complex to be used with some patients.

6.9.3 Conclusions

This study explored HCPs' perspectives on the potential utility of Keele anticoagulation therapy decision support tool in anticoagulation management in clinical practice through a mixed-method approach. A number of outcome measures were studied to provide a multi-faceted perspective on potential system utility and implementation. Findings from both research methods provided a comprehensive and complementary data of the impact of the DST use and the perceived concerns associated with implementation in clinical practice.

The findings showed that the DST had potential to improve anticoagulation therapy prescribing decision. Healthcare professionals regarded the tool as helpful for providing them with evidence-based information and resources required for anticoagulants prescribing and promoting patient interaction and discussion. In addition, they perceived the DST useful for supporting safe prescribing, and improving adherence to recommendations from NICE and current international guidelines. However, HCPs revealed potential concerns to the implementation of the DST in clinical practice. Lack of time was the commonest perceived concern to effective uptake of the DST in clinical practice. Other lower rated concerns were potential threats to the doctor–patient relationship, the fact it was a standalone system, and potential deskilling of HCPs.

The analysis of the data concerning implementation and post-intervention evaluation in clinical practice will now be discussed.

Chapter 7: Implementation and post-intervention evaluation in clinical practice: Analysis of second interviews

The aim of this stage of the study, as discussed in section 4.5.1, was to conduct a second set of semi-structured qualitative interviews with the HCPs approximately eight weeks after the first interview to explore any changes in their perspectives on the impact of the DST on anticoagulation decision making and decision quality. This aim of this chapter is to discuss the analysis of the data from these third stage semi-structured interviews with the HCPs who implemented the tool in clinical practice. HCPs were allocated the same research number that was used in the initial interview.

The process of re-recruiting the HCPs is included in section 7.1. HCPs' experiences from implementing the DST into their routine clinical practice are discussed in section 7.2. Section 7.3 concerns barriers and facilitators to the DST uptake and effective use, which includes barriers pertinent to the health organisation (section 7.3.1), barriers pertinent to the HCPs (section 7.3.2), barriers pertaining to patients (section 7.3.3), barriers pertinent to healthcare setting (section 7.2.4), and barriers specific to the decision support tool (section 7.2.5). The main findings from this stage of the study are discussed in section 7.4.

7.1 Demographics and the process of re-recruiting the HCPs

Following the pre-intervention evaluation study, HCPs were asked to implement the DST and associated PDA into routine clinical workflows and to invite patients to partake in the PDA evaluative study, as discussed in section 4.5.3.

Thirty-one HCPs initially agreed to implement the DST into their routine clinical practice. Sixteen HCPs made their decision to drop out from the study at the end of the initial contact. Each HCP dropped at this stage were asked to identify reasons for the decision made either immediately during initial contact or later using a topic guide to prompt participants to identify perceived barriers to implementation (discussed in section 4.5.3 and illustrated in figures 4.3 and 4.4).

Out of thirty-one HCPs, only eighteen HCPs, provided feedback to reflect their actual experiences from integrating the tool into clinical workflows. They were; one HCP from NHS Foundation Trust Hospitals (2), four HCPs from NHS Foundation Trust Hospitals (3), eight HCPs from NHS Foundation Trust Hospitals (8), two HCPs from NHS CCG Primary Care (1), and three HCPs from NHS CCG Primary Care (5).

The eighteen HCPs (38.3% of stage-one research participants) who implemented the tool in clinical practice had a mean age of 44.3 years. On average, the tool users had 9.3 years of experience in their field of speciality (range 1–33 years). Half of the sample constituted of hospital-based consultants and registrars (N=9, 50 %) (They were, three stroke consultants, two haematology consultants, one senior cardiology registrar, and three acute medicine consultants), GPs represent 22.2% (N=4) of the sample, and non-medical independent prescribers (They were, three nurses, and two prescribing pharmacists) represent only 27.8% of the sample (N=5). Demographic information about the HCPs is summarised in table 7.1.

Table 7. 1: Demographic characteristics of the DST users

Characteristic	N (%)
Age (mean) in years 44.3 years	
Gender	
Male	10 (55.6)
Female	8 (44.4)
Number of years of experiences (mean)	9.3 years
Profession	
Hospital-based consultant	9 (50)
GP	4 (22.2)
Non-medical independent prescribers	5 (27.8)
Specialist nurse	3 (16.7)
IP-pharmacist	2 (11.1)

During the period of field-testing, all research participants were encouraged from the beginning to provide feedback via personal email, whenever they recognized specific issues or questions for the tool developer or researcher. Also, they were encouraged to briefly provide feedback on their experiences with using the tool immediately after each consultation, for example, they were asked to report on the usefulness of the tool, how often they used it, and any problems, they were having with using the tool in practice. Longer interviews with HCPs following regular use of the tool aimed to explore their overall views and experiences of the tool.

7.2 Usefulness from implementing the decision support tool into routine clinical practice

This theme focuses on presenting HCPs' experiences from implementing the DST into their routine clinical practice. Healthcare professionals' feedback confirmed and reinforced themes identified during the pre-intervention evaluation of the utility of the DST in anticoagulation prescribing decision. Four sub-themes related to the DST impact on HCPs' prescribing decision were identified, and they were:

- Provided HCPs with reliable information
- Improved the quality of anticoagulation prescribing decision
- Encouraged patients' participation in decision-making
- Reduced variation in clinical practice

In summary, HCPs indicated that the DST was a reliable source of information during the implementation stage, and provided them with all information needed to support anticoagulants prescribing decision. Therefore, increased confidence and reassurance that better information was used and a better decision was made. Healthcare professionals stated that using PDA improved patients' decision quality.

7.2.1 Provided healthcare professionals with reliable information

During the implementation stage, all HCPs valued the information presented in the DST. They indicated that the tool was a comprehensive, accurate and useful source of information during the implementation stage, as shown below:

"I found the information on the tool to be accurate and presented in an easy to read form..." GP, 47

"I felt the information was shown in a very clear way – and I felt confident that it was accurate…" GP 47

For example, most HCPs revealed that the DST satisfied their information needs during consultation, in that they were able to access all information required to support prescribing decision for both, prescriber and patients

"it was quite useful having access to all the stuff in one place" GP, 17

"It gets a good balance between the information that the clinician needs to put in and know about and then the information that the patient needs to be given. So, it supports both." Stroke consultant, 40

"…the patient decision aid is a comprehensive resource for information" (AM consultant 3)

They indicated that the tool contained all the information needed to make an appropriate prescribing decision and need not to seek information from alternative resources.

"The added value is probably the fact that you can get all the recommendations based on evidence which is right in front of you and you don't have to actually go looking for it." AM consultant, 33

Moreover, all HCPs regarded the DST as a robust, reliable, and comprehensive source of information in clinical practice.

"It's robust tool." Stroke consultant,12

"it's accurate, and it's reliable" AM consultant, 33

"a comprehensive resource for information" AM consultant, 3

All HCPs indicated that the tool was a valuable resource for learning, and useful for helping them to be aware of the evidence, adhere to clinical guidelines, and make an appropriate and safe decision. They revealed that it was a trusted resource because recommendations presented by the tool were based on guidelines, e.g. NICE guidelines, as illustrated below:

"I learn something new every time I use it." Stroke consultant, 8

"It's balanced and obviously based on guidelines, so it's evidence-based" Stroke consultant 8

"It's evidence-backed, it follows the NICE, and I trust it." GP, 45

All HCPs regarded the DST reliable in clinical practice because they could follow same steps each time in a structured and organised way and that they were less likely to overlook anything during the decision-making process.

"I think you get basically a structured way of providing information to the patient" Haematologist, 1

"you are never going forget an important area, and that all the information was in one place, so that was advantageous" GP, 15

"I think it's very useful" IP-pharmacist, 2

7.2.2 Improved the quality of anticoagulation prescribing decision

Healthcare professionals revealed that the use of the DST in anticoagulation decision-making process improved their prescribing practice, in the following aspects:

- **Increased safe prescribing**

"It helped me to make a more informed decision… and increased safe prescribing… that obviously improved patient safety." Stroke consultant, 8

"it was *quite helpful for the clinician to arrive to a proper decision, especially we're not sure of all the interactions with the other drug, so it [was] very helpful to make sure we're giving the safer option." AM consultant, 33*

"Useful checklist to make sure nothing was forgotten when starting medication." GP, 47

- **Improved the quality of consultation**

"*A more consistent approach to consultation and shared decision-making" Haematologist, 1*

"*It means if you're like to forget something maybe, it's going to prompt you; so, everyone should get the same" IP-pharmacist, 35*

"using the decision aid gives a structured approach to AF consultation." Senior cardiology registrar, 23

"helped to standardise treatment and consultations" GP, 47

"I think it does enhance the quality of the consultation" AM consultant, 33

- **Increased HCPs' confidence and reassurance about their prescribing decision**

Overall, all HCPs were keen to point out that using the tool in their clinical practice improved the feeling of reassurance regarding the decision made, in that the tool reassured them that they had made the right decision

"I mean I think it's an added-on [the] benefit to current practice, Yeah and you have something to back it up saying that you've done the right thing…Yes to support your decision." AM consultant 41

"I like to think that I'm secure enough in my practice…" AM consultant 37

"…just to give you some reassurance that you're on the right lines…" Senior cardiology registrar, 23

The majority of HCPs indicated that using the DST for anticoagulant prescribing decision enhanced the feeling of confidence that they have prescribed the best agent to patients and created perceptions that better information was used and a better decision was made

"…. once you've made that decision, by doing this as well, reinforces and makes you more confident…that the decision you've made that it's a good one." nurse 13

"I suppose you could ensure that the evidence you were using, taking all the other factors out, that the most evidence-based agent was being used for that patient, it would give you some, sort of ratify your decision, support your joint decision-making with the patient that you had picked the best agent for that patient..." IP pharmacist 35

"I felt the information was shown in a very clear way – and I felt confident that it was accurate…" GP 47

"[it] reinforces the decision I've made that it's a good one." nurse, 13

7.2.3 Encourage the implementation of shared decision-making approach

All HCPs indicated that the DST helped to improve the decision-making process and decision quality by promoting shared decision-making, in that patients, were empowered to make an informed decision about their treatment.

- **Improved communicating the treatment decision to patients**

Healthcare professionals indicated that the integration of interactive features into the DA had a positive impact on quality of the decision-making by involving patients in the decision-making process.

"Helped to give patients an accurate assessment of their risk of thrombosis and bleeding…And printing out information leaflet for patients" Senior cardiology registrar, 23

"the pictorial smiley faces of what are the benefits and what are the risks. I think that's an easy way to show a patient" GP, 45

- **Provided personalised information to patients**

"it's personalised information giving which is good" Stroke consultant, 8

"It is a good source of patient information for patients to take away and read at home." GP, 47

- **Improved patient understanding of health information and encouraged patient participation in treatment decision**

Building on HCPs detailed feedback on the content and presentation of the PDA during the pre-intervention evaluation, the post-intervention evaluation revealed that these criteria facilitated high-quality decision-making, in that patients, were able to make a decision that was as informed, consistent with personal values, and acted upon, and in that patients were comfortable with the whole decision-making process and the decision. Healthcare professionals tended to explain how the tool facilitated the shared decision-making approach, in that, it helped patients be actively involved in each step of the process, and that the treatment recommendation was tailored to them. As a result, patients felt they have made their own informed choice.

"I think [it] facilitated the discussion. Also, it allowed the patient to come to an informed decision" AM consultant, 37

"It's not only communication, but it makes it much better informed" Stroke consultant, 8

"The tool was very useful in allowing patients to be involved in their care and joint prescribing decisions really…So, that they fully understand the risks and the benefits of either treating or not treating, specifically what is the clot risk and what is the bleed risk" IP pharmacist, 35

All HCPs revealed that the process of involving patients in the prescribing decision was reflected positively on patients' confidence in that the right decision was being made for them.

"So, in a way, the patient feels a bit more confident as well that the right decision [was] being made for them." AM consultant, 33

7.2.4 Help HCPs to structure and standardise their practice

Most HCPs perceived the use of the DST in the decision-making process in routine clinical practice advantageous over their usual practice, partly, because this kind of decision support intervention was seen rather more structured, more organised and that they were less likely to overlook anything during the decision-making process.

"Well, it gives me a guideline, so it supports my practice really." Nurse,21

"I think it's more organised and more structured and I'm less likely to miss something out ..." AM consultant, 37

Most HCPs said that implementing the DST improved their prescribing practice by reducing variation in the decision-making process and helped to streamline clinical workflows.

"*it also standardises the practice. That's the most important." Stroke consultant, 40*

"helped streamline workflow" (all GPs)

7.2.5 Healthcare professional interpretation of patients' attitudes during the consultation

All HCPs were consistent in the descriptions of patients' attitudes presented to them. For example, most HCPs commented that their patients were quite happy, felt informed, and

were more confident that the right decision was being made for them. However, few HCPs revealed that some of their patients were confused during the consultation. As indicated below:

"it clearly helped, in terms of making a shared decision and making an informed decision from the patient's point of view." AM consultant 37

"They found the visual aids useful. They preferred to know their risk estimate of complications with or without treatment." Senior cardiology registrar 23

"the patient was definitely quite happy to have the counselling and to be involved" IP-pharmacist 35

"*the patient also feels more confident as they discuss all the options and look at the evidence" AM consultant 33*

AM consultants indicated that using the tool helped the discussion during consultation.

"It facilitated the discussion, also allowed the patient to come to an informed decision" AM consultant 3

"*…enhanced dialogue with patients" AM consultant 33*

A cardiology registrar indicated that the tool is a comprehensive consultation tool in that using it during consultation helped him to answer all questions patients need to know about, as stated below:

"Yes. Answered all the questions of the patients. They did not have any further questions." Senior cardiology registrar 23

However, only two stroke-consultants revealed that some of their patients felt confused, and was unable to understand the information provided. In probing, more deeply to

understand this issue, one of the reasons was the fact that it was also a research study, so they spent quite a bit of time with the consent process, and explaining the research process, so by the time they got to use the tool it was quite difficult for patients to concentrate. Other HCPs revealed that it was difficult to assess exactly how it affected the patient because they didn't know what confused them but certainly the process was confusing for some patients.

"*the fact that it was also a research study, so you need to spend quite a bit of time with the consent process so you already have an information giving process, you have a consent process, and so by the time I got to using the tool it was quite difficult" Stroke consultant 8*

The other stroke consultant indicated that the amount of information delivered to patients during the consultation was hard to understand, as indicated below:

"the patient was exhausted and said to us that [he] would prefer a simpler explanation" Stroke consultant 12

7.3 Barriers and Facilitators to the DST uptake and effective use

This section provides a comprehensive understanding of barriers faced HCPs during the intervention stage of the project. The main aim of this section was to indicate reasons for why HCPs may or may not use the DST with patients exploring a number of actual and perceived barriers that hindered the DST uptake and effective use in clinical practice.

All stage one HCPs provided feedback describing their experiences of barriers to using or adopting the DST into their clinical practice. Respondents were classified into non-users (NU) (29 HCPs who did not use the tool at all), and users (18 HCPs who integrated the tool into their clinical workflows).

Although all HCPs had positive attitudes towards the DST in general, several barriers were reported that could have affected the uptake and effectiveness of the intervention. Findings from this study revealed that HCPs were hindered by five overarching types of barriers when faced with the decision to use (or not) the DST in routine clinical practice. Which were; organisational-related factors, healthcare professional-related factors, patient-related factors, healthcare setting-related factors, and issues specific to the decision support tool.

7.3.1 Barriers pertinent to health organisation

The availability and quality of information technology (IT) infrastructure provided in the healthcare setting where the DST intended to be used were key factors impacting on the effective integration into routine clinical workflows. All HCPs consistently reported that limited computer availability at the point of care impeded DST use. Further, even when computers were accessible, they identified ongoing technical problems such as malfunctions of the browser, poor internet connection and slow computer speeds as barriers to use. This often resulted in deterrence for many HCPs. Moreover, they also reported that DST use was compromised if the system could not be integrated with existing systems (e.g. EMIS) and health organisation protocols and guidelines.

A key facilitator to the DST uptake was the integration and an IT department approval of the web-page link. Further, communications of the tool benefits to stakeholders within the health organisation and providing buy-in from stroke and cardiology departments who are making these decisions were reported to facilitate uptake.

7.3.1.1 Information Technology (IT) infrastructure

The majority of HCPs reported that the basic facilities needed for the operation of the DST might be the most barriers to implementation in clinical practice. For example, for HCPs who intended to implement the DST but could not say that this kind of consultation

requires the availability of computers when sometimes it was difficult to find one at the point of patient encounter. A similar view was shared by other HCPs who made their decision to opt out from the study for the same reason. In this sense, a prescribing pharmacist who works mainly on hospital wards and closely involved in the process of patient counselling and medication review added that this was the main block to using the tool with his patients, and he could not find an alternative to solve this.

"We often don't have enough portable devices to go to the patient's bedside…We just don't have those on the ward, so how would we use the tool? We can't wheel them around to the nursing station and make them sit there..." IP pharmacist 36, (NU)

"…one problem is it does tie you to having a computer screen. So, that may not always be available in hospitals…" AM consultant 37, (U)

"…you may not have the computer at the time of your discussion…" Stroke consultant 43, (NU)

The following acute medicine consultant indicated that the main reason caused his irregular use of the decision support tool was related mainly to the unavailability of IT support during inpatients acute admissions shifts compared to accessibility to IT devices during his ambulatory care shifts

"Issues I am having with using surround informatics support by the bedside in inpatients/acute admissions, and we don't have bedside IT support where the tool can be accessed" AM consultant 3, (U)

Healthcare professionals who did not use the DST indicated that the technical requirement was also perceived as a barrier. In this sense, most HCPs who had the intention to use the tool, however, reported that the responsiveness of trust computers was a problem. They mentioned that because of poor internet connection the system became slow to use and that

it took them a long time for screen loads and that the tool slowed to the point of becoming unusable, an example provided below:

"I have tried to load this but despite waiting more than 1min and refreshing it still won't load, and I don't have time to keep trying" Cardiologist 20, (NU)

Few users of the tool reported issues related to the 'print' function. This issue did not affect their level of use of the tool but to some extent affect their satisfaction with the process. For example, two GPs from two different CCGs practices explained that the browser they are using seemed to have blocked the pop-up print window, so they were unable to get printed material.

"...I had a few problems with the browser, our browser that's installed by our local NHS wouldn't support some of the software so you couldn't print out..." GP 17, (U)

Other users of the tool mentioned that they got black-and-white printers in the clinic, and obviously was unable to give their patient coloured printout. A stroke consultant stated:

"Printing graphs in black-and-white makes no sense" Stroke consultant 8, (U)

7.3.1.2 Implementation

The majority of HCPs who were reluctant to integrate the tool into their workflow said:

"If it is approved by the Trust, if it is integrated, so we are more than happy to use it. So, it's within the policy" IP-pharmacist 36, (NU)

"If it is authorised then I can use it" AM consultant 5, (NU)

"I think the most important thing is we need to get the IT department to agree for the link" AM consultant 41, (NU)

"First thing, talking to the managers and the IT department to see if we can integrate it." Stroke consultant 11, (NU)

"I think it should be implemented in the Trust" Senior cardiology registrar 22, (NU)

Most HCPs in this category reported accessing an un-authorised website while on the ward was perceived as a barrier to using the decision support tool.

"The governance issue is always going to be a barrier… sometimes we have generic computer logins, for the ward, which then blocks you from having access to any website except that which has already been authorised, which limits you to things… so that would be potential barriers, the IT system and the governance systems..." Stroke consultant 11, (NU)

7.3.1.3 Facilitator to organisation-related barriers

A unique facilitator to the tool uptake and effective use was the integration into existing clinical workflow. All participating GPs and most of the hospital-based professionals reported that the key facilitator to most barriers to implementation in clinical practice was the integration, and Further, approval from Information technology (IT) department to authorise the website, as well as, having adequate buy-in from stroke and cardiology departments who are making these decisions. Moreover, GPs emphasised the importance of integrating the tool with their clinical software, EMIS (Egton Medical Information Systems) not only to resolve issues related to technical problems and access but also to remind GPs to use the tool when they code a new AF patient.

"I think integration within the clinical system will be really useful…using a pop-up tool within the clinical software (ours is EMIS) to remind GP's for example when they code new AF or start a new prescription of anticoagulants" GP 7, (NU).

This GP also indicated that if the tool was not integrated within the EMIS then *"it's about us asking practices to use another tool." GP 7, (NU)*

"Embedding it in EMIS. Definitely." GP 15, (U)

"...if [it] was incorporated into EMIS; it might be that we could actually use it in a much more effective way..." Nurse 21, (U)

"The tool is useful but should be used in conjunction with [the] integrated hospital system." Senior cardiology registrar 23, (U)

"...integrate it directly into EMIS primary care system…" GP 47, (U)

"Definitely integration within the EMIS or the GP computer systems to make it a routine thing that can be done when a patient's seen, and something that we can possibly flag up…then we could have a little pop-up box…kind of – a trigger on the computer system to prompt people..." Nurse 21, (U)

One haematology consultant who succeeded to integrate the tool into his workflow suggested that providing evidence from users and patients who have experienced the use of the tool in the consultation would facilitate its integration within the trust guidelines.

"I think the other suggestion would be a patients' survey for the patients who have used it and ask their views on it and see whether they found it helpful and then that information needs to be sent back to nurses and healthcare people to say what patients thought about it." Haematologist 1, (U)

7.3.2 Barriers pertinent to healthcare professionals

The lack of awareness of the DST was the most commonly identified barrier by HCPs (potential users). Healthcare professionals indicated that lack of knowledge that such tool

exists and remembering that the tool does exist when they identify a new AF patient were flagged repeatedly as a significant barrier to use. The DST use was perceived by clinicians with several years of experience and research in the field as threatening to their professional autonomy. In some cases, clinicians reported resistance to change existing practice and a change in doctor-patient interactions.

7.3.2.1 Awareness

Remembering to use the DST was repeatedly mentioned as a barrier to use. This view was shared by two GPs and one hospital consultant who intended to use the tool.

"it's just going to be remembering the web page that it's there and I have to use it..." GP 7, (NU)

Other HCPs were talking about barriers to using the tool by other colleagues and wide dissemination of the tool. In this sense, they mentioned lack of awareness and insufficient advertising was perceived as a barrier among HCPs.

"The lack of awareness ... most of them [consultant colleagues] do not know that a tool like that exist" AM consultant 5, (NU)

"Well, obviously if people don't know it's there then they wouldn't know..." Haematologist, 6, (NU)

7.3.2.2 Challenge to autonomy

All speciality consultants presented high confidence in their own experiences in anticoagulation therapy, research background, own communication skills and in their ability to communicate information to patients. Most cardiologists and one stroke consultant did not perceive a need to look for external or extra support to their clinical practice.

"we are the largest prescribers in the country …Therefore I felt that we have a lot of experience in prescribing in this area and I cannot see the benefit of utilising this prescription aid..." Stroke consultant 19, (NU)

"….so, I think I've got all the data my end so for me this tool will be a hindrance rather than a help and that's a very specific thing, I think for tertiary doctors who are very much involved in this every day several times each day perhaps this isn't necessarily…" Cardiologist 9, (NU)

Moreover, they seemed to have assumed that they were already practising in an evidence-based fashion and they held the perception that the introduction of the tool might threaten their autonomy.

"I think if somebody who is less confident and has less experience with prescribing in this field would find this very helpful, but not for me." Cardiologist 16, (NU)

7.3.2.3 Resistance to change existing practice

Among healthcare professionals who did not use the tool, an anticoagulation nurse with several years of experiences revealed general resistance to change existing practice.

"… Barriers in the sense of change really. That is a difficult one" nurse 24, (NU)

7.3.2.4 Impact on doctor-patient relationship

Only two HCPs, a senior cardiology registrar and a GP revealed that using the DST during patient encounter affected the dynamics of the doctor-patient interaction, and felt that they lost eye contact with patients. Examples included:

"The personal touch was bit lacking. It affected my interaction with patients to some degree but not excessively. This was made up by objectivity of the tool" cardiology registrar 23, (U)

"I feel my usual consultation has more eye contact with patients which might be a bit lacking with the computer in the middle…Some patients can be easily distracted" cardiology registrar 23, (U)

"I felt that I was able to interact with the patient much less freely than usual" GP 47, (U)

7.3.2.5 Facilitators to healthcare professional-related barriers

As facilitators to the decision support tool uptake, HCPs suggested advertising to enhance the widespread use of the tool.

"so mainly advertising, putting it out there and making sure everyone's aware of it would probably be the best way." Stroke consultant 40, (U)

"just let people know it's available…Make them aware… Obviously, you could do some more advertising … Yeah, it's just reminding people it exists I suppose, making people more aware and making people aware of how easy it is..." Stroke consultant 8, (U)

7.3.3 Barriers pertaining to patients

Healthcare professionals were very specific when asked about barriers related to patients during the intervention period. In this regard, they clarified that patient-related characteristics was a hindrance from using the PDA on that specific occasion, but did not affect overall using of the DST. All HCPs who integrated the DST into their workflow indicated that patients' clinical and non-clinical characteristics played a major role in the PDA use, adoption, and implementation process. Therefore, patients' attitudes and views of the tool were key factors in the overall success of the consultation.

