Factors influencing the commissioning and provision of community pharmacy Emergency Hormonal Contraception services in England

by

Nicholas Mark Thayer

October 2022

Thesis submitted to Keele University for the degree of

Doctor of Pharmacy

School of Pharmacy

Keele University

Dedication

This thesis would not have been possible without the unwavering support (and suffering) of my family – especially my wife Jo. I started this process on the day my son was born – he has never known me not to be studying. I'm not sure what's next, so I suppose it's time for a (short) rest now.

Acknowledgements

Firstly, I must thank my supervisors, Dr Martin Frisher and Dr Simon White. Many conversations and significant patience have led me from a rather nebulous idea to something that I can almost explain in a few sentences. I have learnt so much, and you have both been so supportive throughout.

Secondly, when I started this process, I hesitantly approached my then boss – Prof. Janice Perkins. I couldn't have even started this process without knowing she was in my corner. I owe many things to her leadership; this is another thing that she supported without even realising how important it was to me.

I've mentioned my family to whom this is dedicated. However, my wider family have always been there for me – you know who you are!

Finally, thanks go to my 'course-mates'. We started as a six and are ending as a three. But Wes and Kiran – thanks for the WhatsApp, the teams' calls, and the coffee chats. I couldn't have done this in isolation.

Contents

Publications

Work from this thesis has been accepted for poster presentation at the 2022 Health Services Research and Pharmacy Practice conference and the abstract published in the International Journal of Pharmacy Practice.

Investigating the relationship between community pharmacy and GP Emergency Hormonal Contraception (EHC) Provision: A linear regression analysis; Thayer N, White S, Frisher, M. International Journal of Pharmacy Practice, 2022, Vol. 30 (S1)

A manuscript has also been accepted for publication in the International Journal of Pharmacy Practice.

Thayer N, White S, Frisher M (2022) Describing the impact of community pharmacy organisation type on emergency hormonal contraception services in England, International Journal of Pharmacy Practice, 2022; riac067

At the point of submission, another paper is awaiting final peer review with BMJ Open:

Path Analysis of Community Pharmacy and GP Emergency Hormonal Contraception (EHC) provision in England

Abstract

In England, community pharmacies provide services commissioned either nationally or locally. Local commissioning exhibits variation in specification and implementation, exemplified by Emergency Hormonal Contraception (EHC) services. A literature review did not reveal how routine data inform commissioning decisions. This study aimed to determine if analysis of data yield insights into factors influencing local service commissioning. The study uses data to evaluate factors influencing EHC services through a proxy-measure of GP EHC prescribing.

Freedom of Information requests were submitted to all Local Authorities in England, requesting EHC provision data for the financial year 2017/18. GP EHC prescribing, and data identified in the literature (deprivation, pharmacy organisation type (large chains, independent pharmacies etc.) and pharmacy provision) were collected. Analysis was undertaken at two levels of aggregation: Local Authority and individual pharmacy. Statistical methods included linear correlation and multiple regression. A model portraying EHC pathways was developed using path analysis.

Data from 80 Local Authorities were analysed (60% female population, aged 12-55). Significant negative correlation was found between rates of community pharmacy provision and GP EHC prescribing. Rates of community pharmacy provision positively correlated with the proportion of commissioned pharmacies and greater deprivation. Path analysis described factors influencing community pharmacy provision and GP EHC

prescribing. Commissioning all community pharmacies in England (from 47% currently) may decrease GP EHC prescriptions by 15%.

Bivariate correlations indicated significant negative correlation between deprivation and individual pharmacy rates of EHC provision. Larger organisations provided greater volumes of national services (specifically Medicine Use Reviews). There was no relationship regarding EHC suggesting local commissioning should not be dependent on organisation type.

Analysis of routine data and path analysis provide insight into EHC provision and present a method to identify ways to guide commissioning decisions. Where data are available this method could be used to inform decisions for other services.

Preface

Personal background and practice

Early years

I graduated from an MPharm course in 2010, and immediately began practice in community pharmacy. Whilst my career has developed since then, I remain linked to the community aspect of the profession due to the unique nature of the sector. Providing care in people's communities and being part of the social fabric of a local area is very powerful and something I value highly. My initial years of practice were influential on my outlook, showing me the potential of community pharmacy.

Early in my career I quickly identified the importance of 'services'. Services in the context of community pharmacy relate to non-dispensing activity. Community pharmacy services are often considered additional, optional activities and interventions. Usually led by the pharmacist, they are an opportunity to provide extra care beyond dispensing medication. As a newly qualified pharmacist this seemed the best and most immediate way to use the clinical skills and knowledge I had gained. Undertaking the training for and then providing services is often seen as an opportunity for professional development. Working in a small pharmacy, distant from other healthcare providers, I was regularly called upon to provide health advice and interventions. Emergency Hormonal Contraception quickly became a regular part of my practice, raising both professional challenges and a clear, immediate patient benefit.

A facet of community pharmacy often not understood by other parts of healthcare is the blend of commercial and patient objectives. Despite a national health service in England, the way in which that care is provided varies. Hospitals are directly funded and controlled by the NHS, whereas much of primacy care is more separate. Community pharmacies are individual, private businesses. Whilst most of their income derives from the NHS, they enjoy the benefits and perils of private enterprise, and there is a limit to the control the NHS has on these businesses. However, like all private businesses they can fail and go out of business if not managed well. The presence of the free market yet with a majority NHS funding, creates an almost unique competition within community pharmacy. General Practice is often a comparator for community pharmacy, but the list-basis of the GP contract creates quite different environments and behaviours.

The market conditions of community pharmacy have, I have always felt, both benefitted and hampered the profession. There are examples of private healthcare and innovation leading the profession forward. Similarly, the independence of the sector makes a unified stance and direction difficult to achieve. Like GPs, pharmacy contractors operate individual businesses each with their own priorities and ways of working. Creating one approach, patient journey, and standardisation of intervention remains incredibly difficult.

An appreciation of commissioning

After a few years of pharmacy management, I moved into a professional role within the Superintendent Pharmacist's team of the company. Responsible for service provision by all pharmacies in the country I was able to witness the value, the importance, and the satisfaction these services offered to patients and professionals alike. What I noted however, was the apparently haphazard way these services were commissioned. Services designed for identical patient groups, offering what should have been practically identical care, varied widely in design, operation, and criteria. Despite contracts setting out aims to reduce pressure on other healthcare professionals or meet patient expectations – there was no evidence these aims were critically or routinely evaluated. Similarly, there was no clarity on the criteria for determining that these aims had been met and despite contractual requirements for data to be collected that would allow evaluation of the contracted service, this was rarely (if ever) enacted.

Following my departure from Well I joined Community Pharmacy Cheshire and Wirral – a Local Pharmaceutical Committee. My role was to represent community pharmacy contractors in conversations with local commissioners, such as the local councils, Clinical Commissioning Groups, or the NHS England regional team. Often, I suggested new services that could be commissioned from community pharmacy, and then supported the implementation of services, or reviewed contracts and service specifications with commissioners. As before, there were very few recognised markers of value. Despite commissioners reviewing the activity and cost of these services, these were rarely matched to externally recognised values. Even with minor ailments services, which are generally designed to increase access to urgent care and reduce GP appointments, had cursory evaluations. There was little attempt to directly correlate activity to the assumed reduction in GP activity.

There is a wealth of evidence, both anecdotal and peer-reviewed, considering the merits of pharmacy services. Yet my practice, despite being wholly linked to service provision, design, and commissioning from the start, has yet to see this rigorous evaluation of pharmacy services. There is of course literature supporting the service intentions, design, and setting. The benefits (to patients) of many community pharmacy services are set out in the literature. However, the decision to commission these services needs to be based on a broader evidence base and include, for example, pharmacoeconomic or epidemiological evaluations of value. It was regularly suggested to me by commissioners that existing service provision should be a pre-requisite for the commissioning of new services (i.e., those who do not provide high volumes of a current service may not provide a new service). Yet there is no evidence to suggest that a providers' previous service activity would necessarily correlate to their activity in providing a different service. Commissioning of pharmacy services, appears to be influenced by relationships and perceptions, rather than rigorous evidence.

As such, I have not yet witnessed a clear data driven process for commissioning. I would expect collection of evidence, identification of influencing factors, and an attempt to describe the benefit of a service to be routine. If not before commissioning, this should be part of the evaluation process.

Deciding on a research subject

At this point I began thinking about the exact nature of my research. With the starting point of investigating community pharmacy services, I decided to research the factors that could influence ‘successful commissioning’. This topic could have been approached from several different ways, but two obvious ones were the beliefs and opinions of commissioners, or a ‘quantifiable measure of value’. My experience to date had suggested that a key decision maker in commissioning is a member of the finance team who is often relatively un-swayed by relationships and perceptions. It seemed quantifying the value of service provision would be welcomed by pharmacy and commissioners alike.

Quantifying this relationship could be articulated in monetary terms, Pharmacoeconomics (Rai and Goyal, 2017). Pharmacoeconomics is a branch of health economics which “deal with identifying, measuring, and comparing the costs and consequences of pharmaceutical products and services” (Rai and Goyal, 2017). This helps decision-making when evaluating interventions (such as two drugs). For instance, the cost reduction or cost avoidance of a “substance misuse service” would likely pull from both societal and health benefits. Whilst not always completed in a community pharmacy setting, this type of work is often understood and already undertaken. For example, a literature review from 2009 identified the cost-effectiveness of community pharmacy smoking cessation services as “£83 per life-year saved”, costing £525 for each successful quit (Anderson, Blenkinsopp and Armstrong, 2009). A more recent cost evaluation placed the value of each EHC interaction as saving “at least £384.29 for the NHS” (Chalati et al., 2020). This is one example of the Pharmacoeconomic analysis that could be undertaken. During my work I had not seen an attempt to understand the factors that influenced successful service provision / commissioning.

There are numerous examples determining the effectiveness of a specific intervention, or opinions and values of professionals, patients, and the public. What is specifically missing is an attempt to quantify the structural and organisational factors that may determine the success of a service 'post-launch'. Accordingly, this research (as described in chapter 3) aims to identify and quantify factors that indicate and influence successful commissioning.

Since starting this research my job has changed again, moving to a national policy role. What has not changed is the variability in service commissioning without rationale, or the lack of clear evidence to guide commissioning decisions. Early in the research the Covid-19 pandemic began. Whilst providing challenges in my professional (and personal) life, it did help target my research. The practicalities of the pandemic meant Emergency Hormonal Contraception was the only data available for study. This did mean the work could be focussed to a single service and a single set of variables.

The relationship between researcher and practitioner

Reflexivity refers to "a process by which we as researchers hold ourselves accountable for the assumptions we enact when we do research, a process of justifying why we are inquiring about people and the world in particular ways" (Shaw, 2016). It is vital for any researcher to consider how their own experiences, views, and knowledge shape the research they undertake.

Reflexivity is well established in qualitative research, but not routinely expected as a feature of quantitative research (Usher, 2021). This is in part due to the paradigms and approaches taken in different research methodologies. The methodology of this thesis is explored in chapter 5 (page 89). Despite the lack of reflexivity in much of quantitative research, there is a field of thought that it is equally valuable for consideration. For example, in the case of questionnaires, which can certainly be analysed with a quantitative approach, are heavily influenced by the researcher (Ryan and Golden, 2006).

In the case of quantitative research, considerations include data that are collected, the parameters for collection, exclusion criteria or identification of outliers, and decisions on the analysis undertaken. Often knowledge of the subject matter informs these decisions, which is derived from the researcher's experience.

Using large data sets without direct patient/participant contact, such as in this thesis, minimises the impact of these decisions. Despite this there is a need to add context to the data collected – what is relevant, what are perhaps environmental facets that explain results only known because of the researcher's prior knowledge?

My own practice is heavily involved in commissioning and service provision. Accordingly, this gives a knowledge base from which to inform the research. It also adds a potential conflict, with prior experiences driving analysis decisions and interpretation of the data. There is a need to recognise that my own experience may have created preconceived views, which could hamper impartial conclusions.

Much of this is explored in the methodology where the approach to minimise bias is described (page 97). Indeed, it could be argued that the use of secondary data further supports the independence between researcher and practitioner. The participants had no knowledge of how the collected data would be used, nor myself as the researcher at the time of collection.

To address this potential conflict, I have used the literature to inform the approach taken. The methods were presented in advance of data collection, and the analysis is included in this thesis in full. There are occasions where practitioners and researchers need separation, but in this case the complex environment requires the knowledge of a practitioner to articulate the findings. The approach taken here, should recognise this balance and bring them together in a complimentary fashion.

Thesis outline

The thesis has already included reflection on my own experiences and practice to date. As part of a professional doctorate, rather than a traditional PhD, linking the research undertaken to the student's professional practice is one of the key differences between the two qualifications. It has set out my experience to date, which suggests the process of commissioning varies, often driven by policy, opinions, or relationships.

A good example of this variation in commissioning is Emergency Hormonal Contraception (EHC) services. Despite evidence showing its effectiveness for patients (both as a therapeutic option, and community pharmacy as a palatable location for patients) there is little evidence of data driven decisions informing the commissioning of services from community pharmacies. What is the purpose of commissioning EHC from community pharmacy (given it is already available from several other locations/providers) and how do commissioners determine if this purpose has been met?

This thesis describes factors influencing the commissioning and provision of community pharmacy Emergency Hormonal Contraception (EHC) services. Community pharmacy commissioning is a complex area of policy, contracting, and competing budgets. Focusing on local commissioning, this thesis considers what routine data is available and/or used in decisions to commission services and evaluate them.

Chapter 1 sets out the background to community pharmacy commissioning. This includes outlining the overall structure of community pharmacy practice and the complexity of commissioning from community pharmacy. One example of overlapping commissioning is contraception/sexual health services, where multiple settings are commissioned to provide equivalent care. The chapter also discusses what is known about the various influences on commissioning and services, before briefly discussing the national organisation of pharmacy and its representation.

The thesis then turns to comprehensively reviewing of the literature supporting community pharmacy EHC services. The policy review in chapter 2 assesses not only the evidence behind community pharmacy EHC services, but the available evidence supporting the commissioning decisions made. It also discusses factors that may influence the provision of EHC, which often centre around individual patient decisions.

Following this, the aims and objectives of this thesis are set out (chapter 3). A systematic literature review (chapter 4) examines the evidence underpinning commissioning decisions. Unlike the policy review (chapter 2) this review does not consider the merit of an individual commissioned service, but the evidence used in the commissioning process itself.

Chapters 2 and 4 review the relevant literature and reveal a gap detailing how to assess whether commissioning goals have been met. This thesis addresses that, specifically in relation to EHC provision.

When considering the methodology, it was necessary to consider available data sources. Following examples from the literature, Freedom of Information requests to Local Authorities about commissioned EHC services were selected as the primary data source, and the reasoning is outlined in chapter 5.

The methods and results are described in chapters 6 and 7. In these chapters (and the subsequent discussion) the text is ordered to include the feasibility study, an analysis of Local Authority data, an analysis of individual pharmacy provision, and a modelling approach to predict future changes. Both the statistical analysis and the path analysis were explored using real world examples and are detailed in chapter 7. This modelling, suggests how commissioners may use the results of this study. The final chapters 8 and 9 provide the discussion of the results, and consideration of the implications of the study, and then the conclusions.

Chapter 1: Introduction

The question posed from personal practice surrounds the commissioning process. Experience to date would suggest a lack of a data driven process to inform, guide, and critique community pharmacy commissioning. To understand how these services could be evaluated there is a need to understand the processes underpinning service commissioning.

The aim of the thesis is described later (page 44), but centres around the use of routinely collected data to describe community pharmacy service commissioning. This thesis focuses on Emergency Hormonal Contraception (EHC) services, aiming to identify the influences on service commissioning and provision. Judicious use of public funds is always necessary, but ongoing financial challenges within the NHS make efficient commissioning essential. Data are an excellent way of objectively judging decisions, and an understanding how this is applied in community pharmacy appears to be missing from the literature.

This introduction chapter explains the basics of community pharmacy commissioning and how the inconsistency of commissioning suggests a need for a universal data led approach to decision making. This is followed by an explanation of why EHC services are a prime example of this inconsistent commissioning approach.

1.1 The national landscape

In July 2019 a new national Community Pharmacy Contractual Framework (CPCF) was agreed for England (Department of Health and Social Care, 2019). This set out the requirements for all community pharmacies in England, what they must do, and the payments they receive. This contract changed the funding model by decreasing the reliance on dispensing and increasing reimbursement for non-dispensing activities – commonly referred to as 'services' (Department of Health and Social Care, 2019). The CPCF defined three levels of services termed essential, advanced, and enhanced. Essential services are those that all pharmacies are required to provide, whereas advanced services are optional and can only be provided by pharmacies that meet pre-requisite criteria. Enhanced services are like advanced but managed locally. Local services are not part of the CPCF and are funded and commissioned locally as described in *Figure 1* (Department of Health and Social Care, 2019; Department of Health, 2013c). The funding sources are complicated, with essential services being paid for from the 'global sum' (£1.792bn). A segregated part of this is an agreed 'margin' on dispensed medication

(National) Essential Services – All community pharmacies must offer these services throughout their opening hours. Services include dispensing, signposting and self-care advice. These are funded by NHS England nationally.

(National) Advanced Services – All community pharmacies can offer these services if they meet the pre-requisite criteria. Services include Medicine Use Reviews, New Medicines Service and Influenza Vaccinations. These are mostly funded by NHS England nationally.

(National/Regional) Enhanced Services – Designed and agreed nationally, community pharmacies can apply to provide these services. Although overseen nationally, the regional NHS Area Teams support the implementation, agree which pharmacies may provide, and manage the contract. The only extensive example is Covid vaccinations.

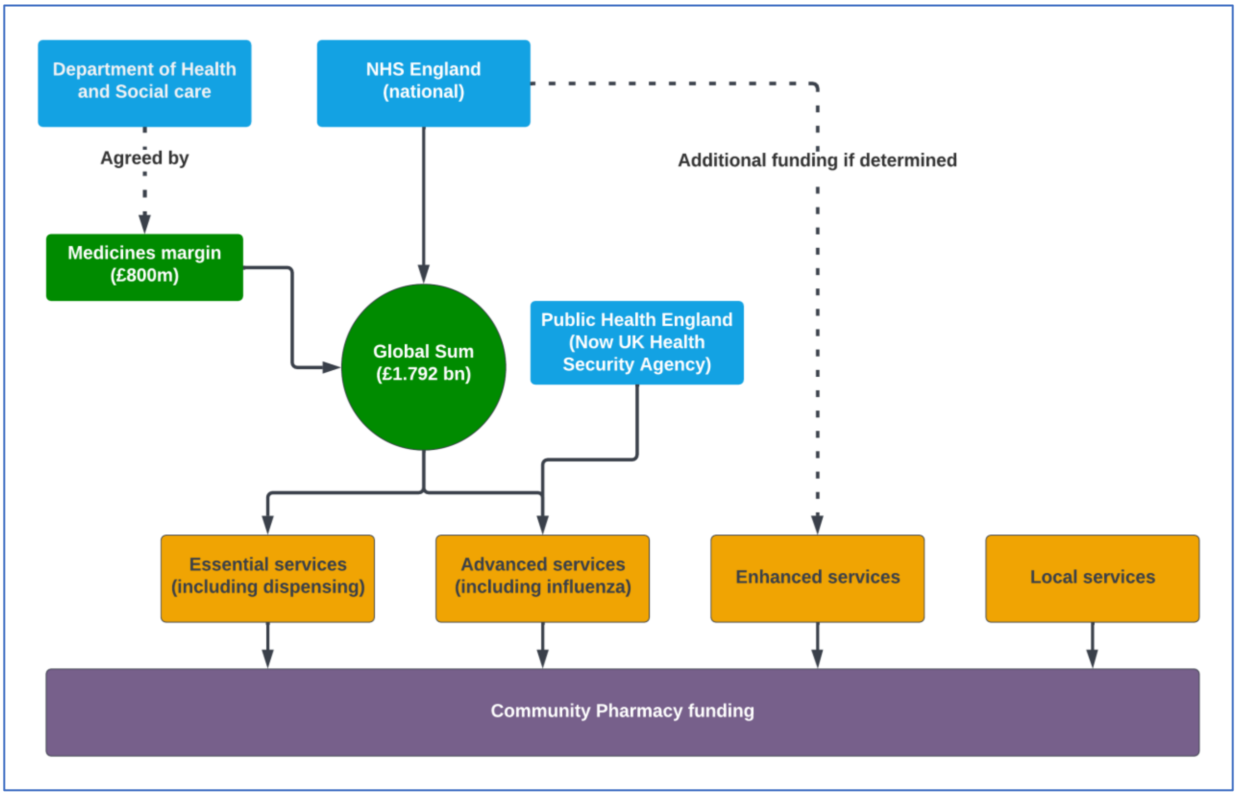
Local Services – Commissioned within localities according to local need and budgets. Local services include Minor Ailments, Emergency Contraception and Smoking Cessation. These are funded locally by Clinical Commissioning Groups (CCGs), NHS England Area Teams and local authorities after negotiation with the Local Pharmaceutical Committee (LPC).

Figure 1: Three different types of community pharmacy services

of £800m agreed with the department of Health and Social Care. This is the profit that community pharmacies can retain on their purchases of medicines, and collectively it is managed to equate to £800m. Negotiation of these two elements of community pharmacy funding form tripartite discussions with NHS England, the Department of Health and Social Care, and the Pharmaceutical Services Negotiating Committee (PSNC). Some advanced services (Medicine Use Reviews (MUR) and New Medicine Service (NMS)) are also funded from the global sum, whereas Influenza vaccines are split, incorporating money from Public Health England. (N.B. the recent break-up of Public Health England means this role is currently held by the UK Health Protection Agency). Finally, enhanced services are funded through separate funding streams. This is depicted in *Figure 2*.

There are growing differences between each of the three countries within Great Britain. This is in part due to different health priorities, and workforce needs, but also in part due to the structure of commissioning bodies. This research has focused solely on England. National funding for community pharmacy in England was reduced in 2016/17 by £170m annually (from £2.8bn to £2.63bn). This lower funding is set to remain until the end of the current 5-year deal (2019/20 to 2023/24) (Ridge and Cavendish, 2015). Against this backdrop, a change in focus from dispensing to services is expected.

Figure 2 Schematic of the Community Pharmacy Contractual Framework in England



Before agreeing changes in the CPCF (Department of Health and Social Care, 2019), NHS England commissioned a review to identify evidence supporting services in community pharmacy. This was completed through a rapid review of evidence (Wright, 2016) which informed the Murray report (Murray, 2016). One of the findings of the review was that many community pharmacy services were effective in achieving specified patient outcomes although there was only a small body of evidence to support this (Wright, 2016). Despite this, Murray concluded:

"reliance on operating primarily as a supply function will not serve patients, the taxpayer or the NHS well in future years and it is in everybody's interest to ensure that the skills of community pharmacists and their staff are better deployed and utilised" (Murray, 2016).

The review referenced a changing healthcare landscape, which reflects both funding and capacity pressures, as well as changing (increasing) patient expectations (Murray, 2016). These expectations range from greater demand for control over their care, reduced willingness to accept wait times, and more and more expensive medicines (McKenna, 2018). There are barriers to realising the benefits of community pharmacy to the NHS. These barriers range from work practices within pharmacies to IT infrastructure barriers preventing pharmacy teams updating or accessing patient clinical records (Murray, 2016). The barriers to utilisation of community pharmacy can be themed by poor integration with other parts of the NHS, poor behaviour/culture, and system design issues (Murray, 2016).

Parallel to reflection on the role of community pharmacy, NHS policy has recognised an increasing pressure upon all routes to healthcare, in particular urgent care and general practice (NHS, 2019). This stems from changing patient expectations, work-force pressures and an increasing range of treatment options for patients (such as novel drug therapies, new surgical techniques, and modern technology including diagnostic testing) (NHS, 2019). The NHS Long Term Plan also recognises financial pressures, and the need for efficiencies (NHS, 2019). Combined with the NHS preference for local commissioning, funding for community pharmacy is evolving, increasing the reliance on locally commissioned services to remain financially secure (The Kings Fund, 2019).

1.2 Local commissioning

Within community pharmacy, local services can be commissioned by a wide range of bodies, depending on the commissioning area. The current commissioning landscape was shaped in 2012 as part of a change in NHS structure by the then coalition government. The Health and Social Care Act 2012 introduced a series of changes to NHS structures, particularly responsibility for and the mechanism of, commissioning clinical services (Department of Health and Social Care, 2012). Commissioning in this context is a broad term reflecting the contracting of NHS care from distinct bodies. This includes specific and targeted initiatives such as a bespoke treatment plans from private companies and other organisations. Alternatively, it can interchangeably be used to refer to healthcare delivered by other providers, for example general practice and community pharmacies, that are not part of the NHS but are contracted by the NHS to provide primary care services.

The primary responsibility for commissioning services within primary care was moved to newly formed Clinical Commissioning Groups (CCGs) (Department of Health and Social Care, 2012). Responsibility for public health was transferred to local government, through the creation of Health and Wellbeing Boards (HWBs) (Local Government Association, 2013). Public health responsibilities were split, with various bodies (including Public Health England) also acting as commissioners, and many NHS organisations providing public health services. The national community pharmacy contract is managed and monitored by the NHS through their regional teams.

The government and NHS are currently passing legislative change to restructure commissioning bodies again (Department of Health and Social Care, 2021). It is currently unclear to what degree this will impact local commissioning but aims to introduce 42 Integrated Care Systems (ICSs) across England. These new partnerships are designed to "bring together providers and commissioners of NHS services across a geographical area with local authorities" (The King's Fund, 2021). ICSs will have commissioning responsibilities, although the details are not yet clear.

1.3 Understanding the practicalities of commissioning

Commissioning has been defined by The Institute of Commissioning Practitioners as:

> *"Securing the services that most appropriately address the needs and wishes of the individual service user, making use of market intelligence and research, and planning accordingly"* (Bennett, 2015).

Commissioning is a broad term that includes all healthcare provision, including the CPCF within community pharmacy. Within community pharmacy, commissioning often refers to services – which is a 'catch-all' term used to describe additional activity, usually patient-facing or 'clinical' which is separate to dispensing.

The complexity of local commissioning arrangements, often leads to uncertainty over what services can be commissioned and who they are commissioned by (Murray, 2016). Furthermore, specifications (the detailed description of the activity and conditions of providing the service) vary by commissioner. The result of this is that local service provision within community pharmacy varies by geographical area, and the service offered varies in scope and intervention type. Each commissioner may choose how to commission community pharmacy services, leading to differences in the activity, the remuneration, and the service requirements.