Patient-related factors such as age, clinical condition, and patients' preferences and attitudes (e.g. acceptance of technology and desire to be actively involved in the

consultation) impacted on the PDA use. For example, HCPs indicated that old-age; sight problems; and poor cognitive function were deterrent to using the PDA during the consultation. Further, there was a range of views expressed about the effectiveness of using the tool with patients presented with low educational level and language barrier. Bed-bound patients were repeatedly flagged as a barrier to use. Other HCPs felt that using the DA with their patients contributed to confusion and information overload, whereas in others, it enhanced the communication and patient involvement in the treatment decision discussion. These responses also appeared to be linked to the level of acceptance of computers within the consultation by patients and using the tool as part of a research study. Similarly, there were divergent views about the benefits of DST; the majority of HCPs reported that integrating the PDA enhanced the quality of consultation and had a positive impact on patient care while others stated that it was overwhelming for a group of patients.

7.3.3.1 Patients' clinical and non-clinical characteristics

Healthcare professionals' decision to integrate the PDA into workflow was influenced by a wide range of patient-related clinical and non-clinical factors. Healthcare professionals did not separate clinical and non-clinical factors from each other, as they were interrelated and equally influenced the decision to use (or not) the PDA. During the intervention period, HCPs were encouraged to feedback using personal email describing their experiences with integrating the DST into their clinical workflow.

Healthcare professionals made it clear that the decision depended very much on the patient clinical and non-clinical characteristics. They reported that judgement was made at the very beginning whether to use (or not) the PDA during the patient encounter. An example provided below:

"So, you have to make a judgment; is the patient going to understand what you're telling them? If they are then it was very helpful." AM consultant 33, (U)

For example, patient cognitive function and more specifically patient mental integrity and dementia were realised limiting factor to using the PDA during the patient encounter. Other HCPs, however, mentioned patients' educational attainment level. In this sense, patient level of understanding, and ability to read was reported crucial to using the DST during the patient encounter. Patient age was another reason reported which hindered professionals from using the DST during the consultation.

"educational attainment level…quite a lot of our patients don't read – can't read or have poor education…" AM consultant 3, (U)

"level of understanding, and education level and level of mental integrity as well." GP 47, (U)

"…Part of the problem may be that they [patients] did not understand some of the terms that are written and needed a bit of clarification..." AM consultant 37, (U)

"…having dementia … elderly and don't know much about computers… it was very difficult." Senior cardiology registrar 23, (U)

"…a lot of my patients are elderly patients…mine tend to be kind of 85-90 and certainly over the age of 70. So, showing them was, they might be like, 'What is she talking about?' Because they just didn't like computers, … So that was a barrier. That's why I liked the diagram because you can show them a diagram and that was easier to understand, but I think just the fact that it's computerised and I have an elderly population was a bit of concern for me." nurse 13, (U)

Also, few HCPs talked about patients presented to the clinic with limited communication skills due to language (e.g. the English language was not their mother tongue) as another reason for deciding not to use the PDA during the consultation.

"language was a problem, about maybe – 20% of my patients probably don't have English as their first language… so that was an issue." AM consultant 3, (U)

Moreover, the problem with sight was another important reason mentioned by nurse practitioner during patient counselling, which then she decided to communicate only verbally with her patient.

"patient can't read from computer screens, so it's really basic stuff – eyesight." Nurse 21, (U)

On the other hand, HCPs were also consistent in describing challenges with using the PDA during in-patient setting. As indicated below:

For example, the following stroke consultant reported that her patient could not see the computer screen because he did not have his reading glasses, so she waited till a family member came and brought the reading glasses before contacting the patient for the second time.

"the patient couldn't see, haven't got his reading glasses" Stroke consultant 8, (U)

Also with another patient from same clinical setting, she mentioned that the patient was unable to move to get near the computer, so she tried her best to show the patient the graphics by printing the leaflets and used them to discuss the treatment choice with the patient.

"*can't mobilise to get near the computer to look at the pictures on the screen but printing them out I think that was a nice thing, and hand it over to him" Stroke consultant 8, (U)*

7.3.3.2 Patients' preferences and attitudes

Other HCPs described their experiences with using the PDA with patients who were not interested to be involved in the treatment choice decision and were more likely to leave the final treatment decision up to the doctor.

"…The patient just wanted me to make the decision" Stroke consultant 12, (U)

"She seemed to have the mind to understand all that, understand what I was showing [her] but just said, 'Decide what's best for me'…obviously not willing to participate." AM consultant 33, (U)

Few HCPs reported that using the PDA with some patients was not helpful. Lack of understanding and feeling confused were the main reasons that force them to use verbal communication only, miss out some questions, or use simple explanations.

"the patient did not understand anything, showing him all that where he got more confused, and then it was better just to tell him verbally what the best options are. So, I wouldn't call that necessarily that it was not helpful in that situation. It was helpful to me, but the patient thought, 'This is a bit too much,' for him to take in." AM consultant 33, (U)

"Unfortunately, his understanding wasn't as great as I had expected, however, once I went through it with him he was unable to continue" AM consultant 3, (U)

"The patient did not understand everything that I was asking, even though it was simple…" AM consultant 37, (U)

A nurse practitioner from GP practice said that her patient was wondering why she was going through many questions during the consultation

"The patient wondered why I was asking some questions..." Nurse 21, (U)

Also, she said that with other patients, she thought that she has to use more simple language for her patient to understand.

"…I needed to use a bit simpler language with that patient for him to understand…" Nurse 21, (U)

"miss out some of the points because it was probably too much for that patient" Nurse 21, (U)

For other HCPs, challenges were mainly related to the length of consultation and amount of information given. Few HCPs were concerned about the ability of their patients to concentrate for that long.

"there was a lot of information." Haematologist 1, (U)

"there was a lot of writing and a lot of reading to go through, so…, you know, people might struggle to concentrate for that long, but it was fine." GP 17, (U)

Another GP decided to use the clinical decision part during the first encounter and print out information leaflet for patients, and ask her patient to read and to book another appointment to discuss treatment options.

"working over two appointments… first, I used the clinical decision-making side, I gave leaflets and asked patients to book another appointment…" GP 15, (U)

The use of computers during consultation was another issue reported by a pharmacist, for example, old-age was seen linked with patient's preferences to accept using computers during the consultation, as indicated below:

"the thing was, they're not ready to accept the technological age…" IP pharmacist 2, (U)

Likewise, a haematologist emphasised the point that old-age is associated with lack of interest to using technology in health care.

"I think it's lengthy and the other thing was that some patients are not computer savvy and that's a bit difficult for them. Most of the patients are elderly, so going through many pages in front of the patients was not a friendly thing." Haematologist 1, (U)

The following GP shared the same view about her patient being computer illiterate, and she explained that the consultation took longer than expected because of the patient inability to read from the computer screen and work out simple computer skills.

"... I think that for that patient I did use it with the barrier of actually having to look at it on a computer screen was quite a big barrier for her. I hadn't realised that she wasn't really computer-literate at all. So, that was a problem for her really that, you know, just the practical thing to having to move a mouse around the screen was quite a big barrier to her, and actually, she found it difficult to read the print on the screen..." GP 17, (U)

"A long time. Partly because the patient, I tried it with really had fewer computer skills than I really even realised…" GP 17, (U)

A few HCPs indicated that with some patients, providing them with information about different options and asking their opinion on which specific agent to prescribe were recognised to contribute to patients feeling overwhelmed, confused, exhausted and felt that the decision was difficult for them to handle. As reflected below:

A stroke consultant said:

"...but is too cumbersome to go through with patients. Patient prefers much simpler explanation. The patient I interviewed yesterday got very confused." Stroke consultant 8, (U)

"We did pilot this in our AF clinic, and it took a good 30 minutes of our time, and the patient was exhausted. The patient said to us that he would prefer a simpler explanation" Stroke consultant 12, (U)

"The information sometimes can be a bit too much and overwhelming but in general patients appreciated the fact that they were being involved." Senior cardiology registrar 23, (U)

The following GP attributed this, as have others, to poor patient understanding, patient inability to quantify risks and benefits, failure to comprehend enough, and by the fact that these ideas were completely new to them.

"…we forget that sometimes some of these ideas are completely new to patients and they really don't understand kind of the scientific ideas of risks and benefits and those kinds of things. So, I think it just takes a lot, and there's a lot to think about really for a patient, so there are a lot of ideas to consider." GP 17, (U)

The majority of HCPs attributed patient confusion due to using the decision support tool as part of research and was not a typical standard clinical situation. They indicated that by the time they started to talk about treatment options, patients have already had information overload. As illustrated in examples below:

"…a lot of them were already half overwhelmed by the conversation about the consent and reading the consent form and the patient information form. But by the time you got to talking about the treatment they had information overload, it's probably not a typically normal clinical situation anyway…" Stroke consultant 8, (U)

"I think they were very confused, it's the fact that it was also a research study, so you have to give information about the study, and then consent to participate, and so by the time I

got around to using the tool, therefore, she'd already confused… so as a concept it was quite difficult" nurse13, (U)

"It is a too taxing study" Stroke consultant 12, (U)

"cause it's trying to get patients enrolled in study" GP 17, (U)

"Study information appears very detailed and lengthy for patients to absorb to understand fully. Just it would act as a deterrent to participation for some patients" GP 15, (U)

"For many patients, was just difficult to consent and understand the process in the limited time I have on the wards." IP pharmacist 2, (U)

7.3.4 Barriers pertinent to healthcare setting

Users of the DST described their experiences of using the PDA with bed-bound patient problematic. Access to computers at bed-side was an issue. Further, even when computers were accessible, HCPs identified patient physicality and other health problems after recovering from the stroke as barriers to use.

Inpatient setting was seen challenging to efficient use of the PDA, a pharmacist revealed:

"*the physicality of the patient and whether they're in bed, sitting or they're ambulant; that's number one. Technology, I'd say, is number two, from that perspective, because again, an iPad or something else is still going to be really difficult for those patients who are in bed and who aren't able to sit in a Consultation Room" IP pharmacist 35, (U)*

Other HCPs were very specific in describing issues within the inpatient/hospital environment which make the use of the tool with patients quite difficult, as reflected below:

- Availability of computers and portable devices by the bedside was reported difficult

"…One problem is, it does tie you to having a computer screen. So, that may not always be available in hospitals…" AM consultant 37, (U)

- Time was a limiting factor

"…on the ward round setting, we don't have enough time to sit down with the patient, go through everything" AM consultant 33, (U)

- Bed-bound patients

A pharmacist spoke of his experience of using the tool with a patient who was lying in bed and unable to move. He said that he was to lean over the patient's bed holding the laptop and show the patient the screen.

"The technical was the real problem I had in an In-Patient setting and leaning over the patient's bed and trying to hold a laptop, type and show them the screen. I think, even with an iPad, if a patient is lying in bed that does make it quite difficult, even with slightly better technology…" IP pharmacist 35, (U)

This pharmacist continued to describe his experiences when he used the tool with an ambulant patient; he described his experiences as:

"That was much easier" IP pharmacist 35, (U)

"…with ambulant [patients] where you can take them to a Consultation Room… You can obviously share the view of the computer screen…You just need a computer screen that can be tilted for both of us. At least, you can pull up a chair next to them and the computer being shared…" IP pharmacist 35, (U)

"It was more difficult to use it in the inpatient setting due to the time and bed pressures." IP pharmacist, 2

Acute medicine consultants reported that it was more unlikely to use the PDA in the ambulatory emergency care unit (AECU) compared to acute medicine unit, as indicated below:

"The AECU is quite difficult due to the nature of inpatient stays and access to the IT was harder" AM consultant 37, (U)

"…I have to say I did find this quite difficult in a ward-based setting having only my laptop placed on the bedside table and leaning over the patient's bed (i.e. it was hard for us to both observe the screen at the same time, and I use the keyboard etc…). Therefore, to me, it seems this is a tool that would be best suited for a clinic-based appointment. Getting the patient away from the bedside is the struggle, or getting a computer screen to the patient bedside…" AM consultant 3, (U)

Another stroke consultant spoke about differences between using the PDA in a clinic setting and inpatient setting.

"I tried to see [patients] in clinic … I've got it all setup, I've got it all ready and setup…It wouldn't take an awful lot of time because you've got it all set up. But obviously, some of the patients I saw on the ward, a lot of them were just ready to go home really, and you just want to get everything organised for them to go home…" Stroke consultant 8, (U)

7.3.4.1 Facilitators to improve HCPs' uptake experiences

Healthcare professionals felt that, in principle, the use of the DST was useful and could promote their prescribing decision and enhance communication of the decision to patients. In this context, they were keen to describe practical procedures they used to smoothly facilitate using the DST into their clinical workflow.

Interestingly, suggested strategies were exactly same to previously recommended strategies during early evaluation stage of the DST. To mention:

Clinic setting: many have suggested that this tool would perfectly fit in a clinic setting more than in the inpatient setting.

"I think when you have a desk sitting in front of the computer, and the patient walks into your room. In that setting, it's very helpful…" AM consultant 33, (U)

"I imagine clinic would be much more suited to implementing this tool as the tool itself is very useful in allowing patients to be involved in their care and joint prescribing decisions really." IP-pharmacist 35, (U)

Getting used to it: others indicated that the more they used to the tool, the better they get used to it, and less time needed

"There was an initial learning curve, but it became easier after using it a couple of times." Senior cardiology registrar 23, (U)

"I was sceptical at first but using it a couple of times made me realise that it was easy to use" Senior cardiology registrar 23, (U)

"In the beginning, if you're not used to it, it will take longer, maybe 20-25 minutes. But, then probably ten or 15 minutes." AM consultant 33, (U)

"If I was proficient in its use, I'm sure I could speed up by five to ten minutes, but it would still be 20 minutes of using the tool with a patient..." Nurse 21, (U)

Be prepared and use of paper format and leaflets: Healthcare professionals from different healthcare setting described what strategies they used to streamline the tool into their clinical workflow.

"…we could actually put things and do things before we actually saw the patient, so it would take half the length and just concentrate on the information we've already got. So, all that stuff about the coagulation…, I could have done all of that without the patient in the room. There was so much of it that the patient didn't need to be involved in and …" Nurse 21, (U)

"I think there are areas within the tool that we can populate without the patient which would be quicker to do when they are not with us, then use sections to complete the patient decision aid with the patient." GP 17, (U)

"If you do it beforehand then you can come armed with the information…" Stroke consultant 8, (U)

"…In the ward setting, you are obviously using the computer on wheels, that's provided and in order to kind of get the best experience out of it you ideally need to be able to use the tool online and then get a print-out version and take it to the patients and involve the patient…" Stroke consultant 40, (U)

Two-stage approach: Two stroke consultants (from inpatient setting) and one GP indicated that they found the two-staged approach useful to use in their clinical settings, which seemed to match how they usually break the consultation into two parts.

"Basically, the only realistic way to use this was to go through the information in my office, then talk to the patient (as I usually do) …Get a printed leaflet with the resulting data/ risk/benefit which I could leave with the patients and come back once they read it would be more feasible." Stroke consultant 8, (U)

"as I only had a 10-minute appointment, I am bringing her back in a week after giving her some patient information. So, working over two appointments." GP 15, (U)

7.3.5 Barriers specific to the decision support tool

Three concerns relate to the DST were identified as impacting on the uptake. The first concern relates to the tool complexity. The second concern relates to integration with clinical workflows. The third concern relates to its content.

A range of the DST-specific factors contributed to its complexity, such as the amount of information, length of presentation, and the use of scientific language. Other HCPs indicated that sequential nature of the tool presentation made it less likely to be adopted.

On the other hand, few HCPs indicated that using a computer during the consultation requires organising the consultation room, in that, everyone in the room can see the screen, which was another factor that seemed to affect use and acceptability.

Also, other HCPs stated that the tool did not account for local constraints in their health organisation. In that, the availability of some anticoagulants as formulary in their health organisation might limit the applicability of the tool recommendations to their patients. The tool cannot make off-label prescribing recommendations was a recurring theme reported consistently, which probably an important barrier to uptake.

7.3.5.1 Complexity

Most of the HCPs who failed to integrate the DST into their routine workflow indicated that the tool was too complex for routine use.

The length of the information provided was seen another source of complexity, as indicated below:

"I think on the patient side it's a little bit too complicated really and I think it needs to be slimmed down to provide more simplified, I mean summary data based on what's been already entered in the earlier part of it." Cardiologist 20, (NU)

"... I think it's going to be difficult because it's complex, for patients to understand, older patients will not understand it nor will they be able to see the level of text..." Cardiologist 9, (NU)

Moreover, a cardiologist commented that the tool complexity could arise from the sequential nature of it, which might drive the decision-making process slower than usual approach.

"Well, the complexity of it and the sequential nature of it which means you have to go through one page after another, after another and just the fact that it's quite slow really, that's the main thing." Cardiologist 20, (NU)

"...My only concern is that it's too long and it's too complex, and I worry that to do this properly is beyond the capacity of most consultations with patients." IP pharmacist 36, (NU)

Conversely, other HCPs who successfully integrated the decision support tool indicated that:

"It seemed relatively clear, and, as I say, I think once you've actually used the tool and the more you use it. [It was] easy to navigate. It didn't seem complicated, and I'm not computer –literate." GP 17, (U)

"... it was a bit tricky .... at first glance, it seemed quite complicated... but it was relatively easily digestible" AM consultant 33, (U)

"I think it can go both ways, a lot of people felt more engaged, and other patients found the consultation more complicated..." Stroke consultant 12, (U)

7.3.5.2 Integration within clinical workflows

Integration of the decision support tool into clinical workflow was consistently identified as one of the key barrier influencing uptake. For instance, few HCPs, in particular, cardiology specialists pointed that interface rigidity and navigation features significantly influenced how easily they would be able to use the tool in the way they need it. They perceived the sequential flow of the tool a key factor influencing uptake.

"…the sequential nature of it which means you have to go through one page after another…" Cardiologist 20, (NU)

"A simpler version of the tool, because then sometimes you just go for the medical part and not for others, it would be easier and faster for us… then probably it's better too if we can choose which part we would like to use" Cardiology specialist 18, (NU)

In this sense, they suggested breaking the decision support tool and associated patient decision aid into two discrete components to facilitate the tool integration into their clinical workflow.

"It helps enormously…So there's something about having a healthcare tool and a patient tool, separately. Separate, so that you're saving time. Yeah, if there were two different tools, that would make us use it a lot more..." GP 15, (U)

HCPs in this scheme perceived accessibility to computers at point of care contributed to the integration of the DST into workflows.

"We often don't have enough portable devices to go to the patient's bedside…We just don't have those on the ward, so how would we use the tool?" IP-pharmacist 36, NU

Among HCPs who were reluctant to integrate the DST into their clinical workflow indicated that the tool did not account for local guidelines in their setting, as shown below:

"Again, the barriers would be the fact that we've got the Dudley guidelines here so, we would have to make sure that the decision tool followed our local guidance and it took into the practicalities of ensuring that they actually, when you choose an agent, that they were able to take it safely, so there are some safety things that seem quite not to be built into the decision-making tool." IP pharmacist 29, (NU)

Time factor and perception of time were commonly perceived by research participants to limit uptake. In this sense, many users indicated that the tool took longer time which makes its integration into clinical workflows difficult.

"…The other thing was the length of time it takes to do this with the patients is another barrier…" Haematologist 1, (U)

"I think that time was the main issue…" GP 17, (U)

A stroke consultant has indicated, as have others that integrating the DST as a research project contributed to increasing the total time required for completion of certain tasks, for example, the consent process and explain the research.

"…it's the fact that it was also a research study, so you need to spend quite a bit of time with the consent process, so you already have information giving process, and a consent process…" Stroke consultant 8, (U)

The following quotes were given in chronological order (feedback using personal email) from a stroke consultant who managed to integrate the decision support tool into her clinical workflow gradually. It showed how she changed her view about the time needed during the patient encounter. Initially, she was reluctant to take the first step. Her first time experiencing the tool, it took her one-hour and half, then, the time shortened to one hour,

and then to 30 minutes, and finally, she reported that it took her between 10 to 15 minutes to complete the task. As indicated below:

"There is no chance to complete screening, consent, moving the patient to a computer where they can see the screen, going through the information in 10 minutes…" Stroke consultant 8, (U)

I have recruited one, and it took 1 ½ hours..." Stroke consultant 8, (U)

"…it took a whole hour… as I say finding somewhere to print, printing out your consent forms, getting the consent, whether you want to read the materials, so it's a long, because you weren't just testing the decision tool you were also conducting a study which took a lot of time so that clearly includes the time for consenting…" Stroke consultant 8, (U)

"Including the consent, finding a computer to print, and talking it through with him still took 3o min better than over an hour with the previous patients." Stroke consultant 8, (U)

"I have used the tool ... It worked well, and took about 10-15 min..." Stroke consultant 8, (U)

"…If you use it for yourself, it probably doesn't take more than five minutes if you've got all the relevant information at hand, if you use it with a patient an extra work time would probably be another ten minutes…" Stroke consultant 8, (U)

This emphasized what other HCPs said earlier, that the more they used the tool, the shorter the time needed to use it.

"In the beginning, if you're not used to it, it will take longer, maybe 20-25 minutes. But, then probably ten or 15 minutes." AM consultant 33, (U)

"It did take some time. That was the first patient, so perhaps with a bit of practice, you could get a little bit slicker with using the tool…" IP pharmacist 35, (U)

A cardiology registrar stated that:

"I was sceptical at first but using it a couple of times made me realise that it was easy to use. Also, one feels confident to skip the unrelated bits as they are more experienced in using the tool." Senior cardiology registrar 23, (U)

"In a very busy clinic sometimes it can take an extra 5 minutes." Senior cardiology registrar 23, (U)

In addition, many HCPs indicated that the benefits of using the tool in practice outweighed the time it took.

"I guess it does take more time to use it. I think it will but actually, I think an extra couple of minutes spent so that a patient makes a shared decision with you and understands the real key benefits and risks, those extra few minutes are a pretty effective few minutes to use." IP pharmacist 35, (U)

"…the benefits were, certainly outweighed the time it took." Stroke consultant 40, (U)

One cardiologist (non-user) and one pharmacist (user) perceived the need to organise the consulting room being another factor that could limit the integration of the tool into routine workflows, as indicated below:

"…the need to organise your consulting room in such a way that the patient can see your computer is a potential barrier as well…it also means they have to be in a position where they can see the computer screen without reflections and get close enough to it to see what it's saying, so there are some constraints to organising the seating arrangements plus the patients often come with a partner and they both have to be able to see the screen…so you

have to have three people able to see the screen at once all close enough and all without reflections..." Cardiologist 20, (NU)

"As I stated previously … having the right equipment and location for both clinician and patient to observe a computer screen is challenging in this setting" IP pharmacist 35, (U)

7.3.5.3 Content

Few HCPs reported that the DST did not support the off-label prescription of new anticoagulants. They provided cases from their clinical practice where the tool recommended "no anticoagulant", whilst in their opinion, the patient meets NICE (*CHA_2DS_2-VASc)* threshold for anticoagulation. Clinical scenarios are illustrated in table 7.2

Table 7. 2: Example of clinical scenarios where the DST recommended no anticoagulant

Healthcare professional	Case
AM consultant, 33	A 69 yr.-old, Female patient, newly diagnosed with AF. (Weight >60 Kg), and was diagnosed with vascular disease. Normal renal and liver function, no bleeding or bleeding disorders. She takes aspirin, omeprazole, propranolol, and atorvastatin. When checked for interactions she was found to have significant and severe interactions with warfarin, dabigatran, and edoxaban. The recommendation was "no oral anticoagulant" is recommended for this patient.
Specialist nurse, 32 Haematologist, 44	• A patients with *CHA_2DS_2-VASc* 0 who needed anticoagulation for AF cardioversion • Also we have since noticed that it excludes men with a *CHA_2DS_2-VASc* score of 1 for age over 65 and females with *CHA_2DS_2-VASc* 2 for sex and age over 65, from NOAC.

"The biggest stumbling block for us is the unlicensed use of NOACs in AF patients with risk factors of age 65-75 +/- female sex… We were proposing that this group of patients would be offered anticoagulation with warfarin or NOAC. This would, of course, create a mismatch in practice if we were using the tool." nurse 32, (U)

A key facilitator to the decision support tool uptake was direct-to-colleague communication about the tool usefulness which may help make other healthcare providers aware of the tool and thus encourage its use, as indicated below:

"Really, I just think facilitation are those clinicians who are in the right setting; if they've had practice and they support the use of the tool, then I suppose they need to spread that out through their team. So, if consultants are trying it, then they should be speaking to their colleagues and peers to encourage their use..." IP pharmacist 35, (U)

7.4 Discussion

This study aimed to explore the impact of the DST on anticoagulants prescribing decision-making in the HCPs' natural environment. The qualitative element of the study was used to explore changes in the HCPs' perspectives from the initial evaluative study. The potential utility of the DST reported from the pre-interventional evaluation was confirmed in this study as an actual utility that positively influenced the decision-making process. However, additional concerns were found from implementing the DST into routine clinical workflows.

The purpose of this section is to discuss the main findings from this stage of the study. Consideration is then given to how these findings compared to findings from the previous chapter and the literature, especially the literature on barriers to implementing decision support systems in clinical practice that was discussed in chapter two (section 2.2). Finally, Key points are summarised in the final section of the chapter.

7.4.1 Impact of the decision support tool on anticoagulation prescribing decision

Findings from this study confirmed that characteristics, design features and functions identified during the pre-intervention evaluation of the DST positively influenced the decision-making process, hence, successful implementation at an individual level in clinical practice was achieved. Previous studies and systematic reviews identified measures indicating successful implementation of CDSSs in clinical practice. Whilst physician performance and patient outcomes were the most studied impact of CDSSs on clinical care process and outcomes (Garg et al., 2005; Hunt et al., 1998; Jaspers et al., 2011; Osheroff et al., 2007). Other studies considered the impact on the decision-making process and workflows as important measures of successful implementation (Jao and Hier, 2010; Kawamoto et al., 2005; Miller et al., 2007; Murray et al., 2004; Musen et al., 2014;

Osheroff et al., 2007). The main emphasis of this study was to assess the impact of the DST in targeting specific aspects of the anticoagulation therapy decision-making process.

Qualitative findings from this study revealed that implementation of the DST in routine clinical practice was found to have a consistent impact on HCPs' decision-making process and was found to address key suboptimal determinants contributing to HCPs' uncertainty and doubt in anticoagulants decision making.

As illustrated in the literature review chapter, sufficient RCTs were available to provide evidence related to CDSSs impact on medication management. Computerised decision support systems for OACs prescribing were found promising to improve both the quality and efficiency of anticoagulation management in clinical practice (Chatellier et al., 1998; Fitzmaurice et al., 1998; Pearson et al., 2009). Similar qualitative studies evaluating the impact of implementing decision-support intervention on anticoagulants decision-making process and decision quality were scarce, and only a few studies focused on assessing non-clinical outcomes as their main endpoint measures (Fitzmaurice et al., 1996; Fraenkel et al., 2012; Papaioannou et al., 2010; Thomson et al., 2007; Wess et al., 2011). However, the literature on the impact of CDSSs on anticoagulation therapy prescribing decisions are constantly evolving (Arts et al., 2013; Arts et al., 2017; Clark et al., 2016; Deitelzweig et al., 2014; Eckman et al., 2016; Wess et al., 2007; Wess et al., 2011).

Addressing HCPs information needs was reported by the majority of HCPs who were involved in both the pre-and-post intervention evaluation studies. During the intervention stage, all HCPs indicated that they made use of the information and resources of information included in the tool to support their prescribing decisions. Adherence to guidelines and best practice recommendations were frequently reported by research respondents. Themes related to improvement in the quality of prescribing decision were

comparable between the pre-and-post implementation evaluations. Importantly, improved HCPs adherence to NICE recommendations and other international guidelines; improved anticoagulants prescribing safety; reducing the co-prescribing of interacting medications; improved prescribing practice through interactive alert messages and information texts.

Qualitative findings from this study revealed that successful implementation of the DST helped HCPs to standardise their prescribing practice. Jao and Hier, (2010) explained that the influence of the CDSS implementation to standardise HCPs' clinical practices came from its ability to impact variables surrounding the decision-making process, for example, knowledge, clinician's prior experiences, external resources, individual patient-related factors, and time.

7.4.2 Barriers to implementing the decision support tool in clinical practice

Despite consistent findings demonstrating the ability of the DST to replicate the natural flow of thought for clinical decision-making at the point-of-care and improve the quality of the decision-making process, the mere provision of the DST did not guarantee its uptake. In fact, of the original 47 HCP who initially agreed to participate in this evaluative study, approximately a third followed through with this intention. HCPs' intentions to use the DST were related to their level of comfort in offering the DA to their patients and were related to their concerns about implementation issues. Barriers and facilitators to implementing the DST in clinical practice were sought from both HCPs who were directly engaged with the DST and from interviews with HCPs who were reluctant to implement the tool in clinical practice. In comparison to potential concerns revealed during the initial evaluative study, further concerns were identified, and were classified as; organisation-related barriers, HCP-related barriers, patient-related barriers, and issues specific to the DST.

7.4.2.1 Organisation-related barriers

This study revealed that barriers related to technical infrastructures, such as, limited computer availability and poor internet connection provided at the point of care delivery were key factors that hindered successful implementation. Prior studies on organisational-related barriers to using CDSSs found that particularly the quality and quantity of technical infrastructure provided were key factors impacting on the uptake of DSSs (Moxey et al., 2010). Further, HCPs from this study indicated that even when computers were accessible, they identified ongoing technical problems such as system malfunctions and slow computer speeds as barriers to use. This often resulted in frustration for users (Moxey et al., 2010). Consistent with our findings, previous studies (Bastholm Rahmner et al., 2004; Rotman et al., 1996; Saleem et al., 2005) found that technical issues with computer hardware and software were indeed relevant.

Healthcare professionals from this study seemed to have assumed that integration of the DST with existing healthcare systems was a key facilitator to the DST uptake. Previous studies reported that integration of CDSSs into current electronic health systems would have potential to address organisational barriers and should facilitate ease of CDSSs uptake into clinical practice (Moxey et al., 2010). In that stand-alone systems which need double data entry once into the medical record system, and again, into the CDSS can limit the usefulness of such systems (Berner and Lande, 2007; Clayton and Hripcsak, 1995). Findings from this study revealed that the key facilitator to most barriers to implementation in clinical practice was the integration, and Further, approval and buy-in from stakeholders in the health organisation to integrate the DST into routine use in clinics. Heathfield and Wyatt, (1993) mentioned that organisational attitudes and support play an essential role in the development, implementation, and integration of CDSSs into routine clinical workflow. In that, successful integration of CDSS requires changes in organisational

policies and goals (Heathfield and Wyatt, 1993). Jao and Hier (2010) related successful integration of CDSS into practitioner's workflow to the motivational effect of the organisation's enthusiasm and access to technical support and training which are critical to good system performance.

7.4.2.2 Healthcare professional-related barriers

Findings from this study revealed that general resistance to change existing practice and a perception that the use of the DST may threaten HCPs autonomy were repeatedly identified as a barrier to use. Conversely, other studies indicated that the limited computer skills of HCPs and lack of training in the use of CDSSs were the most frequently reported barriers impacting uptake by end-users (Leslie et al. 2006; Moxey et al., 2010; Short, Frischer, and Bashford, 2004; and Toth-Pal, Wardh, Strender & Nilsson, 2008). This may indicate that participants in this study were computer literate and had good familiarity with technology. On the positive side of the DST, good system design and that the interface was easily learnt and user-friendly may also explain the ease associated with the use of the DST. User-friendliness was cited as a facilitator to CDSS adoption in clinical practice by Graham et al. (2008); and Robertson et al. (2011).

In addition, some HCPs in this study were reluctant to use the DST in front of patients to avoid the negative perception of patients in that they used the DST due to a gap in knowledge. Similar findings were reported in the studies of Harrison et al. (2009); Leslie et al. (2006); Macy et al. (2005); Toth-Pal et al. (2008); and Varonenet al. (2008) which noted that lack of acceptance as barriers to the use of CDSS in clinical practice.

Among barriers related to HCPs, findings from this study found that lack of the awareness existence of the DST was reported as a facilitating condition barrier to its use. This barrier

was cited in the study by Hor et al. (2010) to implementation and widespread dissemination of CDSS systems in clinical practice.

7.4.2.3 Issues specific to the decision support tool

A range of the DST-specific factors was identified in this study as impacting on the uptake. The most prevalent barrier found was the perception of time or time constraints to use the DST. This particular concern was consistently reported during the pre-and post-intervention evaluative studies as having an impact on the HCPs' decision to use the tool in clinical practice. The following studies cited time constraints or practitioner's lack of time as a significant barrier to the usability of CDSSs in practice. For example; Toth-Pal et al. (2008), in a qualitative analysis of attitudes of general practitioners in implementation of a CDSS in clinical practice, Peek et al. (2011), in the evaluation of a guideline based DSS for cardiac rehabilitation study, Robertson et al. (2011), implementing CDSS for prescribing in GP practice, Harrison et al. (2009), in a study of implementing patient decision aid, Lugtenberg, et al. (2015) in implementation of multiple-domain covering CDSS in primary care, and Short et al. (2004), in qualitative study to identify barriers to the adoption of CDSS in general practice consultations.

This study revealed considerations about the complexity of the tool and the fact that the DST did not account for local constraints, such as the availability of specific drugs to influenced HCPs' perceptions regarding ease of using the DST in clinical practice. Among the literature reviewed, the complexity of the system or its content created a barrier in the studies of Leslie et al. (2006); Harrison et al. (2009); and Murray et al. (2004) when implementing patient decision support tools during the consultation. The lack of flexibility within the system acted as a barrier to implementation in the study of Hor et al. (2010) and hindered its use by practitioners. Further, few HCPs reported that the DST did not support the off-label prescription of new anticoagulants, whilst in their opinion, the patient meets

NICE (*CHA_2DS_2-VASc)* threshold for anticoagulation. In brief, the tool developer provided the following explanation*: "the gap in evidence resulted because the licensed indications for the NOACs actually reflect the risk assessment criteria previously used in CHADS rather than the currently used CHA_2DS_2-VASc which NICE recommends. In practice, this means that there are a small number of patients who meet the NICE criteria for anticoagulation - CHA_2DS_2-VASc score of 2 or above, (or is male with a CHA_2DS_2-VASc score of 1) - but who do not technically satisfy the label's exact wording for the NOACs. In practice, if HCP interpreted the licensed indications for NOACs literally, there are some patients who whilst they meet the NICE (CHA_2DS_2-VASc) threshold for anticoagulation they do not fulfil the licences for the NOACs. This group of patients would indeed represent off-label prescribing of a NOAC" Tool developer*

Healthcare professionals from the pre-and post-intervention evaluative studies found pop-up messages useful as they present important reminder and alert texts that improved prescribing decision. However, this was not always the case; physicians in a study to assess the utility of computerised support intervention found the recommendations provided in pop-up alert messages to be intrusive and time-consuming to comply with all of them (Murray et al., 2004). Such interventions could be typically viewed as disruptive and should be reserved for urgent clinical situation only (Ash et al., 2004). Pop-up fatigue can occur when too many alerts disrupt clinical workflows (Ash et al., 2004) and systems designers have to maintain balance between practitioners' need for an effective intervention versus systems disruption and demands on user time and attention (Ash et al., 2004; Murray et al., 2004; Overhage et al., 2001).

7.4.2.4 Patient-related barriers

Consistent with other studies, findings from both the pre- and post-intervention evaluative studies revealed that patient-related factors may create an additional layer of complexity in HCPs' decisions of uptake in clinical practice (Kortteisto et al., 2012; Martens et al., 2008; Sittig et al., 2006; Varonen et al., 2008 Zheng et al., 2005). Healthcare professionals from this study revealed a range of views expressed about the benefits of the DST within the consultation and its influence on the patient–doctor interaction. Most HCPs indicated that it enhanced discussion with their patients, whereas few HCPs revealed that they often lost eye contact with patients by spending much time looking on the computer during the patient encounter. Similarly, several studies reported opposing views about the impact of the CDSS on the doctor-patient interaction during the clinical encounter (Moxey et al., 2010; Roshanov et al., 2013). However, Entwistle et al. (1998) revealed that CDSSs might affect doctor-patient relationships in the longer term as well as interactions in the short-term. Hence, it has potential to affect patients' and doctors' satisfaction.

To deal with this patient-related barrier, HCPs suggested involving patients in using the DST during the consultation. A review study (Roshanov et al., 2013) showed that CDSSs that involve both practitioner and patient are more effective in terms of improving quality of patient care. Another way to deal with this barrier, which also partly addresses the perceived time constraint, is more preparation before actual patient consultation and get leaflets and written material printed and ready. In return, this was reported helpful in optimally using the DST, while at the same time focusing more on communication with the patient during the consultation and minimise harm to patient–doctor interactions.

With more widespread use of computers in clinical practice over time, the potential for harm to the doctor–patient interaction was magnified in this study. Acceptance of the

technology by HCPs and the efforts of involving patient in using the CDSS during consultation are likely to dispel some of the concerns (Moxey et al., 2013).

According to Venkatesh et al. (2003) classification of performance expectancy and effort expectancy barriers to CDSS adoption, our findings suggested that the DST under consideration had less number of barriers related to performance expectancy compared to barriers related to effort expectancy. These findings indicated that the DST was useful and improved the quality of anticoagulants decision-making process when implemented successfully. According to Venkatesh et al. (2003), factors related to performance expectancy of DSSs was perceived as the strongest predictor of intention to use.

7.4.3 Conclusion

This study explored HCPs' perspectives on the utility from implementing the Keele anticoagulation therapy decision support tool into routine clinical practice. These findings add to the literature by suggesting that anticoagulation therapy prescribing decision is feasible for a standalone DSS to improve the decision-making process when used by HCP at the point of care.

The DST assisted in the field of anticoagulants prescribing decision-making process, an area in which CDSS has rarely been studied for its influence on HCPs' prescribing decision-making. Following a step-wise evaluation process, HCPs have previously shown that the DST could have potential to impact their prescribing decision-making when demonstrated in the pre-interventional evaluation. In this multi-centre interventional study, further evidence has been generated that supports the findings of previous evaluation step. Additionally, this study showed that HCPs' concerns from the extra time associated with implementing the tool in clinical practice were averted by using the DST in the real clinical

environment. Nevertheless, the fear from potential influence on doctor-patient relationship remained a concern for few HCPs.

The current study indicated that initially, two-thirds (31/47, 66%) of HCPs sought to access support from the DST. However, only third (18/31, 38%) was followed with this intention. This two-fold difference between trying to access the DST and actually using it was a key finding in this study. Several barriers existed between HCPs perceiving the need for decision support and actually using the DST. In fact, the computer accessibility was shown to be a factor predicting the use of the DST. It was possible that the provision of additional IT portable devices for the study may have encouraged the tool usage; however, this was avoided since the study aimed to test the DST in the usual clinical environment. Patient clinical and non-clinical factors seemed to have compromised ease of access to the PDA. Patients' preferences and attitudes were other factors leading to inadequate PDA use.

Barriers identified in this study were consistent with the literature and had not changed over time. Although some of these barriers are difficult to overcome, the facilitators suggested in this study would increase HCP acceptance and therefore the effectiveness of the DST. The analysis of the data concerning patients' perspectives on the usefulness of the DA during the consultation will now be discussed.

Chapter 8: Analysis of interviews with patients who experienced the decision aid

The aim of this stage of the study (as discussed in section 4.5.1) was to conduct semi-structured qualitative interviews with a sample of AF patients after they had experienced the DA to explore their perspectives on the value the DA had for them during the consultation. This aim of this chapter is to discuss the analysis of the qualitative and quantitative data from the interviews that concerns the fourteen patients' perspectives on the DA.

Demographic information about the patients is included in section 8.1. Their views about involvement in the decision-making process are discussed in section 8.2, and section 8.3 concerns their views about the DA, which includes involvement in the treatment decisions (section 8.3.1), amount of information (section 8.3.2), and views about the DA content and presentation (section 8.3.3). Patients' attitudes from implementing the DA in clinical practice are discussed in section 8.4. Section 8.5 concerns patients' perspectives on concerns related to using the DA during the consultation. Quantitative findings are discussed in section 8.6. Discussion of how these findings relate to the literature is presented in section 8.7.

8.1 Patient demographics

Demographic information about the patients is summarised in tables 8.1 and 8.2. As discussed in section 4.5.3, of the twenty-eight eligible patients invited to participate in this study, fourteen consented to participate in the qualitative interviews and completed the research questionnaires as illustrated in figure (4.5).

A descriptive analysis of the sample revealed that of the 14 patients, eleven (78.6%) were male and three (21.4%) were female. The sample had a mean age of 73.9 years (SD= 10.37), where the majority of the sample (78.6%) were older than 65-year-old, and half of the sample were older than 75-year-old. Approximately two-thirds of the sample (71.4%) completed secondary school, and approximately one-third (28.6%) had a university degree.

Table 8. 1: Patients' Characteristics

Research code	Age in years	Gender	Research site	Education level
P1	76	F	Outpatient	Secondary education
P2	86	M	GP-practice	Higher education
P3	80	M	Inpatient	Secondary education
P4	69	F	Ambulatory care	Higher education
P5	66	M	GP-practice	Secondary education
P6	56	M	Ambulatory care	Higher education
P7	90	M	Inpatient	Secondary education
P8	60	M	GP-practice	Secondary education
P9	82	M	Outpatient	Secondary education
P10	81	M	GP-practice	Secondary education
P11	68	M	GP-practice	Secondary education
P12	73	F	GP-practice	Higher education
P13	64	M	Outpatient	Secondary education
P14	84	M	Outpatient	Secondary education

F: female, M: male

Table 8. 2: Summary of demographic characteristics of patients

Characteristic	N (%)
Gender	
Male	11(78.6)
Female	3(21.4)
Age group (years)	
<65 year old	3(21.4)
75> age ≥65	4(28.6)
≥75 year old	6(50)
Education level	
Secondary school	10(71.4)
Higher education	4(28.6)

8.2 Patients' views about involvement in the decision-making process

Patients were asked for their views on the level of involvement and who should take the lead in making the treatment decision. They were asked to select one of five responses: the doctor alone, the doctor after discussion with the patient, the doctor and patient together, the patient after consultation with the doctor or the patient alone. Overall, 78.6% said the doctor and patient should make the decision together, giving a total of 21.4% who said the doctor should decide after discussion with the patient. Similar views were found from the interview findings, where, the participating patients revealed two main approaches to involvement. They were; patients who wanted to be involved in the treatment decision, receive all the information but found it difficult to choose between the available options and preferred to leave the final decision to doctor, and patients who wanted to be involved in the decision and share the prescribing responsibility with the doctor. As indicated in the examples below:

"So that I know exactly what's going on rather than just being told take this, this is of benefit, they should explain two ways so to give you an option." P8

"I think they should be involved, but we've obviously got to take the doctor and the medical people's advice and opinion. I would think you've got to let the medical people make the final decision really. Just discussion and being informed really" P4

Patients seemed to have assumed that the doctor-patient interaction during the consultation as an important aspect of patient involvement in the treatment decision-making. They indicated that the approach to patient involvement during consultation should include; communication and receiving information, understanding patients' needs through a good doctor-patient relationship, and an inclusive discussion that leads to a shared treatment decision.

All patients perceived communication with the HCP and receiving information about AF and treatment options as an important aspect of patient involvement in the treatment decision.

"... So rather than say take a tablet and they let you read what it can do and can't-do ... I think they should explain that you monitor this, that you can't have this rather than just they give you a box of tablets and you have to read the leaflet and stuff ... I think they should explain more." P8

"Well as long as they have the information and there's negotiation and that both sides can put their case forward and reach an agreement I think that's the best way forward." P5

In his view, P14 emphasised the need for either one-way or two-way asking of questions to enhance patient involvement in the treatment decision, as stated:

"Well, when I go see the doctor, he asks you things, you know, you want him to ask you things… you ask him. Well, vice versa, I suppose. There's got to be either one or the other or both." P14

Patients suggested a good relationship with their doctors as another indirect approach towards patient involvement in the treatment decision. Patients emphasised that they value the good relationship with their doctors. The one that is built on trust and support that he knew his patients and provided a tailored approach.

"Well the knowledge that you know that you're getting the best care and the best drugs too, that's going to help you" P9

"…so, you have to have confidence, and you have to feel that they've got confidence in you, it's a two-way thing." P5

"…You just trust the doctor basically. You have a trust in the doctor." P6

"Well, it's better for you as well and better for the doctor so as you've both got an idea because what suits one person might not suit … I think they listen to me more that way, so they understand it more" P8

Patients further discussed an inclusive discussion that leads to patient involvement in the treatment decision. Patients emphasised that they wanted to participate in the decision about anticoagulation therapy and they expected their HCP to provide them with the necessary information to enable them to take an active role in deciding about treatment decision.

"Yes, they got to be involved. Well, you have advice from the doctor himself or medical people then the decision is yours really. So, after [you] have advice and then make the decision as well together really." P10

Few patients suggested that they wanted to be passive but wanted to leave the final treatment decision to their doctor. As shown in the example below:

"Well, I think they should be given all the options, but I also think that giving all the knowledge the doctor has the last word because they know more than the patient." P12

8.3 Patients' views about the decision aid

This theme emerged after prompting participating patients to talk about the value the DA had for them during the consultation.

In summary, all patients agreed that the DA was a comprehensive and efficient source of information, in that; it provided information in detail about all available options. Also, they suggested that the tool was useful in clarifying their preferences. They added that the use of graphics in combination with verbal communication supported their understanding of benefits and effects of anticoagulants, therefore enhancing information communication and recall.

All patients indicated that the DA promoted a shared decision-making with HCP and patient together. The majority of patients said that the tool helped them to get involved in the decision-making process, in terms of, providing detailed and clear information, introducing all available choices, helping them to explore their preferences, and finally, combining identified preferences with information about available options to make joint decision about which agent to prescribe.

This overarching theme includes three main themes: involvement in treatment decisions, amount of information, and patients' views about the tool content and presentation.

8.3.1 Involvement in treatment decisions

Interviewed patients were consistent in describing the decision-making process with using the PDA during the consultation. For example, patients said that they were actively involved and shared information with their HCP to reach an agreement about the treatment choice. Several patients indicated that because they were participating in the decision process, they understood better and felt more confident. For all patients, it was a process of receiving information and active participation in decision-making.

Patients' experiences provided:

For P9, an 82 year old, indicated that the use of graphs helped him to understand the risks and benefits straightaway.

"The graphic things. The most useful thing I think it is, yes. You, I mean it's, you know, you can look at that, and you know straight away…I think it's very, very good, putting a graph up like that because, you know, you think, 'Well I'm down there, and there are hundreds of people in front of me'…" P9

He also explained how his understanding would improve his perception of his disease and associated risks.

"In one word, visual. Because looking at the computer and that I think, it just reassures you and you can see where you are on the chart and if I'd been halfway up or anything I'd, well, I'd have thought, 'Well I'll have to alter my way of living and things like that'. But yes, I think it can help people quite a lot, you know, just see where they are on the chart like… Yes, I found it quite interesting. Yes, useful and interesting." P9

Another patient indicated that the presentation of benefits and effects of treatment using visual aid improved communication of information and enhanced his understanding.

"It explained the different ways, how my stroke was lower or a bleed or anything like that, it was all clear." P8

"Because it's like you talking to me but if you have got some facts to show you up it's much better so you could say something and you say these are the facts… So, verbal and visual facts [yeah]" P8

P3, who is 80 years old and had experienced the DA during his hospital stay after recovery from stroke, felt that the decision aid was very useful in helping him to think more carefully about his medication and had everything explained to him and said he found it very beneficial.

"Oh, it's very good. Things have been explained. We've looked at the medication. We've looked at the side effects. We've looked at the benefits. We've looked at other medications, prior to my stroke, that I had been taking. We've had a look at Omeprazole. We've looked at other things Yeah. Ibuprofen, we've looked at that. We've realised that it can cause bleeding in the stomach or elsewhere. So, it's been very beneficial. I've learnt a lot." P3

"Yes, I've learnt a lot from [decision aid] tool…and I've had things explained to me... she [the consultant] has taken me through the different stages of medication. I've had everything explained to me and one-to-one is marvellous…" P3

This patient valued the use of visual aids presented in the DA because the information had last longer compared to the use of leaflets and verbal communication only.

"Well, I like the idea of leaflets. I think it's something you can think about and look at it. Word of mouth is okay, but it soon passes away, doesn't it?" P3

For P7, who is 90 years old, said that despite his advanced age, he generally found the decision aid understandable and the language was easy for him. There were some aspects he found confusing; this is discussed further in section (8.5.2).

"It is easy to understand; the language is easy…I think it's good… Bearing in mind the fact that it's not usual for a person of 89.3 to cope with this sort of [consultation]" P7

Another patient indicated that given the time constraints in a typical GP visit, the use of this decision aid could help to share the information and shared the decision-making process with patients, as illustrated below:

"Well, I feel that if your GP had something like this although they've only got a 10-minute slot for most patients. If there was something that they could present to a patient just to explain this is where you are and if you don't take this or if you do take this, then you could be okay." P9

"I found it very interesting seeing the tool and my overall experience was, you know, very good." P9

All patients described how they saw the treatment decision having been made for them. P5 (66 years old) for instance, described in detail the decision process with the consultant. For her, the decision aid helped her to understand and accept the treatment offered.

"Yeah well the Warfarin had weekly blood tests, this one was a new one and had been recommended by NICE, I know that there were certain things on that but when we put the other medication in that I was on you could see the recommendation was there so yes you had to go with it and decide whether it was the one a day or the two a day and I felt that was the right decision and it has been, yeah." P5

This patient revealed that being able to share all the decision-making process with her consultant helped her to feel confident and reassured that the right decision had been made, as illustrated below:

"Right because when we put in the medication I was already on it knew how that would react with both of them and then it was just a case of tweaking it to know, so it was good to see that the things I was taking were there and that the information was there, so I did feel confident with that." P5

For this patient, as for others, this consultation served as a reassurance through adequate information was given and the ability to explore their preferences to decide on which particular treatment to prescribe. As emphasised by P5:

"To be able to see the different medications that I was on and to make sure that I felt that it was taking into account the interaction between that and the other ones that I [had] the choice of. And it explains everything that you should be [thinking about] so there are a couple of questions you need to know about, and they explore your preferences." P5

She revealed that the tool provided a step-by-step way of thinking about the prescribing decision and discussing them with her consultant. She said, it was a useful, structured and organised and did not overlook anything.