This approach to 'localisation' is a deliberate NHS England policy (NHS England, 2014). In line with the broader government devolution of powers and funds, NHS England has encouraged 'place-based commissioning and decision making' (NHS England, 2016a). One implication of this policy decision is that local commissioning and therefore local services, are likely to become ever more important to patient care as they are replacing care that was previously commissioned nationally. This applies across the healthcare industry, including community pharmacy.

Local Pharmaceutical Committees (LPCs) represent community pharmacy contractors (i.e., the individual(s) or company that hold the contract to operate a pharmacy with NHS England). Their role is to negotiate with commissioners the nature and payment terms for local services, whilst representing pharmacy locally. The combination of locally dictated priorities and distinct LPCs (with individual priorities and ways of working), has led to many different services. The Pharmaceutical Services Negotiating Committee (PSNC) maintains a database, which in November 2019 listed 68 different types of services in numerous different clinical areas (PSNC, 2019). These 68 service types range from care home medication reviews to supplying naloxone to patients.

Within these 68 service types there is variation. For example, supervised consumption of medicines (e.g., methadone) is one of the 68 service types, yet there are 128 services recorded, all of which will vary slightly in their requirements, as dictated by the local commissioner.

The most common services across England (with the number of variations in parenthesis) are: Supervised administration of medicines (e.g., methadone) (128), needle & syringe replacement programmes (120), smoking cessation advice and support (including provision of pharmacotherapy) (106), treatment of minor ailments (105) and emergency hormonal contraception (EHC) provision (99) (PSNC, 2019). The list is not exhaustive, but there are 1,272 unique service contracts listed within England.

The commissioners of these services vary greatly, encompassing CCGs, Local Authorities, Hospital Trusts, private pharmaceutical companies, and NHS England regional teams. There is no consistency across the country, for example with minor ailment services being commissioned from CCGs in some areas, NHS England in others, and a local authority in another (PSNC, 2019). This causes several challenges. Firstly, variability in local commissioning means there is poor understanding within the health service (particularly relevant for NHS111 who wish to refer patients to community pharmacy) as to what services are available and when (Murray, 2016). This is replicated amongst the public, where the expected service “can vary on different days according to qualifications of pharmacists ... compounded by the postcode lottery issue” (Murray, 2016). Furthermore, there are advantages in scale to pharmacist training, understanding, and expectations. Slightly different services increase the administration burden, especially when pharmacy companies span commissioning boundaries (Hindi, Jacobs and Schafheutle, 2019). There is no rationale nationally for why the commissioning process varies so widely across different parts of the country. As described in the NHS England devolution plans, this is part of commissioning intended to reflect the local processes and priorities (NHS England, 2016a).

EHC is an excellent example of commissioning variation across England that also contrasts sharply with EHC provision in Scotland and Wales. In England, sexual health services are a public health responsibility, and therefore commissioning is the obligation of Local Authorities. Wales and Scotland have not segregated public health from general health care in the same manner, and both remain the responsibility of the NHS Health Boards. Despite this segregation in England, General Practice routinely provides both on-going and emergency contraception as part of their general NHS contract. This includes advice, examination, and the writing of prescriptions (NHS England, 2020). The split responsibilities of sexual health commissioning are set out in *Figure 3*. In some cases provision is duplicated, such as contraception. It is not surprising, given the overlapping commissioning responsibilities for this one aspect of health, that pharmacists and their teams are uncertain which bodies commission services in pharmacy (Murray, 2016).

Local authorities commission: comprehensive sexual health services including most contraceptive services and all prescribing costs, but excluding GP additionally provided contraception

- sexually transmitted infections (STI) testing and treatment, chlamydia screening and HIV testing
- specialist services, including young people's sexual health, teenage pregnancy services, outreach, HIV prevention, sexual health promotion, services in schools, colleges, and pharmacies

CCGs commission:

- most abortion services
- sterilisation
- vasectomy
- non-sexual-health elements of psychosexual health services
- gynaecology including any use of contraception for non-contraceptive purposes

NHS England commissions:

- contraception provided as an additional service under the GP contract
- HIV treatment and care (including drug costs for PEPSE)
- promotion of opportunistic testing and treatment for STIs and patient-requested testing by GPs
- sexual health elements of prison health services
- sexual assault referral centres
- cervical screening
- specialist foetal medicine services

Figure 3 Commissioning responsibilities in England (GOV.UK, 2018)

1.4 Local commissioning with community pharmacy

The complexity of local commissioning is further highlighted by the various influences on the commissioning process. Local Pharmaceutical Committees (LPCs) formally represent community pharmacy contractors within their defined geography and are 'recognised' by NHS England under the NHS Act 2006 (PSNC, 2013). There are similar bodies representing other primary care professions, such as general medical practitioners, dentists, and opticians. All these bodies simultaneously work to promote the interests of their contractors with local commissioners.

There are many commissioners across England. These represent both the split between public health and social care (Local Authority) and health care (NHS). However, local arrangements can also allow for other commissioners in community pharmacy including pharmaceutical companies, NHS teams locally, CCGs, NHS Trusts, charity organisations and others.

The practice of ''sub-commissioning' allows a single organisation (provider) to take responsibility for a broad set of health needs, and then commission additional providers to undertake specific roles. A local example is Liverpool University Hospitals NHS Foundation Trust, who are commissioned by Warrington Council to provide sexual health services. Part of this responsibility requires the Trust to commission community pharmacies to provide EHC services. Without careful arrangements and clear communication, responsibility for managing providers can be confused.

1.5 Influences on commissioning

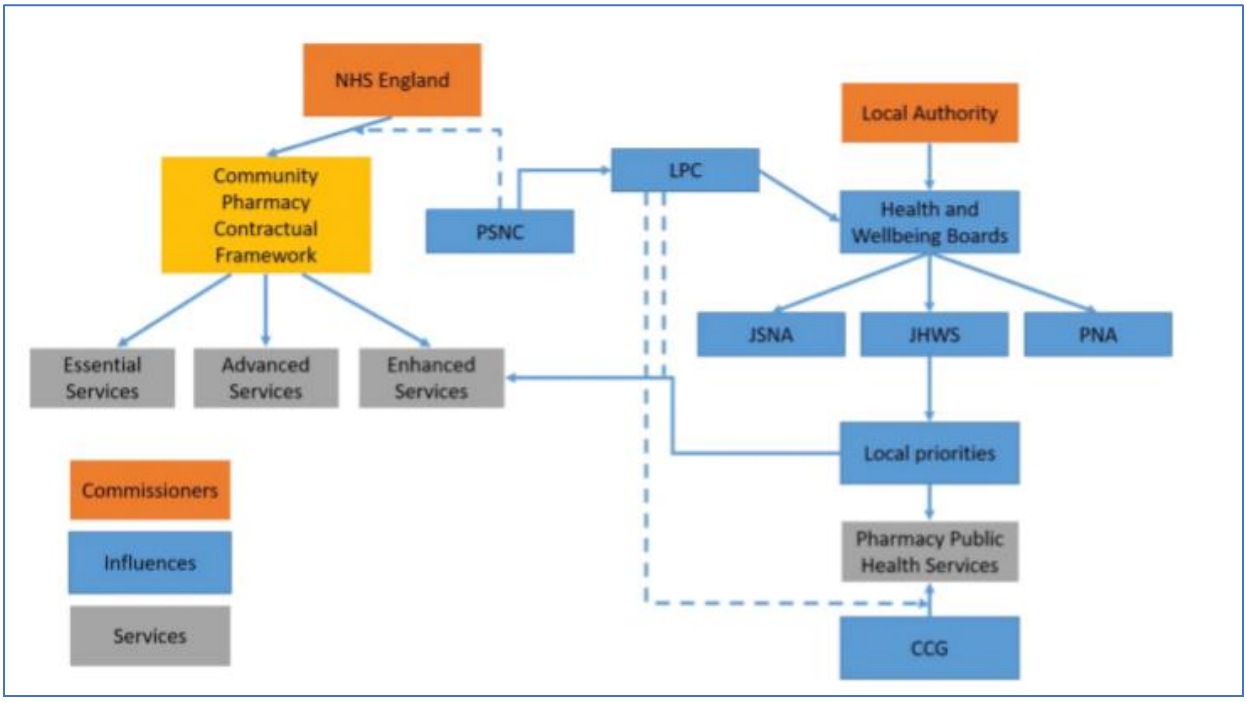
Commissioning of pharmacy services is also influenced by local health priorities. These are overseen by Health and Wellbeing Boards who have a statutory duty to produce a 'Joint Strategic Needs Assessment' and a 'Joint Health and Wellbeing Strategy' for their populations (The King's Fund, 2016). The Health and Wellbeing boards are formal committees within Local Authorities. Whilst they have limited formal powers, they comprise of representatives from CCGs, Health Watch, and other local partners. These two documents (and the recommended actions) are designed to ensure commissioning meets the local needs of a population.

Technically, commissioning of services includes pharmaceutical services and ultimately community pharmacies. The numbers and locations of community pharmacy premises are regulated, and opening a new community pharmacy or moving locations, is overseen by NHS England. The process for this and requirements are dictated in regulation and decisions are informed by Pharmaceutical Needs Assessments (PNA) (National Health Service England, 2020). PNAs are intended to determine the appropriate local need for pharmacy care in a location (Local Authority boundary). PNAs determine how many community pharmacies are required, what services are needed, and crucially any gaps in supply. Companies wishing to open a new community pharmacy need to demonstrate a 'gap' in provision which they can fill to justify opening a new premises. It is noteworthy that there are few (if any) examples of an oversupply of community pharmacies – despite the variation in pharmacy numbers per head of population. This raises questions over the use of PNAs, beyond maintaining the status quo.

A different type of pharmacy is a Distance Selling Pharmacy (DSPs). DSPs (often called 'internet pharmacies' or 'online pharmacies') do not require identification of a local need as they are required to operate across England meeting the pharmaceutical needs of the entire population. Theoretically they have no impact on their immediate local population as they may not advertise to local patients (exclusively), nor allow any patients to receive essential services in person. Dispensed medication must be delivered (i.e., the patient cannot collect dispensed medication from the pharmacy site). It is an odd quirk that whilst patients may not receive essential services (such as dispensing/prescription collection) in person, they may provide additional commissioned services. Until recently there were few (if any) examples of DSPs providing local services. However, the largest DSP, Pharmacy2U provided COVID-19 vaccinations across the country from over 50 locations in 2021 (Fiore, 2021).

The interplay of these different influences on community pharmacy commissioning, and the interplay between national and local were described by Nazar and Nazar (2019). The diagram they produced is displayed in *Figure 4* (Nazar and Nazar, 2019).

Figure 4 The Commissioning Landscape (Nazar and Nazar, 2019)



Abbreviations in Figure 4: PSNC – Pharmaceutical Services Negotiating Committee, LPC – Local Pharmaceutical Committee, JSNA – Joint Strategic Needs Assessment, JHWS – Joint Health and Wellbeing strategy, PNA – Pharmaceutical Needs Assessment, CCG – Clinical Commissioning Group

1.6 Community pharmacy organisation

In the UK there are no restrictions on ownership, but there are legal requirements such as a Responsible Pharmacist to directly oversee the pharmacy during its opening hours, and a Superintendent Pharmacist to take responsibility of the company's pharmacy practice. Across the globe there are different regulations managing community pharmacy practice, including ownership restrictions (Hattingh, 2011). Countries such as Australia, Italy and Germany specify that only a registered pharmacist can own a pharmacy (with different definitions of ownership from sole proprietor, shareholder etc.) (Hattingh, 2011). Currently within England there is a mix of single pharmacies, often owned by an individual, and larger businesses owning several pharmacy premises. There are no restrictions on the business type to own a pharmacy, with examples of direct ownership, limited companies, and large corporations. The 'contract' for operating the pharmacy premises can be held by any individual or entity, but each premises has an individual contract. There is no signed contract between any pharmacy and the NHS that is updated, however the contractual agreement (CPCF, described on page 2) is applied directly as set out in regulation.

Commonly, community pharmacy is split into three groups: independents, small multiples, and large multiples. These three groups are represented nationally by the National Pharmacy Association, the Association of Independent Multiples, and the Company Chemists Association. There are examples in the literature exploring the impact of these different ownership models, and it is a subject of much discussion – especially in countries where variation is not allowed (Hattingh, 2011; Bush, Langley and Wilson, 2009).

1.7 Summary

This chapter has set out the environment in which community pharmacy services are commissioned. The commissioning landscape is complex, with many different organisations working together. Community pharmacy is equally complex needing to balance both national and local commissioning – each with different needs, priorities, and representative bodies. Despite this complexity there is evidence of community pharmacy as a publicly accepted and effective location to provide non-dispensing services. What is not clear is whether there is a common data-led process for guiding this commissioning.

Community pharmacy services are numerous (see page 7) making a study of all commissioned services either too lacking in detail to generate meaningful findings or having too many variables to draw statistically significant conclusions. Exploring a single service allows a specificity to the investigation and analysis which may suggest broad themes for future review.

EHC services offer an ideal candidate for study. Regardless of the setting (e.g., general practice, hospital, or community pharmacy) there are only two pharmaceutical options for clinicians. There is limited impact of previous medical history or contraindications that may create complexity and variation in the decision to provide EHC. Additionally, EHC services are not new to community pharmacy and are prolific across the network. Other services may have several competing patient pathways, treatment options, or relevant clinician scopes of practice – making comparison difficult. It is the relative simplicity of the service, the standardisation across the healthcare network, and the prevalence, that meant EHC services were chosen for analysis in this thesis.

EHC services are commissioned from many different health care settings, sometimes from multiple providers (*Figure 3*). So, meeting patient need cannot be the sole measure of success, as this is already met (to some degree) through existing services.
From this basis questions can be asked, what is the purpose of commissioning EHC services from community pharmacy? What evidence is available to support this commissioning, or the process that is undertaken?

Given the complexity of commissioned services, making decisions of what to commission, where, and with whom, must be difficult. Identifying quantitative data that can describe the various factors influencing commissioning will support these decisions, as well as enable both explanation to others, but also external critique. It is from this that premise that the aims (page 44) are generated: determining influences on EHC service commissioning and provision through routinely collected data.

The next chapter reviews the literature surrounding EHC services in community pharmacy, to understand what measures of success may be in place.

Chapter 2: Emergency Hormonal Contraception Services: Policy and commissioning

2.1 Introduction

The introduction set out the landscape of community pharmacy commissioning, and the complex environment it operates in. Local commissioning is not subject to a single pathway or process. This results in variability across community pharmacy services, with many influences on the commissioning process. There is evidence of the efficacy of community pharmacy services. What is not clear from the commissioning structures described is evidence of a data led process to commission and then evaluate the success of these services.

Emergency Hormonal Contraception (EHC) is a good example of this – the service is already provided elsewhere (e.g., in General Practice), so what metrics are used to assess the success of commissioning? Often comparing community pharmacy care to other healthcare settings is difficult due to the restrictions placed upon community pharmacy as generally prescribing is not available (many patients/circumstances will need to be referred onwards as they require the input of a prescriber making care difficult to compare). EHC services are limited to two therapeutic options (levonorgestrel and ulipristal) making comparison across settings possible. EHC is also commissioned from a high number of pharmacies increasing the breadth of data available. This chapter reviews the literature, to understand existing literature on EHC services. What are the perceptions and priorities for EHC commissioning?

In the systematic literature review (page 46) a brief overview of EHC care is provided, followed by a review of factors influencing general community pharmacy service commissioning. This policy review focuses on EHC, and aims to explore possible factors or influences that may feature in the commissioning process, or evidence of service review processes.

2.2 Contraception Policy

A key strand to global public health policy is that of timely access to high quality sexual health services, including planned and emergency contraception (United Nations Population Fund, 2014). Aside from any moral or equality considerations, part of this is due to the association between unplanned pregnancies and an increased risk of adverse outcomes (Gipson, Koenig and Hindin, 2008; Wellings *et al.*, 2013). The incidence of unplanned pregnancies also increases with deprivation (Wellings *et al.*, 2013).

Within England, the under 18 conception rate in 2016 was 18.8 pregnancies per 1,000 women (aged 15-17) (Office for National Statistics, 2016). Of this number, 51.8% led to abortion and 2020 saw the highest number of abortions on record among all women (200,083) (Office for National Statistics, 2016; Department of Health & Social Care, June 2021). It is notable that women in the most deprived areas were more than twice as likely to have an abortion than those in the least deprived (Department of Health & Social Care, June 2021). It is therefore, entirely logical that meeting unmet contraceptive needs is a key objective of UK (and global) public health policy (United Nations Population Fund, 2020; Depatment of Health, 2013). Furthermore reducing the absolute number of teen pregnancies is a key measure of public health within England (although no specific target has been published) (Depatment of Health, 2013).

Within England and Wales the total number of recorded abortions had demonstrated a decreasing trend since 2007 (17.9 and 16.0 per 1000 residents aged 15-44 in 2007 and 2016 respectively) until 2017 when the rate increased to 17.3 per 1000, a 4% increase on the previous year (Department of Health and Social Care, 2018). Reasons for this are not certain, but the Association of Directors of Public Health were of the view that that the funding of, and access to, sexual health services were strong influences (The Association of Directors of Public Health, 2017).

There have been cuts in public health funding within England in recent years. There has been a local average spending reduction of 3.9% a year between 2013/14 and 2020/21 (British Medical Association, 2018). Specifically within sexual health services, there has been a reduction of £30 million between 2016/17 and 2017/18, a 5% cut in spending (British Medical Association, 2018). This reduction in spending has resulted in sexual health provision being a service frequently redesigned to reduce costs, leading to 24% fewer contacts with dedicated clinicians and concerns being raised by the Faculty of Sexual and Reproductive Health that fewer people are able to access the services they need (British Medical Association, 2018; The Association of Directors of Public Health, 2017).

This funding reduction is important. Unwanted pregnancies have become a prominent measure of health because there is increasing evidence that unplanned pregnancies lead to poorer health and social outcomes and the resulting children have poorer non-verbal and special skills (Department of Health, 2013a). Women who experience an unplanned pregnancy are likely to be younger or older than those with a planned pregnancy (Bitto *et al.*, 1997), and population data shows a generational change, with the average age of first sexual intercourse and becoming a parent reducing greatly during the 20th century (Wellings *et al.*, 2013). In addition to the risks of being pregnant outside the optimal medical age, it is hypothesised that women with an unplanned pregnancy delay accessing medical pre-natal care, reducing the opportunities for intervention (Bitto *et al.*, 1997). Furthermore, women with unplanned pregnancies are more likely than women with planned pregnancies to experience prenatal and postnatal depression, and the child having poorer mental and physical health during childhood (Wellings *et al.*, 2013; Mohllajee *et al.*, 2007; Herd *et al.*, 2016).

Despite, abortion being recognised as an outcome from unplanned pregnancy, Wellings *et al.* (2013) found that four out ten abortions resulted from planned or ambivalent pregnancies. It may be that abortions should not be used as the sole measure of the success (or otherwise) of public health policy. Unplanned pregnancies that proceed to birth have been found to cause financial, housing and relationship pressures (Department of Health, 2013a).

As stated earlier, the incidence of unplanned pregnancy increases with deprivation (The Association of Directors of Public Health, 2017). Research by Smith found pregnancies in women under 20 years displayed a six-fold increase in unplanned pregnancies between the lowest and highest areas of deprivation (Smith, 1993). Despite this increase in incidence, Smith (1993) also found that the rate of abortions was higher in the most affluent areas (two out of three ended in abortion compared to one out of four in the most deprived areas) (Smith, 1993). It is hypothesised that social pressures strongly influence the outcome of pregnancies, both planned and unplanned (Smith, 1993; Bitto *et al.*, 1997). Smith and Roberts found that this difference is in part due to differing employment opportunities impacting the future mothers ability to care for a child (higher affluent areas more likely to have mothers with higher future aspirations), but also the access to education and opportunities (Smith and Roberts, 2009). Accordingly, although the incidence of unplanned pregnancies may be higher in more deprived areas, the need for service provision is universal.

2.3 Using community pharmacy to support contraception policy

A lack of emergency contraceptive services has been found to lead to negative outcomes for the women and any subsequent child (Bitto *et al.*, 1997; Wellings *et al.*, 2013). Community pharmacies are known to be more populous in deprived areas, a correlation which is much stronger than with GP access in deprived areas (Todd A et al., 2014; Todd et al., 2015). This may be due to the increased prescription volume in deprived areas (Chen et al., 2019). Given the increased number of community pharmacies in areas of greater deprivation and the increased incident of unplanned pregnancies, this seems a logical place for EHC services (The Association of Directors of Public Health, 2017).

It is widely asserted in government statements and within the professional representative bodies that pressures upon the NHS are unprecedented and there is a need to change (Royal Pharmaceutical Society, November 2013; Robertson et al., 2017). Community pharmacy has long been cited as having the potential to influence both patient outcomes and the long-term challenges the NHS faces, as part of a wider integrated service (Murray, 2016). The government white paper “Pharmacy in England, Building on strengths - delivering the future”, published in 2008, began a changing focus in government policy to expand community pharmacy patient-service provision beyond dispensing (Department of Health, 2008). The new government ambition was to create pharmaceutical services that ensured pharmacies were centres promoting healthy living, supporting self-care and “pressing public health concerns” as well as “treating minor ailments” (Department of Health, 2008). This new government action and intention led to the increasing prevalence of community pharmacy services, beyond traditional medicine dispensing.

NHS England portrayed community pharmacy as a key means of reducing workload in other parts of the healthcare system, as evidenced by their “Stay Well Pharmacy” public health campaign, encouraging the public to use community pharmacy before other services, e.g. GP or A&E (NHS England, 2018). Since 2008, the Department of Health have had a vision of pharmacy as “health-promoting centres” located within communities (Department of Health, 2008). Whilst arguably slow to implement change, the Pharmacy Integration Fund, set up in October 2016 has led to greater integration of pharmacy into primary care systems to “drive greater use of pharmacists and pharmacy technicians in … integrated local care models” (NHS England, 2016b).

This ambition to develop community pharmacy's non-dispensing activity is not limited to areas directly within the NHS remit but extends to public health and the role of local government. A key public health role of local government is the provision of sexual health care (described on page 11). The government have said that "highly visible, accessible contraception services … play a key part in improving outcomes" (Department of Health, 2013a) and support the commissioning of community pharmacy sexual health services. This was acknowledged by Public Health England who stated that pharmacy is well placed to implement services recognising that "95% of the population is within a 20-minute walk of a local community pharmacy and access is greatest in areas of highest deprivation" (Public Health England, 2017).

In 2019 a number of national bodies in England publicly recognised the value community pharmacy provides and the role it can play within EHC (Company Chemists' Association, 2019; Public Health England, 2019). However, it is reported that the "fragmented" nature of local commissioning places obstacles in place of effective service provision (from all settings) and an accordingly leads to poorer health outcomes (House of Commons Health and Social Care Committee, 2019; Company Chemists' Association, 2019).

It is assumed that better utilisation of community pharmacy skills and a decrease in pressures across the system is an underlying goal of any community pharmacy service (as per NHS England and Department of Health statements referenced earlier). EHC in particular is designed to change public behaviour and routes of access as GPs (and others) currently provide EHC services across the country. There is research supporting the principle of both the theoretical benefit of, and the public acceptance of, this re-modelling of patient pathways (Gidman, Ward and McGregor, 2012; Pharmacy Research UK, 2014; Baqir *et al.*, 2011). Understanding the factors that influence this behaviour change may be important to commissioners.

2.4 Emergency Contraception

Emergency contraception is defined as “using a drug or copper intrauterine device (Cu-IUD) to prevent pregnancy shortly after unprotected intercourse” (Cheng *et al.*, 2008). Emergency Hormonal Contraception (EHC) has been available via a prescription within the UK since 1984 (Killick and Irving, 2004) initially as the “Yuzpe regimen”, commercially licensed by Schering Health Care Ltd. as Schering PC4 (Kirkman and Bigrigg, 2002). Guidelines currently indicate either a Cu-IUD or EHC depending on patient history, time since unprotected sex and likely ovulation date (The Faculty of Sexual and Reproductive Healthcare, 2017). After clinical assessment, if EHC is indicated, the two recommended medications within the UK are levonorgestrel 1.5mg (LNG-EC) and ulipristal acetate 30mg (UPA-EC) (The Faculty of Sexual and Reproductive Healthcare, 2017).

LNG-EC has been available to purchase without prescription, a pharmacy-only medicine, since January 2001 with an age restriction of 16 and above, the age of consent in England (Killick and Irving, 2004; Schenk, 2003). This restriction was designed to reduce the expected media and public backlash from the introduction of more readily available EHC however, this has remained a barrier to more complete access for younger women wanting EHC (Schenk, 2003). If is of note, that whilst women generally believe accessing

EHC via pharmacy increases the availability of the service, this is not always seen as a positive by the women themselves, with a small number having said that accessing EHC should “not be too easy” (Larsson et al., 2004). However, in previous studies it was reported that the majority of women said that that increased access to EHC was a positive change in regulation (Folkes, Graham and Weiss, 2001).

A concern that was reported by both women and healthcare professionals was a change in societal attitudes to sexual health and individuals’ sexual activity, with some respondents saying that easier access to EHC would encourage poor sexual health (Folkes, Graham and Weiss, 2001). A postal questionnaire sent to pharmacists in 2001 found that 66% (1,205 of 1,827) of the respondents were in broad agreement with EHC deregulation (Wearn *et al.*, 2001). It was reported that some pharmacists commented that free access to EHC would lead to “abuse of the system” and that payment (by the women for receiving EHC) would ensure women were “more careful” (Wearn *et al.*, 2001). A more recent study (in 2015) reported that pharmacist’s most frequently cited reason for providing these services was professional responsibility (76.6% of the 778 pharmacist respondents) (Dewsbury, Rodgers and Krska, 2015).

Research by Killick and Irving (Killick and Irving, 2004) found that making EHC available without a prescription appeared to have no negative impact on women’s knowledge or intention to take regular contraception (Killick and Irving, 2004; Marston, Meltzer and Majeed, 2005). Black et al. (2008) studied consultations in different settings and when comparing, the appropriateness of receiving EHC when indicated, and incidence of repeat use of EHC, found no significant difference (Black et al., 2008). However, women reported feeling more informed and more comfortable with the service received in a clinical setting (in this case a Health Action Zone) (Black et al., 2008). It was also reported that 70% of the women who attended a community pharmacy (35 of 50) attended with 24 hours of unprotected sex, whereas only 43.4% (36 of 83) were able to in clinical settings such as general practice and family planning clinics.