"I could just ask things, and the consultant tried to find my preferences…he let me come to a decision I feel like and then said yeah that's probably the right thing to do." P5

"… that it was more structured." P5

Also, P5 described and compared her interaction with the consultant during the consultation. She said that in the usual consultation she used to sit and listen. Whereas, in the consultation with using the DA, although the consultant went through everything in

detail, however, she was satisfied as she had the chance to see how the decision was made and could stop the consultant to ask questions. In her opinion, such style of consultation needs more time, but that time is well spent. She stated:

"Usually you're used to sit and listen. That's right, and then you get an opportunity perhaps to ask [later] yeah, but you can't always remember especially if you've waited a long time outside you sort of glaze over a little bit. So, no, I know that it's much more in detail and you would need a lot more time, but I think that time is well spent, really. Because you both feel that it has been the right decision" P5

"Well, I imagine so because you wouldn't be going through all that normally, you would just get the finer points and there would be lots of questions you would want to ask when you got home whereas [with this [the decision aid]] you could see everything there and ask… So, yeah you can stop him and ask him…yeah that's right, he didn't just keep running" P5

For P14, using the DA during consultation helped him to follow the consultant, ask direct questions, get more information and better recall of information. This patient showed his preference toward using a DA over usual consultation which is basically verbal communication of information. As indicated below:

"… because it explains it better doesn't it. So, your question is to be directed to that, 'oh, what's that for then?' And things like that. If he's talking to you, you won't get all that information, would you? You probably would, but you wouldn't have it in your mind would you…" P14

"…You know, I think you take more in when you see it like that." P14

For P6, who indicated that because the DA was clear, concise, this enabled him to understand the decision made. And he revealed that he was fully involved in the decision-making process. P6 stated:

"It set out in detail all the options, so made the decision quite easy…I think it was that the decision tool was clear, concise and lots of information…I think just enough…I was fully involved" P6

It was a conversation; this is how P12 described how the consultation went with using the DA. She added that this helped her to accept the recommended treatment.

"It was very informative; it was generally – can I say – it was a conversation between GP and patient. It wasn't the GP saying to me 'this is what you want and this is…'; it was 'let's have a look, and we'll do it together, but this is what is recommended', and I went along with the recommendations." P12

8.3.2 Amount of information

There was a consistency in patients' perceptions about the amount of information and the length of the decision aid, with the majority of patients indicating that the information included was comprehensive, concise, and direct to the point. None of the patients felt there was too much information or that the decision aid was too long. All participating patients seemed to have assumed that the tool provided all the necessary information in sufficient details, and that, it was easy to understand and absorbable even for a layman. Examples provided from participating patients:

"The amount of information included in the tool is excellent" P1

"It's comprehensive" P2

"Well, I found this is shorter and more to the point." P3

"I think it was just about right. I could understand it without it being too complicated." P4

"Clear and concise." P6

"It is easy to understand; the language is easy." P7

"It included enough information to help patients understand the decision. I think it does for the layman. Yes, it was just enough, yeah." P9

"It's absorbable." P11

8.3.3 Content and presentation

Participating patients showed positive initial impressions in describing the DA content and presentation. The use of easy language and terms made the DA beneficial for the 90-year old patient. Other patients commended the DA layout indicating that it was straightforward and very well put out. All participating patients assumed that the DA was clear, informative, thorough, and easy to understand. All patients tried to use the word "comprehensive" and "balanced" to describe the DA content. Examples illustrated below:

"Very thorough and it went through everything …was very good." P1

"very informative" P13

"it's comprehensive… is quite efficient…" P2

"It set out in detail all the options, so made the decision quite easy." P6

"Yes, it's understandable; it's easy to understand so yeah." P8

"Yes. It wasn't too much; it was just enough for anyone to understand and to grasp what was happening and what you needed to do." P12

The following quotes list some interface-design features highlighted by research respondents as excellent, clear, easy to explore, and structured.

"Presentation is excellent" P1

"it's flowed, the presentation is very good. That was excellent. It was clear" P3

"Very good. Excellent. It followed a pattern all the way through. It was very well put out. I thought it was excellent from the very beginning right to the graphs at the far end. Excellent." P3

"… that it was structured." P5

8.4 Patients' attitudes and impressions from experiencing the DA during consultation

All participating patients appeared to be consistent in describing their attitudes from experiencing the DA during the consultation. Patients commented that they were quite happy, felt informed, clear and were more confident that the information was tailored and they assumed that the right decision was being made for them.

In the following quote, P1 stated that he was happy for being informed about treatment options and his risk scores. While for P4, that because the DA was thorough.

"Quite happy… I think it would give a lot of peace of mind in being informed about the drugs and the risks." P1

"So, I think it is quite thorough… I'm quite happy…" P4

For P2, the way the consultant communicated the information was described as easy. He called it a question and answers session, as indicated in the quote below:

"It's quite easy… It's just a question and answers session which was quite good. Fine." P2

"Without a doubt" phrase was used by P3 to emphasise the usefulness of the DA. He explained that the DA presents the information in a methodical and accurate way.

"Without a doubt. Without a doubt…It helped me, yes. There's been no confusion because everything has been explained in a methodical and accurate way." P3

Other patients liked the DA for its content. For example, P7 and P9 described it as very educational and very informative, in order.

"Very educational." P7

"I think it's very informative…I found it quite interesting. Yes, useful and interesting." P9

"I think I had enough information" P10

P5 revealed that using the DA during consultation made her feel confident that she had made the right decision using the right information. P5 stated:

"That's right, and when I got home I really felt that I had made the right decision and that I had the right information and I did feel confident…I think it's brilliant, really good, yes." P5

P12 felt positive about using the DA during consultation because there was a lot of communication.

"…So, there was lots of communication." P12

All participating patients were positive about the presentation of information which they perceived as helpful for improving the communication of information through the use of graphics formats of benefits and effects of treatment. Overall, there was a high level of

consistency of comments about the usefulness of visual aids for improving patients' understanding, and potential recall of information.

The following patients explained the impact of using the DA on their ability to understand key messages and recall of information.

"… I find this most beneficial because I don't have what I call a retentive mind. In other words, I can be told something, and two weeks later, I've forgotten all about it but when I've seen it… …you don't forget it …" P3

"Very good because it's all in front of you rather than you just saying well this is so and so. So, you can actually see it on there… it's much better so you could say something and you say these are the facts… So verbal and visual facts" P8

Most patients revealed that showing them graphs reassured them because they were able to see how treatment can benefit them visually.

"Slightly anxious, I suppose you could say, but when I saw how it is going to benefit me, I just relaxed. I thought to myself, 'It's doing me good'. Fine." P2

"I think it's very, very good, putting a graph up like that because, you know, you think, 'Well I'm down there, and there are hundreds of people in front of me', so yes, it gives you more reassurance I believe…I think it can help people quite a lot, you know, just see where they are on the chart like…Yes, I found it quite interesting. Yes, useful and interesting." P9

Calculating patients' bleeding and stroke risks and showing these to them in graphs and faces was reported interesting, and was perceived better than just verbal explanation. Patients reported:

"Calculating the stroke and the bleeding risk and showing these in faces and graphs I thought that was quite interesting." P2

This visual presentation helped all patients to understand their risk score better, as shown below:

"Well, you can see for yourself what the risks are, what the benefits are. Someone is talking to you, yes, and you are understanding, but if you look and see the actual…I think it brings it home more to you." P12

"…when you see it, … you get it more in perspective than if he explained." P14

"Well, it's put over in a very clear way, so that it makes sense. You can see what your chances are the way it's presented." P3

8.4.1 Patients' initial satisfaction

Up to this point during the interview, participants were asked about initial satisfaction with using the decision aid during the consultation. All respondents were enthusiastic about the tool and replied as were satisfied. Example from patients' responses provided:

"Yeah, excellent" P1

"Yeah, fine." P2

"Yes, more than satisfied." P3

"Oh, very satisfied." P7

8.5 Perceived concerns related to the use of the decision support tool

Participants were also asked a series of questions to elicit their opinions of concerns related to the use of the decision aid in clinical practice. Only two main concerns were reported by participating patients, Time pressure and patient-related factors.

8.5.1 Time

Most patients commented that using the decision aid during the consultation can be time-consuming and more likely lead to longer consultation time. Patients were asked 'How long it took?' Patients' responses were varied as illustrated below:

"I would think longer than 10 minutes. 15 minutes I would have thought." P4 (clinic-based consultation)

For P12 who stated that it was 20- minute long consultation, which was fine for her, but not for other patients waiting outside.

"I suppose so, yes. I think it was about 20 minutes…Yes. It didn't matter to me but the other patients perhaps." P12 (GP practice)

"Well, I should think a minimum of an hour." P7(inpatient consultation)

"About the same really." P10 (GP practice)

There appears to be a big difference between an inpatient consultation and a GP consultation. Talking to patients did not reveal any reason for the time it took. However, going back to chapter seven section 7.3.5.2, some HCPs indicated that integrating the DST as a research project contributed to increasing the total time required during the consultation. While other HCPs attributed this to their unfamiliarity with accessing the DA during the consultation.

Like the HCPs opinion, patients indicated that the benefits of using the tool in practice outweighed the time it took. Most patients showed that they felt they should accept the fact that using the tool in practice would impose extra time because it was detailed and comprehensive decision aid, but the time was very well spent during the consultation.

"...I know that it's much more in detail and you would need a lot more time but I think that's time well spent, really do because you both feel that it has been the right decision" P5

For P4, as for other patients, who felt that the use of the DA can make the consultation time longer but that because of the nature of the decision, that time needs to be made.

"I think the only thing that would be against it is the time. The time it takes… [because] if you want to help people more, then you've got to spend more time… So, if it's longer then, it's better." P4

8.5.2 Patient-related characteristic

Despite the fact that the mean age of participating patients was approximately 74 years old, all patients felt that the DA was absorbable and easy to comprehend. However, only one patient, who is 90 years old indicated that the DA was easy to understand, but he would rather prefer the use of percentages to present risks and benefits, as shown below:

"…it's a bit confusing because as I say at my age, your brain doesn't work as efficiently as you'd like it… well, easy to understand when it's been explained to you." P7

"Well it's a bit confusing because all those figures there you can't relate if it was given to me as a percentage, you follow me, and I know it's difficult to do that but when you show me the analysis before and after… if you could say, you'll notice that in percentage terms you've reduced the risk from that to that, so that's a two-thirds reduction. That's something that I could easily understand, the pictorial they're fine, but you've got to understand how that works whereas if you just talk in terms of reducing the risk from 30 to 10, that's a two-thirds reduction in risk then that's something I could understand more easily." P7

This patient complained that during the consultation with the consultant, he was unable to see the prints from some screens because of his sight problem. This was solved by providing him with a printout, which he showed it to me during the interview, and was unsatisfied because it was white and black. This issue was reported by HCPs who integrated the DST into their routine clinical workflows (discussed in section 7.3.1.1).

"…I couldn't see the little prints … I've got that printout all blobs, and you can't see the colour contrast; white and black." P7

Although all interviewed patients felt that the DA was clear and easy to understand its content, they emphasised that they need guidance to go through it as there are things needs to be explained to them. An example provided from P6:

"I think you need some guidance... because there [are] things you probably don't understand. Therefore, you need those people to explain them to you… because a lot of things you wouldn't understand." P6

Overall, participating patients were asked about any concerns or barriers related to the decision aid, healthcare setting, healthcare provider, or anything they were concerned about, they all were happy with the DA as it is. Examples provided:

"I can't think of anything" P2

"Not for me, no" P11

"Overall I can't see that there are any drawbacks really." P5

"No problem whatsoever." P13

"No, I can't see anything. I think it's going to help more." P14

8.5.3 Patient-professional relationship

Participating patients were specifically asked whether using this DA during consultation did affect the patient-doctor relationship, had changed the dynamic of interaction, or confidence in the doctor. Responses were consistent, and there was a general sense that using the tool had effectively enhanced the relationship and made it stronger and better relationship. Although HCPs initial impression and feedback was that the use of such intervention might affect the dynamic of the consultation and that some patients might feel uncomfortable with this style of consultation, patients who experienced the tool in consultation did not express any concerns and were satisfied.

All interviewed patients were fine with the use of a computer to deliver information during the consultation. An example provided:

"All the doctors I go up to see, they all use the computer obviously, and it's obviously a quick way of telling me what's good for me or what's not good for me. Yeah, and I'm quite happy with that." P2

"Yeah well, it's all computers in this day and age…Yes, I don't mind, we've got them at work anyway so I'm used to them now" P8

Participating patients seemed to have assumed that using the DA during the consultation did not influence the dynamic of the doctor-patient interaction, as shown in the example below:

"No, she looks at the screen then she looks at me so no problem at all." P8

Further, patients seemed to have a similar opinion when asked whether using the DST by their HCP would change their confidence in doctors. All patients replied as "confident", example provided,

"I'd be quite confident." P2

For instance, P8 added that using the DST did not create reliance on the software to make recommendations, rather his GP discussed the recommendation with him and went with what suits him.

"I'm very confident yeah because even though it showed me, she still told me what she thought as well." P8

Few patients were keen to suggest integration of the tool into routine clinical practice as a solution for any potential concerns if exist so that patients will get used to this style of consultation.

"I can't see there needed to be any concern really if people become used to seeing things like this and accept them." P9

8.6 Quantitative findings

This section presents the data gathered from questionnaires given to all participating patients after conducting the semi-structured interviews. The questionnaire consisted of four parts; demographic section, acceptability scale, preparation for decision-making scale, and patient decision conflict scale (attached as appendix sixteen). Data analysis was mainly descriptive statistics to describe the sample via mean (M), standard deviation (SD), and percentage (%). At this stage of the research, descriptive statistics were sufficiently suitable to exploring patient's perspectives on the utility, acceptability of the DA and patient's level of decisional conflict after experiencing the DA. Data was gathered from all fourteen respondents.

All descriptive statistics were computed using the Statistical Package for the Social Sciences (IBM® SPSS®, version 24, using a personal computer).

8.6.1 Acceptability

The acceptability questionnaire for design by the Ottawa Decision Support Group (ODS) was identified as appropriate to explore patients' perceptions of the decision aid (discussed in section 4.3.2.2).

All interviewed patients were asked to assess the acceptability of the DA using a Likert scale ranging from poor to excellent and structured response categories. The questions addressed the comprehensibility of components of the DA, the length of the DA presentation, the way the information was presented, amount of information and balance. Responses regarding the acceptability of the DA are summarised as percentages in table 8.3.

The majority of respondents felt that the DA was acceptable: 85.7% felt that the length of the DA was appropriate, all respondents (100%) felt the amount of information in the presentation was sufficient, that the presentation was balanced, and found the presentation of risks graphs easy. Thirteen (92.9%) perceived the DA useful and was easy to understand. The tool was compatible with the way things should be done.

Overall, participants' responses indicated that they were content with the information presented on AF and treatment. These findings were comparable to patients' responses during the qualitative. Overall, patients' responses were in agreement with HCPs responses from the qualitative interviews regarding the DA content and presentation (discussed in section 6.1.2).

Table 8. 3: Acceptability scale outcomes

Items	Number (%)
Ratings of quality of information presented	
Mean Scores (SD)	3.64 (0.5)
Poor=1, Fair=2, Good=3, Excellent=4	
Length of decision aid presentation	
Too long	2 (14.3)
Too short	0 (0.0)
Just right	12 (85.7)
Amount of information	
Too much	0 (0.0)
Too little	0 (0.0)
Just right	14 (100)
Presentation of information	
Slated	0 (0.0)
Balanced	14 (100)
The decision aid useful	
Yes	13 (92.9)
No	1 (7.1)
Calculate and present risks of stroke and bleeding	
Easy	14 (100)
Difficult	0 (0.0)
The rest of the decision support tool	
Easier	13 (92.9)
More difficult	1 (7.1)
The decision aid included enough information	
Yes	14 (100)
No	0 (0.0)

8.6.2 Preparation for decision-making

In this study, the PrepDM scale (patient version) enabled research participants to initially assess the potential usefulness of the DA in preparing patients to communicate during the consultation and to make an informed decision (as discussed in section 4.3.2.2).

The mean score across all items was 4.46 (SD=0.725) with a possible range of 1 (low satisfaction) to 5 (high satisfaction) (table 8.4).

Table 8. 4: Mean score of all items of the Prep-DM scale

PrepDM Statements No.	PrepDM 1	PrepDM 2	PrepDM 3	PrepDM 4	PrepDM 5	PrepDM 6	PrepDM 7	PrepDM 8	PrepDM 9	PrepDM 10
Mean (SD)	4.36 (1.15)	4.36 (0.929)	4.50 (0.65)	4.43 (0.852)	4.64 (0.497)	4.36 (0.745)	4.36 (0.842)	4.50 (0.855)	4.57 (0.646)	4.57 (0.646)
Minimum	1	2	3	2	4	3	2	2	3	3
Maximum	5	5	5	5	5	5	5	5	5	5

Table 8. 5: Patients' responses to all the items from Prep-DM scale

Did this educational material...	Quite a bit/Great deal	
	N	%
1. Help you recognize that a decision needs to be made?	12	85.7
2. Prepare you to make a better decision?	12	85.7
3. Help you think about the pros and cons of each option?	13	92.8
4. Help you think about which pros and cons are most important?	13	92.8
5. Help you know that the decision depends on what matters most to you?	14	100
6. Help you organize your own thoughts about the decision?	12	85.7
7. Help you think about how involved you want to be in this decision?	13	92.8
8. Help you identify questions you want to ask your doctor?	13	92.8
9. Prepare you to talk to your doctor about what matters most to you?	13	92.8
10. Prepare you for a follow-up visit with your doctor?	13	92.8

PrepDM scores at this stage of the project suggested that the patient decision aid had potential as a tool in preparing patients to communicate with their practitioner about their treatment decisions.

As illustrated in table (8.5), responses were grouped into categories to give meaning to patients' responses. The majority of respondents perceived the decision aid helpful for patients to understand risks and benefits of treatment options thoroughly, be involved in the decision process, enable patients to make more informed decision, and helped patients

to organise their thoughts and ask relevant questions. Similarly, the majority of respondents indicated that the tool helped them to explore their preferences and tailor the consultation to meet their needs. These responses were most of the time similar to the HCPs initial perceptions that the PDA had potential as a tool in preparing patients to communicate with their practitioner about their treatment decisions and to make more informed decision.

8.6.3 Decision conflict

The participant's level of decisional conflict was measured using the 10-item DCS. The scale was used to measure patients' perceived perception of uncertainty and explore the factors contributing to that uncertainty (discussed in section 4.3.2.2).

The scale consists of four sub-scales: feeling certain about best choice, feeling informed, feeling clear about personal values for benefits and risks, and feeling supported in decision-making. The total DC mean score and mean scores of each subscale are summarized in table (8.6).

After use of the decision aid, the mean total DCS score was low at 0.214 (SD 0.277) on a scale from 0 to 4. Consistent low scores within each subscale indicated that participants felt supported during the decision-making process, informed, clear about their values, and certain, in order.

The low mean decisional conflict score indicates that participants were on a whole confident and comfortable with their treatment decision.

Table 8. 6: The total decision conflict mean score and mean scores of each subscale

Decisional conflict scores (scale from 0 to 4)	Outcome Mean score (SD)
Informed subscale	0.191 (0.408)
Values clarity subscale	0.286 (0.611)
Support subscale	0.095 (0.242)
Uncertainty subscale	0.357 (0.633)
Total DC score	0.214 (0.277)

8.7 Discussion

This study aimed to explore patients' perspectives on the value the DA had for them during the consultation. This study employed a mixed-method approach to exactly understand patients' views and attitudes after they had experienced the DA during the consultation. Interview findings revealed that patients valued the DA for its educational content. Patients suggested that the DA also provided a way to engage with the decision-making process and make personally appropriate decision about treatment.

The purpose of this section is to discuss the main findings from this stage of the study. Consideration is then given to how these findings relate to the literature, especially the literature on the impact of patient decision aids on anticoagulation decision-making that was discussed in chapter two (section 2.4). Finally, Key points are summarised in the final section of the chapter.

8.7.1 Patients' views about the decision aid

The PDA evaluated in this study was assessed for its content, amount of information, and the length of its presentation. In this context, findings from both qualitative interviews and quantitative measures (e.g., acceptability score) showed that the DA was found to provide participating patients with information regarding risks and benefits of therapy and helped them to clarify their preferences regarding treatment options. Specifically, the value clarification screen and the use of graphical presentation to compare the benefit and effect of treatment were in line with the results of the characteristics of the DAs reviewed in the included studies (as discussed in section 2.4.1).

Study participants seemed to have valued using the DA when making treatment decisions about anticoagulants, finding it acceptable and understandable. The pattern of results from research participants suggested that the DA provided comprehensive, balanced, accessible

information to support patients thinking about all available options. Given that the literature highlighted the importance of complete, balanced, and unbiased presentation of all available options in PDAs to foster informed decision-making (Elwyn et al., 2006; Stacey et al., 2014). Studies included in the literature review emphasised that the provision of a DA that is comprehensive and involves several elements that are intended to enable patients to participate in the decision-making process were more likely to improve patient's knowledge of probability information and improving clarity about personal values (Fraenkel et al., 2012; Man-Son-Hing et al., 1999; McAlister et al., 2005; Protheroe et al., 2000; Thomson et al., 2007).

Qualitative data revealed that the use of graphs to present individualised bleeding and stroke risks helped patients to clarify their views and share their reflections about the advantages and disadvantages of treatment approaches. These finding were similar to the conclusions made by the authors who found that discussions that included visual aids in the consultation supported the explanations of medical conditions and treatments and helped to increase patients' sense of participation (Fraenkel et al., 2012; Man-Son-Hing et al., 1999; McAlister et al., 2005; Protheroe et al., 2000; Thomson et al., 2007). Moreover, Findings revealed that values clarification screen was reported as a positive addition and provided a way to engage patients in decision-making by making them weigh up what matters most to them. Prior research indicated that values clarification components lead to decisions in agreement with personal values (Thomson et al., 2007), reduced anxiety and uncertainty (Holbrook et al., 2007; McAlister et al., 2005) and improved perceptions that one is better prepared for decision-making (Fraenkel et al., 2011; Man-Son-Hing et al., 1999; Thomson et al., 2007).

8.7.2 Effects of the decision aid on attributes of the decision and decision-making process

In this study, the impact of the DA on attributes of the decision and decision-making process was assessed by investigating whether the DA was effective with regard to providing patient with sufficient information about treatment, risk perceptions and informed choice. Findings regarding attributes of the decision process mainly concerned decisional conflict score, patient-HCP communication, involvement in decision-making and patients' initial satisfaction. These findings on decisional conflict and preparation for decision making are in line with the results of the literature review on the effectiveness of using a decision aids in anticoagulation management (as discussed in section 2.4.3). Although the effects on decisional conflict score are less strong than in the literature review (based on a study design, sample size, and follow-up period), however, this indicates that the DA might be valuable for AF patients and suggests that DAs have potential to support AF patients in decision-making. Findings showed that the DA was found to have potential to improve patients' knowledge, promote discussions with HCP about the benefits and risks of anticoagulants, and be involved in treatment choice according to patient's value and preferences to make an informed decision. Consistent with the present findings, patients in Fraenkel et al., (2012) study and in Man-Son-Hing et al., (1999) study felt involved when sharing information and knowledge about AF and its treatment and cooperate in decision-making. These findings confirm and add to previous work on the impact of DAs on patients' involvement in decision-making about AF treatment in consultations (Fraenkel et al., 2012; Man-Son-Hing et al., 1999).

The use of the DA was not without barriers, and participating patients seemed to have assumed that time constraints and the need for longer consultations for delivering DA may have potential to influence successful implementation in clinical practice. This result is

consistent with the all previous studies of implementation of computerised support systems into routine clinical practice (as discussed in section 7.4.2). Further barriers to adoption of DAs were reported in the literature, such as concerns about requiring too much time, concerns about patient preferences, and patient characteristics (as discussed in section 7.4.2).

8.7.3 Conclusion

This study explored patients' perspective view of the value from implementing the DA into clinical consultation. These findings add to the literature by suggesting that the positive effects of DAs tool on improving individuals' knowledge of risks and benefits, feeling informed and feeling clear about their values provide sufficient evidence for using them in clinical practice.

The DA assisted in the field of patient involvement in anticoagulants prescribing decision-making process, an area in which DAs has rarely been studied for its influence on attributes of the decision process. Following a step-wise evaluation process, HCPs have previously shown that the DST seemed to be successful in improving anticoagulants decision process and the decision. In this study, further evidence has been generated that supports the findings of previous evaluation step but from patients' point of view. Patients seemed to have valued the DA for its content and presentation of information. All of the patients felt that the DA was effective with regard to providing them with sufficient information about treatment, and risk perceptions. All of the patients talked about aspects of the DA impact on patient-HCP communication, involvement in decision-making, and that all patients seemed to have made an informed choice.

Additionally, this study showed that HCPs' concerns from the influence on doctor-patient relationship seemed not a concern for patients. Nevertheless, the need for extra time during

consultation associated with implementing the tool in clinical practice appeared to be of concern for few patients.

The significance of these findings is now discussed in the final chapter of this thesis.

Chapter 9: Conclusions and research implications

The final chapter of this thesis reviews the aims and objectives of the research in light of this study's findings. In section 9.1 summary of the key findings of this study which highlights the key stages in the research and how these relate to the research objectives are discussed. The significant contribution of this research is discussed in section 9.2. Discussion of the quality issues of this research is then considered in section 9.3. Section 9.4 presents strengths and limitations of the study, and the implications of the findings for future research and practice (section 9.5) is then discussed.

9.1 Summary of the Key findings of the study

The aim of this study was to evaluate the utility of the DST and associated PDA in anticoagulation decision making at the point of care. The objectives of the research were to:

- Identify the suboptimal determinants in anticoagulation therapy decision making process and explore the evidence that the intervention (the DST in our case) might have the desired effect through exploratory design
- Assess the components of the DST to improve understanding of how the intervention works
- Explore HCPs' perspectives post implementation process in clinical practice and to identify potential and actual barriers to its implementation and to examine the difference in their responses between pre-and-post intervention evaluation

- Assess patients' perspectives of the usefulness of the DA in decision making process and quality of the decision made and to compare their responses with HCPs' responses

The aim and objectives of this research were achieved. The researcher's assumption about usefulness of the DST and associated PDA was investigated through a mixed method approach using a qualitative and quantitative methods based on sequential exploratory design.

9.1.1 Identifying the suboptimal determinants in anticoagulation therapy prescribing decision

An important theme that emerged from the initial interview stage data concerned how HCPs' perceptions of anticoagulation prescribing decision may be related to their perspectives on barriers to optimal use of anticoagulants.

For example, HCPs identified numerous patient sociodemographic and clinical characteristics influencing the decision to prescribe anticoagulants. Factors influencing the choice of anticoagulant included patient age, cognitive function, and a wide range of patient non-clinical characteristics, such as the patients' education level, lack of understanding about AF and AF-related stroke risks, and perceived language barriers. There seemed that there were other influences on the prescribing decision of HCPs that were found to be more dominant compared to patient-related barriers. Qualitative findings revealed that HCPs' knowledge of evidence-based recommendations from national guidelines regarding safety and efficacy of oral anticoagulants, as well as practical experiences to prescribe them, were deficient most of the time. This study revealed that compared to cardiologists, GPs, acute medicine, and haematology consultants showed a

lack of familiarity with best practice recommendations at the time and location of care delivery. Lack of education and knowledge appeared to be the most frequently mentioned factor that contributed to uncertainties and hesitation in the anticoagulant prescribing-decision.

Also, this study revealed that several GPs thought that they were less familiar with NOACs compared to warfarin and were, therefore, less likely to prescribe NOACs. They also tended to delay the decision to second appointment or to refer patients to a cardiologist-led clinic in hospital regarding initiation of the NOACs.

Except for cardiology and stroke consultants, HCPs felt that the availability, as of now, of four new treatment alternatives to warfarin, expanded the options available to them, but introduced uncertainty when they attempted to prescribe the most appropriate agent. Lack of practice experiences with the NOACs seemed to be of concern for most HCPs, and they expressed hesitancy prescribing them due to concerns about the quality of evidence used to support the use of NOACs and the applicability of trial data to a non-real-world population.

In addition, HCP's uncertainty about the benefit versus the risk of anticoagulation therapy in patients with co-morbidities appeared to have been identified as common barriers to prescribing anticoagulants. Most HCPs expressed concerns about fall risk in elderly and often assumed that the bleeding risk in elderly patients outweighed the benefits of anticoagulation. Further, interview findings revealed that real-world implementation of patients' comprehensive assessment was not ideal, in that, assessing patients bleeding risk score was rarely used by non-cardiology HCPs and that the treatment decision was based solely on assessing patient risk of having a stroke, in particular, ischemic stroke.

Healthcare professionals' resources to make the decision, either personal resources (in terms of knowledge and experiences) or external resources have been assumed suboptimal. Lack of support strategies available to GPs was consistent with suboptimal external resources in clinical practice, for example, quick access to advice from consultants or availability of dedicated clinic and meetings with other colleagues who can offer advice and support.

This study found that HCPs prescribing practices in the setting of AF depended principally upon:

- Personal knowledge
- Previous practical experiences with the new agents
- Understanding and perceptions of net clinical benefits and risks
- and support strategies available at the point of care delivery

The evaluation of the perspectives of HCPs highlighted that determinants in the decision-making process around anticoagulation therapy were suboptimal and uncertain. As such, uncertainty and doubt about anticoagulants prescribing in AF continue to be common despite the availability of effective therapies. Findings revealed that HCPs were more likely to prescribe anticoagulants, including NOACs, when they have achieved a comfort level through education and experience and when they believe the benefits of treatment outweigh the risks.

Based on the qualitative findings, the introduction of the NOACs over a short period of time and the lack of practical experiences added an additional layer of uncertainty for prescribers. When there is such uncertainty, doctors and their patients are usually expected to share responsibility for the decision, with the doctor sharing his or her knowledge and

expertise and the patient revealing his or her preferential attitudes. In this wat they can together arrive at an informed, preference-based choice among several available options (Charles et al., 1997). Shared decision-making is most applicable in situations in which there is unclear or equivocal clinical evidence, or variation in patients' attitudes towards available treatment choices (Kassirer, 1994).

The paternalistic mode of consultation adopted by the majority of research respondents was at odds with the above principles and conflicts with current NICE guidance on appropriate prescribing of NOACs, in that, an essential part of appropriate prescribing of NOACs is to ensure that patients are fully informed and actively involved in decision making about the risks and benefits of NOAC compared with warfarin and the other NOACs (NICE CG TC 180, 2014). NICE has produced a patient decision aid to support patients and clinicians in choosing between the recommended options for stroke prevention in AF.

The significance of this was that HCPs' perspectives on barriers to anticoagulation therapy decision-making in clinical practice seemed to be linked to their assumptions of the need for educational intervention and a decision support tools to help to overcome these barriers. In conjunction with the findings from the literature on barriers to anticoagulation therapy uptake (sections 1.2 and 4.5.1), this suggested that if their proposed recommendations became accessible in clinical practice, their perspectives on barriers to optimal use of anticoagulants, and in turn, perceptions of anticoagulation prescribing decision might change.

9.1.2 Pre-intervention evaluation of the decision support tool

The second stage of the study focused on a pre-intervention evaluation of the DST with HCPs using a vignette to explore the features and functions of the DST and associated

PDA and understand their potential usefulness in supporting decision-making. As discussed in sections 4.5.1, 6.3, and 6.4, there appeared to be two issues that emerged from the interviews with HCPs. Firstly, All HCPs liked the DST for its format (online format, layout, presentation, ease of navigation, user-friendliness), and content (relevance, reliability, accuracy, evidence-based, content organisation), that were assumed to enhance its use in clinical practice. Further, HCPs talked about the particular features of the tool that were assumed to have a potential impact on their prescribing decision-making process, and these were:

- Providing systematic approach in decision making
- Providing evidence-based information
- Providing efficient estimation of the risk–benefit ratio for an individual patient
- Considering a wide range of factors in the assessment for therapy
- Clarifying patients' values and elicit preferences regarding treatment, and
- Supporting the implementation of shared decision-making in clinical practice.

In addition, HCPs appeared to have assumed that the DST would have potential to help them to address many of their information needs and support their prescribing decision due to lack of experiences in the era of NOACs prescribing decision.

All HCPs provided detailed feedback regarding content and presentation of the PDA, and they seemed to have assumed that it was practical, evidence-based, and flexible enough to be tailored to patients' needs. Findings from both qualitative and quantitative measures suggested a favourable level of acceptance and satisfaction with the DST. The particular features of the PDA that were assumed to be of benefit to facilitate high quality decision making, include: using plain language to provide patients information about AF and

treatment in sufficient detail, providing structured guidance for communication by using an interactive visual aid to support patients understanding of benefits and risks from treatment, and including sections to clarify patients' values and preferences.

Secondly, HCPs raised several concerns that were assumed to be associated with the DST use in clinical practice, but only three were perceived as important; time pressure, the fact it was a stand-alone system, and the potential impact on doctor-patient interaction during the consultation.

The majority of HCPs indicated that compared to their usual decision-making approach, more time might be needed to effectively use the DST and involve patients in the decision process using the DA. Nonetheless, almost half of the HCPs seemed to have assumed that using the tool in a consultation could save their time from searching information needed to make the clinical decisions, documentation issues, and providing tailored information leaflets to patients. The provision of standalone DST was perceived as a concern by HCPs from both primary and secondary care settings. HCPs thought that if the tool were integrated into the electronic clinical health system, e.g. EMIS, in turn, this would more likely enhance its uptake by them, in particular, by GPs. Qualitative findings revealed that HCPs' were concerned with the potential impact on the doctor-patient relationship during the consultation. While some HCP's main worries from using the DST concerned effects on communication during the consultation, in that, it might change the dynamics of the doctor-patient interaction, other HCPs expressed their concerns regarding patients' potential attitudes towards them when they used a decision aid to help them to decide on treatment. These perceptions were while not common among research respondents; they did exist.

9.1.3 Post-intervention evaluation of the decision support tool: HCPs' perspectives

The findings from the third stage of the study suggested that HCPs' perspectives on the utility of the DST in anticoagulation prescribing decision process were extremely similar to their perspectives at the second stage interviews. This was suggested by the following similarities. Both HCPs from the third stage and HCPs from second stage interviews seemed to have assessed the information presented in the DST and indicated that the tool was a reliable source of information, and provided them with a comprehensive, accurate and useful source of information needed for a better prescribing decision (sections 6.3.2 and 7.2.1). HCPs from both stages seemed to remain consistent in describing the DST as a valuable resource for learning and helping them to be aware of current evidence-based information, adhere to clinical guidelines e.g. NICE guidelines, and make an appropriate and safe decision (sections 6.3.2 and 7.2.1). The similarities between the HCPs' perspectives on potential utility from implementing the DST in clinical practice in that they could follow same steps each time in a structured and organised way and that they were less likely to overlook anything during the decision-making process (sections 6.3.1 and 7.2.4). Most HCPs said that implementing the DST improved their prescribing practice by reducing variation in the decision-making process and helped to streamline clinical workflows (section 7.2.4). HCPs from both stages tended to have assessed the PDA incorporated within the DST in terms of its utility to promote shared decision-making (sections 6.3.3 and 7.2.3) and what they had perceived about the usefulness of the DA to support communication of treatment decision to patients (sections 6.1.4 and 7.2.3, 7.2.5). However, HCPs from the second stage spoke about their perceptions of the potential utility of the DA to help them to explore patients' values and preferences of the treatment decision and involve patients in the discussion during consultation (sections 6.1.2, 6.1.3, and 6.1.4), whereas HCPs from the third stage spoke from their actual experiences of using

the DA with their patients during the clinical consultation. As such, HCPs from the third stage revealed that the DA facilitated high-quality decision-making, in that patients, were able to make a decision that was as informed, consistent with personal values, and acted upon, and patients were comfortable with the whole decision-making process and the decision.

Having said this, many HCPs in both research stages expressed their concerns about using the DST in routine clinical consultation (sections 6.4 and 7.3). The HCPs from the second stage were mainly concerned about time constraint during consultation as well as potential impact on patient-doctor relationship (sections 6.4.1 and 6.4.4), whereas HCPs from the second stage who successfully implemented the DST into routine clinical practice during the intervention period seemed to change their attitudes as they started to integrate the DST into their routine practice and get familiar with using it (section 6.4.1 cf. section 7.3.5.2). This suggested that lack of training in the use of the system or experience with exploring the web page might have make the time to use the DST longer than it should take if the user were trained on how to navigate the system. Although the HCPs from the third stage did not cite information overload as a likely concern, unlike some of the HCPs from the second stage (section 6.4.5 c.f. section 7.3.5). Few HCPs from both stages seemed to remain uncertain about the likely influence of using the DST during clinical consultation on the doctor-patient relationship (sections 6.3.1 and 7.4.3). The similarities between their perspectives on the potential influence on doctor-patient relationship were seen in relation to their concerns regarding patients' potential attitudes towards them when they used a decision support system to decide on treatment. This view was common between cardiologists and some of the stroke consultants, who felt that patient may view them as incompetent. In general, HCPs from both stages seemed to assume that using the DST during a clinical encounter might change the dynamics of the doctor-patient interaction in

that both were looking at the computer screen rather than looking at each other. However, in contrast to the minority view, the other HCPs talked about using the tool would effectively enhance the relationship, making it a stronger relationship. This was potentially in part due to improving communication with patients by giving them more information and involving them in the decision process (sections 6.4.4 and 7.2.3).

Furthermore, it seemed that reasons for why HCPs did not use the DST during the intervention stage of the project were mainly found to be related to the quantity of IT devices and quality of IT infrastructure provided in their workplace as an important factor impeding the use in clinical consultation (section 7.3.1.1). Further, HCPs who successfully implemented the DST did not cite integration into current electronic systems as a likely cause for not integrating the DST into their routine clinical practice, unlike some of non-user HCPs who seemed to have assumed that integration of the DST into the existing electronic systems (e.g. EMIS) and local protocols might facilitate the DST uptake and effective use in clinical practice. (section 7.3.1.2 cf. section 7.3.1.3). This suggested that integration of the DST into the health organisation electronic system was seen a facilitator to the tool uptake and effective use, but not a pre-requisite.

Furthermore, HCPs from the third stage who implemented the DST in routine clinical consultation seemed to have difficulty using the DA with patients during their hospital stay, in which patients were bedridden and unable to move to fit the computer closer to them, relying instead on a computer printout (section 7.3.3.1). This lack of direct interaction between patients and the DA can lead to misleading estimates of the tool's utility and benefits on clinical decision-making.

The introduction of DST into routine clinical practice, even when highly promising, is far from straightforward. Multiple factors were found to affect the success or failure of DST

intervention implementation. Clearly, a successful DST intervention is not just about content or technical design; DST interventions also involve workflow.

Many HCPs who did not use the DST during the intervention period of the project expressed a sense of disquiet about using the tool in clinical consultation due to the sequential nature of it, and they suggested to decouple the PDA (section 7.3.5.1). While time constraint during consultation was the reason behind this suggestion, the implication of decoupling the DST does not seem the solution to time pressure in clinical practice. For instance, decoupling the DST and the PDA, in which, rather than simply going through the whole pages to get to the PDA, they suggested breaking the DST and associated PDA into two discrete components without completing patient health information section incorporated in the HCP part of it. While HCPs assumed that decoupling the PDA might improve uptake in clinical practice, the feasibility of doing it seemed a hindrance, as this may affect the evidence to inform the PDA, the evidence-based decision-making process, and adherence to NICE clinical guidelines.

This study identified a range of factors influencing the DST use and demonstrated that making the tool freely available and accessible in electronic format did not change HCPs intention to use or guarantee uptake. Our overall findings suggest that there is no “one size fits all approach” to influencing prescribing via CDSSs, and factors beyond software and content must be considered when developing CDSS systems for prescribing. Fundamental issues include the availability and accessibility of hardware, sufficient technical support and training in the use of the system, approval of the system by the various stakeholders (eg, IT management team, administrative staff, and end users) and fitting the DST within the current workflow are important to guarantee successful implementation.

9.1.4 Evaluation of the decision aid: Patients' perspectives

The fourth stage of the study focused on patients' perspectives who had experienced the DA during the consultation. As discussed in sections 4.5.1, 8.3, 8.4 and 8.5, there appeared to be three issues that emerged from the interviews with patients, which when considered together suggested that their perspectives on the utility of the DA in anticoagulants decision-making were similar to the HCPs' perspectives. Such that there seemed to be no major differences between their perspectives. This was suggested by the following similarities. Both HCPs and patients seemed to have assessed the information presented in the DA and seemed to have assumed that it was clear, informative, thorough, and easy to understand (sections 7.2.3, 8.3.2, and 8.3.3). Furthermore, it seemed that the patients' perspectives on the utility of the DA to facilitate the decision process during consultation were extremely similar to the HCPs' perspectives at the second and third-stage interviews, including: using understandable language to provide patients with information about AF and treatment in sufficient detail, providing balanced and comprehensive approach to aid communication with their healthcare provider by using an interactive visual aid to support patients understanding, and including sections to clarify patients' values and preferences (sections 8.3.2 and 7.2.3).

In addition, HCPs' perspectives from the third stage of the study on the DA utility to promote shared decision-making during consultation were extremely similar to patients' perspectives, in that patients, were able to make a decision that was as informed, consistent with personal values, and acted upon, and in that, patients were comfortable with the whole decision-making process and the decision (sections 7.2.3 and 8.4).

However, in contrast to HCPs' perspectives on patient-related factor that might be a hindrance from using the DA during clinical consultation, interviewed patients talked

about the improvement in their understanding and perceptions of AF and treatment that was evident from achieving low scores on decisional conflict scale, and by pointing out that they were involved in the decision process and had the chance to make a decision that was informed and consistent with personal values (section 7.3.3 cf sections 8.4 and 8.5). The significance of this finding is that patient-related factors (e.g. clinical and non-clinical factors) were not the only determinant of the patient ability to use the DA and participate in the decision-making process, but also the quality and suitability of the DA they have accessed during the consultation.

In short, the findings of the fourth stage of the study support the idea that patients' perspectives were similar to HCPs' perspectives. The findings suggested that the use of a DA that delivers tailored information by including appropriate visual aids could lead to an even better impact on patients' participation in decision-making and improve patient-doctor communication (section 8.5.3). Therefore, including different perspectives on DA usefulness in the clinical consultation is a step towards better understanding of the DA impact on the decision-making process. Having discussed the significance of the findings the discussion now turns to consider the practical application of reflexivity in the study.

Patients' opinions and attitudes are a pre-requisite to determine the success of the DST adoption in clinical practice. The results from this study reflect encouraging attitudes of patients towards the DA, potentially paving the way for its future adoption, as part of an integrated care pathway for patients.

9.2 The significant contribution of this research

This thesis provides a review of the research that has investigated the use of CDSSs in anticoagulation therapy prescribing decision. The literature review describes the range of CDSS developed and the methods used to investigate them in a challenging clinical

environment. Through a critical appraisal of the methodological aspects of the CDSSs studies the significance of the results of the published research has been identified and the paucity of using qualitative studies exposed. The research methods knowledge gained through reviewing the evidence and conducting this study is of significance. A mixed-method approach is a suitable method for evaluation research in healthcare. A qualitative semi-structured interview can generate data that provides a detailed investigation of participants' accounts. The quantitative approach provides a rich and comprehensive picture of the evaluative approach, as such, it provides complementary data to support findings from qualitative interviews. The use of a before-after approach is relatively simple and easy to undertake when a new CDSS system is introduced. This research approach allows the researcher to identify any change in perspectives is assumed to have occurred because of the actual utility of the system.

This research approach cannot conclusively say that the DST caused a change in the decision-making process in clinical practice, but it can identify aspects in anticoagulants prescribing decision process that is feasible for the DST when used by HCPs at the point of care. These insights are of value to clinicians, researchers, and developers wanting to explore the benefits of their own systems.

The findings of this research provide a unique contribution to the existing CDSS research literature on anticoagulation management. Initially, the findings of this study support the researcher's initial assumption that the DST and associated PDA would likely to be useful in supporting anticoagulants decision-making in clinical practice.

Following a series of distinct stages of evaluation, starting from evaluation of the DST performance against a standard case through to evaluation of its impact in clinical practice, HCPs showed that the DST fulfils several characteristics of a successful CDSS, that is

rapid, reliable, and provides high-quality knowledge base from an easy to use system that takes up to ten minutes to complete in a shared decision-making consultation.

Implementation in clinical practice showed that the DST performed with adequate and consistent performance when used to support clinicians' decision-making, there are several significant findings, of which:

- Improved the quality of anticoagulants decision-making made by all grades of HCPs in clinical practice
- Increased the uptake of the relevant NICE guidance and hence evidence-based management of AF
- Displayed treatment recommendations consistently despite wide variability of the data entered
- Encouraged patients' involvement in the treatment decision in a shared decision-making consultation
- Provided HCPs a feeling of confidence and reassurance that they have prescribed the best agent to patients
- And it was capable of changing HCPs' prescribing decision-making process in a reasonably short time.

The ability of the DST to produce benefits with minimal user effort indicates that its widespread use in clinical practice may result in improved anticoagulants prescribing decision and may lead to a reduction in patient harm from delayed decisions to prescribe anticoagulants. Although these aspects were not investigated as part of the work described in this thesis, they form a crucial part of the argument for clinicians to adopt the DST widely.

While the evaluations mainly focused on qualitative data, some quantitative aspects of the DST acceptability and measuring its potential usefulness in preparing patients to communicate during the consultation and to make an informed decision were also studied. Quantitative outcomes strengthened the work described in this thesis and provided further information to support why HCPs and patients used the DA and what aspects of its design they found useful.

The sequential evaluation undertaken to explore various issues related to interactions between the system, user and the clinical environment provided useful lessons for the design and implementation of the DST as well as future CDSS. A successful standalone system needs to provide a consistent and trustworthy recommendation to clinicians in their workflow rapidly in response to minimal user interaction.

Challenging the barriers to implementing the DST and enhancing the facilitating factors could eventually disclose the benefits of its use. This research identified some of those factors. Dedication and commitment to supporting the introduction of the DST and associated PDA would help to support HCPs and patients facing these difficult decisions.

9.3 Quality Checks

An important feature of any study is the rigour within its design and the degree to which its results are valid and reliable (Mays & Pope, 2000). The selection of a mixed methods design in itself has contributed to increasing this study's internal validity. In addition to reflexivity that is discussed in section 9.3.1, the internal validity was maintained by comparing findings from two different research methods and data sources (interview data and questionnaires). The external validity was maintained by an effort to describe details of context and the reliability by an effort to describe the details of the research process as described earlier in chapter four.

The fundamental question to be asked of any research when assessing the credibility of the results is, “are the results biased in any way?”

Therefore, a decision was made to apply the following checks recommended by O’Cathain et al. (2008) as appropriate. Includes:

Scrutiny of the analysis –The quality of the coding was independently checked by the supervisory team and the input from them was valuable in ensuring that the coding was informed by a range of views, and also reflected the research questions.

Audit records– Records were kept of the processes involved in shaping the research, such as, the coded transcripts, records of key decisions, and various copies of the coding template. Notes were taken of meetings about the analysis and were documented. The idea of documenting the processes from interview to reporting of findings is to make explicit the processes, so that it can be open to scrutiny.

Reflexivity – A process of reflexivity (discussed in section 9.3.1) was undertaken, in order to create an awareness of myself within the data analysis, with the aim of producing a more objective outcome.

Further steps in ensuring quality were: to ensure that the interviews were transcribed accurately and that the written findings were a product of a thorough approach (as described in section 4.6). Consideration was also given to the use of quotation in the report to ensure that they reflected the views of the participants rather than, for example, picking out striking quotes. In addition, by describing the epistemological stance, and methods of data collection and analysis, the reader can make their own judgements about the quality of the study. Further, description of research limitations related to the mixed methods approach was discussed in section 9.4.

9.3.1 Reflexivity

The theoretical consideration of reflexivity has been discussed in section 4.2.1.5, where it was pointed out that in reflexivity, researchers tended to reflect continuously on how their actions, values and perceptions impact upon the research setting and may affect data collection and analysis (Horsburgh, 2003), that is fundamental to quality in qualitative research methodology (Lambert et al., 2010). As a pharmacist undertaking a research in healthcare field the scientific background influences on this research are a fundamental part of data collection and analysis. The following sections reflect on influences my personal and professional journey had on the interaction between the research participants and myself rather than representing some sort of objective reality.

9.3.1.1 Reflexivity during interviews

Up to this point in the research, I attempted to present the HCPs perspectives objectively, however, I know that this thesis is the product of the interaction between the HCPs and myself and is affected by a variety of factors.

The first set of interviews were conducted with cardiologists and some stroke consultants, and I felt somewhat anxious. This was something that I noticed during all the interviews with all the cardiologists and with some stroke consultants. I think that this was because I perceived them as the experts on AF and treatment that I felt that the DST could not offer anything more than what they already knew. However, this feeling subsided when I did interviews with the other HCPs, probably because of the interest they showed in the DST and also because they expressed their willingness to support the project.

There were numerous occasions in the interviews where HCPs referred to medical and specific terms, for example, when talking about risk scores, evidence from the literature, types of AF, patients' conditions and other medications, and in such terms, that may have

been problematic for a researcher without scientific background in pharmacy, and detailed knowledge of national and international guidelines on AF management. This did not affect the flow of conversation because HCPs expected me to know what they meant, but this did introduce shared understandings or shared meanings into the construction of the data because I did know what they meant. This means that my account of that shared understanding remains my interpretation of what they meant, rather than necessarily what they actually meant. In addition, showing in the interview that I did understand what HCPs meant potentially put me in the situation of being seen as a representative of an institution, which affected what they said, especially talking about sensitive topics.

In this study, although I was careful to introduce myself as a PhD student conducting this evaluative study of the DST and that I was not involved in the tool design and development, I felt that my professional identity as a pharmacist who is evaluating a prescribing support tool did seem to overshadow my personal characteristics and led to a tendency to talk about design issues and practicalities associated with implementing the DST in routine clinical practice than they might otherwise have done.