2.5 Public access to Emergency Hormonal Contraception

In January 2001 the legal status of EHC (levonorgestrel, branded as Levonelle) changed from a Prescription-only medicine (POM) to Pharmacy-medicine (P) (Killick and Irving, 2004). An articulated argument for this change was an anticipated increase in the access to EHC, as well as elimination of barriers such as anxiety related to attending GP or family planning clinics (Killick and Irving, 2004). Following this legal status change emergency departments exhibited a marked decrease (52% reduction between 2000 and 2001 in two hospitals) in EHC requests (Kerins *et al.*, 2004). Later, in 2015, a second option became available through community pharmacies, Ulipristal (branded as ellaOne) (The Pharmaceutical Journal, 2015). This offered a clinical advantage, in that the effective time window (i.e., how long you must take it after unprotected sex) was longer but was also more expensive.

Accessing EHC through pharmacies, as a purchase, has been found to allow “more rapid access” (Black *et al.*, 2008). Black *et al.* (2008) measured accessibility as the proportion of women who accessed their chosen location within 24 hours of unprotected sex. There was a marked difference between community pharmacy (70% of women attending) and family planning clinics (43.4% of women attending) (Black *et al.*, 2008). This is important because the time between treatment and unprotected sex is critical to the efficacy of the intervention, with an effectiveness window of 96 hours (LNG-EC) or 120 hours (UPA-EC) with increased effectiveness the sooner it is taken (The Faculty of Sexual and Reproductive Healthcare, 2017). The literature exploring the changed legal status show a change in patient behaviour with some women choosing to access care (in this case EHC) through community pharmacy when available. This gives strength to the hypothesis that community pharmacy services influence patient routes of access to care.

Clinical guidelines state that a Copper Intrauterine Device is usually the first line recommendation following unprotected sex – however, this isn't possible in a community pharmacy setting (The Faculty of Sexual and Reproductive Healthcare, 2017). If this is not chosen, either because the woman prefers EHC, or there is a view that the woman may not access another care setting then EHC is recommended. The exact ordering of EHC varies depending on a woman's ovulation and weight, but in many cases UPA is the preferred option (The Faculty of Sexual and Reproductive Healthcare, 2017). However, the guidance was updated in 2017 to encompass this (UPA was available only from 2015), just one year before the period of study in this thesis – meaning clinician knowledge, common practice, and service pathways may not have been updated (The Faculty of Sexual and Reproductive Healthcare, 2017).

Furthermore, whilst prices vary, UPA is more expensive than LNG (UPA=£14.05, LNG=£5.20) (NHS Business Services Authority, 2022b). It has been found that the price of purchasing EHC can be prohibitive to access with willingness or ability to pay for treatment being found to be only 20% of under 20-year olds, 49% of women in their 20s and 31% of those aged 30 years or more (Killick and Irving, 2004).

Further difficulties were found accessing pharmacy professionals able and willing to provide EHC at the point it is most commonly requested, weekend care (Killick and Irving, 2004). Despite price being a barrier to access to some, women do purchase EHC from pharmacies (Killick and Irving, 2004). Interestingly, the limited available literature suggest access to EHC without a prescription resulted in no marked increase in the total number of women using EHC (Marston, Meltzer and Majeed, 2005).

Evidence suggests that access through purchasing pharmacy-EHC is due to requests moving from other routes e.g. Accident and Emergency departments (Marston, Meltzer and Majeed, 2005). In 2001 an NHS-funded service was commissioned, allowing community pharmacies to supply EHC free-of-charge. In this example, Accident and Emergency departments and family planning clinics remained consistent in their EHC provision. However, general practice volumes decreased (Lloyd and Gale, 2005). In this example the overall volume of EHC provision increased (the community pharmacy volume was greater than the assumed shift from general practice) indicating an increased access to the service (Lloyd and Gale, 2005). This increased access argument was found in Wales, following the introduction of their advanced service (Mantzourani *et al.*, 2019). In this respect, it is important to consider multiple patient access routes, when determining the impact of a change (e.g., a commissioned service).

2.6 Community pharmacy EHC services

Publicly funded (either NHS or local authority) EHC services are becoming common within community pharmacy, and this may be in response to the purchase price barrier. The use of Patient Group Directives (PGDs) allows for the supply of treatment direct to patients without the need for medical intervention or supervision. This means there is no difference in treatment options between community pharmacy services and GP prescriptions, creating equity between the two services. PGDs permit supply of Prescription Only Medicines and for medicines 'off-license' i.e. outside their product license, and in this instance are used to allow LNG-EC supply according to The Faculty of Sexual and Reproductive Healthcare treatment pathways and guidelines (The Faculty of Sexual and Reproductive Healthcare, 2017; (NICE). 2017). In 2013 community pharmacy EHC services, supplying free of charge EHC to patients, were available to 86% of the population (Price Waterhouse Coopers LLP, 2016).

There is little evidence demonstrating the relationship between community pharmacy EHC services and GP EHC prescribing rates. The sole example (from 2005) considered the introduction of a community pharmacy service in a single rural location (Lloyd and Gale, 2005). This paper did demonstrate an apparent trend but lacked the data to make generalisations about this relationship. Whilst not an exact determinant, GP prescribing rates do provide a proxy for GP interventions. They may inform methods to determine the impact of community pharmacy sexual health services on GP workload and potentially wider assertions about patient behaviours.

2.7 Patient perceptions of community pharmacy

It has been found that women felt less comfortable obtaining EHC from a pharmacy because the consultation was less likely to have sufficient privacy (Black et al., 2008). Findings from a self-completion questionnaire suggested “two-thirds of respondents would like to be able to talk to the pharmacist in private, while only 5% had found and used such facilities to date” (Anderson, Blenkinsopp and Armstrong, 2004). These data, however, were collected in 1991 and since then pharmacy practice has developed. A growing number of pharmacies have installed a private consultation room in recent years (in 2017 over 90% of community pharmacies had a private consultation room (Public Health England, 2017)). It is common practice for commissioned services to require the use of a consultation room. Private transactions have no such restrictions, although this may be offered. This is important because despite a general positive opinion from women over pharmacy supply of EHC, the ‘open pharmacy environment’ was considered a ‘major concern’ (Anderson, Blenkinsopp and Armstrong, 2004). However, there is some negative perception of these rooms being associated with substance misuse treatment (Gidman, Ward and McGregor, 2012).

Furthermore, there remains a reported low awareness amongst patients and the public about the availability of consultation rooms (Hindi, Schafheutle and Jacobs, 2018). This finding was from a few years ago (2016) since which there has been a continued increase in community pharmacy service volume. However, the original finding reported only 19.4% of 1,000 patients stated they had received advice in a consultation room showing the large scope for improvement (Rodgers et al., 2016).

The concept of privacy is an important one, with some women feeling uncomfortable providing details during a consultation (linked to both concerns about sharing information with pharmacists, as well as the perceived lack of privacy in a high street setting) (Higgins and Hattingh, 2013). This may be linked to private sales of EHC, rather than commissioned services which commonly are required to take place in consultation rooms. Unfortunately, there is no publicly available data providing sales figures of EHC in community pharmacy, preventing a true understanding of the impact of this aspect of emergency contraception access.

It has been found that a proportion of women in need of emergency contraception may forgo treatment, risking an unwanted pregnancy, if they are dissatisfied with key aspects of an EHC service (Seston *et al.*, 2007). Privacy (or perceived privacy) has been reported to be a key driver of service uptake as well as opening hours or access and staff attitude (a feeling of judgement from pharmacy teams) (Seston *et al.*, 2007). Despite some expression of privacy concerns, some women were reported to view community pharmacy services favourably due to an anonymity not found with GP services (Bissell and Anderson, 2003). In one survey 9.7% of respondents reported that they would choose to pay for EHC from community pharmacy due to a desire for anonymity not perceived to be available for NHS-funded services (Anderson, Blenkinsopp and Armstrong, 2004).

Despite concerns raised in interviews with women (Seston *et al.*, 2007) research on attitudes of pharmacists through interviews with pharmacists, focus-groups with women, and self-reported patient feedback reported very few incidents of judgemental behaviour, which may be a reflection of the multi-disciplinary training pharmacists receive (Bissell and Anderson, 2003).

2.8 Benefits of community pharmacy commissioning

Evidence shows every incidence where non-medics (e.g., pharmacists) have provided EHC services "more women have used the service and there have been no safety problems", demonstrating the validity of allied healthcare professional led services (Ellertson *et al.*, 2000). Research has also shown no difference in the quality of the service provided, with no additional advice (or greater comprehension amongst women who received the advice) provided between GP or pharmacy provision (Killick and Irving, 2004). However, there is some evidence that patients and the public have varying perceptions of professional roles and responsibilities. (Hassell, Rogers and Noyce, 2000). Interviews with patients (over 20 years ago) suggested that lay beliefs about pharmacists' roles may lead some patients to choose GP care over community pharmacy due to a belief of a GP's legitimacy to diagnose and treat (Hassell, Rogers and Noyce, 2000). Furthermore, focus groups of mothers with young children, seniors and men (from ten years ago) reported greater trust of, and a preference for services provided by GPs (Gidman, Ward and McGregor, 2012). Whilst some patients' views have likely changed, this may inhibit uptake of community pharmacy led EHC services. It is of note that a study of pharmacist's perceptions found that pharmacists reported that part of their role is to counsel about future contraception and sexually transmitted infections (Higgins and Hattingh, 2013).

It may be this preference and differing understanding, that explains trends in activity found by Lloyd and Gale (2005). Introduction of an NHS-funded community pharmacy service increased the overall number women accessing EHC, with a drop in GP consultations – but not a complete replacement (Lloyd and Gale, 2005). This is suggestive that community pharmacy is successful in increasing access (Lloyd and Gale, 2005), but that not all women choose community pharmacy services, whether that be for practical, emotive or preferential reasons. These factors are difficult to measure quantitatively, especially across the entirety of England.

In addition to broadening access to emergency contraception treatment, community pharmacy services have also been found to reduce the average time from unprotected sex to EHC (16 hours in community pharmacy compared to 41 through family planning clinics) (Wright, 2016). This is of particular importance as efficacy of EHC reduces the longer it is taken after unprotected sex (The Faculty of Sexual and Reproductive Healthcare, 2017). Additionally, treatment options may be reduced by time delays between unprotected sex and seeking intervention (The Faculty of Sexual and Reproductive Healthcare, 2017). Research has also shown no difference in the quality of the service provided (measured through clinical outcomes or adherence to treatment guidelines) or the advice provided to patients between community pharmacy provision and GP care, again indicating equity between the clinical settings (Killick and Irving, 2004).

A report commissioned in 2015 by the Pharmaceutical Services Negotiating Committee (PSNC), from Price Waterhouse Coopers LLP attempted to assess the value community pharmacy adds to NHS England and the wider community (Price Waterhouse Coopers LLP, 2016). Regarding EHC services, the analysis found four key benefits community pharmacy provided: reduced costs to the NHS, reduced travel time for women, a reduction in NHS costs from unwanted pregnancies and a reduction in public sector costs from unwanted pregnancies (Price Waterhouse Coopers LLP, 2016). The total value provided by community pharmacy to England, through commissioned, PGD-led services only (EHC purchases were excluded and assumed to remain static if funded services were terminated) was estimated to be £24.9 million in 2015 (Price Waterhouse Coopers LLP, 2016). Whilst a significant impact, the assumption that all EHC was supplied via a pharmacy service (and therefore at no cost to the women) is likely to have skewed the data (Price Waterhouse Coopers LLP, 2016). This means that it likely underestimates the total benefit if private sales had been accounted for.

There is a small body of evidence demonstrating the value of emergency contraception services within community pharmacy (Murray, 2016). A recent study (published after the comprehensive review by Murray (2016)) used several assumptions of cost-effectiveness (Chalati et al., 2020). The cost of an EHC consultation in community pharmacy was found to vary, but the median cost of the service (consultation plus medication) was calculated to be £17.68 in England (Chalati et al., 2020). Using data from several scenarios it can be estimated that each consultation saves the NHS at least £384.29 through avoiding unintended pregnancy costs (Chalati et al., 2020).

2.9 Variation in commissioning

Since 2013 part of the funding allocated to Local Authorities has been ring-fenced for public health services (in 2017/18 the allocated funding was £3.3 billion) (Wenzel, 2017). Local Authorities have autonomy to meet the public health needs of their population through local systems, which combined with challenges to budgets has led to service redesign (The Association of Directors of Public Health, 2017). This has led to variation through different ways of working and different commissioning arrangements (there is no legal requirement for local authorities to commission EHC services from community pharmacy). This in turns leads to the potential for differing community pharmacy activity and provision to have an inferable impact on GP prescribing (Royal Pharmaceutical Society, November 2013).

Across England, the nature of community pharmacy service commissioning means there is variation in the availability and nature of EHC services available to patients (Mackridge, Gray and Krska, 2017). Despite providing EHC services to 86% of the population, only 47% (in 2014/15) of community pharmacies provide EHC (Price Waterhouse Coopers LLP, 2016; Mackridge, Gray and Krska, 2017). Previous work has demonstrated large variation in the proportion of community pharmacies providing EHC services between different geographical areas (4% - 99% uptake) (Mackridge, Gray and Krska, 2017). This variability is known to be a barrier to patient uptake and may lead to an effect on GP prescribing rates in the local area (Murray, 2016).

Beyond service provision, a key difference is adherence to standard treatment guidelines – for example provision of LNG or UPA in line with FSRH guidelines (The Faculty of Sexual and Reproductive Healthcare, 2017). GPs may prescribe according to agreed treatment guidelines, or outside these as they see fit, whereas pharmacists must supply EHC according to the criteria set out in the PGD(s) determined locally by the service commissioners (National Institute for Health and Care Excellence (NICE), 2017).

Previous work investigating community pharmacy services has highlighted the variability of service provision and the impact this can have on public/healthcare partners' confidence in the service, uptake, and outcomes (Murray, 2016; Saramunee *et al.*, 2014; Nazar and Nazar, 2019). Whilst there is literature investigating opinions and views of both the public and professionals, searching the literature did not reveal any study investigating any variation in community pharmacy provision and the correlations this may have to GP prescribing (or identifying factors that may confound such correlations). One study did attempt to investigate links between community pharmacy services and local health outcomes and found poor correlation (Mackridge, Gray and Krska, 2017). This study investigated the variability in community pharmacy service availability on local health outcomes (e.g., EHC and under 18 pregnancy rate, supervised consumption of methadone and deaths from substance use, and smoking cessation support and adult smoking rate) and used Freedom Of Information (FOI) requests to source data from local authorities.

FOI requests gives individuals "the right to access recorded information (that is) held by public sector organisations" (Government Digital Service, 2019). This includes any person providing “pharmaceutical services under the National Health Service Act 2006” or local authorities or organisations/boards set up to provide health services (Legislation.gov.uk, 2000). The implication of this is that all community pharmacy data ‘should’ be available, within a 20-working day timeframe for analysis. This only applies to publicly funded activity, therefore private sales of EHC would not be subject to an FOI request.

However, there are some caveats that can influence the responses, as FOI requests can be refused: if the request is unclear; the information is deemed too sensitive (e.g., individual patient level detail); or the cost of preparing the information (including admin time) exceeds £450 (£600 for central government) (Government Digital Service).

The work by Mackridge *et al.* (2017) used FOI requests to determine the variation in local authority commissioning, receiving a 96.0% response rate, which was further improved by re-submitted requests for less data to 97.3% completeness of the data (Mackridge, Gray and Krska, 2017). This is in contrast to response rates of mailed questionnaires to clinicians, which has been found to average at 61% (Cummings, Savitz and Konrad, 2001). A study using questionnaires to determine public health services provision (supervised consumption of medicines, needle & syringe replacement programmes, EHC, blood pressure checks and others) in community pharmacy in the UK also used postal questionnaires, achieving a 51% response rate (Bush, Langley and Wilson, 2009).

2.10 The impact of commissioning variation

Variation of community pharmacy service provision across England is a known barrier to patient uptake and future development of clinical intervention (Lewis and Jenkins, 2002; Murray, 2016; Mackridge, Gray and Krska, 2017). Even for common services, collection of detailed information that would support assessment of the service or development is 'patchy' (Elvey *et al.*, 2006). A national survey of Primary Care Trust (PCT) commissioning in community pharmacy revealed possible trends in commissioning behaviour (PCTs were commissioning bodies before CCGs and the 2012 changes to NHS structure) (Department of Health and Social Care, 2012).

One such trend in PCT commissioning was that the only significant predictor of service commissioning was other locally enhanced services (Elvey *et al.*, 2006). There was some element of correlation with deprivation (increased commissioning with increased deprivation) and rurality (decreased commissioning with increase rurality) but there was no clear association between 'objective patient need' (Elvey *et al.*, 2006). For example, areas with greater numbers or proportions of smokers, were not more likely to commission a smoking cessation service (Elvey *et al.*, 2006).

These trends (existing commissioning correlating to new commissioning, and no association between commissioning and patient need) do not suggest a link between local population health needs or data. Studies involving qualitative interviews with commissioners have found that relationships appear to be one of the main drivers to service commissioning (Elvey *et al.*, 2006).

Studies have also explored incentives to promote service activity. EHC is remunerated on a fee-per-service basis, and studies have found that financial incentives did not enhance service quality (Elvey *et al.*, 2006). Whilst performance management could have been expected to reduce variation in service delivery (if not commissioning), only 35% of PCTs set any form of targets, or collected any data that would allow this (Elvey *et al.*, 2006).

Evidence linking community pharmacy service provision to expected outcomes (such as population health or abortion rates) is not strong, and there is poor correlation between the proportion of community pharmacies providing EHC services in England and the local under 18 pregnancy rate (Mackridge, Gray and Krska, 2017). A pharmacoeconomic evaluation by Chalati *et al.* (2020) further supported this showing that, although there are more community pharmacies in Local Authorities with higher rates of teenage pregnancy, this did not translate into higher numbers of pharmacies commissioned to provide EHC (Chalati *et al.*, 2020). No significant correlation was found between teenage pregnancy rate and community pharmacy provision. It is however, notable that there was a higher provision rate in Local Authorities with fewer commissioned community pharmacies (Chalati *et al.*, 2020). Despite this, Chalati *et al.* (2020) demonstrated that the cost of EHC interventions "fall well below NICE Quality-adjusted life year recommendations for cost effectiveness" (Chalati *et al.*, 2020). The Quality-adjusted life year cost-effectiveness threshold range is between £20,000 and £30,000, meaning an intervention resulting in one year of perfect health should not exceed this cost (McCabe, Claxton and Culyer, 2008).

Despite there being poor correlation to health outcomes, the availability of 'catch-all' services e.g., GPs or local bespoke solutions (such as sexual health clinics), would suggest that community pharmacy service provision is unlikely to correlate to local health needs. The study by Mackridge *et al.* (2017) failed to identify confounding factors, such as indirect supply, which would account for any lack of correlation (Mackridge, Gray and Krska, 2017). For instance, areas where there is no locally commissioned community pharmacy EHC service are highly likely to have alternative arrangements (such as well publicised family planning clinics), which would in turn influence health outcomes locally.

2.11 Summary

This review of policy has shown the detrimental impact of intended pregnancies on health outcomes. It has also shown a clear relationship between EHC use and need with deprivation. For this reason, providing access to EHC services is a policy priority for commissioners and government.

There are two primary treatment options for unprotected sexual intercourse: LNG-EC and UPA-EC. Both are available from several settings, but two key locations are, general practice and community pharmacy. There is some evidence suggesting a relationship between these two routes of access to treatment. However, whilst GP treatment remains constant across England, community pharmacy EHC services vary by local authority, and this leads to barriers in service access.

This review provides a supportive evidence base for commissioning community pharmacy services – they appear effective and accepted by patients. However, the only attempt to determine the benefit in terms of local health outcomes showed poor correlation. There is some evidence that community pharmacy commissioning increases patient access (i.e., more locations to obtain interventions or increased opening hours) and some patients appear to prefer this. However, there is an uncertain evidence base to explain community pharmacy commissioning solely in terms of improved health outcomes.

If patient needs are met by existing services, and community pharmacy commissioning does not improve public health metrics – then what is the purpose of these commissioned services? The correlation between GP and community pharmacy activity may hold the answer. The purpose of community pharmacy commissioning may be to increase accessibility to deprived populations, but also to increase overall system capacity. Through commissioning pathways, patient behaviours can then be influenced to encourage judicious use of NHS resources. If this is the case, then neither can be measured through local population outcomes as community pharmacy activity is either targeted to small numbers of people (in deprived communities) or for patients who would have received care elsewhere.

There are many influences on patient access to EHC. A key measure appears to be privacy, although other factors seem to include marital status and age. Deprivation also appears to be a strong influence on EHC use. What has not been found in this review is a measure of the success of a service. If targeting specific populations or moving workloads are the objectives, how are these measured by commissioners? What processes are available to estimate the impact a new service will make, or the success of an existing one.

This chapter has highlighted an apparent gap in the literature, namely a description of data that quantifies or supports community pharmacy EHC service commissioning. The only evidence shows poor correlation to public health outcomes, and the policy and literature suggest commissioning is designed to move patient access (from general practice to community pharmacy). This is not described nor measured in the literature, and it is this gap that the thesis attempts to answer.

The next chapter sets out the aims and objectives that follow from this. Given the extensive qualitative literature on patient and professional views on EHC, the focus will be quantitative data. This data will support the generalisation of conclusions, that may support applying these to other community pharmacy services. Following the aims and objectives, chapter 4 will detail a systematic literature review of local commissioning, to look for evidence of commissioning processes.

Chapter 3: Aims and Objectives

3.1 Introduction

The systematic literature review (page 61) did not reveal a method based on quantitative data for informing the commissioning of community pharmacy services or subsequently assessing their impact. EHC has been identified as a prime example of a service where the role of data in commissioning decisions remains difficult to determine (page 16). It is possible that the provision of the service is influenced by other parts of the healthcare system.

The literature also revealed FOIs as a possible source of data. Using variables identified in the literature and the potential data sources (routinely collected data), it may be possible to determine a method of determining influences on the commissioning and provision of community pharmacy services. The aims and objectives of this work are set out below.

3.2 Aims

The aim of this thesis is to determine what influences EHC service commissioning and provision, through the use of quantifiable, routinely collected data. This includes describing:

- What influences GP EHC provision?
- What influences community pharmacy EHC provision?
    - This includes the role of pharmacy organisation type
- A model that illustrates factors influencing EHC services

3.3 Objectives

1. To quantify the variables influencing a Local Authority commissioned EHC community pharmacy service by:
    a. Determining the correlation between the rate of community pharmacy EHC activity and its association with the rate of GP EHC prescribing
    b. Identifying data-driven variables and analyse their relationship to EHC activity within local authorities
    c. Creating a path-analysis model to represent the relationships between the variables

2. To identify and quantify the variables influencing EHC provision from an individual community pharmacy by identifying organisational and environmental factors that influence community pharmacy EHC activity

Chapter 4: Factors influencing the commissioning of community pharmacy services (Systematic Literature Review)

4.1 Introduction

The policy review (page 18) in Chapter 2 has shown that EHC is a service that can meet the immediate healthcare needs of individual patients. The literature also identified that community pharmacy EHC services do not show significant positive correlation with local health outcomes (under-18 pregnancy rate). It is possible that commissioning EHC services from community pharmacy aims to either target specific populations or increase capacity elsewhere in the healthcare system. This commissioning intention has not been described in the literature so far identified.

What has not been found is evidence of how data driven metrics inform commissioning decisions. Other than a single study of a small rural area, there appears to be no evidence of large data sets demonstrating or quantifying shifting patient behaviours (Lloyd and Gale, 2005). Objective measures of success are crucial to ensure value for the taxpayer. Accordingly, a literature search of all local commissioning was undertaken to identify data-points that may influence service commissioning decisions, particularly those for community pharmacy services. From this, either existing routinely collected data or new data collection may be identified that could inform future commissioning decisions.

As can be seen from the introduction (chapter 1) there is no single commissioner, body, or process for any element of community pharmacy service provision. Accordingly, the systematic literature review needed to capture any evidence about community pharmacy commissioning decisions from a range of commissioning bodies. EHC does not have a single defined pathway, so evidence from multiple sources may be relevant.

The systematic literature review intended to identify any existing evidence of data showing the influences or variables that impact local community pharmacy commissioning. The focus of the review is to identify literature relating to the commissioning process of services, rather than the relative successes (or otherwise) of individual service designs or interventions.

4.2 Developing the search strategy

There are several methodologies that can be used for conducting systematic reviews, based on the likely evidence, the question being posed, and the focus of the literature. Munn *et al.* (2018) have proposed that there are ten different forms of systematic review. Depending on what the question posed aims to determine, different approaches are suitable. The authors stress caution in attempting to “force their question into the PICO format” (Population, Intervention, Comparator and Outcome) (Munn *et al.*, 2018). In the case of the question being addressed in this literature, this review was not attempting to determine the success of an outcome. Nor was it comparing the outcome to alternative service provisions, or no action. The question attempted to determine if routine data can yield insights into factors that affect/influence commissioning decisions and provide metrics of successful delivery of these services (s described in the aims on page 44). This study is considering the example of community pharmacy EHC services and the effect on GP EHC prescribing, but this search strategy will not be limited to EHC services.

Without a specific outcome to be investigated an experiential (qualitative) or expert opinion/policy approach was taken. These approaches investigate the "experience or meaningfulness of a particular phenomenon" and "review and synthesise current expert opinion, text or policy on a certain phenomenon" (Munn et al., 2018). This approach takes a PICo format (Population, Interest, and Context). These reviews focus on the engagement between participants (in this case commissioners) and the intervention (in this case the commissioned service).

The inclusion and exclusion criteria are set out below, to restrict the results to commissioning of local healthcare services.

Table 1 Search inclusion and exclusion criteria, PICo format

PICo	Inclusion	Exclusion
Population or problem	Commissioners of local community pharmacy services (the search is targeted at community pharmacy commissioning, but not excluding other providers)	Secondary care, or national commissioning.
Interest	Views on the influences of local commissioning and successful delivery of the locally commissioned services. Reasons for commissioning and criteria used to determine commissioning decisions.	Provision of services. Patient / health outcomes of services.
Context	England (preference).	Studies were not excluded based on their location.

The review did not exclude results detailing the commissioning of local services outside community pharmacy as the results may inform the methodology and later research. However, given that the focus of the thesis was specifically targeting community pharmacy service commissioning, the search terms did not attempt to capture other commissioning streams. Similarly, the search terms were designed to target literature concerned with the English commissioning environment but did not exclude evidence based outside England. In that instance the context was considered to determine if there were parallels that may support the thesis aims.