During the interviews with GPs, I sometimes felt that they thought I was promoting the DST to them which influenced me in explaining to them before the start of the interviews that I was not looking for endorsing the DST into their GP practice, but rather looking for participants to evaluate the utility of the DST in clinical practice. Another issue I struggled with during the interviews with HCPs was to help them focus on their experiences rather than just evidence and facts. Using interview guide helped during this process. During the interviews and before I started I was always careful to remind interviewees of the research aims and objectives and that their participation will help us to answer the research questions.

Other factors that influenced the construction of the data included the HCP recruitment procedure. As discussed in section 4.5.3, HCPs were invited by sending them an invitation email to introduce myself, the research protocol, and a brief description of the DST development procedure and endorsement by NICE. To a certain extent, HCPs' decisions to volunteer to participate in this evaluative research would have been influenced by their perceptions about parties involved in the tool development process and probably more so than by the Participant Information Leaflet about the study (sections 4.5.2.4 and 4.5.3). For example, some HCPs did not like including the pharmaceutical company name when introducing the DST as they perceived this a biased. Further, I got the impression that for some HCPs volunteering to participate in the initial interview was for the curiosity of awareness and interest in the decision support intervention in general. As a result, the construction of the data was to some extent influenced by the way that I presented the study to the HCPs.

The construction of the data from interviews with patients is the product of the interaction between the patients and myself and is affected by a variety of factors, rather than representing some sort of objective reality. There were numerous occasions in the interviews where patients talked about their disease and anticoagulation therapy (such as arrhythmia and INR test), and in such terms, that may have been problematic for a researcher without a scientific background in pharmacy, and detailed knowledge of AF and anticoagulation therapy. This did not affect the flow of conversation because patients expected me to know what they meant, but this did introduce shared understandings or shared meanings into the construction of the data because I did know what they meant. This means that my account of that shared understanding remains my interpretation of what they meant, rather than necessarily what they actually meant. In addition, showing in

the interview that I did understand what patients meant potentially put me in the situation of being seen as a representative of an institution, which affected what they said, especially talking about sensitive topics.

In this study, despite efforts to introduce myself as a PhD student from Keele University and not a healthcare professional, it became clear in the interviews with the patients that they thought that I work in the hospital in collaboration with their healthcare provider and it seemed that this was why they especially expected me to know about AF and their treatment, for example. Subsequently, I felt that their perception of me as a healthcare professional did seem to overshadow my personal characteristics and led to a tendency to be asked health-related questions. Similarly, I felt that patients talked in more detail about issues concerned with taking their anticoagulation therapy (e.g. side effects) than they might otherwise have done.

Other factors that had an influence on the construction of the data included the patient recruitment procedure and the location of interviews. Although patients' decisions to participate would have been influenced by their perceptions of the Patient Information Leaflet about the study (sections 4.5.2.4 and 4.5.3), I got the impression that for some patients volunteering was a way of expressing their gratitude for the care they had received during recent consultation because I wrote to them to invite them to participate, although they did not meet me in person prior to the interview.

The interview location was entirely the patients' choice, and while most chose to be interviewed at home, few patients chose to be interviewed at the GP clinic. Efforts were made to provide an environment that was as informal as possible under the circumstances (as discussed in section 4.5.4), but I recognise that the location was more likely to make me appear to be working in collaboration with the GP practice, than if the interview had

been conducted in the patient's home. The effect of this may have been that patients were more likely to avoid talking about sensitive topics. An example of this was talking about issues associated with using the DA during the clinical consultation, as was discussed in sections 8.4 and 8.5.

Since the focus of the study was on the patient's perspective, partners did not present during interviews, and the data were collected from the patient's perspective only. In these situations, the data remains, a construction between the patient, and myself, although I have not mentioned anything about partners attending the interview in the Patient Information Sheet. This did not affect the main findings of the study on patients' perspectives on the utility of the DA in anticoagulants decision process.

9.3.1.2 Reflexivity during analysis

I used reflexive note-taking throughout the analysis process. I added reflections from my journal such as thoughts, questions, and trends. Keeping a record of my thoughts, feelings and activities associated with the research process helped to refresh my memory regarding my views and perceptions during the data collection process, and helped keep track of my interpretations during analysis. The use of the journal, help to demonstrate a methodological and theoretical appreciation and self-awareness of interactions between myself and research participants. The reflective journal I had kept during the interviews, was a critical feature to cope with the multitude of data throughout each analytical step, especially when synthesising the single groups (patients, consultants, registrars, non-medical independent prescribers, and GPs) and even more crucial when synthesising the analysis across the individual studies (the patients' study, and the HCPs' study). Using the reflexive activity together with the supervisory discussions helped me to control the level of interpretation, in terms of being objective and make assumptions which were based on evidence, as well as to think about new emerging connections between themes, or possible

alternative interpretations. Having discussed the practical application of reflexivity in the study the discussion now turns to consider the significant contribution of this research.

9.3.2 Generalisability

The results of this study are not generalisable to a population outside the study as the investigation was specific to a DST developed and used to assist in anticoagulants prescribing in AF. There is criticism within the literature that many findings from CDSS research are not transferable beyond the research setting (discussed in section 2.3.7).

Despite the volume of CDSS research the wide variety of systems being investigated makes it difficult to identify the effectiveness of factors or features within systems. However, this study contributes to the methods debate in the literature and identifies a study design suitable for evaluating the impact of DST on decision and decision-making process. Prescribing decision-making was improved as HCPs were more likely to make a safe prescribing decision by increasing the uptake of the relevant NICE guidance. This in turn resulted in an improvement in the quality of anticoagulants decision-making when the DST and associated PDA were used.

9.4 Strengths and limitations of the study

This is the first study to evaluate the utility of the NICE-endorsed DST and associated PDA in clinical practice across multiple UK primary care and NHS trust hospitals. Whilst this is not generalizable to the whole of the UK, the evaluation outcomes provided data representing various HCPs from different specialities and healthcare settings. This study is also the first to identify perceived and actual barriers that hindered the implementation of the DST into clinical practice. To the best of our knowledge, this is also the first study

which attempted to adopt the ODSF to evaluate the utility of anticoagulation DST in both healthcare settings.

The main strength of this study is the use of one-to-one semi-structured interviews with a cohort of HCP from both primary and secondary healthcare settings, including consultants, registrars, speciality doctors, GPs, and non-medical independent prescribers; specialist nurses and pharmacists. Interviews were conducted with all research respondents using the same interview guide. As far as we are aware, this qualitative study investigated a topic that has received only limited attention so far and is the first that explicitly identified the suboptimal determinants in the anticoagulation decision-making process in the UK healthcare settings since NICE CG 180 launched in 2014.

The inclusion of different HCPs from a variety of clinical backgrounds, therefore, reflects a multidisciplinary view on decision-making. Previous research suggested taking the views of different HCPs into account as the prior focus was mainly on physicians' perceptions (Elwyn et al., 2008; Légaré et al., 2008). Including different perspectives of HCPs is a step towards better understanding of the whole decision-making process, as proposed by researchers (Elwyn et al., 2008; Légaré et al., 2008).

The more obvious strengths are that most of the participating patients were newly diagnosed with AF and did not have previous exposure to anticoagulants, and they were open to receive information and explore the DA during the consultation. The results accurately reflect the values and opinions of patients who are making a real decision about their treatment.

Moreover, we aimed to identify perceived and actual barriers that hindered the implementation of the DST in clinical practice qualitatively rather than quantifying their relative importance. The framework of barriers to implementing the DST that emerged can

be used as input for quantitative studies assessing the relative importance of the barriers. Results of our study can be useful in designing DSSs that are tailored to the identified barriers of their specific user and thus are potentially more effective in improving quality of care than DSSs using non-user-centred designs (Bosch et al., 2007; Horsky et al., 2012).

This study has several limitations. Participation in the study was voluntary; introducing the possibility of self-selection bias and there is potential that the sample has been biased toward those wanting to express a particular viewpoint. As recruitment also took place through forwarded emails, the researcher was not completely in control about who and how many HCPs were invited by emails. Also, it could have been the case that the local collaborator, for instance, forwarded the email specifically to colleagues, who are more open to the concept of anticoagulation and DST which might have biased the study sample. Further, it can be the case that some HCPs were explicitly required to participate by their supervisor/consultant. This was especially obvious in the interview with specialist nurses as two reported that their stroke consultant had asked them to participate. Although the recruitment process introduced sampling bias, yet, it enabled the researcher to reach a greater diversity of participants.

Other limitations of the post-intervention evaluative study include the small sample size of HCPs, and the fact that the information received was in the form of informal feedback using personal emails, face-to-face interviews or phone interview rather than using one consistent interview topic guide; thus obvious sources of bias were present.

Intervention period of the study was also a limiting factor. There were only eight weeks where the DST was implemented, and patients had only one chance to see the PDA during the consultation. One might question whether a single exposure to the PDA can substantially change patient attitude and involvement in the decision-making process. For

chronic diseases, a decision aid should ideally be used when needed and repeatedly over time, and more effect of the DA could be anticipated when it is used more often in the course of disease management (Denig et al., 2014). We did not assess what actually happened during the consultations but evaluated the use of the DA in post-intervention qualitative interviews with patients. Lack of follow-up interviews with HCPs and their patients to detect important differences and sustained outcomes limits the usefulness of data obtained from questionnaires during first contact (baseline data).

The response rate of patients was low as well, which reduces the ability to generalise the findings. The recruitment was limited to patients' acceptance and preferences to participate in the research. Most important limitations of this study were the small sample size and the lack of information of the non-responders. These findings have implications for the future practice and research, which the discussion now moves on to consider.

9.5 Future recommendations

The following recommendations relate to future research that this study has identified using the DST and further CDSS developments.

The research described in this thesis focussed specifically on the impact of the DST on the decision-making process rather than outcome measures (e.g., outcomes of clinical processes). The available results of the DST impact do not provide any indication of how the system would influence the incidence of delayed prescribing in clinical practice. Future evaluations of the DST would need to specifically address these research questions.

One of the main findings from this research was the relatively low response rate to use the DST in clinical practice. The main barrier cited in this study was access to computers. However, it is unclear whether the increased availability of wireless local area networks, handheld devices and mobile tablet personal computers (PCs) alone would lead to the

realisation of the benefits of decision support, or whether integration into electronic health records (EHRs) is essential to achieve the promised effects. The success of integrated CDSS in other areas such as preventive care, diagnostic, and medication administration in improving patient outcomes (Kawamoto et al., 2005) indicates that prescribing DST have to be integrated into EHRs to achieve similar results. Future research has to focus on the ease of use and impact of an integrated DST on changes in decision-making process and outcomes.

9.5.1 Implications of the study results

There are implications for clinicians, policy makers, and developers both at a national and international level as a result of this research. Since prescribing uncertainty only occurs in a subset of healthcare professionals, decision support interventions will need to be targeted, rather than being universally applied across all grades of HCPs in clinical practice. It is likely that users would be the best judges of when to seek advice from a DST, although there is considerable evidence that HCPs' perception of the need for decision support and their actual performance are poorly correlated. Even in the current research, cardiologist and stroke consultants perceived that the system was not useful in many cases where the DST encouraged them to improve prescribing decision-making in practice.

There was poor correlation between the subjects' own perception of the potential usefulness of the DST for anticoagulation management and the actual implementation in clinical practice, further lending support to the fact that users may not necessarily be aware of the actual benefit offered by DST. Perhaps the best model might be an active decision support engine running continuously within an EMR, which prompts users when they consider an AF patient.

Since GPs are more likely to use and benefit from the DST, the educational role of the system is significant and that it was seen as a means to facilitate GPs education on a group level where GPs themselves were openly concerned about prescribing. GPs felt that the system could feasibly be incorporated into primary care EMIS and that it was easy to learn how to use, easy to navigate and sufficiently quick to be drawn upon in a consultation. The system was also thought to be potentially valuable to health professionals other than GPs: non-medical independent prescribers (e.g., pharmacist and nurse specialist) and secondary care clinicians were identified by interviewees. Therefore, the system has the potential to be used as training tool or in a wider educational role.

Further, this study has demonstrated that the web-based decision aid has a positive impact on informed decision making, in accordance with the NICE atrial fibrillation guidelines. However, in order to maximise its impact, and benefit the greatest number of AF patients, its use need to be promoted amongst the public and health professionals, as such, the DST and associated PDA require an implementation strategy in both healthcare settings potentially paving the way for its future adoption, as part of an integrated care pathway for patients.

Overall, this study used a mixed method approach to explore the HCPs' and patients' perspectives on the utility of the DST and associated PDA in anticoagulation prescribing decision-making in clinical practice. The results of this research provide a unique and significant contribution to the existing CDSS research literature on anticoagulation management. This research has demonstrated that the introduction of DST and associated PDA have been a useful and successful undertaking. The research was well designed

conferring a reasonable degree of confidence in the results. The results of this study indicate that anticoagulants prescribing uncertainty frequently occur in practice and that it is feasible for a standalone CDSS to improve the decision-making process and the quality of the patient experience when used by clinicians during real-life decision making.

Appendices

Appendix 1: Research Ethics Committee approval (pilot study)

Keele University

RESEARCH AND ENTERPRISE SERVICES

23rd January 2014

Rima Hijazeen
Room 1.36
Hornbeam Building
Keele University

Dear Rima,

Re: 'An evaluation of the utility of computer-aided decision making for the management of new anticoagulants'

Thank you for submitting your application to amend study for review.

I am pleased to inform you that your application has been approved by the Ethics Review Panel.

The following documents have been reviewed and approved by the panel as follows:

Document	Version	Date
Summary Proposal	3	21/01/2014

If the fieldwork goes beyond the date stated in your application you must notify the Ethical Review Panel via the ERP administrator at uso.erps@keele.ac.uk stating ERP2 in the subject line of the e-mail.

If there are any other amendments to your study you must submit an 'application to amend study' form to the ERP administrator stating ERP2 in the subject line of the e-mail. This form is available via http://www.keele.ac.uk/researchsupport/researchethics/

If you have any queries, please do not hesitate to contact me via the ERP administrator on uso.erps@keele.ac.uk stating ERP2 in the subject line of the e-mail.

Yours sincerely

Dr Bernadette Bartlam
Chair – Ethical Review Panel

CC Supervisor

Research and Enterprise Services, Keele University, Staffordshire, ST5 5BG, UK
Telephone: + 44 (0)1782 734466 Fax: + 44 (0)1782 733740

Appendix 2: Research Ethics Committee approval (main study)

London - Central Research Ethics Committee

3rd Floor, Barlow House

4 Minshull Street

Manchester

M1 3DZ

Telephone:

0161 625 7820 13 November 2015

Professor Stephen Chapman

Hornbeam Building 3.06, Keele University

Keele

Staffordshire

ST5 5BG

Dear Professor Chapman

Study title:	**Evaluation of the utility of a computerised decision support system for the management of oral anticoagulants.**
REC reference:	**14/LO/2053**
Protocol number:	**1**
IRAS project ID:	**157385**

Thank you for the email of 10 November 2015 from Rima Hijazeen. I can confirm the REC has received the document listed below and that this complies with the approval conditions detailed in our letter dated 18 November 2014

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Other [Email confirming device now endorsed by NICE]		**November 2015**

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Keele verification of insurance]	1	28 July 2014
GP/consultant information sheets or letters [HCP information letter]	1	17 October 2014
Interview schedules or topic guides for participants [HCP interview guide stage 1]	1	17 October 2014
Interview schedules or topic guides for participants [HCP interview guide stage 1.2]	1	17 October 2014
Interview schedules or topic guides for participants [HCP interview guide stage 2]	1	17 October 2014
Interview schedules or topic guides for participants [Patient interview guide]	1	17 October 2014

IRAS Checklist XML [Checklist_03112014]		03 November 2014
Letters of invitation to participant [HCP invitation letter stage one]	1	17 October 2014
Letters of invitation to participant [HCP invitation letter stage two]	1	17 October 2014
Letters of invitation to participant [Patient invitation letter]	1	17 October 2014
Non-validated questionnaire [HCP questionnaire stage 1]	1	17 October 2014
Non-validated questionnaire [HCP questionnaire stage 2]	1	17 October 2014
Non-validated questionnaire [Patient questionnaire]	1	17 October 2014
Other [HCP reply slip]	1	17 October 2014
Other [Patient reply slip]	1	17 October 2014
Other [Independent peer review feedback letter]	1	31 July 2014
Other [independent peer review approval letter]	1	24 September 2014
Other [HCP reminder letter to use the tool]	1	17 October 2014
Other [Email confirming device now endorsed by NICE]		10 November 2015
Participant consent form [HCP consent forms]	1	17 October 2014
Participant consent form [patient consent forms]	1	17 October 2014
Participant information sheet (PIS) [HCP information sheet]	1	17 October 2014
Participant information sheet (PIS) [patient information sheet]	1	17 October 2014
REC Application Form [REC_Form_03112014]		03 November 2014
Research protocol or project proposal [study protocol]	1	17 October 2014
Summary CV for Chief Investigator (CI) [Chief investigator CV]	1	17 October 2014
Summary CV for student [Student CV]	1	17 October 2014

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

14/LO/2053 **Please quote this number on all correspondence**

Yours sincerely

Elaine Hutchings

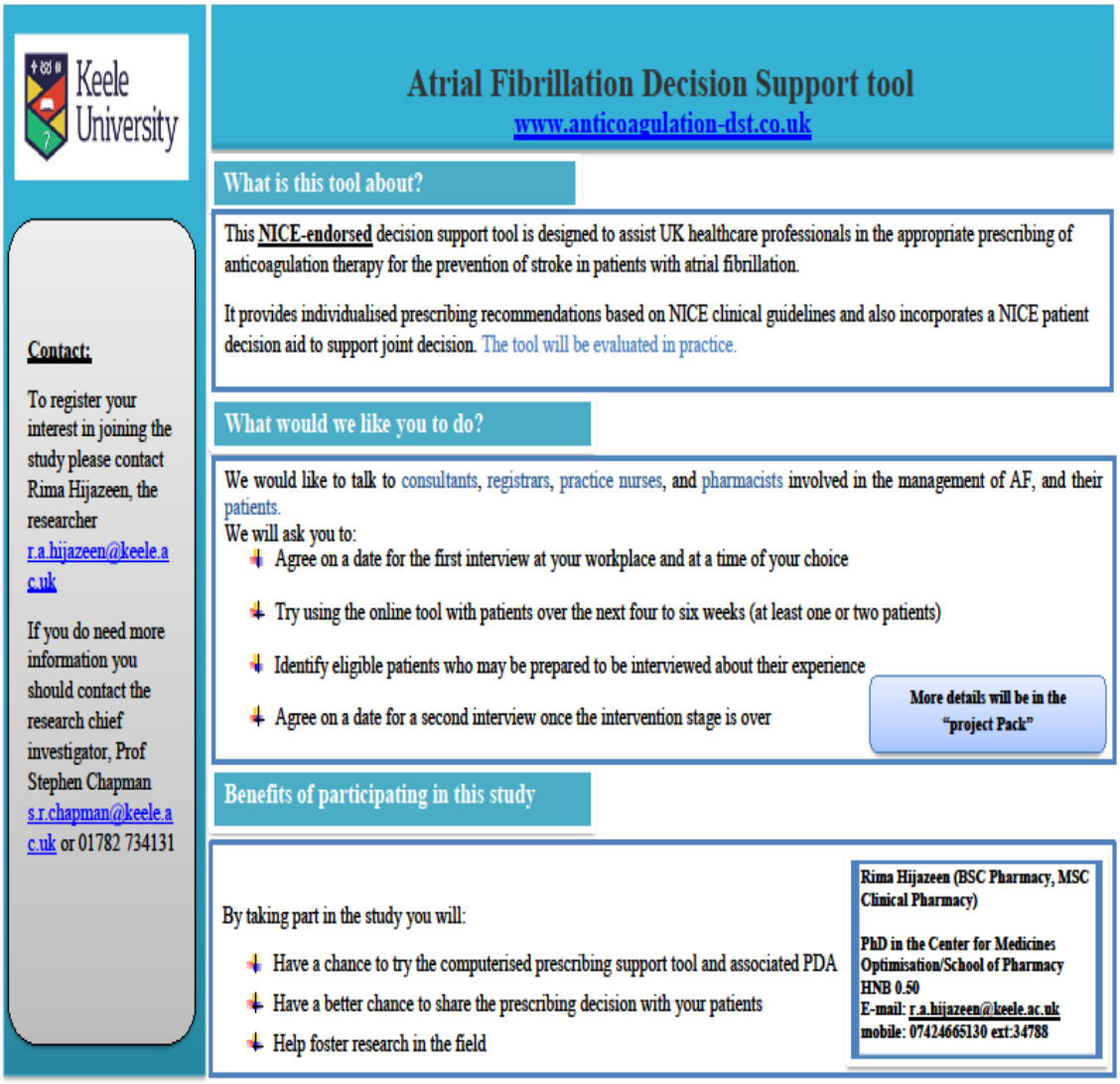
Elaine Hutchings

REC Manager E-mail: NRESCommittee.London-Central@nhs.net

Copy to: *Mrs Emma Skinner*

Dr Darren Clement, University hospital of North Staffordshire NHS Trust

Appendix 3: Research flyer



Keele University

Contact:

To register your interest in joining the study please contact Rima Hijazeen, the researcher r.a.hijazeen@keele.ac.uk

If you do need more information you should contact the research chief investigator, Prof Stephen Chapman s.r.chapman@keele.ac.uk or 01782 734131

Atrial Fibrillation Decision Support tool

www.anticoagulation-dst.co.uk

What is this tool about?

This **NICE-endorsed** decision support tool is designed to assist UK healthcare professionals in the appropriate prescribing of anticoagulation therapy for the prevention of stroke in patients with atrial fibrillation.

It provides individualised prescribing recommendations based on NICE clinical guidelines and also incorporates a NICE patient decision aid to support joint decision. The tool will be evaluated in practice.

What would we like you to do?

We would like to talk to consultants, registrars, practice nurses, and pharmacists involved in the management of AF, and their patients.

We will ask you to:

- Agree on a date for the first interview at your workplace and at a time of your choice
- Try using the online tool with patients over the next four to six weeks (at least one or two patients)
- Identify eligible patients who may be prepared to be interviewed about their experience
- Agree on a date for a second interview once the intervention stage is over

More details will be in the "project Pack"

Benefits of participating in this study

By taking part in the study you will:

- Have a chance to try the computerised prescribing support tool and associated PDA
- Have a better chance to share the prescribing decision with your patients
- Help foster research in the field

Rima Hijazeen (BSC Pharmacy, MSC Clinical Pharmacy)

PhD in the Center for Medicines Optimisation/School of Pharmacy
HNB 0.50
E-mail: r.a.hijazeen@keele.ac.uk
mobile: 07424665130 ext:34788

Appendix 4: Healthcare professional information sheet

(to be printed on headed paper)

Healthcare professional information sheet

Title of Project: Evaluation of the utility of a computerised decision support system for the management of oral anticoagulants.

Names of Researchers: Professor Stephen Chapman (Chief investigator) and Rima Hijazeen (Researcher).

Invitation to take part

You are being invited to take part in my research study. I am Rima Hijazeen, a PhD student supervised by Prof. Stephen Chapman in the Centre for Medicines Optimisation in the School of Pharmacy at Keele University. Of course, you do not have to take part but before you decide, it is important you understand what the project involves. Please take time to read the following information carefully and discuss it with others if you wish. Please do ask me (r.a.hijazeen@keele.ac.uk, Tel: 01782 734 788) if there is anything that is not clear or if you would like more information. Do take the time to decide whether or not you wish to take part, and thank you for reading this leaflet.

What is the purpose of the study?

This study is divided into three stages. The purpose of stage one is to explore your experiences, concerns, barriers, and the challenges with the prescribing of and consultation about oral anticoagulants, for example, warfarin, dabigatran-Pradaxa™, rivaroxaban-Xarelto™, and apixaban-Eliquis™. Stage two, when you will use the tool in routine practice with your patients. The purpose of stage three is to explore your experiences and views about using the computerised decision support (CDS) and associated patient decision aid (PDA) tool in practice.

What is the CDS tool about?

The CDS is accessible online from http://www.anticoagulation-dst.co.uk/

The computerised decision support (CDS) tool and the associated electronic PDA have been developed under a Joint Working Agreement by NICE, Keele University, and Boehringer Ingelheim. This decision support tool is designed to assist UK healthcare professionals in the prescribing and consultation of antithrombotic therapy for patients with atrial fibrillation.

The CDS tool provides individualised prescribing recommendations based on NICE technology appraisals and The European Society of Cardiology guidelines. Each prescribing recommendation is supported by a rationale, important management considerations, common treatment side-effects and appropriate references. To facilitate the patient consultation, each patient's stroke and bleeding risk can be displayed graphically and included in a personalised print out as part of a personalised patient decision aid. The tools have NICE approval and have been checked for impartiality and adherence to NICE guidance by both Keele University and NICE.

Why have I been invited?

You are being invited to take part in this study because you are a healthcare professional who has specific experience and a role in the management of patients with atrial fibrillation.

Do I have to take part?

You are free to decide whether or not to take part. If you choose to, you will be asked to confirm your consent (verbally and by completion of consent forms). You are still free to withdraw at any time and without giving a reason. However, please inform the researcher about your decision using the reply slip and the freepost envelope or by email (r.a.hijazeen@keele.ac.uk.)