A search of the Cochrane Library, PubMed, and Google Scholar was conducted to attempt to identify any relevant systematic reviews that may inform the search strategy. One review published in 2019 mapped the research conducted in community pharmacy public health service provision, although not commissioning (Stokes et al., 2019). Whilst the findings were of limited relevance, the search terms were helpful for formulating the search strategy. Research conducted to inform The King's Fund Community Pharmacy Clinical Services Review may have been useful, but the full search strategy was not made publicly available (Murray, 2016; Wright, 2016). None of the systematic reviews identified directly addressed the commissioning of community pharmacy local services.

Grey literature, and community pharmacy policy, were reviewed both in preparation for the review and when preparing the introduction chapter. These were particularly helpful for formulating search terms.

4.3 Main search strategy

The question for the review was "Can routine data yield insights into factors that affect the commissioning of services within England and provide metrics of successful delivery of these services".

Electronic searches were undertaken of the following databases, hosted by EBSCO:

- AMED (Allied and Complementary Medicine Database)
- ASSIA (Applied Social Science Index and Abstracts)
- Proquest, MEDLINE
- PsycINFO

Depending on the database two slightly different search structures were used. The search terms used were:

"community pharmacy services" AND/OR "commissioning" AND/OR "community pharmacy" AND/OR "local commissioning"

Version 2

Community pharmacy OR community pharmacy services OR pharmacy

AND

Commissioner OR commissioning OR local commissioning

Due to the introduction of the Health and Social Care Act 2012 (Department of Health and Social Care, 2012) and the transfer of public health commissioning to local authorities (Local Government Association, 2013) a year later, searches were initially restricted to results from 2012 and later. This is because the radical shift in the nature of commissioning means research into a commissioning environment before this time is less likely to be relevant to current practice. This gave a small number of results, so to increase the number of results the final search criteria were extended to 2002 (an additional ten years).

Accordingly, the inclusion criteria were:

1. Any literature relating to the commissioning of primary care services, including qualitative studies, literature reviews and systematic reviews
2. Full article available
3. English Language

The exclusion criteria were:

In the search engine:

1. Publication before 2002
2. Language: not English
3. Location: not England

When reviewing titles and abstracts also:

4. Research not involving humans
5. Research not relating to commissioning (e.g., service outcomes excluded)

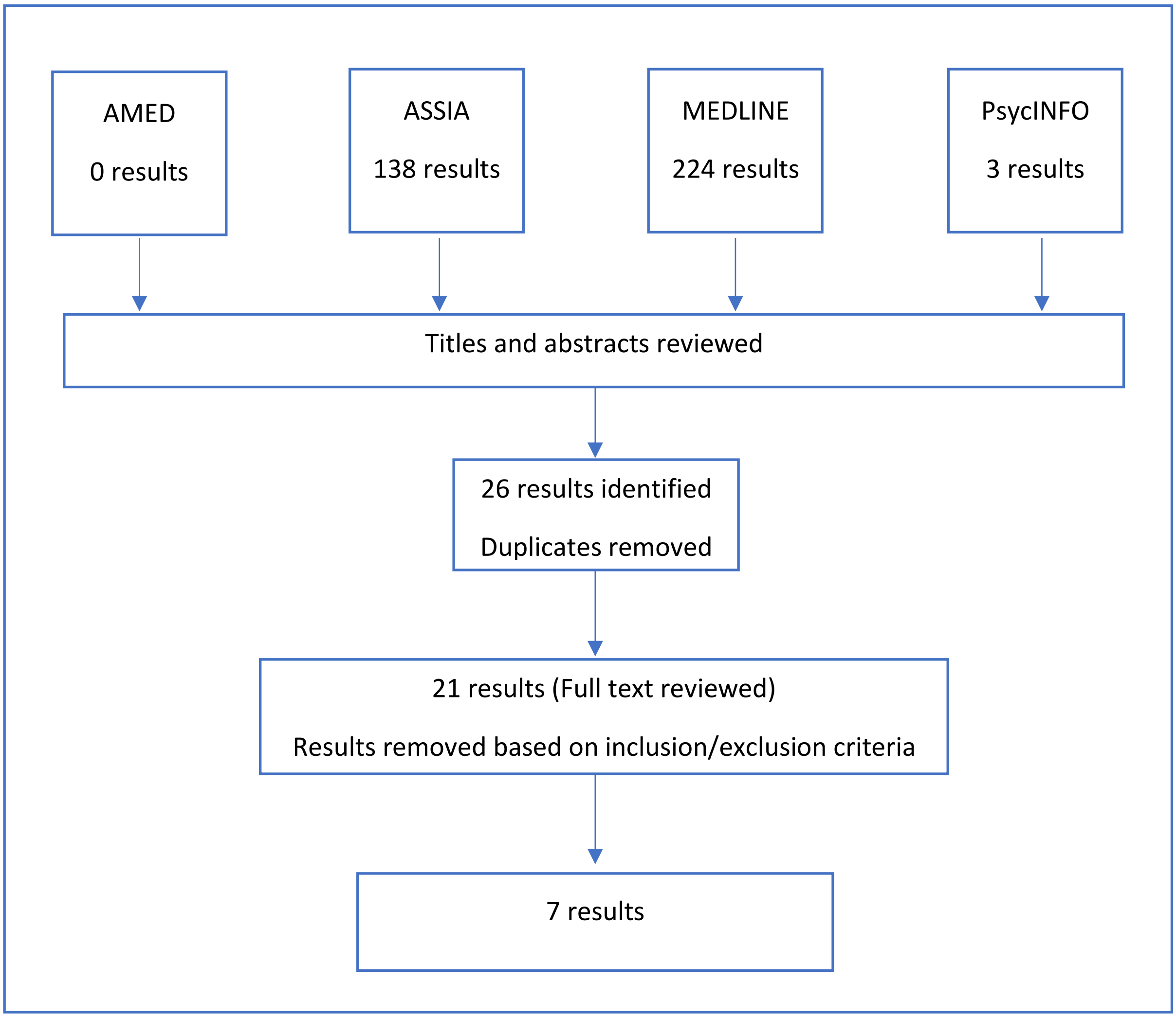
6. No reference to community pharmacy, commissioning, or primary care local services in the abstract
7. Quantitative results of local service performance (unless linked directly to commissioning decisions)

When reviewing full text also:

8. Focus on benefits/value of community pharmacy interventions
9. Focus on patient or carers views
10. Focus on national services

After reviewing the titles and abstracts and excluding results (exclusion criteria 1 – 7), 26 full text results were reviewed for eligibility. After reviewing the full text 7 results were included in the systematic review analysis. Data were extracted from each paper and are tabulated later in this chapter (*Table 4*). The results of the full search process are detailed in *Figure 5*.

Figure 5 Systematic Literature Search Results



4.4 Critical appraisal of the quality of the included studies

There are numerous theories and frameworks that are used to examine the implementation of interventions in healthcare, as well as more traditional systematic reviews of data and meta-analysis. The search strategy aimed to understand the influences in commissioning of local services and any cited subsequent markers of success. From this routine data points may be identified for analysis.

The purpose of the literature search is not to determine the strength of evidence underpinning any clinical intervention. It is understanding the influences behind commissioning decisions and how data features in these decisions that is the focus. The search results did not directly address commissioning decisions but made several references to possible influences. To structure the analysis a framework analysis was used to theme the findings and identify possible ways data currently influence commissioning decisions. More detail on the chosen framework and the rationale is presented in section 4.5.2 (page 64).

Before applying a framework to the results, it was necessary to critically review the results. There are several critical appraisal tools that may be used to review the quality of the literature. The Joanna Briggs Institute criteria appeared to align more closely with the subject matter, and so this was selected.

The seven results (as detailed in *Figure 5*) were reviewed using the Joanna Briggs Institute (JBI) criteria (Joanna Briggs Institute, 2020). The qualitative checklist was used for six of the results, and the cross sectional studies checklist for the final result (Joanna Briggs Institute, 2020). The checklists direct the researcher to review the results by considering different facets of the literature and respond “yes”, “no”, or “unclear”. Using these answers the results were RAG rated (Red-Amber-Green) to indicate their relative “trustworthiness, relevance and results” (Joanna Briggs Institute, 2020). There are no standard definitions for the RAG rating, and it was decided that 7 or more “Yes” responses to the questions would be defined as “good”, between 5 and 7 “Yes” as

"Adequate" and 4 or less as "Bad". This allows objective comparison of the quality of the results.

None of the results comprehensively provided all the criteria expected in the checklists. However, most of the literature was either adequate or good. The answers to the questions are set out in *Table 2* and *3*.

Table 2 RAG rating of the search results (qualitative search results) (7 or more "Yes" = Good, 5-7 "Yes" = Adequate, 4 or less "Yes" = Poor)

Studies	**Firth (2015)**	**Jacobs (2018)**	**Jacobs (2017)**	**McNaughton (2011)**	**Nazar, H & Nazar, Z (2019)**	**Norman (2014)**
Is there congruity between the stated philosophical perspective and the research methodology?	No	No	Yes	No	No	No
Is there congruity between the research methodology and the research question or objectives?	Yes	Yes	Yes	Yes	Yes	Yes
Is there congruity between the research methodology and the methods used to collect data?	Yes	No	Yes	Yes	Yes	Yes
Is there congruity between the research methodology and the representation and analysis of data?	Unclear	Yes	Yes	Unclear	Yes	Yes
Is there congruity between the research methodology and the interpretation of results?	No	Yes	Yes	Yes	Yes	Yes
Is there a statement locating the researcher culturally or theoretically?	No	Unclear	No	No	No	No
Is the influence of the researcher on the research, and vice- versa, addressed?	No	No	No	No	No	No
Are participants, and their voices, adequately represented?	Yes	Yes	Yes	Yes	Yes	Yes
Is the research ethical according to current criteria or, for recent studies, and is there evidence of ethical approval by an appropriate body?	Yes	Yes	Yes	Yes	Yes	Yes
Do the conclusions drawn in the research report flow from the analysis, or interpretation, of the data?	Unclear	Yes	Yes	Yes	Yes	Yes
Overall rating	Poor	Adequate	Good	Adequate	Adequate	Good

Of the six qualitative results, there was a mix of quality. Most of the results failed to state the philosophical perspective, or match this to the research methodology. It is also of note that none of the results successfully discussed the researchers, either culturally or theoretically. This is particularly important given the nature of the research. The researchers background (for instance, if they were pharmacists or commissioners) would likely be a factor in the interpretation of the responses provided. Similarly, participants may be aware of the researchers which may impact the results provided. There is no consideration of the researcher's role in the results.

Table 3 RAG rating of the search results (Analytical cross-sectional studies)) (7 or more "Yes" = Good, 5-7 "Yes" = Adequate, 4 or less "Yes" = Poor)

Studies	**Mackridge (2017)**
Were the criteria for inclusion in the sample clearly defined?	Yes
Were the study subjects and the setting described in detail?	Yes
Was the exposure measured in a valid and reliable way?	Yes
Were objective, standard criteria used for measurement of the condition?	Yes
Were confounding factors identified?	Yes
Were strategies to deal with confounding factors stated?	No
Were the outcomes measured in a valid and reliable way?	Yes
Was appropriate statistical analysis used?	Yes
Overall rating	Good

The final paper is a cross-sectional study which meets many of the quality criteria listed. The only critique is the way confounding factors are managed. Their possible presence is acknowledged, but there is no attempt in the discussion or analysis to control for their presence.

4.5 Main search results

A total of 365 results were identified through the search strategy (AMED 0, ASSISA 138, MEDLINE 224, PsycINFO 3), the search was last run on 03/01/2022. The papers were reviewed, and 339 were excluded based on the exclusion criteria (as described in *Figure 5*). Papers in the excluded cohort commonly provided details on the nature and effectiveness of community pharmacy local services or focused on specific clinical interactions or policies with no relation to the commissioning process. Following this, 5 duplicate papers were removed leaving 21 papers where the full text was reviewed. Again 14 results were excluded based on the exclusion criteria, leaving 7 results for analysis (*Figure 5*).

From the 7 results, 5 focused solely on community pharmacy, one on primary care commissioning and a final source considering GP commissioning. The details on the identified sources of evidence are detailed in *Table 4*. This includes the year of publication, country, and setting.

Table 4 Summary of systematic literature review results

Studies	Year	Place of study	Sampling / recruitment procedure	Setting	Participant characteristics	Main Findings	Limitations
Firth	2015	England	Purposive sampling	Community pharmacy	22 pharmacy staff; 4 local authority commissioners	Commissioners lack an understanding of areas outside their area of expertise (and therefore potential barriers to service delivery). Community pharmacy is well distributed across England, with greater numbers in areas with high deprivation. It is this fact that makes community pharmacy a highly attractive place to commission local services.	Only 15% of the respondents were commissioners, and the sampling is from a single part of England.
Jacobs	2018	England	Purposive sampling	Community pharmacy	10 commissioners, 30 pharmacists / superintendent pharmacists	Appropriate staffing and skill-mix are important in promoting service quantity and quality. Organisational features (including culture of different providers) should be considered when commissioning from private sector providers.	The study broadly focused on national services where commissioning decisions are largely made differently to local services.
Jacobs	2017	England	Mixed Methods	Community pharmacy	Pharmacies and commissioners	Ownership type is an important influence on service provision. Organisation, skill-mix and culture, as well as relationships with local GPs are important factors in service provision. Commissioning landscapes and remuneration were cited as barriers to service provision.	The study focused specifically national services where commissioning decisions are largely made differently to local services.

Mackridge	2017	England	FOI requests to all Local Authorities	Community pharmacy	Local Authorities	There is poor correlation between current (2015/16) commissioning and local health needs	The outcomes (population health) are proxy measures of patient need. The paper assumes other healthcare provision is unaffected by commissioning.
McNaughton	2011	England	Purposive sampling	Community pharmacy	10 PCT staff members (commissioners) and staff from 8 pharmacies	Despite an apparent clear case for commissioning there were several barriers to commissioning. Complexities increased the cost, priority was not given to the service (by commissioners or pharmacies), and the use of targets vs. service availability is a key issue.	The evaluation is of an 'early adopter' pilot service, which has since undergone changes to the specification. It also undertakes data collection early in the commissioning process before initial challenges can be resolved.
Nazar, H and Nazar, Z	2019	England	Purposive sampling	Community pharmacy	53 stakeholders invited for online questionnaire (79.2% response), 20 provided consent for interview (all interviewed)	Lack of integration of community pharmacy prevents engagement with local pathways and the competing financial interests of various providers influences delivery. Services do not always align with community pharmacy key interests and investment/commitment to the service does not follow.	Whilst the participants were recruited in 2016 the paper does not specify the commissioning process undertaken. Furthermore, this paper reflects the views of individuals within a single region in England.
Norman	2014	England / Scotland	Purposive sampling	GPs with a link to medical education	13 participants, 7 GP partners & 6 salaried GPs.	Introduction of GP QOF payments (and thus a combined remuneration model) was greatly influential in shaping engagement and behaviour.	This paper explores the impact of QOF payments, which are subtly different in nature to local community pharmacy services. This difference may limit the application of the findings.

4.5.1 Comparing and contrasting the findings

The lack of evidence to commission services was a key theme that emerged from the literature. Commissioners reported that health checks (and by implication other services) are commissioned more based on policy, rather than strong evidence of value (Firth, Todd and Bambra, 2015). This theme was supported regarding pharmacy Minor Ailments services, that stated commissioning across the country has “failed to generate sufficient evidence to support a model of care” (Nazar and Nazar, 2019). There was a reported consensus that commissioners do not have metrics to monitor service quality, and that the only data available for ready use were service provision (Jacobs *et al.*, 2017).

Reviewing GP commissioning again cites the role of evidence (or lack of) in commissioning. Many of the interviewed GPs reported that “there is no evidence to say this is actually good practice”, but completed the requested actions (in return for payment) (Norman, Russell and Macnaughton, 2014). Norman *et al.* (2014) echo the arguments of Nazar and Nazar (2019), that the commissioned activity is more closely linked to policy decisions rather than a solid evidence base (Norman, Russell and Macnaughton, 2014; Nazar and Nazar, 2019).

The introduction of health checks into community pharmacy in Tees Valley was based on a theory that the public rarely visit general practice, but do visit community pharmacy which would offer greater access (McNaughton *et al.*, 2011). Despite this, the rationale reported for commissioning was “the department of health had said they wanted us to look at other providers, and community pharmacies, they thought, would be a good venue” (McNaughton *et al.*, 2011). There is a lack of quantified metrics to justify commissioning, or continued commissioning reported in the literature. However, as a novel service design it is possible the data were not available to make predictions or base decisions on.

Interviews with community pharmacy commissioners reported a desire for metrics to monitor quality (Jacobs *et al.*, 2017). It was theorised by the interviewed commissioners that the pharmacy organisation type (i.e., the size of the pharmacy business) is a factor that influences both service provision and decisions to commission (Jacobs *et al.*, 2017). A review of national service activity found statistically significant differences between pharmacy organisations, suggesting larger companies are more likely to provide higher volumes of services supporting this assertion (Jacobs et al., 2017).

Factors cited as influencing commissioning and service provision included deprivation, population characteristics and contractual arrangements (Jacobs *et al.*, 2018). Population characteristics and deprivation were linked in the discussion to the demand for the commissioned service(s), whereas contractual arrangements (for example payment levels) were linked to pharmacies’ ability and willingness to provide services (Jacobs *et al.*, 2018). This was also supported by Norman *et al.* (2014), which reported GPs stating that payment impacted behaviours and adherence to commissioned services (Norman, Russell and Macnaughton, 2014).

The role of relationships was highlighted as a critical factor in commissioning decisions. The “effectiveness of the relationship with local pharmacy influencers” and commissioners contributed to the commissioning decisions made (Nazar and Nazar, 2019). This finding was not replicated it the other studies. It was reported that both the staff profile of pharmacies (i.e., how many of different roles) and the relationship with local partners, particularly GPs, were important factors in service provision (Jacobs *et al.*, 2017).

The quantitative study examined correlations between pharmacy services and local health outcomes (e.g., EHC and under 18 pregnancy rates, and needle and syringe exchange programmes and deaths from substance misuse) (Mackridge, Gray and Krska, 2017). This study found weak correlations between the commissioned services and local health outcomes, concluding that “there is a need to re-visit the benefits of local commissioning … which may be influenced by a range of factors other than need” (Mackridge, Gray and Krska, 2017). The paper does not draw conclusions about what factors do inform commissioning, but notes there is variation in commissioning of services across England that does not align to perceived local need (Mackridge, Gray and Krska, 2017).

The studies identified did not reveal a data-driven commissioning process. Whilst it is acknowledged that these processes are not likely candidates for peer-reviewed subject matters, a comprehensive search has not revealed any evidence of this existing consistently. Indeed, interviews with commissioners have reported policy driven decisions and a lack of information to assess decisions made.

The literature review did suggest several data points for consideration in the development of any data-driven decision tool. These included deprivation, population characteristics, contractual specifics (such as remuneration), and pharmacy organisational type (business size). Other factors included local relationships and staffing which do not lend themselves to a data-driven metric.

4.5.2 The Consolidated Framework for Implementation Research

The Consolidated Framework for Implementation Research (CFIR) was used as a theoretical framework to inform the analysis. CIFR is the "most widely cited and used implementation framework" and applied extensively in community pharmacy practice research (Curran and Shoemaker, 2017; Nazar *et al.*, 2019; Moecker *et al.*, 2021). What was identified when reviewing the literature was that the results focussed on service provision, either successes or challenges. These were often linked to the implementation of services and using the CFIR tool provided a way to identify the different themes in the literature. From this, future potential datapoints that may yield insights into factors that influence commissioning can be identified. This supports the aim of the thesis – to determine what influences EHC service commissioning and provision, through the use of quantifiable, routinely collected data can be achieved.

The CFIR framework is a tool that supports systematically assessing possible barriers and facilitators to interventions. CFIR separates the various influences into 5 constructs: Intervention source; outer setting; inner setting; characteristics of individuals; and process. In particular CFIR can provide a "practical guide for systematically assessing potential barriers and facilitators", which can support development of "context-specific logic models or generalisable middle-range theories" (CFIR Research Team-Center for Clinical Managment Research, 2021). A middle-range theory is an approach to theory construction used frequently in nursing (and other disciplines). They include a limited number of variables, focusing on a limited aspect of reality (Liehr and Smith, 1999). These theories lie between the hypotheses developed from the perspective of a discipline, but allow generalisation (Liehr and Smith, 1999). CFIR can be used to identify elements of practice and the context they apply to, to allow theory generation across a discipline.

4.5.3 Using the CFIR

The details of the 5 constructs are set out in *appendix 1*, but in brief, allow grouping of the different elements of implementing a service. Based on personal experience in the commissioning of services, the elements detailed in the CFIR reflect the considerations of commissioners. Whether considering the complexity of a service, the cost, patient needs, or organisational culture (to name a few characteristics) each can be seen as part of the likely influences on a commissioning decision. Accordingly, this framework was judged to be highly relevant.

The constructs consider the nature of the intervention and how it was developed/conceptualised (intervention source), the external factors to success (outer setting), factors controlled by those providing the intervention (inner setting), the skills and attitudes of the individuals/group providing the intervention (characteristics of individuals) and the mechanics of the intervention – the practicalities of providing (process). For each of these constructs there are specific characteristics, totalling 39 different characteristics.

The results were reviewed in line with this framework and possible determinants were identified. Each of these can be found in *Table 5*. Each of the characteristics have a description detailing what it refers to. The 7 evidence sources were reviewed, and where the characteristics were referenced (either positively or negatively) this was counted. A simple tally chart then guides an understanding of both the likely influences on commissioning, but also any gaps in the literature.

Table 5 does not attempt to describe the relative strength of the evidence nor the strength of the influence. The implications of the characteristics referenced in the literature are explored further in the next section.

Table 5 Summary of the CIFR framework outcome

Construct		Firth, H *et al.*	Jacobs, S *et al.*	Jacobs, S *et al.*	Mackridge, A *et al.*	McNaughton *et al.*	Nazar, H & Nazar, Z	Norman, AH *et al.*
I. INTERVENTION CHARACTERISTICS								
A	Intervention Source			X	X	X		X
B	Evidence Strength & Quality	X		X	X	X	X	X
C	Relative Advantage	X						X
D	Adaptability						X	
E	Trialability					X		
F	Complexity	X				X		
G	Design Quality & Packaging							
H	Cost	X				X		
II. OUTER SETTING								
A	Patient Needs & Resources		X	X	X		X	X
B	Cosmopolitanism	X	X				X	
C	Peer Pressure						X	X
D	External Policy & Incentives	X		X	X	X	X	X
III. INNER SETTING								
A	Structural Characteristics		X	X		X		
B	Networks & Communications						X	
C	Culture		X					X
D	Implementation Climate		X			X		X
1	Tension for Change		X					
2	Compatibility							
3	Relative Priority		X			X	X	
4	Organizational Incentives & Rewards		X	X			X	X
5	Goals and Feedback			X				
6	Learning Climate	X	X				X	
E	Readiness for Implementation		X					
1	Leadership Engagement							
2	Available Resources	X	X			X		
3	Access to Knowledge & Information					X		
IV. CHARACTERISTICS OF INDIVIDUALS								
A	Knowledge & Beliefs about the Intervention	X						X
B	Self-efficacy		X			X		
C	Individual Stage of Change		X				X	
D	Individual Identification with Organization		X	X				X
E	Other Personal Attributes							
V. PROCESS								
A	Planning					X	X	
B	Engaging	X						
1	Opinion Leaders						X	X
2	Formally Appointed Internal Implementation Leaders						X	X
3	Champions							
4	External Change Agents							
C	Executing							
D	Reflecting & Evaluating							X

4.5.4 CFIR output

Figure 6 reports CFIR constructs referenced in each of the studies, detailing the number of times the construct is highlighted as a barrier or enabler. Many of the studies referenced at least one construct from each of the domains (n=4) but some only referred to 3 domains or less (n=3). The intervention characteristics and outer setting domains were the most frequently referenced, with process only referenced by 4 of the 7 sources. Evidence strength and quality, and external policy and influences, were found to be the influences of successful commissioning most often cited (n=6). However, the intervention source, patient needs and resources, and cost were also highly cited. Direct comparison between domains is not helpful due to the different number of constructs in each domain, but there appears to be no obvious weighting towards one of the domains. Whilst the studies were selected for their objectives to investigate commissioning, rather than service provision, the studies often included both points of view.

The CIFR review demonstrated a common theme of identifying the patient needs and resources and the external policy and incentives that drive commissioning. There was little reference to the behaviours of other providers or healthcare professionals influencing the commissioning or provision of community pharmacy services. Another common theme to the success and uptake of services, described across professions, was the resource supporting implementation.

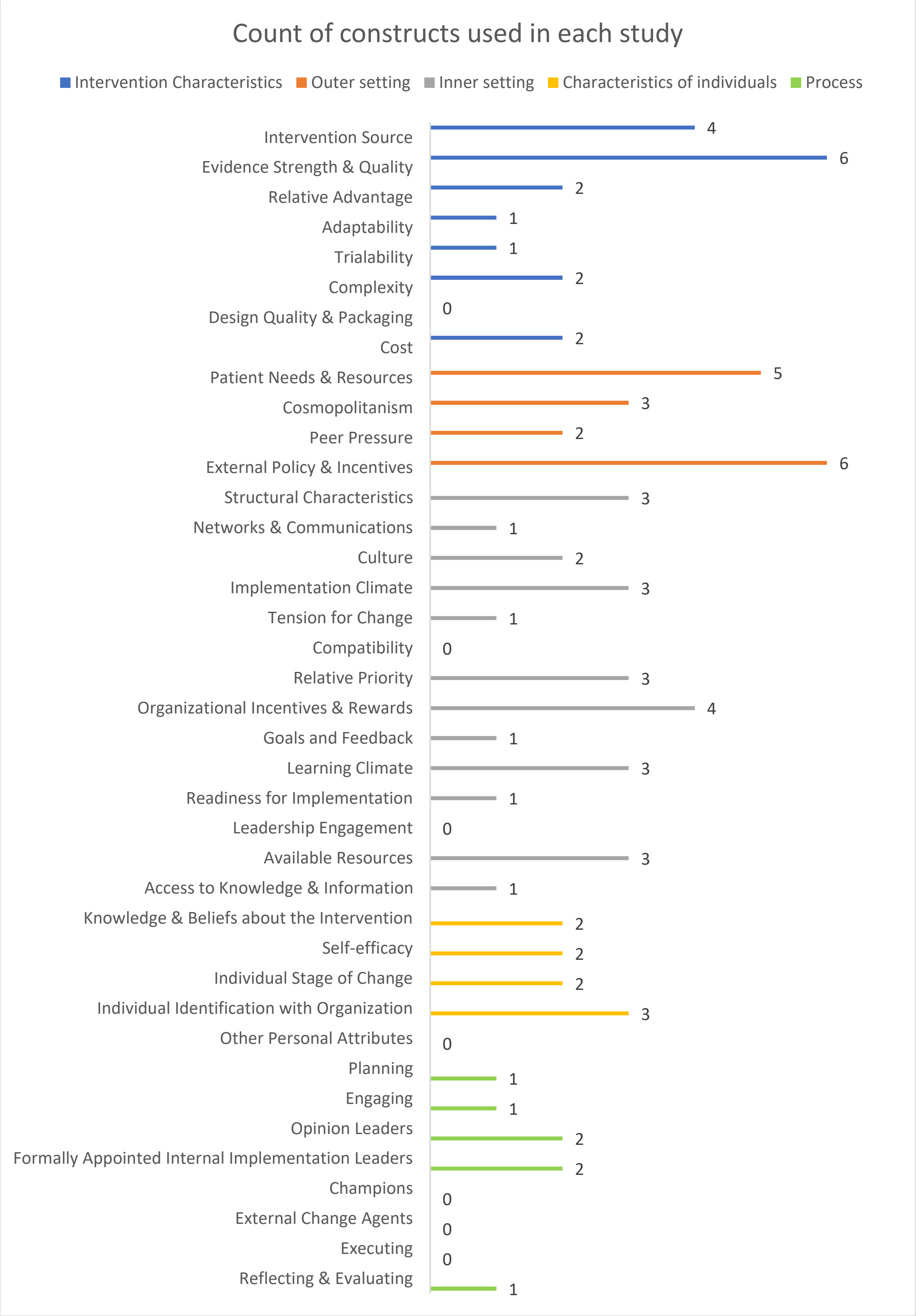


Figure 6 CIFR constructs, number of papers referencing each construct

4.5.5 Reviewing the CFIR analysis

One challenge highlighted in the papers was the strength of the evidence and the driving reason behind the commissioning of services. Health checks in particular, were singled out as a low-quality intervention that was being commissioned for political rather than evidence-based reasons. One reported quote from a commissioner was “*so whatever I think of it, I have to commission a programme*” (Firth, Todd and Bambra, 2015).

The literature made references to the location and access of community pharmacy being a common consideration of commissioning. Work has been undertaken to map community pharmacies to local population, demonstrating the accessibility to populations – particularly in deprived areas (Todd A *et al.*, 2014). Logically, measures of deprivation could be a factor in commissioning decisions. Despite this obvious link, there was little evidence in the literature that this forms part of the commissioning decision process. The only example was McNaughton *et al.* (2011), and this was presented as rationalising a political decision already made.

For clarity, this is not to suggest that the interventions commissioned (e.g., smoking cessation services) lack evidence of efficacy or effectiveness. Nor that there is a lack of evidence for their use in community pharmacy, or by pharmacy teams. What is not evident in the literature is anything suggesting that this evidence drives decisions to commission. Quantitative data such as likely levels of service provision, numbers of patient treated, probably patient outcomes, were not referenced in the literature.

This may be a case of practice not being reflected in the published literature. Commissioners do develop business cases (or similar) justifying expected financial outlay – this is a requirement for any use of public money. This does not feature in the literature reviewed. However, the subject matter may not be of interest to academic publications or commissioners see little value in publishing their work in this manner. The lack of published evidence does not prove a lack of individual strategy or service assessment. It is suggestive however, that there is no single agreed peer-reviewed methodology.

Pharmaceutical Needs Assessments (PNAs) are reviews of the local needs of a population, as defined by NHS Regulations (NHS England, April 2013). These reviews are intended to guide commissioning decisions through an objective consideration of population needs – described originally as Practice Based Commissioning (Celino and Blenkinsopp, 2007). The literature did not reveal examples of this national review process being used to guide commissioning decisions.

The internal domain constructs did not demonstrate a strong published evidence base on the capabilities, culture, or preparedness of the setting. Conversely organisational factors, such as the relative priority or value of the intervention within the business or the cultural norms, were highly referenced. Within community pharmacy a likely measure of this variable is the ownership type (Hann *et al.*, 2017). Commonly, community pharmacy is formed into either large multiple businesses, supermarkets, small and medium chains, or independent pharmacies. Evidence has already demonstrated that the overarching business model impacts the variety of clinical productivity within community pharmacy (Jacobs *et al.*, 2016). The literature indicated that perceptions and features of different organisations featured in commissioning decisions – both positively and negatively. Accordingly, exploring this factor may reveal an influencing factor on local service commissioning. This insight supported the development of the objectives, including identifying organisational factors that influence community pharmacy EHC activity.

Characteristics of individuals were not commonly referenced in commissioning decisions. This may well be due to the expectation that training is provided where needed, or that services are commissioned according to the capabilities of the individuals intended to undertake the service. It was noted by McNaughton *et al.* (2011) that the capability of pharmacy team members was lower than GP support staff, and training was provided in that example. Separate to this systematic review, literature searching has identified evidence of both the acceptability of the most common services to both pharmacists and the public. This includes a confidence in the skills and capabilities required (and exhibited) by pharmacists. A key example of this is emergency hormonal contraception services where the quality of service and advice provided does not differ between GP and community pharmacy services (Killick and Irving, 2004).

The process for implementing a service is of limited importance to the commissioning process. Engagement with the individuals undertaking the service is referred to most frequently, ensuring that the intervention is prioritised within the daily workload. However, the lack of evidence is suggestive but not conclusive that the process of providing a service does not feature within the commissioning decision making process. There are multiple examples reviewing the process of providing pharmacy services and barriers/facilitators to success (Hossain *et al.*, 2017; Moecker *et al.*, 2021).

4.6 Narrative synthesis: study findings

The findings of the literature review are presented below. They are grouped according to the five constructs with the CFIR.

4.6.1 Intervention Characteristics

Intervention characteristics consider many of the practical aspects to an intervention. This includes the cost, nature of the intervention, and the supporting evidence. In particular, the literature made references to funding strongly influencing commissioning success, approach, and attitudes.

There are two distinct remuneration models for commissioned services: capitation (payment for maintaining a list of patients who receive care as required) and activity payment (payment for an individual consultation, medicine supply or treatment) (Aly *et al.*, 2018). Both models have benefits and challenges, however, concerns were raised regarding competing interests in services linked to medicines supply alone (Aly *et al.*, 2018). Whilst it is important that commissioners allocate time and resources efficiently, the variation in remuneration (and the variation in outcomes) is suspected to be highly influential (Aly *et al.*, 2018). However, the systematic review did not reveal any evidence comparing service remuneration and provision.

It is also of note that GPs are remunerated through a combination of salary, capitation and procedures (Norman, Russell and Macnaughton, 2014). Each of these remuneration methods have drawbacks, incentivising both positive and negative behaviour. Changes in the GP contract in 2004 moved to a combination of these remuneration models through the addition of the Quality and Outcomes Framework (QOF) (Norman, Russell and Macnaughton, 2014). This framework adds payments for achieving pre-determined goals linked closely to quality outcomes. There was some concern that this would move GP behaviour away from holistic care, focusing on achieving targets but a more widespread conclusion was that this promoted better patient care (Norman, Russell and Macnaughton, 2014).

It is likely that the ingrained nature of the QOF, is what led to the Community Pharmacy equivalent – the Quality Payment Scheme. Whilst not directly compared, there is a clear resemblance with payment being made to community pharmacies achieving pre-determined criteria for agreed quality patient outcomes (Department of Health, 2016).

Qualitative research with commissioners, influencing groups, and pharmacists highlighted the challenge to successful service provision stemming from funding models (Nazar and Nazar, 2019). Local community pharmacy service provision is hampered by two things: the overwhelming financial incentive to both the national contractual requirements (and its subsequent drive towards quantity of prescription-related activity); and the competing payments structures of general practice and community pharmacy (Nazar and Nazar, 2019). Commissioners recognise that providers (community pharmacy, GPs and others) do not consider the financial reimbursement of local services sufficient to justify the work load or to influence service provision (Mills *et al.*, 2017). Whilst some individuals value the reimbursement, it is also important to note that in some cases due to the complex interwoven nature of patient care, provision of local services may decrease or put at risk income from other areas (Shaw *et al.*, 2016).

4.6.2 Outer Setting

The outer setting construct considers the environment in which the intervention is taking place. This may include patient needs, how they are recognised, or how the intervention meets them. This theme of understanding and designing to patient needs was a key concept within the literature. Furthermore, external mandates, recommendations, and policies form part of this construct. The impact of policy on commissioning decisions was also found.

One subject highlighted more than once was that community pharmacy should be a prime location for delivery of patient-facing interventions (Nazar and Nazar, 2019). Indeed, there are over 11,000 community pharmacies in England, with approximately 42,990 registered pharmacists and 19,311 registered pharmacy technicians (Royal Society for Public Health 2016). For comparison there are approximately 7,000 GP surgeries (NHS Digital, 2019b). This extensive network of community pharmacies receive an estimated 1.2 million health-related visits *every day.* (Royal Society for Public Health 2016). Despite this resource and opportunity for access, local commissioning remains patch-work and undeveloped (Wright, 2016). The access provided by pharmacies, specifically within deprived communities, influenced some commissioning decisions – encouraging commissioners to explore community pharmacy as a new venue for services (McNaughton *et al.*, 2011).

Despite a feeling that community pharmacy is located in such a way to deliver high quality care with easy accessibility, barriers remain around a perception of integration with other healthcare professionals, notably general practice (Nazar and Nazar, 2019). Additionally, community pharmacy is viewed to lack a consistent vision of their role within patient care and ineffective communication strategies for sharing best practice, service objectives and outcomes (Nazar and Nazar, 2019).

A paper considering commissioner views of health checks within community pharmacy highlighted a lack of awareness of the wider role and responsibilities of community pharmacy (Firth, Todd and Bambra, 2015). Commissioners were found to be knowledgeable only within their sphere of commissioning (e.g. smoking cessation) and lacked both awareness and sensitivity to potential barriers and competing interests of community pharmacy (Firth, Todd and Bambra, 2015).

Despite commissioners designing and commissioning services in line with local priorities, there has not been found to be strong positive (or negative) correlations between community pharmacy service contracting and the likely population measures (Mackridge, Gray and Krska, 2017). For example, in the financial year 2014/15, 14 local authorities did not commission a community pharmacy smoking cessation service, yet seven had smoking rates above the national average (Mackridge, Gray and Krska, 2017). Similarly, of the 30 areas with the highest cardiovascular mortality rates, only six commissioned community pharmacies to provide NHS Health Checks, whereas 14 of the 30 local authorities with the lowest rates commissioned the service (Mackridge, Gray and Krska, 2017).

Even if commissioned, the proportion of community pharmacies contracted to provide the service within an area varies from 2% to 100% - adding further complexity (Mackridge, Gray and Krska, 2017). There does not appear to be a national trend to commissioning patterns, whether it be reflecting local population needs or recognising consistent areas of potential for community pharmacy to engage with. It is possible that the effectiveness of local representation (e.g., Local Pharmaceutical Committees) and existing relationships play a role in determined what is commissioned. However, this has not been explored in published literature.

This finding, that commissioning does not reflect local population health needs does not match the expectations of organisations such as the World Health Organization (WHO) who recognise that community pharmacy, due to its accessibility, could play a key role in public health initiatives (Todd *et al.*, 2014). This is particularly relevant in England, where community pharmacy exhibits a ‘positive pharmacy care law’. This is where the number of community pharmacies (and therefore access to) is greater in areas of higher deprivation (Todd *et al.*, 2014). Indeed this correlation and the ubiquitous nature of community pharmacy (approximately 90% of the population are estimated to be within a 20 minute walk of a community pharmacy) would suggest services would naturally be commissioned in community pharmacy to match local health needs (Todd A *et al.*, 2014). In areas of highest deprivation where local health outcomes are likely to be poorer, access to community pharmacy increases to almost 100% within a 20 minute walk (Todd *et al.*, 2014). Furthermore, evidence relating to the provision of influenza vaccination has demonstrated that those in higher deprivation areas are more likely to access community pharmacy services (compared to lower deprivation areas) directly targeting health inequalities (Kirkdale *et al.*, 2017).

Emergency contraception, smoking cessation support, and supervised consumption services were commissioned by at least 90% of local authorities, provided by at least 47% of all community pharmacies (Mackridge, Gray and Krska, 2017). Despite this widespread perceived consistency of delivery (allowing for variation of contracting with local authorities), Mackridge *et al.* (2017) did not find strong correlations to local population health data (Mackridge, Gray and Krska, 2017). However, what is missing from this analysis is acknowledgement of the variation inherent in local commissioning. For example, emergency contraception services often operate through the use of Patient Group Directives (PGDs). These PGDs define both the therapeutic options and the scope of practice, dramatically impacting community pharmacy's ability to influence local health outcomes. What is not considered is whether a restricted service (in terms of therapeutic options) has a measurable effect on the desired outcomes of the service.

Whilst likely to be a negligible effect across a local authority, with numerous community pharmacy providers, there is also likely to be variation in provision rates between community pharmacies. The examined correlations do not adjust for varied levels of provision between community pharmacies. The correlation between pharmacies commissioned and local health outcomes may, although unlikely, be completely negated by varied provision. Those areas with 'positive' health outcomes and a commissioned service may have high performing community pharmacies, compared with other areas with poorly performing community pharmacies. What is not clear from the wider literature is what factors may impact community pharmacy service performance, beyond generic pharmacist opinion and team skill mix.

Another factor, not considered by the authors, is the confounding effect of alternative providers. Many local authorities have a range of service providers, and general practice often provides care in a wide range of therapeutic arenas in line with their patient list remuneration model (Aly *et al.*, 2018; Mackridge, Gray and Krska, 2017). It is entirely possible that highly developed and embedded services outside of community pharmacy provide reasons for the commissioning or lack of commissioning of community pharmacy services.

4.6.3 Inner Setting

The inner setting incorporates influences within the intervention setting. In this case, this means the culture of the organisation, the communication methods available both formal and informal, and the type of organisation including its age, maturity, and size.

Within community pharmacy the varied nature of employment and business ownership adds a further dimension to financial incentive. Business owners (such as in independent pharmacies) are likely to be both professionals providing the service and direct beneficiaries of income. However, larger chain pharmacies are more likely to have complex salary and internal incentive structures which may not align with individual local service delivery. One source highlighted policy barriers within large companies (e.g., restrictions to necessary IT software) inhibiting commissioning (McNaughton *et al.*, 2011).

A comprehensive mixed method study considered the organisation factors associated with variation in clinical productivity in community pharmacies (Jacobs *et al.*, 2017). The report identifies the need for commissioners to "*gain an understanding of the relationship between quantity and quality of service provision as key elements of clinical productivity"* (Jacobs *et al.*, 2017). This is due to a need to safeguard the public purse, through prudent use of NHS funds and the expectation that commissioners provide oversight of service provision. The report identifies the dissolution of Primary Care Trusts (PCTs) within England and the subsequent move to CCG commissioning as a key factor in the loss of organisational memory (Jacobs *et al.*, 2017).

The study analysed the findings of a commissioners workshop in an attempt to develop a toolkit to inform commissioning processes, to improve clinical productivity within community pharmacy (Jacobs *et al.*, 2017). One avenue considered was how the skill mix within a community pharmacy influences the service outcomes. It was felt that pressures on a pharmacist's time, that could be alleviated by more efficient team skill mix, could allow for higher productivity and therefore better outcomes for the commissioned service. A suggestion was made that the length of commissioning may influence a pharmacy business' ability to adapt their workforce to meet the requirements of the service. The need to involve stakeholders in the development of the design of services was suggested as a key metric to good performance. Specific examples included the pharmacy providers, the LPC and other healthcare providers (Jacobs *et al.*, 2017). Funding was also identified as a potential influence on service delivery, not as an incentive to provide higher activity levels, but as an enabler to invest in the business to provide services (Jacobs *et al.*, 2017).

Interviews with commissioners demonstrated concerns about staffing levels and staff turnover affecting the quality of service provided or the reliability and consistency (Jacobs *et al.*, 2017). However, it was not suggested that these concerns would influence the commissioning process, but rather accepted as an unassailable challenge of the environment. Commissioners expressed the view that increased prescription volume was a major barrier to service uptake and clinical productivity. Although both MUR and NMS volume were found to positively correlate to dispensing volume, but multivariate analysis found the relationships to be non-significant. The findings of the report suggest that whilst commissioners may view prescription volume (and therefore workload) as a barrier to delivery, the evidence is that this is not the case. Rather, organisational structure (large multiple, supermarket, independent pharmacy) has the strongest association with service provision (Jacobs *et al.*, 2017).

4.6.4 Characteristics of individuals

This construct recognises that any intervention is “rooted in the individuals” themselves (CFIR Research Team-Center for Clinical Managment Research, 2021). This reflects both individuals’ knowledge and beliefs, their perception of the organisation, and other personal attributes (such as competence, motivation, and capacity).

Successful service commissioning was linked to individual beliefs in the service and the benefits it brings. Pharmacy team members recognised that the training associated with a service brought wider benefits to the team in terms of career development (Firth, Todd and Bambra, 2015). It was also reported that commissioning of one service, has impact on other services. For instance commissioning of health checks increases the provision of smoking cessation services, suggesting that one commissioned service may correlate to other service activity or commissioning (Firth, Todd and Bambra, 2015).

Qualitative interviews with commissioners raised concerns about individual knowledge and reliability. Frequent turn-over of staff and continuity of care was cited as a factor influencing successful service provision, and accordingly shaping commissioning intentions (Jacobs *et al.*, 2020). This was associated with larger organisations, noting contracts are upheld due to ‘organisational memory’ but pharmacy services often did not benefit from this – relying heavily on individual pharmacists. Therefore, when the original pharmacist moved, the service was no longer available (Jacobs *et al.*, 2020). Commissioners also reported concerns about the level of training and competence available within community pharmacy – with many of the skills that are commonplace with general practice being the sole reserve of the pharmacist in a pharmacy team (McNaughton *et al.*, 2011). In one example specific additional training was provided for the pharmacy team, but this was reported by commissioners as a barrier to commissioning – given the greater set up needs.

4.6.5 Process

Process is described as the most difficult to “define, measure or evaluate” (CFIR Research Team-Center for Clinical Managment Research, 2021). This construct considers planning, engaging, executing, and reflecting and evaluating. It attempts to determine why interventions succeed or fail (rather than determining if it worked) (CFIR Research Team-

Center for Clinical Managment Research, 2021). This section is designed to closely reflect the PDSA cycle developed by the Institute for Healthcare Improvement. This quality improvement plan has four components acting as a cycle of learning and development: Plan, Do, Study (reflect and evaluate) and Act (adjust and/or execute) (Institute for Healthcare Improvement, 2003).

The process construct highlights the importance of opinion leaders (CFIR Research Team-Center for Clinical Managment Research, 2021). Interviews with pharmacists, commissioners, and local representatives highlighted a lack of coherent vision in pharmacy, as well as a lack of "collective awareness" of key service objectives and the political agenda(s) underpinning them (Nazar and Nazar, 2019). This lack of awareness resulted in behaviours contrary to service aims (for example diverting patients from purchasing medicines privately to NHS services), which was found to have a detrimental impact on commissioner perceptions of pharmacy (Nazar and Nazar, 2019). It may be the case that commissioner perception is adversely swayed by the lack of demonstratable pharmacy leadership.

4.7 Outputs from the systematic review

The systematic literature review has described many influences on the commissioning of local community pharmacy services. The results have not identified a single influencer. No routine data points were highlighted in relation to commissioning decisions, with some interviewed commissioners reporting policy rather than data guided commissioning decisions. Furthermore, evidence discussed that the location of the pharmacy is important, both in terms of commissioning intention and patient need. Linked to this is the interplay between national and local priorities, and assertions that commissioning drives professional and business behaviours and actions.

There were two sources in this literature review that were particularly relevant for their impact on the research: Mackridge *et al.* (2017) and Jacobs *et al.* (2017). Both were described in some detail earlier in the chapter.

The Mackridge *et al.* (2017) paper provided two things, an approach to data collection and analysis through the use of Freedom of Information requests, and an assessment of local community pharmacy service provision (Mackridge, Gray and Krska, 2017). It was determined that commissioning of public health services does not match health outcomes. This considers community pharmacy service provision in isolation, and as highlighted in the review, patient care is interwoven – meaning it is difficult to assess patient outcomes by reviewing one intervention (Shaw *et al.*, 2016). Arguably, given many (perhaps most) community pharmacy services are commissioned in addition to existing care they can only be considered in terms of their ability to increase provision, increase access, or move patients from one setting to another. If there is another viable option for patient care, then in the absence of community pharmacy provision, presumably the patient will access the alternative source. Whilst this does not negate the findings of Mackridge *et al.* (2017) it is importance context and attempting to quantify any increase in care or shift in patient behaviours is useful.

The second source, Jacobs *et al.* (2017) sets out many influences of both commissioning and service provision. Focussing on national service provision and local commissioning, Jacobs *et al.* (2017) highlight several factors influencing successful service provision. Focussing on individual pharmacies and pharmacy teams, Jacobs *et al.* (2017) use ‘clinical productivity’ to determine the output from teams (Jacobs *et al.*, 2017). From this work we can conclude that there are influences on individual pharmacies that may influence commissioning decisions and outcomes.

These two papers lead to two ways of approaching the same question. Community pharmacy commissioning can be considered from a ‘health system’ view, or from an individual pharmacy level of analysis.

Unless a service is commissioned for patient care unmet elsewhere (i.e., truly novel therapy) then it can be assumed patients already receive this care from another location. There are many different local services within community pharmacy, as detailed in the introduction (page 7) there 68 different types of clinical service across the country (PSNC, 2019). None of these are for novel therapy. The assumption that community pharmacy services are mainly intended to target patient groups or move patient pathways therefore seems sound.

EHC has been advanced as a prime example of a commissioned service that replicates care elsewhere for the prime purpose of moving workload within a health system. Comparing multiple services directly, with their different commissioners, outcomes, and populations is unlikely to facilitate analysis. Supervised consumption for example is restricted to a small patient group who are opiate-dependent drug users (usually). Conversely, minor ailments services are open to any patient suffering a variable list of minor conditions – determined by commissioners locally.

It is hoped that principles from this research may lead to principles of measuring successful service provision, which may influence future commissioning decisions. Accordingly, there is a need for a service that is both widespread, but also easily comparable – with generalisable results. Emergency Hormonal Contraception is commissioned in 144 (97%) of local authorities (Mackridge, Gray and Krska, 2017). As highlighted in *Figure 3* emergency contraception is available from several sources, including community pharmacy. Crucially, there are limited treatment options making comparisons much more feasible. Accordingly, EHC remains the focus of this thesis.

4.8 Summary

So far literature has been explored to determine if there are universally accepted measures to describe commissioning outcomes, ideally through data. A review of the literature and policy surrounding EHC has shown it to be successful for individual patients (i.e., it is an accepted way of receiving the treatment desired). Following this a systematic review was undertaken to determine what influences there are of service provision, and how these are (or could be) measured.

Whilst there are many factors influencing individual pharmacy service provision, there is limited evidence on criteria for success. The most significant evidence suggests community pharmacy services have limited impact on the proposed prime outcome metric – local population health.

If it can be assumed that the primary purpose (or benefit) of community pharmacy services is to target patient groups or move workloads – there is little evidence of measuring this in the literature. This sort of evidence may not appear in peer-reviewed literature due to the nature of the subject matter likely of interest to researchers and academic publications. This presents a gap in the evidence. What routine data can yield insights into commissioning decisions and provision?

Lloyd and Gale (2005) began answering this question when reviewing the introduction of an EHC service, and monitoring EHC provision from alternate sources (Lloyd and Gale, 2005). This study was however limited in both scope and the ability to reproduce it (since it evaluated the launch of a new service). It also relied on data not easily accessible to external research.

What data may be available and useful to consider? Mackridge *et al*. (2017) provide some answers through their use of FOIs. The literature has presented several possible predictors of commissioned service activity (especially regarding EHC). It has also suggested possible data sources, including FOIs, national databases, and direct pharmacy intervention (questionnaires etc.).

From these possible data points, a method was developed that analysed routinely collected data to achieve the aim of determining what influences EHC service commissioning and provision. The two primary sources Mackridge *et al.* (2017) and Jacobs *et al.* (2017) led to the separate objectives – focusing on Local Authorities and individual pharmacies.

Chapter 5: Methodology

5.1 Introduction

The problem being addressed in this research is an apparent lack of a data-driven method to influence commissioning decisions and predict the subsequent outcome of commissioned community pharmacy services. EHC has been selected as a prime example of where this is useful, as the available evidence shows no significant correlation between service commissioning and health outcomes.

There are two approaches being taken, firstly considering the wholistic service impact on the health system. This is being done by considering a local authority unit of analysis, quantifying the influence community pharmacy services have on comparable patient pathways – specifically GP care.

The second considers some of the factors that may influence individual pharmacy activity. These may form part of the consideration when determining the success of a service and how to influence this. This chapter details the approach taken to answer these questions

5.2 Determining the approach to research

Prior to my DPharm I had undertaken an MSc, focussing on Medicines Use Reviews and their relationship to local population health. I found this approach of using secondary data particularly satisfying, re-enforcing my own preference for the use of data. This is described as a "ontological positivist approach" and is quite different to many examples of pharmacy research that often use a more qualitative approach (Tuli, 2010). It is interesting that whilst pharmacy is arguably a traditionally pure physical science, much of my interest rests in pharmacy practice which could easily be described as a social science. Social sciences are historically split between quantitative and qualitative approaches, broadly creating two epistemological positions – positivism and interpretivism (Tuli, 2010). Epistemology can be considered as a reflection on a view of how knowledge can be gained, literally "a theory of knowledge" (Lowndes and Stoker, 2018).

Specifically, positivism views social sciences as an "organised method for combining deductive logic with precise empirical observations … to predict general patterns of human behaviour" (Tuli, 2010). Positivism recognises the need for a theoretical framework, but then tests these against data (Fox, 2008). This approach rejects non-observable knowledge, but also aims to create an objective approximation of reality (Fox, 2008; Tuli, 2010). In this way facts are positioned in front of the reader, with conclusions creating general laws (Corry, Porter and McKenna, 2019).