What will happen if I decide to take part?

If you decide to take part, Please fill in the reply slip specifying a time to suit you for an interview, which will be audio recorded and with the researcher at your clinic.

How the study will run?

The study is a before-after design, which means there would be two data collection stages.

Stage one concerns exploring your experience with prescribing of oral anticoagulants and any barriers, and challenges you feel you may face. The interview will include completing brief questionnaires, demonstrating the decision support and associated PDA tool using clinical vignettes, and then a qualitative semi-structured interview. I will then leave with you instructions on how to access the tool in practice, and ask you to try using this with patients over the next eight weeks.

We will send you a reminder letter prompting you about the tool every week to optimise the possibility of you using it in practice.

After eight weeks I will return to complete second stage of data collection and ask you about your experiences, using the decision support tool with patients.

Who else beside me would be recruited in the study?

By referring to medical records, and excluding the vulnerable. I will ask you to identify patients from your clinic who have been diagnosed with AF, using or going to start oral anticoagulants, for example, warfarin, dabigatran, rivaroxaban, and apixaban, and have experienced the decision support and associated PDA during consultation. Initially, it is expected that you use the tool in consultation with patients, and then speak to eligible patient about the study during the clinic and if they are potentially interested in participating, you will seek agreement to pass patient's contact details to the researcher, the extent of identifiable patient information that will be accessed locally will be limited to the minimum necessary for the purpose, and will be transferred securely. It will include patient's name and telephone number. If the patient is happy for this to happen, you will pass their names to the practice manager/ department manager/secretary or to the researcher directly (whichever is most appropriate). Names will be written on a piece of paper and enclosed in sealed envelope. The researcher will contact patients at a later stage, by telephone and by sending an invitation letter or at their next meeting at the clinic. We do appreciate your effort to identify patients and talk to them about the study during the clinic.

What will happen to patients if they take part in the study? What do they have to do?

I will contact patients as soon as possible after I received their names to invite them to take part in the study. If s/he agrees to take part, I will ask for an interview at their convenience, and place of their choice for example, their homes. The aim of the interview will be to

explore their views and opinions when they have experienced the CDS and associated PDA tool in consultation.

What will happen to me if I take part and what do I have to do?

If you decide to take part, you will be invited to have an hour face-to-face interview with me at a time that is convenient for you and at a location of your choosing, for example, your workplace. The interview will start with briefing you so that you understand the nature of the research. I will then ask you to sign a consent form and a consent form for use of quotes before the start of any data collection. The interview will be audio recorded and you are free to decline to answer any question or not to discuss certain aspects of your experiences. Before the interview, the researcher will explain how the interview will run and at the end of the interview there will be an opportunity for you to ask questions. The interview will include: filling the questionnaire, demonstrating the CDS and associated PDA tool using a clinical vignette, and I will use an interview schedule to guide the interview.

What do I have to do next?

I will then leave with you instructions on how to access the tool in practice, and ask you to try using this with patients over the next eight weeks.

I need your help to identify patients from your clinic. Patients are eligible for inclusion if they have been diagnosed with AF, and using or going to start any of oral anticoagulants, for example, warfarin, dabigatran, rivaroxaban, and apixaban, and they are excluded if they are vulnerable, their first language is not English, and if they can't understand written English. I would appreciate it if you use the CDS and PDA tool for prescribing of and

consultation about their oral anticoagulants, speak to them about the study, and then pass their names and contact details securely (with their verbal consent) to the practice manager/department manager/secretary or to me directly as described earlier.

I will send you a reminder letter prompting you about the tool every week to optimise the possibility of you using it in practice.

I will send a letter to inform you about patients who have agreed and given their consent to take part in the study.

What will happen after eight weeks of using the tool in practice?

During the eight weeks I will send you a reminder letter every week to prompt you to use the tool in your routine medical practice. When the eight weeks are over, I will send you an invitation letter to arrange the second interview at your convenience and at a location of your choice. During the second interview, the researcher will check with you if you are still happy to carry on and agree to take part. You are free to withdraw at any time and if you do, I will discard any collected data from the first interview immediately. During the second interview I will ask you to complete brief questionnaires and a semi-structured interview. This should last approximately 45 minutes.

What will happen if I don't want to carry on with the study?

You are free to withdraw from the study at any point during the different stages of the study and if you do, I will discard all the data collected from you immediately.

Will I be recorded, and how will the recorded media be used?

The digital recording made during this project will be used only for analysis. No other use will be made of it without your written permission, and no one outside the project will be allowed access to the original recordings.

What are the possible disadvantages and risks of taking part?

There are no disadvantages or risks to you in taking part in this study. This study is to explore your experiences, concerns, and the challenges you might experience or have with prescribing oral anticoagulants including warfarin and new oral anticoagulants. However, the number, style, and length of the interviews may possibly cause some discomfort.

What are the possible benefits of taking part?

By taking part in the study you will have a chance to try the computerised prescribing support tool and associated PDA, which might facilitate the progress of your clinic by having the evidence-based practice and updated guidelines and recommendations handy and navigable. You would have a better chance to share the prescribing decision with your patients. Also taking part in this study would contribute to research on this topic, and this may lead to benefits for all health care professionals and patients. This should in turn make the decision support and PDA tool, if possible, available for use in the future to support healthcare professionals and patients.

Who will have access to information about me?

All personal information collected about you during the course of the research will be protected. This means that personally identifiable information about you will be kept strictly confidential and no one outside the project will be allowed access to it. Electronic data containing personally identifiable information about you will only be stored on

password-protected media to which only the research team (researcher and chief investigator) have access. Hardcopies of documentation containing personally identifiable information about you will be kept secure in a locked cupboard at Keele University that only the research team have access to, and that data protection regulations will be observed and strict confidentiality maintained. All data and documents containing personally identifiable information about you will be destroyed at the end of this study or earlier if you request this.

Anonymity: All data will be anonymised; names will be omitted during the transcribing process and consent forms with your name will be stored separately from the data, and only the members of the research team will have access to the identity codes on data collection documents. You will not be able to be identified in any reports or summaries.

How will information about me be used?

The results (including anonymised direct quotes) will be included in the final research report. No individual person will be identifiable in quotes, reports, presentations or summaries. If you wish, we will send you a summary of our findings and discuss them with you before publication.

Who is organising and funding the research?

The computerised decision support (CDS) tool and the associated electronic patient decision aid (PDA) have been developed under a Joint Working Agreement by NICE, Keele University, and Boehringer Ingelheim. The tools have NICE approval and have been checked for impartiality and adherence to NICE guidance by both Keele University and NICE.

The evaluation of the tool is a project for a PhD degree in pharmacy. The University of Jordan granted a scholarship to Rima Atallah Hijazeen to do this project and is completely independent of the development of the CDS tool and PDA. This research is being organised by Keele University.

Who has reviewed the study?

This study has been reviewed by the NHS Research Ethics Committee (REC) and the research and development office.

What if there is a problem?

If you have a concern about any aspect of this study, you may wish to speak to me. I will do my best to answer your questions. You should contact me (Rima Hijazeen) at r.a.hijazeen@keele.ac.uk or Tel: 01782 734 788. Alternatively, if you do not wish to contact the researcher you may contact the research chief investigator, Professor Stephen Chapman on: s.r.chapman@keele.ac.uk or 01782 734131. If you remain unhappy about the research and/or wish to raise a complaint about any aspect of the way that you have been approached or treated during the course of the study please write to Patient Advice Liaison Service team

.....

Further Information and Contact Details

If you need an independent contact point where you can seek general advice about taking part in this research you should contact Patient Advice Liaison Service team

If you need an independent contact point where you can seek further details about this specific research you should contact Simon Thomas s.thomas@keele.ac.uk at the following address:

Keele University, Hornbeam Building, Room 2.16

Keele

Staffordshire

ST5 5BG

Tel: 01782 734202

Thank you for taking time to read this information

Appendix 5: Healthcare professional consent form

(to be printed on headed paper)

Confidential

Healthcare professional consent form

Healthcare professional trial number: ……..
Hospital/ GP practice number: ……

Study title : Evaluation of the utility of a computerised decision support system for the management of oral anticoagulants.

Names of Researchers: Professor Stephen Chapman (Chief investigator) and Rima Hijazeen (Researcher).

Please tick the box if you agree with the statement.

1. I confirm that I have read and understand the information sheet for the above study (version 1, dated 17/10/14), and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to opt out at any time, without giving any reason, without my legal rights being affected in any way. ☐
3. I understand that data collected about me during this study will be anonymised before it is submitted for publication, and that data protection regulations will be observed and strict confidentiality maintained. ☐
4. I agree to take part in this study. ☐
5. I agree to the interview being audio recorded ☐

Name of participant	Date	Signature
Researcher	Date	Signature

(to be printed on headed paper)

(FOR THE USE OF QUOTES)

Study title: Evaluation of the utility of a computerised decision support system for the management of oral anticoagulants.

Names of Researchers: Professor Stephen Chapman (Chief investigator) and Rima Hijazeen (Researcher).

Please tick the box if you agree with the statement

1. I agree that any quotes may be used ☐
2. I do not agree to any quotes being used ☐

Name of participant	Date	Signature
Researcher	Date	Signature

Appendix 6: Healthcare professional interview guide (stage one)

(to be printed on headed paper)

Confidential

Healthcare professional interview guide

Healthcare professional trial number: ……

Hospital/ GP practice number: ……

<u>Title of Project:</u> Evaluation of the utility of a computerised decision support system for the management of oral anticoagulants.

<u>Names of Researchers:</u> Professor Stephen Chapman (Chief investigator) and Rima Hijazeen (Researcher).

<u>Stage one of the study</u>

"Healthcare professionals' experiences, concerns, barriers, and system specific challenges with oral anticoagulants prescribing and patient consultation"

Rima Hijazeen, PhD researcher

Department of Medicines Management, School of pharmacy

Keele University

Staffordshire

ST5 5BG

United Kingdom

Telephone: 01782 734 788, E-mail: r.a.hijazeen@keele.ac.uk

Obtain verbal consent to participate (Check consent form completed)

Good morning/afternoon/evening. My name is Rima and I am involved in conducting a project to explore more about concerns, barriers, and system specific challenges healthcare professionals might face when they are making decisions about the prescribing of and consultation about the oral anticoagulants.

Oral anticoagulants (OACs) refer to warfarin and new oral anticoagulants (NOACs), for example, dabigatran, rivaroxaban, and apixaban.

It is about complex or difficult prescribing decisions --When you have to consider the pros and cons of the options--, with this type of decision you need to:

- *consider NICE recommendations and other evidence-based practice*
- *discuss the decision with your patient*
- *take a bit more time to stabilize your patient and consider a follow up consultation visit*

I would like to talk to you about any concerns, barriers, and system specific challenges you may face with the prescribing of and patient consultation about oral anticoagulants. I am very interested in your views and experiences on this topic.

This information will help us to provide better support for healthcare practitioners facing these decisions.

All of the information we collect in this interview will be kept confidential. The interview will take about 30 minutes.

Decisions in the management of patients with AF and at risk of stroke

- What decisions do patients with AF and at risk of stroke have to make in your practice?
- What is currently being done? How these decisions are usually made?

  Which decisions are the most difficult to make?

  What decisions do you feel you need assistance with?
- What decisions do patients feel they need assistance with?

  What is your usual role in making this decision?

What is their usual role in making this decision?

- How do you currently support your patients' decision making on this topic?

HCPs' perceptions of anticoagulants decision process

- How difficult is this decision for you to make? Why?

  - If the answer was 'not difficult', then, what makes the prescribing decision easy for you? What facilitators do you have in your practice that make the decision easy for you?
  - If the answer was 'difficult', then, what makes the decision difficult for you? How do these difficulties affect your prescribing of the OACs (warfarin & NOACs)?
- What kind of support do you use during consultation in your routine practice? Do you use a computerised program? If yes, Why? Which ones?

If no, why not?

- What is needed? What kind of support and resources do you think you and other colleagues need to overcome this?
- What are the barriers that make the prescribing decision difficult for you?

What could be done to address any of these barriers?

- Do you have further comments, questions or suggestions?

Reconfirm consent to participate and ask for permission to use quotes (also need to complete consent form). Thank participant

Appendix 7: Healthcare professional interview guide (stage two)

(To be printed on headed paper)

Confidential

Healthcare professional interview guide

Healthcare professional trial number: ……

Hospital/ GP practice number: …..……

Title of Project: Evaluation of the utility of a computerised decision support system for the management of oral anticoagulants.

Names of Researchers: Professor Stephen Chapman (Chief investigator) and Rima Hijazeen (Researcher).

Stage two of the study

"Pre-intervention evaluation of the decision support tool: HCPs' perspectives"

Rima Hijazeen, PhD researcher

Department of Medicines Management, School of pharmacy

Keele University

Staffordshire

ST5 5BG

United Kingdom

Telephone: 01782 734 788, E-mail: r.a.hijazeen@keele.ac.uk

An assessment of the computerised decision support tool (CDST) and associated patient decision aid (PDA) tool

After demonstration of the CDST and PDA tool using hypothetical cases

I would like to talk with you about what we have just done and seen. I want to ask you what you think about this and how did you feel about the CDST and PDA tool.

Please consider CDST and PDA tool in your answer

The comprehensibility of components of the decision support tool

I *would like to know what you think about the material in this decision support tool*

- What you think about the way the information was presented?
- What did you think of the way this tool calculated and presented the stroke and bleeding risks?
- What did you think of the quality of the evidence presented by this tool?
- What you think about how much information is shown at a time, and the total amount of information?

Preparation for decision making

- Would you have found this CDST useful when you were making the decision about anticoagulants therapy? Could you give me any reason for this?
- Do you think the CDST and PDA tool included enough information to help patients decide on the therapy for anticoagulation? Could you give me any reason for this?
- How useful is this CDST in preparing and informing your prescribing decisions and sharing the decision with your patients?

- What screens did you find useful in supporting the shared decision making with patients? PDA and CDST
- To what extent does the CDST and PDA help patients to be involved in the decision-making process?

- How confident would you be to use this CDST to inform your prescribing decision?

Explore barriers and facilitators within the setting

- What is likely to get in the way of using this tool in your practice?
- Are these barriers specific to the format of the tool? Please say in what ways. (e.g., requires computer access, literacy too high, too difficult to use, not accessible)?
- What are the barriers specific to the patients? (e.g. lack of awareness, limited knowledge/skills, poor attitudes, concerns, incompatible with current practice, lack of confidence)
- What are the barriers specific to health professionals? (e.g. lack of awareness, limited knowledge/skills, poor attitudes, concerns, incompatible with current practice, lack of confidence)
- Are any other barriers to implementing the decision support tool within the healthcare setting? Tell me about these.
- What would facilitate the use of such decision aids within the healthcare setting?

  Who needs to approve this tool?

  Who could facilitate (or block) the implementation of this tool in practice?
- What suggestions do you have for recommending this tool to others?

Potential use of the CDS and PDA tool

Thinking about the recommendations which the tool has made.

What do you think about this kind of decision support for oral anticoagulant prescribing decisions? Tell me how the tool might help the prescriber through any prescribing difficulties?

- Now, I am going to ask you how satisfied you are with this decision support tool. Let's begin with what you like about it? What do you think it's good points are? Why?
- Are you dissatisfied with it? What do you think it's bad points are? Why?
- I would like you to tell me if you think there are any advantages /disadvantages of using this tool over your normal practice (Specifically)?

- Could the CDST and PDA help improve your communication of the decision to patients? In what ways might it do this?
- Would the CDST and PDA improve your patients' understanding of the decision? Could you give me any reason for this?
- Would it take long to explain the decision to patients? Why?
- Could the CDST and PDA provision create new concerns? New concerns for practitioners, and patients.
- Could the CDST and PDA affect the patient-physician relationship? Could you give me any reason for this?

- Would you use the CDST and PDA if it were available on your PC in the clinic or on your iPhone?

- Would you use it routinely, or just with a specific group of patients?
- How confident would you be to use this tool if it were available?

Do you think other health professionals could use this tool? Which ones? Overall, what's your opinion of the CDST and PDA now?

Reconfirm consent to participate and ask for permission to use quotes (also need to complete consent form).

Thank participant

Appendix 8: Healthcare professional interview guide (stage three)

(To be printed on headed paper)

Confidential

Healthcare professional interview guide

Healthcare professional trial number: ……..

Hospital/ GP practice number: …..……

Title of Project: Evaluation of the utility of a computerised decision support system for the management of oral anticoagulants.

Names of Researchers: Professor Stephen Chapman (Chief investigator) and Rima Hijazeen (Researcher).

Stage three of the study

"Post-intervention evaluation of the decision support tool: HCPs' perspectives"

Rima Hijazeen, PhD researcher

Department of Medicines Management, School of pharmacy

Keele University

Staffordshire

ST5 5BG

United Kingdom

Telephone: 01782 734 788

E-mail: r.a.hijazeen@keele.ac.uk

Obtain verbal consent to participate

Good morning/afternoon/evening. For today I would like to talk to you about your actual experiences of using this CDST and associated PDA and how you found it. I am also very interested in exploring more about the concerns, barriers, and system specific challenges you faced during that time.

- *I am very interested in your views and experiences on this topic.*
- *All of the information we collect in this interview will be kept confidential. This interview will take about 30 minutes.*

Feedback and experiences

- How would you describe your overall use of the AF DST in the clinic/ward? What value do you think the tool has for you and your patients?
- Please describe how often did you use the tool in your clinical setting?
- Have you used it routinely/randomly, or just with a pre-defined patient? If the answer is "Just with a specific patient",
- How did you decide which patients to use the tool for?
- How would you describe your experiences with the technical process of accessing the

  AF prescribing decision support tool and PDA and its use?

HCPs' perceptions from using the tool in practice

- On reflection, did you get what mattered to you from this tool? What was it?

- What are the reason(s) that motivate you to try this tool in your practice?

- How did your patients feel when you used this decision support tool in the consultation? What do you think his/her preferences were?
- In what ways the recent consultation differs from your usual consultation with patients?
- How useful was this decision support tool in [preparing and informing your prescribing decisions and sharing the decision with your patients, facilitate the consultation] at the point of care?
    - What screens did you find useful in supporting the shared decision making/consultation with patients?

    - To what extent does this tool help patients to understand/be involved in the decision making process?

- Has the tool helped to improve your communication of the decision to patients? In what ways? Has the tool improved your patients' understanding of the decision? In what ways?
- Did the use of the tool affect the relationship between you and your patient? Could you give me any reason for this?
- How confident were you in using this tool to inform your prescribing decision/inform and prepare your patient to decide on the therapy? Could you give me any reasons for this?
- Do you think the tool included enough information to help patients to be involved during the consultation/prompt your patient to ask questions/decide on the therapy? Could you give me any reason for this?

- Did the use of this kind of tool affect your usual consultation time length?

- Have you any suggestions on how to avoid increasing the consultation time while using it?

Explore barriers and facilitators within the clinical setting

Barriers to and facilitators of the AF decision support tool that you have encountered during provision/uptake

- What are the actual barriers that influenced/hindered the use of the tool in routine practice?

What are the healthcare provider related factors impacting on the tool provision/uptake?

- The healthcare professional is unwilling to change/try new ideas
- The healthcare professional sees little benefit for self
- There is not a documented need to change practice
- The healthcare professional feels the benefits of changing practice will be minimal
- The healthcare professional does not see the value of this tool for his/her practice

What are the practice/setting related factors impacting on the tool provision/uptake?

- There is insufficient time on the job to implement new ideas
- The healthcare professional does not have time to read research

- The healthcare professional does not feel she/he has enough authority to change patient care procedures
- The facilities are inadequate for implementation
- Another staff are not supportive of implementation
- Another healthcare professional will not cooperate with implementation

What are the specifics of the tool impacting on provision/uptake?

- The tool is not relevant to my practice
- The tool presentation, format, and content
- Implications for practice are not made clear
- The research has methodological inadequacies
- The quality of the evidence presented by the tool is inadequate

What are the patient related factors impacting on the tool provision/uptake?

- Patient unwilling to participate
- Few eligible patients/patient characteristics
- Patient-doctor interactions

What could be done to address any of these barriers before being able to provide the CDST and PDA for use in practice?

Reconfirm consent to participate and ask for permission to use quotes.

Thank participant

Appendix 9: Healthcare professional questionnaires sheet (stage two)

(To be printed on headed paper)

Confidential

Healthcare professional questionnaires sheet

Healthcare professional trial number: ……

Hospital/ GP practice number: ……

Title of Project: Evaluation of the utility of a computerised decision support system for the management of oral anticoagulants.

Names of Researchers: Professor Stephen Chapman (Chief investigator) and Rima Hijazeen (Researcher).

Stage one of the study

Thank you very much for taking the time to fill in this questionnaire.

The questions ask your opinion about the prescribing of **oral anticoagulants**. The questions cover the following topics:

- Preparation for decision making
- User satisfaction with CDST and PDA
- Acceptability of the CDST and PDA

It should take about ten minutes of your time.

Your responses are voluntary and will be confidential. All responses will be anonymised so that you cannot be identified. If you have any questions or require any further information, either now or at any time during the study, please contact me (Rima Hijazeen) at r.a.hijazeen@keele.ac.uk or Tel: 01782 734 788. Alternatively, you can contact me in writing at the School of Pharmacy, Keele University, Staffordshire ST5 5BG.

Please make sure you answer all the questions. Thank you for your time.

Demographic and general information

Consultant/Registrar/GP/Practice nurse/nurse prescriber/Pharmacist prescriber trial number …

1. Age……. [Year]

2. Sex: □male □female

4. Availability of other healthcare practitioners (i.e. specialist/ practice nurse/GP/consultant)

5. How long have you been a practitioner?

6. How long have you been in your present post?

Preparation for decision making

*The following questions refer to the **CDST and PDA** that you have used with your patient(s) during recent consultation. Please indicate your feedback about the effect of this decision support tool by circling the appropriate number to show the extent to which you agree with each statement.*

To what extent did the use of the patient decision aid (PDA) with your patient	Not at all	A little	Some what	Quite a bit	A great deal
	1	2	3	4	5
1. help her/him to fully understand the risks and benefits of anticoagulation therapy	□	□	□	□	□
2. Help her/him identify the importance she/he places on the risks and benefits of anticoagulation therapy	□	□	□	□	□
3. Prepare her/him for the follow-up consultation visit	□	□	□	□	□
4. help her/him be as involved in the decision making process as she desired	□	□	□	□	□
5. help her/him to make a more informed decision	□	□	□	□	□
6. Help you to more fully understand the issues that are most important to her/him	□	□	□	□	□
7. Help you tailor your counselling to her/his preference for decision participation	□	□	□	□	□
8. Facilitate the follow-up consultation visit	□	□	□	□	□
9. Affect the patient –physician relationship	□	□	□	□	□
10. Improved the way time was spent during the consultation visit	□	□	□	□	□
11. Improved the quality of the consultation visit	□	□	□	□	□

User satisfaction with the computerised decision support (CDST)

*The following statements measure your satisfaction level with the **CDST and PDA**. Please give your feedback from using the decision support tool with patient by circling the number that shows how much you are satisfied: '1' "almost never" and '5' "almost always".*

Statements …….	almost never	some of the time	about half the time	most of the time	almost always
	1	**2**	**3**	**4**	**5**
1. Does the tool provide the precise information you need?	☐	☐	☐	☐	☐
2. Does the information content meet your needs?	☐	☐	☐	☐	☐
3. Does the system provide reports that seem to be just about exactly what you need?	☐	☐	☐	☐	☐
4. Does the system provide sufficient information?	☐	☐	☐	☐	☐
5. Is the system accurate?	☐	☐	☐	☐	☐
6. Are you satisfied with the accuracy of the system?	☐	☐	☐	☐	☐
7. Do you think the output is presented in a useful format?	☐	☐	☐	☐	☐
8. Is the information clear?	☐	☐	☐	☐	☐
9. Is the system user friendly?	☐	☐	☐	☐	☐
10. Is the system easy to use?	☐	☐	☐	☐	☐
11. Do you get the information you need in time?	☐	☐	☐	☐	☐
12. Does the system provide up-to-date information?	☐	☐	☐	☐	☐

Acceptability

*The following set of questions asks about your feedback of the **CDST and PDA**. Please indicate how strongly you agree or disagree with each statement by circling the appropriate number.*

In general	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
	1	**2**	**3**	**4**	**5**
1. It will be easy for me to use	□	□	□	□	□
2. It is easy for me to understand	□	□	□	□	□
3. It will be easy for me to try before making a final decision to use the tool regularly in practice	□	□	□	□	□
4. The output is easy to see	□	□	□	□	□
5. Using this support tool is better than how I usually go about helping patients decide about their anticoagulant treatment	□	□	□	□	□
6. This support tool is compatible with the way I think things should be done	□	□	□	□	□
7. Compared with my usual approach, this support tool will result in my patients making more informed decisions	□	□	□	□	□
8. Using this support tool will save me time	□	□	□	□	□
9. The use of this tool is a more cost effective than my usual approach to helping patients decide about the therapy	□	□	□	□	□
10. Pieces or components of the tool can be used by the patients themselves	□	□	□	□	□
11. This support tool is a reliable method of helping patients make decisions about their therapy	□	□	□	□	□
12. This type of decision support tool is suitable for helping patients make value laden choices	□	□	□	□	□
13. This support tool complements my usual approach	□	□	□	□	□
14. Using this tool does not involve making major changes to the way I usually do things	□	□	□	□	□
15. There is a high probability that using this support tool may cause/result in more benefit than harm	□	□	□	□	□

How likely is it that you would recommend this CDST and PDA to friend or colleague if they needed similar support?