Despite arguable advantages of this approach, positivism has been criticised for failing to recognise various sources of understanding (e.g., qualitative data), as well as ignoring context (Fox, 2008). When attempting to understand EHC service provision, or patient behaviours it is easy to see how a failure to consider context is disadvantageous. For example, the literature review explored many varied aspects influencing behaviours including social stigma, and professional or public perceptions of EHC (Murphy and Pooke, 2019; Hassell, Rogers and Noyce, 2000).

This alternate view of knowledge can be considered as an interpretivist-constructivist perspective (Tuli, 2010). This approach endeavours to understand a particular phenomenon (often from a view point), rather than generalise to a population (Tuli, 2010). This could easily be argued to create a deeper understanding of the research object. The difference is either cause and effect (positivist) or social interaction creating patterns (interpretive) (Tuli, 2010).

Some authors argue that positivism itself is a flawed or out-dated approach, with a post-positivism being more relevant to modern research – particularly within professional research (Corry, Porter and McKenna, 2019). This stems from three main arguments.

First, the 'Kantian challenge', that things and what appears to our senses are distinguishable – therefore as we can only know what our senses tell us, the objective world is unknowable (Corry, Porter and McKenna, 2019). Second, the 'Marxian challenge', that social science is rooted in political views and actions, meaning things cannot be objectively described without considering political viewpoints. This has subsequently expanded to include all forms of inequality, which in turn influence views and interpretations (Corry, Porter and McKenna, 2019). There appears to be some overlap in this case with a transformative methodology which using a strong ethical focus to identify and action change (Kara, 2017).

The final argument is the 'Durkheimian challenge' which latterly developed into critical realism. Positivism as stated before, holds that scientific methods (observation, measurement etc.) can describe the dynamics of society in the same manner as physical science (Kara, 2017). In this way there is an effective causal relationship, described through ‘constant conjunctions’ - where an event and consistently and immediately after another. Critical realism holds that even where this relationship is beyond doubt, there are *always* multiple mechanisms at play in any open system. This means that social structures and human agents cannot be combined and must be acknowledged separately. This often lends itself to a mixed methods approach, using people’s understanding and motivations to explain the observed relationships (Corry, Porter and McKenna, 2019).

Post-positivism is a broader way of considering knowledge, joining theory and practice. In this way facts are acknowledged to be collected, presented, and interpreted through a researchers understanding of the world and assumptions about knowledge (Ryan, 2008). Attempting to apply this approach means acknowledging your own epistemology and underlying assumptions made about day-to-day life. This approach attempts to recognise the complexity of any experience or finding, but still acknowledge objective truth (Ryan, 2008).

Within the context of community pharmacy services and commissioning it is entirely feasible to imagine both positions being equally valid. Indeed, a value/perception based, interpretivist approach would be valid given the strong impact of individuals (Kara, 2017). Locally commissioned services such as EHC, are managed in line with local priorities, beliefs, and values. Commissioners work with internally derived frameworks and guidance. By the nature of the subject, and by political system, the views and values of commissioners, and the perspective of the individuals involved will shape outcomes. This element of subjective commissioning and service provision has been extensively explored in the literature. Jacobs *et al.* (2016) is one example of a comprehensive investigation into the values underpinning commissioning decisions (Jacobs *et al.*, 2016).

Given the existing literature with a post-positivist approach, a gap for a purely positivist study was identified. Much of the literature identified is qualitative in nature, often recognising structures or political systems that shape views and actions. For example Jacobs *et al*. (2017) used interviews with commissioners to explore approaches to commissioning (Jacobs *et al.*, 2017). A similar approach could have been taken here, interviewing commissioners to understand how data informs decisions made. Alternatively, questionnaires to commissioners or policy leads could elicit information on the influences on EHC commissioning.

There are limited examples of data-driven attempts to predict the commissioning of a service or determine and describe the factors influencing outcomes. For this reason (as well as a personal inherent preference for a positivist view) a decision was made approach this study in this manner. With this approach there are several quantitative approaches. A key decision is collecting primary or secondary data. Primary data collection such as through a prospective cohort was considered. This could have compared two different Local Authority areas, one with and one without a commissioned community pharmacy EHC service. However, there was a desire that the analysis undertaken was easily repeatable, and for that reason routinely-collected secondary data were chosen.

5.3 Collecting and using secondary data

As explored earlier, this research aims to quantify the factors influencing EHC provision in community pharmacy. The policy review (page 18) sets out examples of qualitative research into EHC provision, often focusing on patient choice or underpinning social reasons influencing behaviour. Questionnaires have been commonly used to determine views and opinions (as well as social stigma) from both patients, potential patients (i.e., a selection of the public), as well as healthcare professionals. It is evident from much of the literature that a constructivist approach has been taken with reality determined by the perceptions of groups.

Indeed, work by Jacobs *et al.* (2017), which was influential in the development of the aims and objectives, used this approach with commissioners. It could be argued that the analysis of national service design incorporated an element of pragmatism, joining both a created reality and an attempt to understand the truth.

A combination of previous professional experience, and an identified gap in the literature led to a positivist approach being taken here. Policy decisions, and arguably commissioning, is in theory ‘based on evidence’. What is lacking is an understanding of the practical factors influencing community pharmacy provision.

Designing and conducting analyses (particularly of secondary data) require the application of a sound theoretical framework (Faryadi, 2019). What is needed is an application of practical knowledge of the subject, as well as an understanding of what can be measured.

Using secondary data tackles some uncertainty around data collection – as this is already collected. Obviously, the greatest advantage to secondary data collection is the reduced cost and convenience (versus primary data collection) (Johnston, 2014). It also allows larger samples, that are more representative and generalisable. Additionally, the increasing availability of large data sets equalises opportunities, by decreasing the cost of research making it more accessible (Johnston, 2014).

The greatest limitation to secondary data collection is that the data were collected for an alternate purpose. Often data sources do not allow for follow-up, or bespoke queries – meaning care is needed in determining the research question and choosing the source of secondary data (Johnston, 2014). The second disadvantage is uncertainty is the data quality. As the researcher was not involved at any stage in data collection, then there are no sureties that the data are complete, nor accurate (Johnston, 2014).

Theoretically there are two approaches to using secondary data – "research question-driven" (where data is found to answer a question), or "data-driven (where data informs what questions can be asked) (Cheng and Phillips, 2014). In reality, there often is no such a separation, with the two approaches being used jointly. What is important is an understanding of the strengths and weaknesses of the data set, as well as a complete understanding of the source and rationale for original collection (Cheng and Phillips, 2014).

A key piece of literature in developing the methods used in this research was work by Mackridge *et al.* (2017) who used Freedom of Information (FOI) requests to obtain data

(Mackridge, Gray and Krska, 2017). FOI requests are regularly used by investigative journalists to produce news reports, finding great value in their ability to uncover "dirty data" that governments and others prefer to keep hidden (Walby and Larsen, 2011). There is however, a growing trend of using FOI requests to obtain the vast data collected by various authorities, for the purpose of social science research (Walby and Larsen, 2011).

The advantage of FOI requests is the high success rate in obtaining data. If the 'public authority' holds the information requested, they are lawfully obliged to provide that information (Savage and Hyde, 2014). Crucially, 'public authority' is an intentionally widely defined term allowing most of public activity to be interrogated. This includes government departments, regulatory and executive agencies, public bodies, and NHS organisations (Savage and Hyde, 2014). There are of course some exemptions to the obligation to provide data requested by FOIs, and these include: likelihood of causing harm, 'vexatious' requests, requests for identifiable information, or where requests impact on criminal proceedings or national security (Lee, 2007). Since the initial introduction of the law allowing FOI requests, another check has been added on the likely cost of processing the requests. FOI requests are free up to a nominal value (staff time etc.) of £600 for central government or £450 for other authorities. Above this value the request can be refused or is chargeable (Lee, 2007). The agreed fee is £25 per hour for staff time spent processing these requests, so in most cases requests predicted to take longer than 24 or 18 hours respectively, are refused (Savage and Hyde, 2014).

Savage and Hyde provide some useful insight into ensuring that FOI requests are successful including the need for specific and focussed questions (Savage and Hyde, 2014; Walby and Larsen, 2011). In particular, the phrasing used is critical with different organisations potentially referring to the same thing by different terms (Walby and Larsen, 2011). When approaching numerous entities (for example Local Authorities across England) there is value in trailing the question to determine if the data provided meets the researcher's needs. This can be done by sending the question to a small number of destinations (e.g., only some of the Local Authorities in England) to determine likely responses. They also note an element of caution, that data sources often contain identifiable information. Whilst the 'public authority' have a responsibility to strip out identifiable data, mistakes can happen – risking inappropriate data collection (or collection being outside of favourable ethical opinions) (Savage and Hyde, 2014).

FOI requests can be used to determine collected information, perhaps to inform a specific research question or approach. They can provide initial data supplanted by follow requests, such as questionnaires. Alternatively, they can be used to describe phenomena, providing the data is available and there is understanding of its completeness and how (and why) it was collected (Savage and Hyde, 2014).

5.4 Managing bias and analysis with secondary data

FOI requests (and more broadly secondary data collection) is particularly susceptible to two primary forms of bias: confirmation bias and hindsight bias (Baldwin *et al.*, 2020). FOI requests can often lead to large data sets, which allow multiple statistical approaches.

Accordingly, it is much easier to apply statistical methods until the results meet the pre-held assumptions of the researcher – hence confirmation bias. Conversely, hindsight bias is attempting to assume knowledge once data are available. Hindsight bias can also be described as HARK-ing, which is a practice of selectively reporting statistically significant results and Hypothesising After the Results are Known (Baldwin *et al.*, 2020).

Several solutions are proposed to minimise these chances of bias. One option is to apply all practical statistical tests to a dataset and report them all, being open about the results. This is akin to a sensitivity analysis, and is referred to as a multiverse analysis (Baldwin *et al.*, 2020). An alternate approach is to split data files, allowing experimentation on a sub-set of the data, before applying one statistical approach to the remainder. This process is analogous to cross-validation in machine learning (Baldwin *et al.*, 2020). Another key suggestion is to pre-register a decision tree, the research questions, and conditions for interpreting results.

Further details will be provided in the next chapter, detailing the methods. However specifically regarding bias, the FOI questions were set out and the proposed analytical approach was presented during the progression viva. Both were debated and reviewed, before data collection was begun. Whilst not formal publication, the research questions and proposed statistical methods were 'pre-declared' to tackle confirmation bias. Similarly in response to HARK-ing, the hypothesis was presented before data collection and all analysis is presented in the results.

A further source of bias is selection bias or time-lag bias (Bevan *et al.*, 2013). Depending on the data being analysed there may be a gap between data collection, and review. This can be compounded by uncertain measurement / data collection processes by person(s) unknown. Within EHC provision, it was expected that there would be an element of seasonal variation. However, the data is collected for the purposes of payment (with checks in place for errors) which likely increases the chance of accuracy.

5.5 How the chosen methodology supports the aims and objectives

This thesis aimed to determine what influences EHC service commissioning and provision through routinely collected data.

There is little published evidence that community pharmacy EHC commissioning directly correlates to patient need. A key outcome often referenced is under-18 pregnancy rates, but neither the levels of provision, nor the commissioning of services correlate to this (Mackridge, Gray and Krska, 2017). It may be that community pharmacy EHC services have no impact on teenage pregnancy rates because of solutions and confounders created in the locality. For instance, where there is no community pharmacy EHC service commissioned, women will access care from GPs (or other services) so there will be minimal impact on population outcomes. What is not fully understood, is the impact community pharmacy service provision has on patient behaviours i.e., route to treatment and the associated impact on other health care providers. For this reason, health outcomes are not being captured in this thesis.

The research takes a quantitative approach to identifying data and potential processes underpinning commissioning decisions. Consideration of the literature and possible methodologies has led to a method relying on FOI requests. Despite some recognition outside healthcare, there are few examples of their use in community pharmacy. Therefore, to determine the available data (and its value in addressing the aims) a feasibility study was undertaken.

The feasibility study tested whether it was possible to access the data needed and the nature of the data obtainable through secondary data from FOIs. This was used to describe the nature of the relationship between community pharmacy and GP EHC provision rates. Data of prescribing rates from GP surgeries and EHC provision rates from community pharmacy commissioned services were sourced through a combination of Freedom of Information (FOI) requests and publicly available data. The data were also used to test potential variables, for inclusion in later analysis.

Reviewing the literature (page 83) indicated several data that likely influence EHC service commissioning and provision. These include environmental factors, such as deprivation. Other community pharmacy unique factors included organisational (pharmacy business type), or contractual (what pharmacies are commissioned for) aspects that may influence their EHC activity.

One objective of this research was to determine if community pharmacy services influence GP EHC prescribing, infer possible relationships impacting patient access to EHC treatment, and identify factors that may influence this. Highlighted earlier (page 27) was the impact the availability of LNG-EC for purchase had on Accident and Emergency departments (Marston, Meltzer and Majeed, 2005). It is theorised that there is a similar impact on patient journeys with locally commissioned services. Lloyd and Gale (2005) have shown that this relationship may be present, but not shown this outside a single geographical area (Lloyd and Gale, 2005).

An objective of this thesis is to quantify the impact of commissioned community pharmacy services on GP EHC prescribing rates. Understanding the impact a commissioned service could have, will be important to guide commissioning decisions. This is particularly relevant if alternate service providers (GP, A&E, etc.) confound any relationship between community pharmacy services and health outcomes.

The objectives (page 44) show the two different units of analysis used. Specifically, analysis of local authority data, and individual pharmacy data. This led to two different sections to the research. Once complete, the value of this analysis was considered within the role of commissioning. Identifying and quantifying relationships may allow commissioners to identify influences and make predictions of the impact of changes on local services, through commissioning decisions, will have.

5.6 Summary

This chapter has set out a methodological approach, whilst considering alternate options. There is a paucity of literature exploring quantitative influences on community pharmacy

EHC commissioning and service provision. Accordingly, this research aimed to use data to explain broad human behaviours, rather than consider individual patient viewpoints.

To support and facilitate a large dataset, FOI requests were used to collect a secondary dataset. This presented some particular forms of bias, which have been discussed in this chapter. Furthermore, there were practical considerations to approaching data collection, to ensure quality data. FOI requests were proposed as the source of the data, and the literature provided helpful insight into phrasing the request and the subsequent analysis. The next chapter details the feasibility study. As suggested in the literature, testing the FOI request on a sub-set of the eventual study population is helpful for finessing the actual request, as well as ensuring the data are available (Savage and Hyde, 2014). The feasibility study served to test the methodology, as well as determine the validity of the data available.

Chapter 6: Methods

6.1 Introduction

The methodology set out the approach to data collection and analysis, and how these supports achieving the aims and objectives. This chapter describes the feasibility study, the full analysis of all data and the path analysis, followed by the commissioning modelling undertaken.

The feasibility study explored the validity of FOIs in obtaining community pharmacy data and the quality of the data returned. The data allowed for comparisons between different healthcare settings, as well as identifying some likely data-points for developing the model.

The FOI requests throughout this thesis were used to obtain information on the number of EHC provisions made by community pharmacies. All other data were available through publically accessible sources. The only data not presented in this way were community pharmacy public health service provision (i.e., EHC provision), which is why FOI requests were needed.

The feasibility study demonstrated FOI requests remain a credible source of data and can be used to collect data for this research. Following the feasibility study the methods were refined to better reflect the available data. For the main study there were two distinct parts:

1. Analysis of local authority data relating to Emergency Hormonal Contraception
2. Analysis of individual pharmacy data relating to Emergency Hormonal Contraception

There were two separate analyses with different units of analysis. The methods chapter is separated into parts reflecting this. The first part considers the data comparing local authorities, the second individual community pharmacies.

Following the analysis of the data, an exercise in commissioning modelling was undertaken. This attempted to explore how the findings might be applied to real world examples and commissioning decisions.

6.2 Feasibility study

The feasibility study intended to determine the viability of the chosen methodology, in relation to data collection and subsequently determining the quality of provided data. Literature, such as a study by Mackridge *et al*. (2017), suggest that FOIs will provide the data needed for analysis (Mackridge, Gray and Krska, 2017). Despite this, there are limited examples in the literature of community pharmacy local service information being obtained through FOI requests, justifying the need to check the feasibility of this method. Similarly, the literature provides no clarity on the quality of the data obtained through this route, so determining this will also inform the expected level of possible analysis.

Using the collected data, the feasibility study needed to establish:

- Whether it is possible, from FOI data, to calculate the rate of community pharmacy EHC provision, aggregated to Local Authority.
- The quality of the data provided by FOI requests.
- If the collected data allowed calculation of the correlation (at a local authority level of analysis) between GP prescribing rates of EHC treatment and:
    - Rates of community pharmacy EHC provision levels (aggregated to local authorities) and,
    - The activity of community pharmacy providers of EHC services in a local authority area.

Finally, if the data was of sufficient quality, the analysis attempted to determine the variability (in terms of service requirements) between commissioned community pharmacy services. This would allow identification of possible covariates. The analysis during the feasibility study explored various factors through the analysis, to find the most useful variables to include in the main analysis.

6.2.1 Research design - Rationale

One of the objectives (page 44) is to determine the corelation between community pharmacy EHC supply and GP EHC supply. Understanding whether this is possible with the expected FOI data was a key output of the feasibility study. As explained in the introduction (page 11) some community pharmacies supply EHC through Local Authority commissioned sexual health services, the specifics of which vary across different Local Authority areas.

The policy review (page 18, chapter 2) explored some of the many factors that impact an individuals' decision to access EHC services. Some of these factors are subjective to the individual, such as personal beliefs, moral concerns or fear of side effects (Free, Lee and Ogden, 2002). Other factors may be due to access to EHC or the available setting (i.e., the type of service location – A&E, GP surgery, community pharmacy).

The literature set out a conflicting rationale for patient choice of setting. Lloyd and Gale (2005) reviewed the impact of a newly commissioned EHC service within North Yorkshire (Lloyd and Gale, 2005). This research found that introducing a community pharmacy EHC service decreased GP prescribing rates, whilst maintaining rates at Family Planning Clinics and A&E (Lloyd and Gale, 2005). This feasibility study considers only GP and community pharmacy settings, without the context of the other settings.

6.2.2 Research design – Approach

Individual patient follow up, through questionnaires or unique tracking of patient journeys may allow more certainty about the outcomes experienced by patients, rather than relying on proxy measures of EHC access and treatment through EHC prescription/supply figures. This would also allow a better understanding of the rationale behind the decision-making process that determines the route of treatment. However, as detailed in the policy review (page 18, chapter 2), research has already been conducted examining patients' opinions to accessing EHC through different settings, as well as various healthcare professionals' opinions of provision (Black *et al.*, 2008; Gidman, Ward and McGregor, 2012; Seston *et al.*, 2007; Bissell and Anderson, 2003; Ellertson *et al.*, 2000; Lloyd and Gale, 2005). There is also evidence detailing changing public perceptions and reactions to different clinical settings of EHC (Black *et al.*, 2008; Gidman, Ward and McGregor, 2012; Seston *et al.*, 2007; Bissell and Anderson, 2003).

Collecting individual patient data from all Local Authorities (through purposive sampling or otherwise) could support generalisable conclusions. However, aside from practicalities of time and resource limiting this approach, sample recruitment bias and response bias are likely to impact results. Many individuals experience some level of embarrassment when discussing sex and contraception. Cultural differences to contraception and the common practice of anonymising many sexual health interactions increases the likelihood of these forms of bias. Collecting all data from a population, without sampling, reduces the impact of these bias.

This presents two possible strategies to determine the relationship between community pharmacy and GP provision: individual patient analysis or population analysis. There is a wealth of literature exploring individual patient behaviours, attitudes, and interactions with sexual health services. Other than the single study from 2005 (Lloyd and Gale, 2005) the literature review has not found a population level analysis of how women access community pharmacy EHC services and how this impacts GP workloads. Accordingly, it was determined to explore a population level of analysis.

Different types of observational studies allow for epidemiological investigation – measurement of a population (rather than an individual) (Coggon, Rose and Barker, 2008). A common feature of epidemiological research is gaining data from published statistics and therefore preventing the need for expensive or time consuming data collection (Coggon, Rose and Barker, 2008).

An observational geographical comparison study will allow an understanding of the relationship between community pharmacy EHC provision and GP EHC prescribing. Previous literature has shown that community pharmacy provision varies between local authority boundary areas (Mackridge, Gray and Krska, 2017).

6.2.3 Research design – Determining data sources

The literature has revealed many examples of data sets related to patient perceptions, barriers to accessing EHC, and factors influencing commissioner decisions. Large data sets can be obtained from questionnaires, allowing comparison between areas. One challenge is ensuring consistency of *definition* across geographies.

For example, the Health Behaviour in School-Aged Children Survey is conducted in 49 countries across Europe and North America (Roberts *et al.*, 2007). The National Latino and Asian American Study is conducted in the United States and Hawaii (Alegría and Takeuchi, 2006). Both studies explore topics routinely investigated and recorded locally. However, the definition of the subject matter varies, particularly between different countries. For example, there are different markers of poverty that can be recorded in different ways. The primary data is not comparable due to these different definitions. Using a single data collection method independently (and externally) described allows comparison across boundaries.

This is not the case for Local Authority data collected across England. Population data is collected across the country, by one organisation at a single point in time (NHS Digital, 2019c; Office for National Statistics, 2017c). EHC provision is determined from the supply or prescribing of two medicines. There is no interpretation needed and therefore no variation in definitions. Accordingly, direct comparison can be drawn without fear of collection bias. This lack of variation meant pre-collected data could be used and questionnaires were not deemed necessary to collect data.

Previous literature has considered how independent variables influence a dependent variable across diverse geographical areas, for instance comparing differences in legislation in different countries and the impact on illicit substance behaviours. One study considered the impact of alcohol and cannabis legislation and its influence on drinking, cannabis prevalence, and the associated relative risks (Simons-Morton *et al.*, 2010). Despite the difficulty in establishing a causal link, the degree of correlation was determined. There was a strong correlation between reduced alcohol use and legislation, and a weak correlation between cannabis use and legislation. This allowed the authors to draw conclusions about the possible impact of legislation. They concluded strong legislation was consistent with reduced alcohol use but was not consistent with high or low levels of cannabis use.

Similar work used predictive logistic regression to determine the correlation between cannabis use and its impact on clinically-significant side effects in different countries (Fiestas *et al.*, 2010). Epidemiological studies such as these, compare population-wide measures, such as total drug use in different settings. From this data predictions can be drawn about how these variables are likely to affect the dependent variable and relationships can be inferred. This approach was replicated here. The primary difference in this study is that the collected data is from a single country. The unit of analysis is smaller, which may change the possible conclusions and the ability to generalise the results outside of England.

6.2.4 Sampling and inclusion/exclusion criteria

The sample was all Local Authorities in the North-west of England. The reason for this was that the nature of the study (to determine feasibility) warranted a smaller scale data collection to provide justification of further investigation. This pilot approach to understand the data available via the chosen data collection method was limited to the North-west due to existing knowledge of the area. This provided an approximate appreciation of the validity of received data (based on current working practice) and an awareness of the routes of data requests.

In the case of this study, the dependent variable was GP EC supply rate per 10,000 female population aged 12-55 (for 2017/18). In part, this age range was selected for practical purposes based on the available national data sets of population estimation but also the expected age of fertility in practice (Office for National Statistics, 2018a). As discussed in the introduction (chapter 1), general practice is commissioned to provide all necessary care to their patient list (Department of Health and Social Care, 2015). There are no restrictions on who can or cannot receive EHC. Conversely, community pharmacy EHC supply varies between Local Authority areas. Some areas do not commission EHC from community pharmacy. Some apply restrictions (e.g., a cap on the number of commissioned pharmacies) often due to financial requirements.

GP EHC prescribing data and community pharmacy EHC supply data were obtained for all Local Authority areas across the North-west of England with no sampling or exclusion criteria (n=39). This will provide the maximum number of data points for analysis; however, non-random selection of study sites may limit generalisation.

6.2.5 Data collection

FOI requests were submitted in March 2019 to all Local Authority areas following guidance from the UK government, as detailed on their website. (Government Digital Service) The requests, detailed in appendix 2, requested confirmation of a community pharmacy EHC service, and if present the number of LNG-EC and UPA-EC supplies made in the financial year 2017/18. Previous work has highlighted delays in data recording which can prevent access to data from financial years incomplete or recently ended, so the most recent complete financial year was requested (Thayer, Willis and Jacobs, 2017). This allowed for a discrete period of time for data collection to allow comparison to dependent variables. Local Authorities that did not respond to the initial request received a follow-up request in May 2019 (approximately 6 week later).

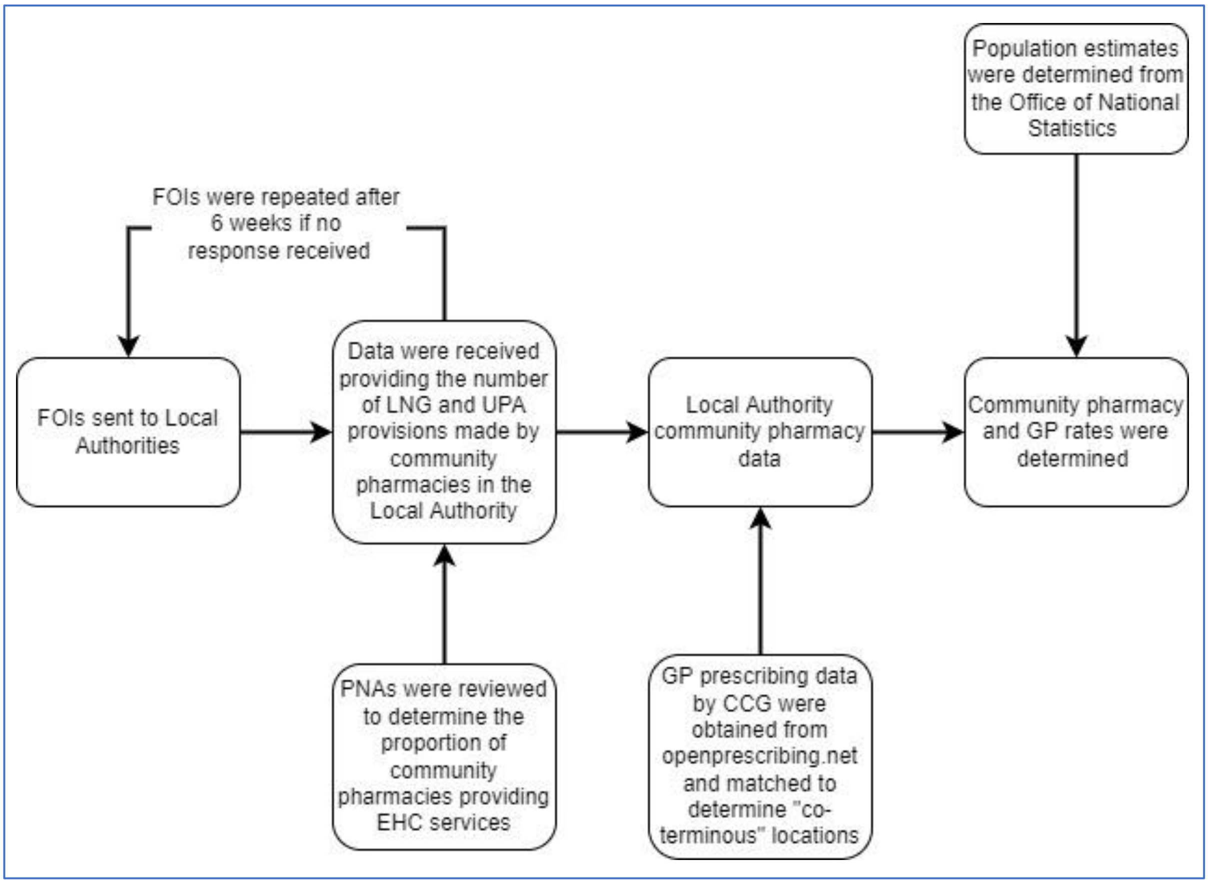
The dependent variable, GP EHC prescribing data was obtained by accessing the publicly available database - openprescribing.net (OpenPrescribing.net, 2017). This database provides a comprehensive dataset of all prescriptions grouped by Clinical Commissioning

Group (CCG) area, and data can be extracted for individual medicines or groups of medicines. Searches were made for both LNG-EC (*Levonelle (0703050A0BC)*, *Levonorgest (Emergency Contracep) (0703050A0AA)* and *Levonorgest (Oral) (0703021L0AA))* and UPA-EC *(Ulipristal Acetate (Emergency Cont) (0703050B0))* for all data nationally. This returned the absolute numbers of LNG-EC and UPA-EC prescribed by all GP surgeries, mapped to CCGs, across England. These data were then prepared to remove data outside the sample area i.e., the North-west of England.

Once obtained, the data were prepared for later analysis (see page **Error! Bookmark not defined.**), and the CCG level data was mapped to Local Authority area using information from the Office of National Statistics. (Office for National Statistics, 2017b) Local Authority area is the unit of analysis. This is because as commissioning for the independent variable (community pharmacy provision) is undertaken by Local Authorities. It is between Local Authorities that variation of the nature of service exists rather than between GP prescriptions in CCG areas. It is the inter-Local Authority community pharmacy variation that is likely to influence the dependent variable (GP EHC prescribing). This is depicted in *Figure 7*.

The data collected had limitations for later analysis. Aside from the low number of variables, covariates have not been identified. This was a recognised limitation of the feasibility study and accepted initially as the key objectives were to determine the quality and availability of data obtained through FOIs.

Figure 7 Data collection flow - Feasibility study

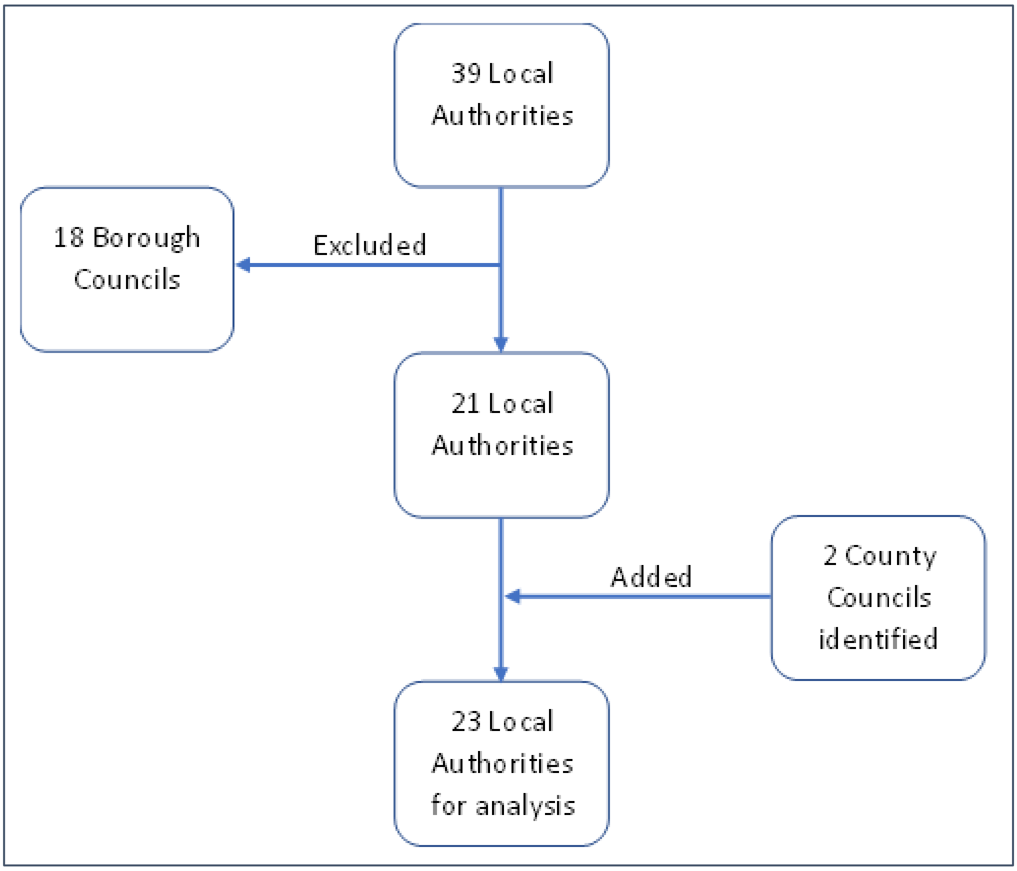


6.2.6 Sample size

The primary independent variable, community pharmacy supply data, was obtained by submitting FOI requests to the 39 Local Authorities within the North-west of England. These requests were completed via a combination of website-based requests and emails according to each Local Authority process. Responses from the different organisations highlighted an unpredicted structural consideration of local government, with public health not being consistently devolved to the identified organisations. 18 (46%) Local Authorities confirmed that they did not hold responsibility for sexual health commissioning, but this was provided by a single larger authority. The populations of these 18 Local Authorities have sexual health services commissioned on their behalf by 2 larger Local Authority organisations. These 2 Local Authorities were added to the dataset.

Two Local Authorities sub-contracted their sexual health services and the FOI requests were repeated to these organisations. This data was provided and is presented in the place of the initial commissioning council. Following this, the number of councils and therefore analysis points, was reduced to 23. This process is detailed in *Figure 8***Error! Reference source not found.**. Data were received via email in a variety of forms, including Microsoft Excel files and tabulated pdf data. All the data was transcribed to Microsoft Excel for later analysis (see page **Error! Bookmark not defined.**).

Figure 8 Detail of data collection, excluded Local Authorities, and clarification of sample size



6.2.7 Data preparation

Publicly available data obtained from the Office of National Statistics on population estimates for June 2017 allowed calculation of the rate of LNG-EC and UPA-EC supply per 10,000 population of women of childbearing age (determined as 12-55). Statistics (Office for National Statistics, 2018a)

EHC supply rates were transferred to IBM Statistical Package for the Social Sciences (SPSS) v24. LNG-EC (GP) and UPA-EC (GP) are the rates of LNG and UPA prescribing by GPs and designated as the dependent variables. LNG-EC (P) and UPA-EC (P) are the equivalent rates in community pharmacy, designated as the independent variables. Once Local Authorities were anonymised with a unique identifier the data were inputted into SPSS to allow analysis. There was a relatively small sample size, meaning outliers would have a large impact on the ability to assess the feasibility of determining statistically significant correlations. Accordingly, outliers greater than 1 standard deviation from the mean were removed.

The outcomes of this feasibility study were to determine the feasibility of obtaining community pharmacy and GP EHC data, the quality of these data, and whether the data allowed analysis. However, to explore any possible covariates a manual review of the service documentation (PGDs, service specifications etc.) was completed. This aimed to determine variability between the pharmacy services. Individual EHC service specification / PGD exclusion criteria (other than clinical) such as age restrictions, and the reimbursement each pharmacy was paid for supplying EC were extracted. This was then manually evaluated to determine the presence of variation in provision criteria that may impact the dependent variable or be identified as a confounding factor.

Manual review of the associated Pharmaceutical Needs Assessments for each local authority area, combined with the information received through FOI requests allowed determination of the percentage of all pharmacies within a Local Authority area that provided EHC to the population and the mean pharmacy supply rate. The mean supply rate was the mean number rate of provisions for all commissioned pharmacies within a Local Authority area.

6.2.8 Data Analysis & Statistical Tests

Linear regression analysis was used to identify any correlation between the dependent variable (LNG-EC (GP) or UPA-EC (GP)) and the corresponding independent variable. The gradient of the linear regression allowed prediction of changes to GP prescribing rates when independent variables changed. Understanding the correlation between variables supports an understanding of the relationships. Later interpretation of this can justify further data collection and development of a model including confounding factors.

Regression analysis aims to "*construct mathematical models which describe or explain relationships that may exist between variables"* (Seber and Lee, 2003). If the independent variable, also referred to as the explanatory variable, displays a statistical relationship this does not imply a causal relationship, but does provide a starting point for further research. Regression models can determine: the validity of a theory, test whether a parameter fits within a theorised range (assuming the theoretical framework is true) and predict further results based on existing data (Seber and Lee, 2003). It is this justification of further investigation that the linear regression analysis was used to provide.

Linear regression models produce R^2 values, the coefficient of determination. This is a measure of the amount of variability in one variable that is shared by another (Field, 2018). The R^2 value provides an indication of the percentage of the dependent variable explained by the independent variable(s). It is this value that is the primary statistical output, providing a guide to future work and a measure of success.

It should be noted that linear regression is limited to linear relationships and can be distorted by small numbers of outliers. There were only 23 data points in this feasibility study. The shape of the distribution informed the appropriateness of linear regression.

6.2.9 Ethics

A favourable ethical opinion was requested and received from The School of Pharmacy Research Ethics and Governance Committee at Keele University before FOI requests were made (appendix 6). As the data were either publicly available or obtained through FOI requests, there was no primary data collection. This made the ethical considerations simplistic with no ethically sensitive considerations or risks to researchers. Clarity was required on the level of data obtained, and assurances were provided that the data were not identifiable on an individual level.

Once data were received the Local Authority specific data were added to the data (see page 115). Following this the Local Authorities were anonymised by giving each a simple numerical value, with a set of reference data held on secure university servers. It was decided that if data were received with patient specific details or other sensitive data this would be immediately removed before data preparation, with a record made of the type of data received. This did not happen.

6.3 Main study: Analysis of EHC service provision (Local Authority)

6.3.1 Introduction

To determine the relationship between community pharmacy and GP settings, provision data were obtained through Freedom of Information (FOI) requests, matched with publicly available data, and analysed alongside national data sets. The data were collected for all available supplies of EHC within the financial year 2017/18. 2017/18 was the most recent complete financial year at the point data collection began – during the feasibility study. To allow inclusion of the originally collected data and maintain consistency this year was used throughout the study. Analysis of the rate of supply allows a determination of the degree of correlation between community pharmacy and GP provision and direct comparison between locations. A model was developed allowing an estimation of the local impact of community pharmacy services on GP provision and how this might change.

6.3.2 Unit of analysis

The aims of this investigation were to establish the relationship between emergency contraception provision in community pharmacy and general practice settings. Within community pharmacy the variable is the provision of EHC, through services commissioned by Local Authorities. Specifically, this is the number of patients supplied with either of two medicines: Levonorgestrel (LNG-EC) or Ulipristal (UPA-EC). Within general practice the corresponding emergency contraception provision is also Levonorgestrel or Ulipristal supply, but through the metric of Levonorgestrel or Ulipristal prescriptions (FP10s) prescribed. There is no substantial difference between these routes (PGD supply from community pharmacy or GP prescribing through FP10s) and are considered directly analogous throughout this study. Patients may access services numerous times during a year, and therefore both community pharmacy and GP rates may include multiple visits by an individual. Private sales of EHC are unavailable and not included in the analysis.

The principle independent variable - community pharmacy EHC provision data, were obtained through FOI requests. The FOI requests supplied data for community pharmacy segregated by local authority. GP prescribing data are available by their commissioning body – the CCG. This means that the two units of analysis are not the same. In some instances, the geographical boundaries of the commissioning bodies are the same – they are co-terminus (e.g., Darlington council and Darlington CCG). In others more than one commissioning body aligns with one or more of the other (e.g., Cheshire East council is co-terminus with Eastern Cheshire CCG and South Cheshire CCG).

If geographic boundaries do not align (they are not co-terminus) then direct comparisons cannot be drawn as different populations are being compared. This means these Local Authorities were excluded.

It is not possible to complete the analysis at a more granular level, which may have provided further insights. General practice does not routinely share the geographic boundaries of patient lists nor restrict access to patients outside these lists (in the case of an emergency, which by its nature EHC is). This means even if patient lists were available, they would not provide an accurate description of the sample population. Community pharmacy does not operate on a list basis, providing service to any presenting patient.

This means the only way to compare GP and community pharmacy is to analyse populations within a defined area. In this instance Local Authorities were chosen.

There is almost certainly a likelihood of supply to patients based outside the determined geography. However, as the comparison is between GP and community pharmacy services, it can be assumed that the patient 'out of area' would have received services from one of these two sources – given that care is not linked to home postcode. While this is a possible confounder, it is not possible to quantify or measure it without patient specific details. For the purposes of this work the unit of analysis is the Local Authority, comprised of data from all community pharmacies and GPs within its geographical boundaries.

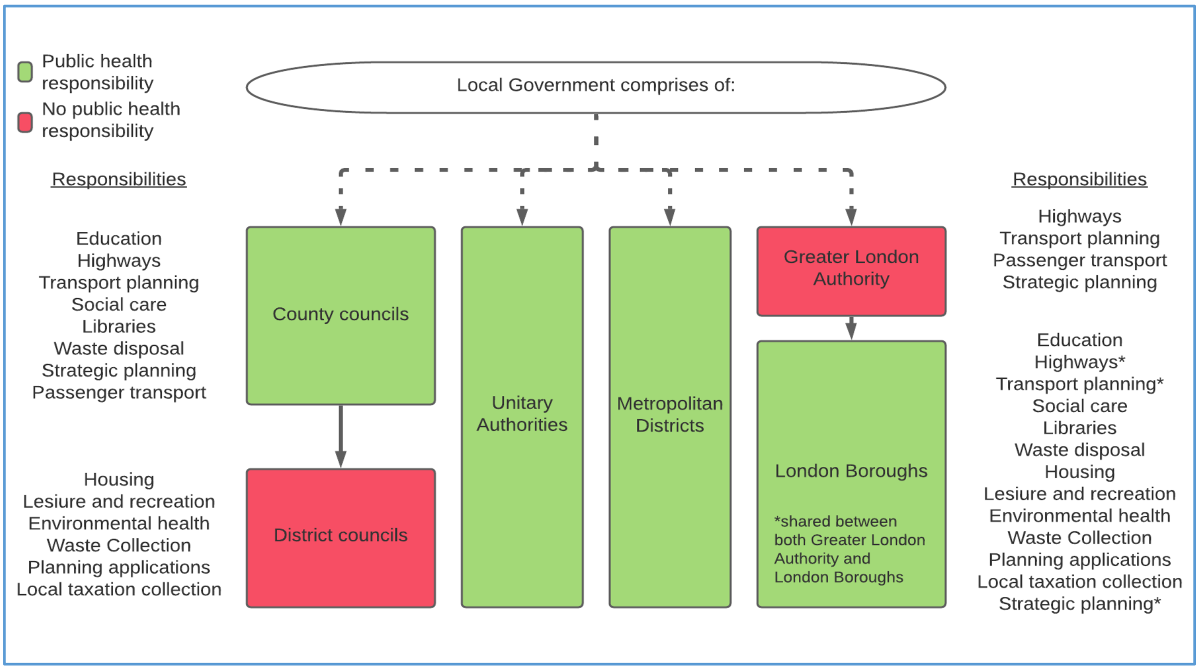
6.3.3 Sampling

As explored in the introduction (Chapter 1) local service commissioning is complex, with split responsibilities between Local Authorities, NHS commissioners (e.g., CCGs) and other third parties. As a public health service, contraception services are mainly the responsibility of local government.

Local government is formed by five types of Local Authorities in England. County councils (cover a whole county), district councils (may be districts, boroughs, or cities), unitary authorities (typically large towns), London boroughs (a sub-set of the Greater London Authority) and metropolitan districts (effectively unitary authorities with subtlety different organisational structures). (Local Government Association) Responsibilities for different elements of local government are split between the different Local Authorities. Unitary authorities and metropolitan districts have sole responsibility for all local government functions, whereas district councils form a layer of bureaucracy under county councils, and similarly London boroughs under the Greater London Authority. The split of responsibilities is depicted in *Figure 9*. This means that it is not always clear which organisation is responsible for commissioning of public health services.

District councils do not have responsibility for public health commissioning. This task is elevated to the county council, that oversee this for numerous district councils within their geography. Conversely, the Greater London Authority does not have responsibility for public health but delegates this to individual boroughs. Commissioning responsibility is set out in *Figure 9* with those authorities with responsibility for public health commissioning highlighted in green.

Figure 9 Hierarchy of local government in England indicating public health commissioning responsibility



This responsibility is complicated by commissioning methods. Local Authorities have responsibility for the commissioning of public health services but have no obligation to directly provide these services. External providers are common, where Local Authorities commission an external organisation to provide a public health service. This can be further complicated by sub-contracting for elements of the overall service objectives. Numerous examples have been found when reviewing websites in preparation for data collection of councils commissioning sexual health services from a single organisation (e.g., an NHS Trust, a charity or private provider), who in turn sub-contract elements of the service. This might include contraception services such IUD fitting from local General Practices and Emergency Hormonal Contraception from community pharmacies.

A list of all Local Authority districts was obtained from the Office for National Statistics (Office for National Statistics, 2017a). This list included all Local Authorities, without clarity on the authority type (e.g., county council, district council etc.). As the nature of a council e.g., district, county or unitary, is not always clear from the name, the data was manually reviewed. The Local Government Association (LGA) website and individual council websites provided some clarity. The LGA website detailed which councils were metropolitan districts. (Local Government Association) Some council websites provided a list of their responsibilities, or clarity of the type of authority. This was not able to be determined in each case.

Where it was not possible to determine the type of council through searching the internet, FOI requests were sent. The responses provided clarity on the authority's responsibilities, or the alternate local authority to contact.

For the purposes of this study only Local Authorities in England were contacted. Within Wales and Scotland there is a different commissioning landscape with NHS Health Boards. As Wales and Scotland commission this through different models and as part of the NHS process (rather than local government) then the areas are not comparable. Additionally, there a several differences in the national community pharmacy contract (services available, requirements etc.) and the training available and local integration with other providers. All these make the different countries difficult to compare directly.

6.3.4 Ethics

A favourable ethical opinion was obtained from The School of Pharmacy Research, Ethics and Governance Committee at Keele University (ref – MH-200114, appendix 6). The majority of data used within this project is publicly accessible and there were no identifiable patient data collected.

As before, once data were received the Local Authority specific data were added to the data (see page 115). Following this the Local Authorities were anonymised by giving each a simple numerical value, with a set of reference data held on secure university servers. It was decided that if data were received with patient specific details or other sensitive data this would be immediately removed before data preparation, with a record made of the type of data received. This did not happen.

6.3.5 Bias

Sources of bias include other factors influencing EHC supply. As explored in the literature (chapter 2) these include population demographics such as deprivation, religion, urban/rural nature of the geography, age etc. Some of these factors were controlled for, for example the variables investigated are the *rates* of supply per 10,000 female population (aged 12-55). This partially controls for differences in age distribution and gender split. Other factors, such as those contained within the Index of Multiple Deprivation (income, employment, education, health, crime, barriers to housing and services and living environment) can be controlled for using publicly available data sources. This is only effective to a limited degree. The unit of analysis is Local Authority, however within this area there is variation in all demographic factors. Any attempt to control for co-variates will have to use an average value for the Local Authority geography reducing its reliability.

Finally, the dependent variable (rates of GP prescribing) is a possible overestimate of the actual rate. Where pharmacy data reflects data recorded of medication actually supplied, the GP data reflects prescriptions generated. No literature was found that indicated the rate of prescriptions not collected for EHC, nor any factors that influence this. However, it is a recognised feature of primary care that not all prescriptions are dispensed (West *et al.*, 2014). This is less likely for urgent medications – such as antibiotics or EHC.

6.3.6 Data collection

As in the feasibility study, FOI requests were submitted to all Local Authority areas in England. The requests, detailed in appendix 2, requested confirmation of a commissioned community pharmacy EHC service, and if present the number of LNG-EC and UPA-EC supplies made in the financial year 2017/18. Again, following the feasibility study a single financial year was collected, using 2017/18 again allowed previously collected data to be retained for analysis.

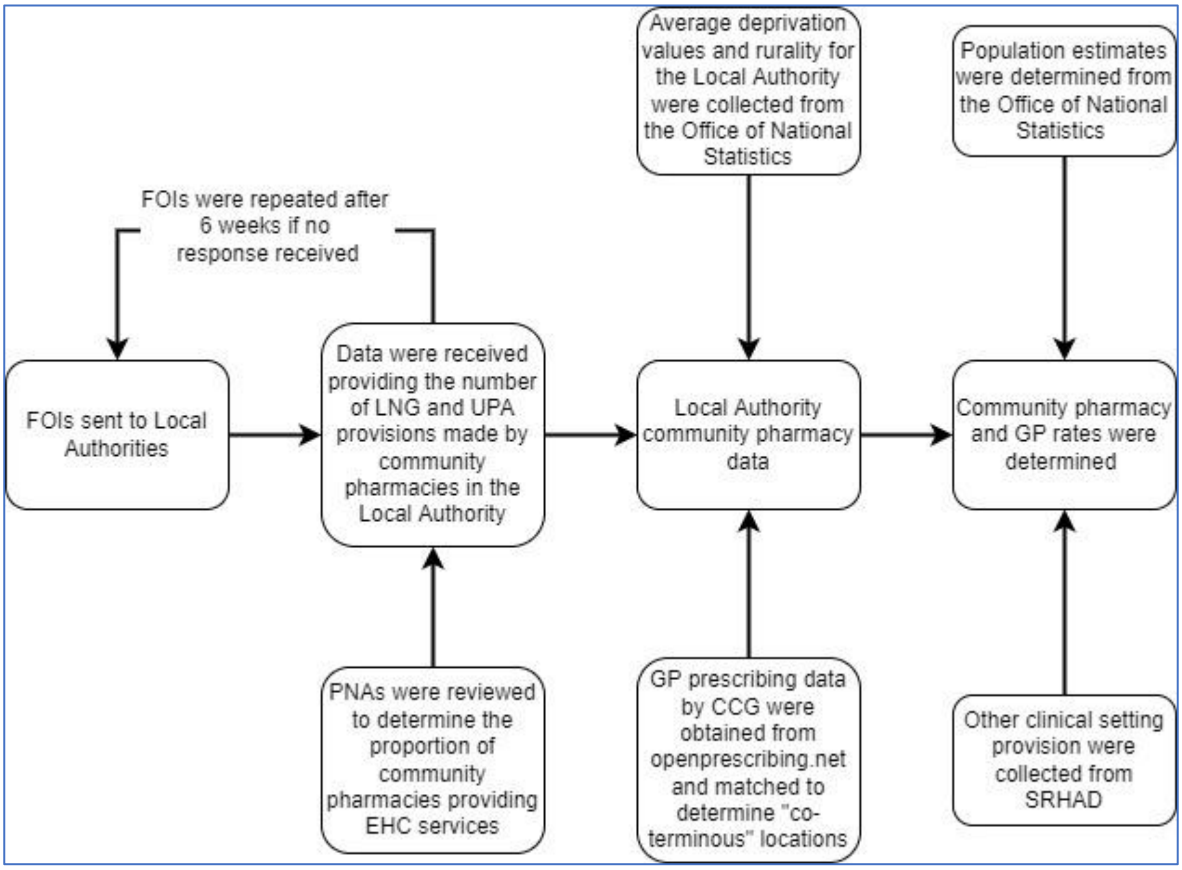
Where the information was available (from practicing knowledge, or Local Authority materials, or FOI responses), FOIs were also sent to service contract holders in place of Local Authorities and if data were provided these were included in place of the commissioning council. There was a lower-than-expected rate of return which was exacerbated by the COVID-19 pandemic. Local Authorities reporting COVID-19 restrictions were not able to give any indication of when their routine services may resume. Given the uncertain likely end point of the pandemic at the time of data collection, it was decided to proceed with the available data.

The dependent variable, GP EC prescribing data, was obtained by accessing the publicly available database - openprescribing.net (OpenPrescribing.net, 2017). Searches were made for both LNG-EC (*Levonelle (0703050A0BC)*, *Levonorgest (Emergency Contracep) (0703050A0AA)* and *Levonorgest (Oral) (0703021L0AA))* and UPA-EC *(Ulipristal Acetate (Emergency Cont) (0703050B0))* for all data nationally. This returned the absolute numbers of LNG-EC and UPA-EC prescribed by all GP surgeries, mapped to CCGs, across England.

Once obtained, the data were prepared for later analysis, and the CCG level data was mapped to Local Authority area using information from the Office of National Statistics (Office for National Statistics, 2017b). As described earlier the Local Authority and CCG data were compared to determine co-terminus areas. Other data were excluded.

Finally, data from the Office of National Statistics and the Sexual and Reproductive Health Activity Data Set (SHRAD) were used to determine variables that may influence community pharmacy or GP EHC provision rates (Office for National Statistics, 2018b; NHS Digital, 2019c). The full data collection process is depicted in *Figure 10*.

Figure 10 Data collection flow - Local Authority analysis



6.3.7 Data preparation

Following data collection, the raw data were transcribed to Microsoft excel. The data were manipulated to determine which geographies were co-terminus (where the Local Authority and CCG geographies matched) and were suitable for analysis. Once the Local Authorities and CCGs were mapped, female populations, GP and community pharmacy data were inputted. To allow direct comparison between community pharmacy and GP data across different locations, the rate per 10,000 female population aged 12-55 was calculated. This age range was selected for practical purposes based on the available national data sets of population estimation and expected age of fertility in practice (Office for National Statistics, 2018a).