Not at all likely					**Neutral**					**Extremely likely**
0	1	2	3	4	5	6	7	8	9	10

Thank you for your willingness to participate in this important research.

Appendix 10: Healthcare professional information letter

(To be printed on headed paper)

Healthcare professional information letter

Dear healthcare professional,

Title of Project: Evaluation of the utility of a computerised decision support tool for the management of oral anticoagulants.

Names of Researchers: Professor Stephen Chapman (Chief investigator) and Rima Hijazeen (Researcher).

Re: Mr/ Mrs/ Miss (patient name)

One of your patients Mr/ Mrs/ Miss ……., has agreed and given his/her consent to take part in the above study. This is described in greater detail overleaf.

What is the purpose of this study?

This study aims to evaluate the utility of the computerised prescribing decision support tool and the associated patient decision aid for the management of oral anticoagulants (OACs) in patients with atrial fibrillation (AF). This allows us to explore patients' experiences, concerns, and challenges with OACs management and consultation.

Why has your patient been chosen?

Your patient has been approached about participation in this study because s/he gave you initial permission for the researcher to contact him/her.

This patient has experienced the prescribing decision support tool and the associated patient decision aid (PDA) in consultation(s). S/He has some experience, concerns, and barriers when s/he experienced that kind of patient care. We are interested in exploring their thoughts and feelings about this kind of consultation compared to routine practice.

What will happen to your patient if s/he decides to take part in the study?

Patient will be required to:

- Arrange for an interview with the researcher. It will take place at his/her home, at time of his/her choice.
- The patient will be asked to complete a questionnaire and then answer questions on the topic.
- The interview will approximately last for one hour.

What will happen if my patient gets discomfort during the interview?

The researcher will stop the interview immediately, and ask if the patient needs additional support or contact people for further advice.

Contact for further information?

Please ask us if there is anything that is not clear, or if you would like any more information (details below).

Contact name and numbers:

Rima Hijazeen

r.a.hijazeen@keele.ac.uk

Tel: 01782 734 788

Prof S. Chapman

s. r.chapman@keele.ac.uk

Tel: 01782 734131

Yours sincerely,

Rima Hijazeen

Appendix 11: Consent to contact form

(To be printed on headed paper)
CONSENT TO CONTACT FORM

Title of Study: Evaluation of the utility of a computerised decision support tool for the management of oral anticoagulants

Name of Researcher: Rima A. Hijazeen

Please complete this form if you are happy for the researcher to contact you to discuss this study.

Please initial the box

1. I confirm that I have read the research information sheet for the above study. ☐
2. I agree that my care co-ordinator can inform the above researcher of my medical condition in order to assess my eligibility to participate in the above study. ☐
3. I understand that my personal contact details below will be stored securely, in line with the data protection act. ☐
4. I agree that the researcher can contact me to discuss my participation in the above study using my contact details below. ☐

Full Name: _____

Address: _____

Telephone: _____ Mobile: _____

Email: _____

Preferred Time to be contacted: Morning Afternoon Evening (please circle)

Preferred Method of contact: Home-landline Mobile Email (please circle)

Many thanks for expressing interest in this study. You will be contacted, as per your stated preferences within 24-48 hours to discuss the research further. As previously explained, there is no obligation to commit to the study at this time and whether you participate or not, this will not affect the care or treatment you receive under normal routine care.

Appendix 12: Patient Invitation Letter

(To be printed on headed paper)

Invitation Letter

Dear Patient,

Re: Evaluation of the utility of a computerised decision support system for the management of oral anticoagulants.

I am Rima Hijazeen, a PhD student in the school of pharmacy at Keele University supervised by Professor Stephen Chapman.

I would like to invite you to take part in this study. The purpose of the study is to explore the usefulness of the patient decision aid tool for blood thinning medicine, I would like to listen to your opinion about it, and how it could help and support the prescribing of and consultation about your blood thinning medicine (anticoagulant).

All that you would be asked to do is have a 60 minute interview with me at a time and place that is easy for you, for example at your house. I would ask some questions about your opinion, concerns, and challenges about the use of this decision aid for the management of your blood thinning medicine. I have enclosed an Information Sheet and consent forms which give more details.

If you are willing to take part, please fill in the reply slip or email me at r.a.hijazeen@keele.ac.uk when I would then meet you for a voice-recorded interview at your house at a time which is convenient for you.

All personal information that I collect about you during the course of the research will be protected. This means that personally identifiable information about you will be kept

strictly confidential and no one outside the project will be allowed to see it, and all data will be anonymised.

If you have any questions about the project please email me at r.a.hijazeen@keele.ac.uk or phone/text me on **07424665130** or leave a voice massage on **01782 734 788**

FYI: You have been referred to us by your healthcare provider

Thank you for taking the time to read this.

Yours sincerely

Rima Hijazeen

Appointment for an audio-recorded interview

I would like to meet you for a voice-recorded interview. When would be a convenient time for me to interview you **at your home OR a place of your choice?**

……

Reply Slip

I would be willing to meet you on …… (date) at……(time) **at my home.**

Signature ……..

Date……

Please do return this reply slip along with signed consent forms using the provided pre-paid envelope.

Thank you and look forward to meeting you soon

Appendix 13: Patient Information Sheet

(To be printed on headed paper)

Patient Information Sheet

Title of Project: Evaluation of the utility of a computerised decision support system for the management of oral anticoagulants.

Names of Researchers: Professor Stephen Chapman (Chief investigator) and Rima Hijazeen (Researcher).

Invitation to take part

Thank you for your interest in this project. I am writing to you to introduce myself and my research. I am Rima Hijazeen, a PhD student supervised by Prof. Stephen Chapman in the Centre for Medicines Optimisation in the School of Pharmacy at Keele University. You do not have to take part but before you decide, it is important you understand what the project involves. Please take time to read the following information carefully and discuss it with relatives, friends and your doctor if you wish to. Ask me (r.a.hijazeen@keele.ac.uk, Tel: 01782 734 788) if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this leaflet.

What is the purpose of the study?

Prescribing decision support tools have been recognised to support patient care and the practice of medicine. A prescribing decision support tool for blood thinning medicines has been developed at Keele University. We are attempting to evaluate this tool for its usefulness in supporting patients and doctors/healthcare providers. I would like to talk to you to explore your opinion and preferences about using a decision support and associated patient decision aid tool in consultation.

Why have I been invited?

You have been approached about participation in this research because you have atrial fibrillation (an irregular heart beat) and are taking one of the available blood thinning medicines to lower your risk of a blood clot forming and reduce your risk of having a stroke.

Recently, your doctor used the decision support and patient decision aid tool during consultation. By this you have been offered an extra support to make a decision about your blood thinning medicine. Your views, preference, and any concerns that you may have experienced when making the decision to take this medicine are important to us.

Do I have to take part?

No, it is entirely your choice. If you decide to take part, you will be given this information sheet to keep, and be asked to sign consent forms. If you take part in the study, you are still free to withdraw from the study at any time without giving a reason for doing so.

If you decide not to take part in the study, or take part in the study then subsequently withdraw from it then the researcher will immediately throw away all the information collected from you, **this will not affect the standard of care you receive.** However,

please inform the researcher about your decision using the reply slip and the freepost envelope or by email (r.a.hijazeen@keele.ac.uk.)

What will happen if I decide to take part?

You will be invited to have a 60 minute interview with me at a time that is convenient for you and at a place of your choosing, for example, at your home or preferred Café (whichever is most appropriate). The researcher will make sure that you understand the nature of the research.

The interview will start by signing the consent forms. The interview will include visiting the online decision support tool using the researcher own machine from http://www.anticoagulation-dst.co.uk/ followed by filling in the questionnaire and answering questions on the topic.

The interview will be voice recorded and you are free to refuse to answer any question or not to discuss certain areas of your experience. Before starting, the researcher will explain how the interview will run and at the end of the interview there will be chance for you to ask questions. The interview will be recorded so that the researcher can write down what you said word-for-word following the interview and analyse it later on.

Will I be recorded, and how will the recorded media be used?

The digital recording made during this research will be used only for research. No other use will be made of it without your written permission, and no one outside the project will be allowed to hear the original recordings.

What will happen if I don't want to carry on with the study?

You are free to stop at any point during the research and I will immediately throw away all the information collected from you. If you decide to, this will not affect your treatment in any way.

What are the possible disadvantages and risks of taking part?

There are no disadvantages or risks to you in taking part in this study. It will look at your experience and challenges you experienced when your doctor used the tool for the prescribing of your medicine. However, since I would like you to talk about your medicine, I know that issues may come up that may be upsetting. If this happens, the researcher will let you decide whether or not to carry on with the interview. The researcher will debrief you at the end of the interview and give you contact numbers if you would need to discuss your treatment further.

What are the possible benefits of taking part?

By taking part in the study you will receive extra support during your consultation with your doctor/healthcare provider. Your doctor /healthcare providers will work with you using a prescribing decision support tool and patient decision aid. You will experience the use of the prescribing decision support tool. The interview would also give you a chance to have your views and concerns listened to.

Taking part in this study would help contribute to research on this topic, and make the decision support and patient decision aid tool if possible available for use in the future to support doctors/healthcare providers and patients.

Who will have access to information about me?

All personal information that I collect about you during the course of the research will be protected. This means that personally identifiable information about you will be kept

strictly confidential and no one outside the project will be allowed to see it. Electronic data containing personally identifiable information about you will only be stored on passwordprotected media that only I have access to. Hardcopies of papers containing personally identifiable information about you will be kept secure in a locked cupboard at Keele University that only the research team have access to, and that data protection regulations will be observed and strict confidentiality maintained. At the end of this study all information and documents containing personally identifiable information about you will be destroyed or earlier if you ask for this.

Anonymity: All data will be anonymous; names will be left out during the transcribing process and consent forms with your name will be stored separately from the data, and only the members of the research team will have access to identity codes on data collection documents. You will not be able to be identified in any reports or summaries.

How will information about me be used?

The results (including anonymous direct quotes) will be included in the final research report. No individual person will be identifiable in quotes, reports, presentations or summaries. If you wish, we will send you a summary of our findings when the study is finished.

Who else is taking part?

In addition to other patients being invited for the same purpose, your doctor/healthcare provider is being offered participation in the study. They will be asked to use the tool with other patients in the same way you have experienced, and then interview them to explore their views and opinion about its usefulness in medical practice and patient care.

Will my doctor/healthcare provider know about my participation in the study?

If you agree and give your consent to take part in the study, I will send a letter to your doctor/healthcare provider to inform him/her which patients agreed to take part in the study. Your doctor/healthcare provider will not have access to any data collected from you, and if you decide to withdraw from the study this will not affect the standard of care you receive by your doctor/healthcare provider.

Who is organising and funding the research?

The computerised decision support tool (CDST) and the associated electronic patient decision aid (PDA) have been developed under a Joint Working Agreement by NICE, Keele University, and Boehringer Ingelheim. The tools have NICE approval and have been checked for impartiality and adherence to NICE guidance by both Keele University and NICE.

The evaluation of the tool is a project for a PhD degree in pharmacy. The University of Jordan granted a scholarship to Rima Hijazeen to do this project and is completely independent of the development of the CDS tool and PDA. This research is being organised by Keele University.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, well-being, and dignity. This study has been reviewed by the NHS Research Ethics Committee and the research and development office from the University of North Midlands NHS foundation Trust.

What if there is a problem?

If you have a concern about any aspect of this study, you may wish to speak to me. I will do my best to answer your questions. You should contact me (Rima Hijazeen) at

r.a.hijazeen@keele.ac.uk or Tel: 01782 734 788. Alternatively, if you do not wish to contact the researcher you may contact Professor Stephen Chapman on: s.r.chapman@keele.ac.uk or 01782 734131. If you remain unhappy about the research and/or wish to raise a complaint about any aspect of the way that you have been approached or treated during the course of the study please write to Patient Advice Liaison Service team.

If you need an independent contact point where you can seek further details about this specific research you should contact Simon Thomas s.thomas@keele.ac.uk at the following address:

Keele University, Hornbeam Building, Room 2.16

Keele

Staffordshire

ST5 5BG

Tel: 01782 734202

Thank you for taking time to read this information

Appendix 14: Patient consent forms

(To be printed on headed paper)

Patient trial number: ……
Hospital/ GP practice number: ……

Patient Consent Form

Study title: Evaluation of the utility of a computerised decision support system for the management of oral anticoagulants.

Names of Researchers: Professor Stephen Chapman (Chief investigator) and Rima Hijazeen (Researcher).

Please tick the box if you agree with the statement.

1. I confirm that I have read and understand the information sheet for the above study (version 1, dated 17/10/2014), and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to opt out at any time, without giving any reason, without my medical care or my legal rights being affected. ☐

3. I understand that data collected about me during this study will be anonymised before it is submitted for publication, and that data protection regulations will be observed and strict confidentiality maintained. ☐

4. I agree to take part in this study. ☐

5. I agree to the interview being audio recorded ☐

Name of participant	Date	Signature
Researcher	Date	Signature

(To be printed on headed paper)

Patient trial number: ……
Hospital/ GP practice number: ……..

Patient Consent Form

(For The Use of Quotes)

Study title: Evaluation of the utility of a computerised decision support system for the management of oral anticoagulants.

Names of Researchers: Professor Stephen Chapman (Chief investigator) and Rima Hijazeen (Researcher).

Please tick the box if you agree with the statement

1. I agree that any quotes may be used ☐
2. I do not agree to any quotes being used ☐

_____	_____	_____
Name of participant	Date	Signature
_____	_____	_____
Researcher	Date	Signature

Appendix 15: Patient Interview Guide

(To be printed on headed paper)

Patient Interview Guide

Patient trial number: …

Consultant/ GP/Pharmacist/Nurse practitioner trial number: …..

Title of Project: Evaluation of the utility of a computerised decision support system for the management of oral anticoagulants.

Names of Researchers: Professor Stephen Chapman (Chief investigator) and Rima Hijazeen (Researcher).

Rima Hijazeen, PhD researcher

Department of Medicines Management, School of pharmacy

Keele University

Staffordshire

ST5 5BG

United Kingdom

Telephone: 01782 734 788,

E-mail: r.a.hijazeen@keele.ac.uk

Obtain verbal consent to participate (Check consent form completed)

Good morning/afternoon/evening. My name is Rima and I am involved in a project to explore patients' perceptions of the utility of the DA in anticoagulation therapy decision-making process in clinical practice.

I am interested in your view and experience on whether the decision aid helped you during consultation.

I am very interested in your views and experiences on this topic.

This information will help us to provide better support for doctors and patients facing such decision.

All of the information we collect in this interview will be kept confidential. The interview will take about 45 minutes.

Patients' experiences of the consultation using the DA

Firstly, I want to hear from you about your earlier consultation and how the prescribing decision was made.

What resources were available to you to support the prescribing of your blood thinning medicine? How you felt about that?

- Would you describe how the consultation went? Tell me about how the decision was made?
- Were you involved in the decision to change/start your blood thinning medicine?

- Did you feel that the decision was difficult for you to make? Why?
- When you considered your decision, what made you feel that you knew enough about the options and ready to make the decision?
- How did you get the information to make this kind of decision?

Now let's discuss who was involved in making the decision about starting/changing your blood thinning medicine?

How did you feel when making this decision? *[Probe manifestations of decisional conflict, for example, unsure, worried, Wavering, or delaying the decision]*

- How satisfied are you with the decision you made? Why? - In any way, are you dissatisfied? Why?

What influenced your decision to accept your blood thinning medicine? Did the extra support helped?

- How much were you involved in the consultation and prescribing decision about your blood thinning medicine? - What was your role?

What do you think about this kind of consultation with using this decision support tool?

How the decision support tool improved the way of communicating the prescribing decision (the information about your medication and risks) to you? In what ways it did that?

Did the decision support tool improve your understanding of your medicine? Could you give me any reason for this?

Did the use of the decision support tool made the consultation visit longer than usual? Why did you say that?

How did that consultation visit differ from previous consultations? Tell me how?

Assessing the patient decision aid

I would like to know what you think about the material in this tool

- What do you think about the way it was presented?
- What do you think about the way of calculating and presenting the stroke and bleeding risks?

What do you think about the amount of information included in the tool and in each screen? Thinking about the information presented by the tool, what do you think about this? And how did you feel about this? What made the information useful for you?

- Did you find this tool was useful for you? In what ways?
- Do you think it included enough information to help you better understand your medicine and your risks values? Could you give me an example?

Now, I am going to ask you how satisfied you are with this decision support tool.

Let's begin with what you like about it? What do you think its good points are? Why? Are you dissatisfied with it? What do you think its bad points are? Why?

- ❖ I would like you to tell me if you think there are any advantages of using this tool over normal routine consultation (Specifically)?
- ❖ Now please tell me any disadvantages of using this tool rather than normal routine consultation (Specifically)?
- ❖ Is there anything else that should be added to the tool and would support you better in making a decision about your blood thinning medicine?

Concerns/barriers from using the DA during consultation

Now let's talk about perceived barriers which might get in the way of using this decision aid into daily medical practice.

- What are the barriers which were specific to the DA?

  Probe; The DA presentation, format, and content

- What are the barriers which were specific to you and other patients?

  Probe; education level, age, language, use of computer, understanding, and relationship with the doctor during consultation

- What were the barriers which are specific to the doctors? Probe; time and attitude, and impact on patient-doctor relationship

- ❖ Do you think the use of the DA in practice would create new concerns for you and other patients?
- ❖ How confident would you be if your doctor used this tool during the consultation?

- On reflection, did you get what mattered to you from this DA? What was it?
- Overall, what's your opinion of this DA, and how would you describe your experience?

Reconfirm consent to participate and ask for permission to use quotes (also need to complete consent form). Thank participant

Appendix 16: Patient Questionnaires Sheet (stage four)

(To be printed on headed paper)

CONFIDENTIAL

Patient Questionnaires Sheet

Patient trial number: ……

Consultant/ GP/Pharmacist/Nurse practitioner trial number: …..

Title of Project: Evaluation of the utility of a computerised decision support system for the management of oral anticoagulants.

Names of Researchers: Professor Stephen Chapman (Chief investigator) and Rima Hijazeen (Researcher).

Thank you very much for taking the time to fill in this questionnaire.

This is a sample set of questions adopted from a variety of research. The questions ask your opinion about important issues within the prescribing and management of your oral anticoagulant.

It should take about 15 minutes of your time.

Your responses are voluntary and will be confidential. All responses will be anonymised so that you cannot be identified.

Please make sure you answer all the questions. Thank you for your time.

Demographics and general information

1. Date of birth - - / - - / - - - -

2. Sex: □male □female

3. Race/Ethinicity/Nationality

4. Education: Secondary school Higher education Other, please specify…….

6. Are you employed? Yes No

Expectation of involvement in treatment decisions

In general, when you need medical treatment and more than one treatment is available, who do you think should make the decision about which treatment is best for you? (Choose one)

- **Doctor should decide**
- **Doctor should make decision after consulting patient**
- **Doctor and patient should decide to gather**
- **Patient should decide after consulting doctor**
- **Patient should decide**

Acceptability

I would like to know what you think about the education material in this decision support and patient decision aid tool

1. **Please rate each section, by circling 'poor', 'fair', 'good', or 'excellent' to show what you think about the way the information was presented on:**

Impact of atrial fibrillation	Poor	Fair	Good	Excellent
Risk factors	Poor	Fair	Good	Excellent
Types of research studies	Poor	Fair	Good	Excellent
Self-care options	Poor	Fair	Good	Excellent
Evidence about self care	Poor	Fair	Good	Excellent
Risks and benefits of available agents	Poor	Fair	Good	Excellent
Medication options	Poor	Fair	Good	Excellent
Evidence about medications	Poor	Fair	Good	Excellent
Stories about others	Poor	Fair	Good	Excellent

2. **The length of presentation was (check one)**

Too long

Too short

Just right

3. **The amount of information was (check one)**

Too much

Too little

Just right

4. **I found the presentation (check one)**

Slanted towards taking self-care or lifestyle options

Slanted towards taking medical therapies

Balanced

5. **Would you have found this decision aid useful when you were making your decision about therapy for stroke prevention?**

Yes

No

Comments:…….

6. **What did you think of the way to calculate and present your risks of stroke and bleeding? Was it**

Easy to find your risk level,

Difficult

Comments:…….

7. **What did you think of the rest of the decision support tool? Did it make the decision**

Easier, or More difficult

Comments:…….

8. **Do you think we included enough information to help patients decide on their medicine for anticoagulation?**

   Yes

   No

Comments:…….

9. **What did you like about the patient decision aid?**

10. **What suggestions do you have to improve the patient decision aid?**

Preparation for decision making

Please indicate your opinion about the effect of the educational material and other decision aid material provided by the tool by circling the appropriate number to show the extent to which you agree with each statement.

Did this educational material……..					
1. Help you recognize that a decision needs to be made?	Not at all 1	A little 2	Some what 3	Quite a bit 4	A great deal 5
2. Prepare you to make a better decision?	Not at all 1	A little 2	Some what 3	Quite a bit 4	A great deal 5
3. Help you think about the pros and cons of each option?	Not at all 1	A little 2	Some what 3	Quite a bit 4	A great deal 5
4. Help you think about which pros and cons are most important?	Not at all 1	A little 2	Some what 3	Quite a bit 4	A great deal 5
5. Help you know that the decision depends on what matters most to you?	Not at all 1	A little 2	Some what 3	Quite a bit 4	A great deal 5
6. Help you organize your own thoughts about the decision?	Not at all 1	A little 2	Some what 3	Quite a bit 4	A great deal 5
7. Help you think about how involved you want to be in this decision?	Not at all 1	A little 2	Some what 3	Quite a bit 4	A great deal 5
8. Help you identify questions you want to ask your doctor?	Not at all 1	A little 2	Some what 3	Quite a bit 4	A great deal 5
9. Prepare you to talk to your doctor about what matters most to you?	Not at all 1	A little 2	Some what 3	Quite a bit 4	A great deal 5
10. Prepare you for a follow-up visit with your doctor?	Not at all 1	A little 2	Some what 3	Quite a bit 4	A great deal 5

Patient decision conflict

Thinking generally about your recent consultation when your doctor used the decision aid, please look at the following statement.

Please indicate how you agree or disagree with these statements by circling the number from 0"yes" to 4"no".

1. Did you know which options were available to you?	Yes 0	Unsure 2	No 4
2. Did you know the benefits of each option?	Yes 0	Unsure 2	No 4
3. Did you know the risks and side effects of each option?	Yes 0	Unsure 2	No 4
4. Were you clear about which benefits matter most to you?	Yes 0	Unsure 2	No 4
5. Were you clear about which risks and side effects matter most to you?	Yes 0	Unsure 2	No 4
6. Did you have enough support from others to make a choice?	Yes 0	Unsure 2	No 4
7. were you choosing without pressure from others	Yes 0	Unsure 2	No 4
8. Did you have enough advice to make a choice?	Yes 0	Unsure 2	No 4
9. Were you clear about the best choice for you?	Yes 0	Unsure 2	No 4
10. Did you feel sure about what to choose	Yes 0	Unsure 2	No 4

Thank you for your willingness to participate in this important research.

Appendix 17: Confidentiality statement from the transcribing company

The Transcription Company

Security & Confidentiality

1. The Transcription Company is registered with the ICO and complies with Data Protection Act Information & Security.
2. Customer information is used only for the purpose of transcribing and not used for any other purpose.
3. The Transcription Company use a business level encrypted file transfer service to receive and distribute sound files. All transfers include comprehensive encryption and security, creating end-to-end 128-bit encrypted file transfers. Data is protected by the industry gold standard for the robust delivery and security of data (SAS70 and SSAE16) Files are encrypted using military-grade 256-bit Advanced Encryption Standard (AES) security (further details available on request)
4. Sound files are securely encrypted whilst temporarily stored on servers and automatically wiped from the server after 8 days. Files are encrypted using military-grade 256-bit Advanced Encryption Standard (AES) security
5. Sound files are immediately deleted from our system on confirmation of safe receipt of transcripts from customer.
6. All transcripts are deleted from our system on confirmation of safe receipt from customer
7. All data supplied by our customers for the purpose of transcription is treated as strictly confidential. The Transcription Company have a Customer Confidentiality Agreement in place (copy available on request) and we are happy to comply with a customer's own confidentiality agreement. All of our transcribers are required to sign a confidentiality agreement (copy available on request)
8. All incoming and outgoing files, documents and emails are checked by up to date anti-virus software which is kept up to date daily.
9. Office computer systems are kept physically secure in locked office in an alarmed building and remain on premises at all times. We do not use any removable media such as USB Sticks hard drives etc. Data is not stored or backed up in The Cloud
10. All Computer disks and Backup disks are encrypted using Bit Locker Security Package and operating systems are kept current and up to date (including windows updates & service packs)
11. All data and documents are scanned with AVG anti-virus software and all incoming and outgoing emails are scanned with the same anti-virus software.

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