Rates of EHC supply were calculated for LNG, UPA and the two medications combined – all consultations. Then possible influencing factors including the measure of rurality, average income, health, and crime data were added. Finally, the data were anonymised for transfer to SPSS Analytics for further analysis.

6.3.8 Analysis

Initially the data were described used frequency tables and histograms to look for outliers. This enabled a full understanding of the data available for analysis. Following this, linear regression analysis was used to determine the association between GP and community pharmacy rates of provision. Box plots were generated to help identify outliers. Data points outside 1.5 times the Inter Quartile Range from the 1st or 3rd quartile were removed before repeating the linear regression. The R^2 value provided an indication of the percentage of the dependent variable explained by the independent variable(s).

Based on the policy review (page 18, chapter 2) and data sources available, possible co-variates were identified. Bivariate corelations were undertaken using Pearson correlation coefficient. This allowed an understanding of the direction and strength of the relationships between the variables. These results were used to later inform the path analysis. Finally, multiple regression was used to understand the relative influence of the variables and the degree of variation explained.

When planning a multiple regression, there are several methods of variable entry. These are forwards, backwards, enter and stepwise (Field, 2018). Generally, step-wise is not recommended as it often amplifies the effect of “nuisance variables” that in reality have no impact of the dependent variable (Smith, 2018). The enter method adds all predictors to the model simultaneously, and this has similar challenges to understanding the true impact of the identified variables (Field, 2018).

The backwards method was chosen in this instance. This approach adds all the identified variables to the model, and the contribution of each one is evaluated with the p-value of its t-test (Field, 2018). In this way, less significant variables are removed until the remaining model includes only strong predictors of the dependent variable. The forward model is the opposite, starting with one variable and adding others if they meet significance tests. The multiple regression was completed using the backwards method, then repeated forwards – which gave the same results.

6.3.9 Structural Equation Modelling

With the completed analysis, there is a need to translate this into a tool that can inform commissioning decisions and predict provision. The example being used in this study is EHC, but the intention is to use a process or framework that could be applied across healthcare environments.

A general linear model (GLM) encompasses a wide range of statistical procedures, including the linear regressions undertaken so far in this chapter. This approach articulates the work already described in this chapter. Often GLM is understood in terms of multiple regression, where several independent (or predictor) variables are used to predict the effect on a dependent variable (Graham, 2008). In this case, the original independent variable - community pharmacy rates of provision and the identified co-variates can be used to predict the effect on GP rates of prescribing. A GLM can understand the relationship between variables and the outcome (the dependent variable – GP prescribing rates).

Structural Equation Modelling (SEM) is an extension from GLM. It is a way of expressing the predictors, their relationship to the dependent variable and the relationship between predictors. This is particularly useful in social sciences when attempting to determine the relationship between observed factors, whilst recognising the unobserved wider determinants – such as human behaviour or characteristics (Hancock, 2003). For this reason, it is valuable above and beyond GLM alone for predicting the likely effect of commissioning decisions.

Latent variables (hypothetical constructs) are inferred variables, rather than observed variables. Examples of latent variables are happiness which cannot be measured directly, or IQ, mathematically modelled from numerous questions. The data available in this study and the theoretically constructed model do not include any latent variables, as all the identified co-variates are directly measured or observed. The SEM used in this instance is a *path analysis model*. This model is conceived only in terms of observed variables (Raykov and Marcoulides, 2000). The explanatory variables are assumed to have no or negligible measurement errors, which is the case with the data available here. Whilst there may be a degree of error in dependent variables, this is assumed to be unexplained by the explanatory variables (Raykov and Marcoulides, 2000).

The relationships described are complex with several co-variates. A more holistic understanding of the interplay between these variables should better enable interpretation of the results and identified relationships. To develop a tool for informing commissioning decisions a theoretical path analysis model was designed based on the literature review (chapters 2 and 4), prior knowledge, and the correlations described in *Table 12*. For instance, the rate of unplanned pregnancies is higher in areas with greater deprivation, and the likely use of EHC is reported to be influenced by monetary deprivation (Cameron, Gordon and Glasier, 2012). Therefore, income deprivation is included in the model. Similarly, access to the pharmacy is recognised as an enabler to EHC use, due to an increased number of venues / access points, as well as the normally increased opening hours of pharmacy (Sucato, Gardner and Koepsell, 2001). Accordingly, the proportion (%) of commissioned pharmacies is included.

The theoretical path analysis included available data from national databases (such as openprescribing.org and SRHAD), the FOI data, and population factors identified in the literature (e.g., deprivation). Using the insight from the feasibility study the proportion of commissioned community pharmacies was included, but mean provision volume was not. This was refined using the insights from the regression analysis, with factors excluded where they were not found to be significant. A path analysis was completed using SPSS AMOS 27 graphics.

6.4 Main study: Analysis of EHC service provision (community pharmacy)

6.4.1 Introduction

It was recognised in the literature that there a many structural aspects to community pharmacy that are likely to impact service provision. To determine which of the known factors influence EHC provision, data were obtained through FOI requests. These data were then matched with nationally held data sets, to determine the strength of correlation(s). Unlike previously, this analysis aimed to determine factors that had a significant influence on the EHC provision rates, at an individual pharmacy level of analysis.

6.4.2 Unit of analysis

FOI requests made to Local Authorities, requested EHC provision for the financial year 2017-18 segregated by individual pharmacy. Community pharmacies commonly use NHS designated codes – 'F-codes' as identifiers. The FOI request asked for data to identify the corresponding pharmacy and their F-code to facilitate later analysis.

6.4.3 Sampling

Within England, in 2017/18, there were 11,619 community pharmacies dispensing a mean of 7,267 items per month (NHS Digital, 2019a). Within England, community pharmacies exist as private businesses holding NHS contracts, similar to General Practice. Unlike

General Practice, there are a variety of business models and ownership models for the pharmacies. Whilst it is possible for a community pharmacy to operate without an NHS contract (and therefore provide no NHS services, including dispensing NHS prescriptions) these businesses are often specialised, few in number and are not considered within this work. The owner / business that holds the NHS contract for a pharmacy is referred to a "contractor" and contractors may hold multiple contracts equating to multiple pharmacy premises.

Within the community pharmacy sector there are numerous organisation types, often described by contract numbers. There is no formal agreed definition, but in common parlance they are termed "independent pharmacies", "small multiples" and "large multiples". To facilitate comparison with the literature, the definition set out by Jacobs *et al.* (2017) will be used here: supermarket, multiple (>200 pharmacies), medium chain (26-200 pharmacies), small chain (6-25 pharmacies) and independent (<6 pharmacies) (Jacobs *et al.*, 2017).

The community pharmacy contract also allows for 2 other business types: appliance contractors (who are restricted to only dispensing appliances, no other services) and distance selling pharmacies. Appliance contractors are prohibited from providing medicines and services including EHC services and are therefore excluded. Whilst it is theoretically possible for a distance selling pharmacy to engage in local services the terms of service mean they cannot allow patients to access their physical premises for any core part of the pharmacy contract. This means in practicality distance selling pharmacies do not engage in local services, such as EHC, and therefore are also excluded from this study.

All local authorities in England received FOI requests for data, with no exclusions. It was intended to receive data from all community pharmacies within England, baring the exceptions already discussed.

6.4.4 Ethics

As stated previously, a favourable ethical opinion was obtained from The School of Pharmacy Research, Ethics and Governance Committee at Keele University (ref – MH-200114, appendix 6). The majority of data used within this project was publicly accessible and there was no identifiable patient data collected.

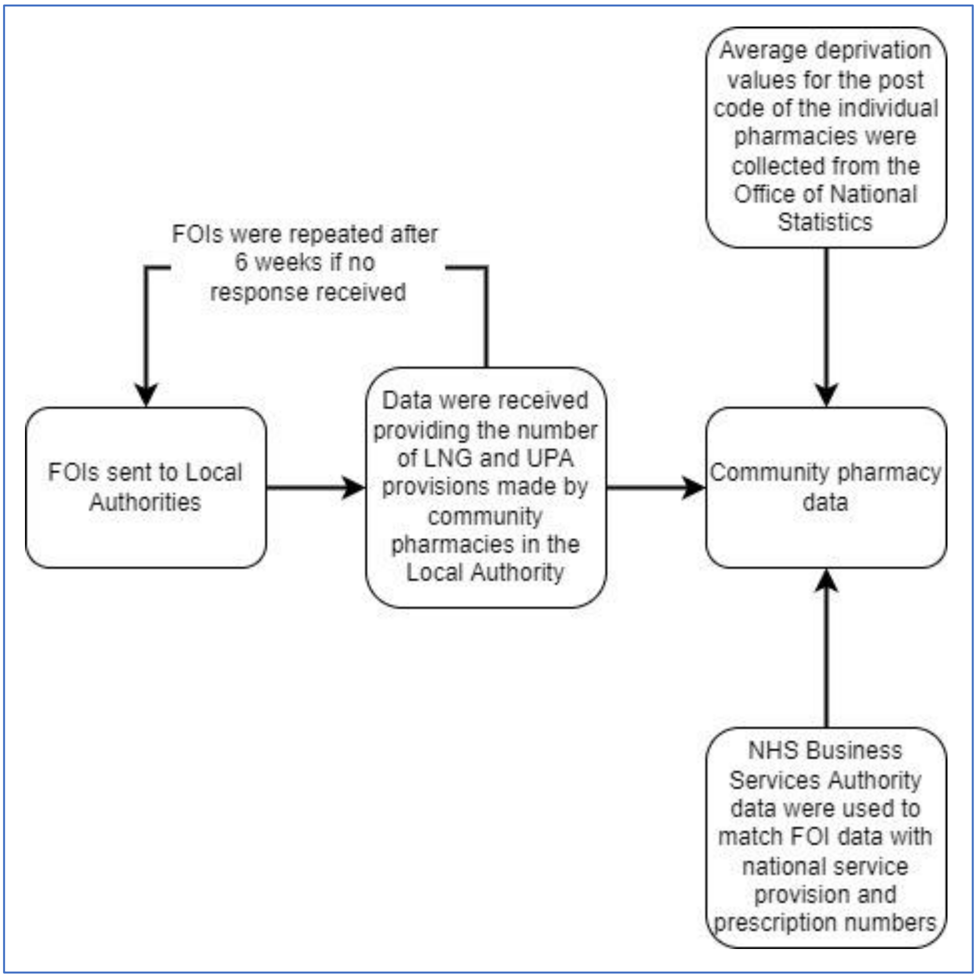
The same anonymising approach was taken as described earlier (pages 117 and 124). Again, no sensitive or non-anonymised data were received.

6.4.5 Data collection

The same data set used for Local Authority analysis was used for individual pharmacy analysis. Data were manually reviewed and matched to independent variables obtained from the NHS Business Services Authority (NHSBSA) contractors dispensing data. (NHS Business Services Authority) The NHSBSA use unique identifiers for pharmacies, "F-codes" and these unique identifiers were used throughout data analysis. Where F-codes were not provided, manual comparison of pharmacy trading names and addresses were used to match the data. If there was uncertainty, for example two pharmacies with the same postcode or a pharmacy with a different name and no evidence of a change in ownership, the pharmacy was excluded from analysis. The data from FOI requests were provided in different ways, depending (presumably) on Local Authority data collection processes. Data were aggregated for the year, and any duplicate entries were combined.

The data collected here were analysed by individual pharmacy. No correlation with GP prescribing rates were drawn. This means there was no need to compare to CCG data nor determine co-terminus locations. What was required was the ability of the Local Authority to provide data by individual pharmacy. This led to a different data set (even though the same FOI responses were used) as different responses were used based on either their co-terminus geography or the detail required to identify different pharmacies. The data collection flow is depicted in *Figure 11*.

Figure 11 Data collection flow - Individual pharmacy analysis



6.4.6 Data preparation

Data from the NHS Business Services Authority is provided in different ways. Prescription, Medicines Use Reviews (MUR), and New Medicines Service (NMS) data are provided monthly, whereas Influenza data are provided annualised. Both mean monthly values and total values for the year were produced if possible.

Data from some months indicated pharmacies did not claim payment for any services or prescriptions. It was assumed if a pharmacy claimed payment for zero prescriptions from the NHSBSA, they were not open to the public. The data likely indicates a month of no trading, but registration with the NHS (either as a precursor to opening a new pharmacy, or as part of closing one). These months were excluded from mean calculations. The same conclusion cannot be drawn for service volume (MUR, NMS) as these are optional services. Therefore, zero service months were included when determining means.

Deprivation data were collected from national datasets and matched to the post code of the pharmacy. (Ministry of Housing Communities and Local Government, 2019a) Following this, the data were transferred to SPSS v.24 for analysis.

6.4.7 Analysis

As previously discussed, the data were described using frequency tables and histograms. In particular the data were reviewed to understand the distribution as previous studies have shown some community pharmacy service provision data to not be normally distributed (Jacobs *et al.*, 2017). Linear regressions were determined, as well as the R^2 values. Using the co-variates identified and available for analysis, bivariate correlations were completed using Pearson's correlation coefficient. As with the Local Authority analysis, this quantified the direction and strength of relationships between variables.

Given the previously identified influence of ownership type, the data were then grouped accordingly. The grouped data were described and mean annualised service values were determined. Following this a one-way Analysis of Variance (ANOVA) was completed, to determine the variance between-groups and within-groups. As the data was now grouped, correlations were determined using Spearmans rho.

The results were reviewed, and supermarket data added complexity to the conclusions. Since they act as both a large company and small company and formed a small portion of the overall data they were excluded and the 1-way ANOVA repeated.

Recognising that deprivation is an important factor influencing EHC services, the influence of deprivation was controlled. This was achieved by completing a 2-way ANOVA, where two independent variables are considered with a single variable. In this case, the relationship of both pharmacy ownership and deprivation were considered with EHC provision. Post-hoc tests are important for understanding the results of a 2-way ANOVA and these were also completed and presented.

Finally, multiple regression was undertaken. As with the previous multiple regression, a backwards method was applied, and the models were presented and discussed.

6.5 Main study: Modelling of findings if applied to current practice

6.5.1 Introduction

The collection of data allowed statistical analysis to describe the relationships between GP EHC prescribing rates and community pharmacy EHC provision rates. Furthermore, the review of individual pharmacy data allowed the identification of any individual pharmacy characteristics that may influence commissioning decisions.

Once the key relationships had been identified and quantified, there was a body of evidence that commissioners could use to predict changes to local services – based on decisions made. For example, commissioning an EHC service where one previously was not available. Using the relationships described it is possible to predict the effect this will have (for example of GP EHC prescribing rates). The strength of the relationships found were explored through a modelling exercise, considering practical examples available within community pharmacy practice.

6.5.2 Predicting changes to EHC provision

The analysis of GP and community pharmacy data provided a quantified relationship. Using the data collected and this relationship it was possible to predict how changing a variable may influence EHC provision. Given that the number of pharmacies in the data set and the total number of pharmacies nationally was also known, it was possible to scale this up, to make estimates on a national impact.

Both Wales and Scotland also have community pharmacy EHC services. These are commissioned differently but provided an opportunity to 'sense check' the estimates made using the collected data. The proportion of commissioned pharmacies was found to be a key variable influencing EHC provision, as well as being one subject to influence by commissioners. Using similar national data from Wales and Scotland to that collected in England (EHC provision, female population, number of pharmacies) comparisons were drawn between the three countries. A scatter plot of the proportion of commissioned pharmacies and the rate of community pharmacy EHC provision was completed to identify trends.

6.5.3 Comparisons to other community pharmacy services (influenza)

After testing the assumptions made regarding EHC with data from Wales and Scotland, a similar exercise was undertaken with influenza vaccination in England. Influenza provision rates were plotted against the proportion of community pharmacies providing the service.

6.6 Summary

The aim of this thesis is to determine what influences EHC service commissioning and provision. This chapter has described how FOIs were used to collect data for different levels of analysis. It has also described the analysis undertaken, including the use of linear regression. Determining correlation, particularly between that of the rate of community pharmacy EHC activity and the rate of GP EHC prescribing is one of the key objectives. This will allow an understanding of the data that best describes the influences on EHC service commissioning and provision.

This chapter has also described many of the data sources, often public databases, that provided quantifiable data to measure the variables identified from the literature. Combining the analysis of the different variables allowed the generation of the path-analysis model described. Finally, the 'real world' implications of the data were tested using existing service provision, and the approach to this was also described. The results follow in the next chapter.

Chapter 7: Results

7.1 Introduction

This chapter details the results and subsequent analysis of the FOI data. As with the methods the results are again separated by the feasibility study and then the two units of analysis, firstly local authorities, then individual pharmacies.

The aim of this thesis was to determine what influences EHC service commissioning and provision, through the use of quantifiable, routine collected data.

Accordingly, the feasibility study sets out the available data from FOI requests, describes the correlation between community pharmacy and GP EHC provision, and explores the available data to identify variables. The results presented show the various statistical tests undertaken, explaining which variables were identified for later analysis and why.

Following this analysis is presented in line with the objectives (page 44). Firstly, the results quantify the variables influencing Local Authority EHC commissioning. It describes the correlation between rates of community pharmacy EHC activity and GP EHC prescribing, analyses the variables identified in the feasibility study, and then describes these relationships using path-analysis. After this, the variables influencing EHC provision from individual community pharmacies are explored and described.

Finally, the analysis and path-analysis model are considered alongside current commissioning activity. Predictions are made of the possible impact on service provision if the variables identified are changed.

7.2 Feasibility study results

7.2.1 FOI response data and sampling

FOI requests were sent to the 39 initially identified Local Authorities. Due to the commissioning responsibilities held by the different organisations, the actual sample size was 23 (*Figure 8*). This meant there were 23 different sexual health commissioning bodies within the north-west of England. The Local Authorities were defined as the unit of analysis. Of these 23 organisations, all responded to the FOI request although one organisation was unable to provide data, other than confirming community pharmacies were commissioned to provide EHC services in the year 2017/18.

There were two Local Authorities that confirmed that they did not commission community pharmacy services directly and this had been tendered to another organisation. In both cases this was the local NHS trust and similar FOI requests were made, both resulting in the requested data. Local practice indicated (based on current professional work and simple searches of the organisations websites) that one response was incorrect. The Local Authority indicated there was no current service, yet this was suspected to be incorrect, and the FOI was resubmitted. More detail was provided, including the likely team responsible for the service. This resulted in a positive response containing the required data. This gave a total of 22 data points received from FOIs, a successful data return rate of 96%.

7.2.2 Description of the data

Of the 22 FOIs returned from Local Authorities, one confirmed there was no community pharmacy service commissioned during the time period of interest (2017/18). From the remaining 21 areas, all community pharmacy services supplied LNG but 13 (59%) of the areas did not supply UPA.

GP data were mapped from their CCG area to the corresponding Local Authority geography. LNG and UPA data were available for all 22 identified areas. For each area, the population numbers of women aged 12-55 were available allowing rates per 10,000 female population (aged 12-55) to be calculated for LNG and UPA.

Supply rates of LNG-EC in community pharmacy (LNG-EC (P)) varied greatly (0 – 875, SD 203.0), whereas UPA-EC (P) did not show the same variation (0 - 153, SD 32.6). UPA-EC (GP) supply showed comparable variation to community pharmacy supply (6 – 102, SD 19.5) but LNG-EC (GP) variation (20 – 146, SD 31.9) was much lower.

Table 6 displays the supply rates of EHC by GPs and community pharmacy. Frequency plots were completed demonstrating the number of Local Authorities and the corresponding supply rates to determine the distribution of the data. None of the plots exhibit normal distribution (*figures 12-15*).

Ref	Female population (12-55)	LNG (Ph)	LNG-EC (P) / 10,000	LNG (GP)	LNG-EC (GP) / 10,000)	UPA (Ph)	UPA-EC (P) / 10,000	UPA (GP)	UPA-EC (GP) / 10,000
1	42,754	2188	512	185	43	0	-	42	10
2	37,757	0	-	337	89	0	-	145	38
3	79,996	2760	345	472	59	0	-	119	15
4	53,569	593	111	281	52	0	-	95	18
5	100,190	8766	875	314	31	338	34	126	13
6	98,507	3640	370	316	32	118	12	128	13
7	147,378	4956	336	461	31	0	-	216	15
8	35,848	610	170	123	34	24	7	53	15
9	43,433	440	101	633	146	30	7	83	19
10	279,755	11114	397	1681	60	0	-	665	24
11	151,100	1585	105	1271	84	0	-	520	34
12	180,085	9516	528	1879	104	0	-	1837	102
13	66,473	1079	162	484	73	0	-	148	22
14	62,299	896	144	409	66	0	-	130	21
15	74,636	1831	245	305	41	59	8	115	15
16	71,444	1454	204	235	33	1090	153	117	16
17	48,982	1551	317	192	39	0	-	31	6
18	80,023	302	38	675	84	87	11	164	20
19	63,780	1102	173	685	107	0	-	153	24
20	67,259	3714	552	190	28	0	-	63	9
21	58,878	1556	264	116	20	94	16	63	11
22	90,499	*No Data*	-	214	24	*No Data*	-	108	12
23	86,590	2270	262	466	54	201	23	143	17

Table 6: LNG and UPA supply from Pharmacy (Ph) and GP locations, including population standardised rates

Figure 12 Distribution of LNG (Ph) supply

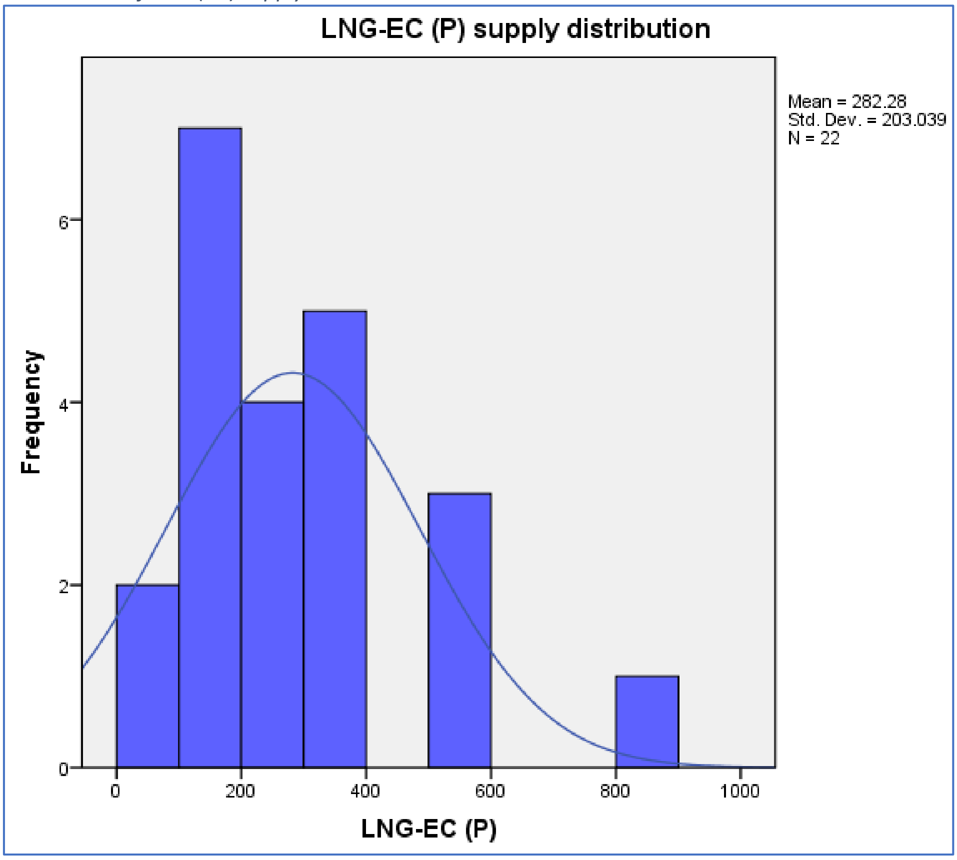


Figure 13 Distribution of LNG (GP) supply

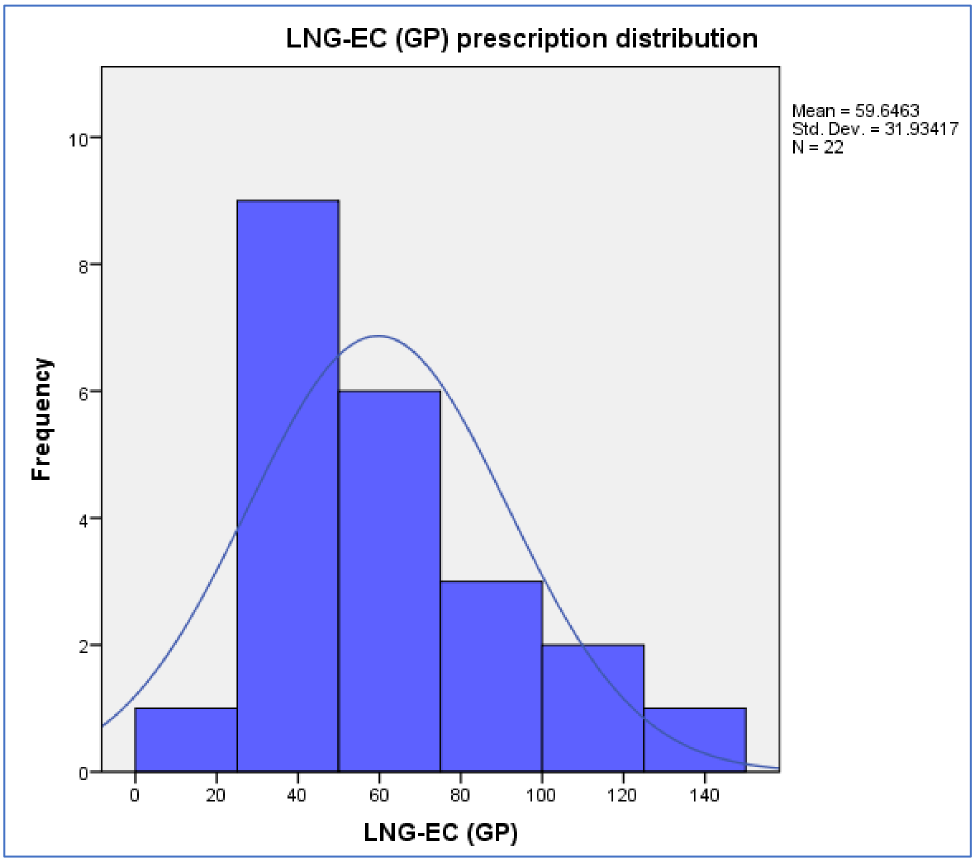


Figure 14 Distribution of UPA (Ph) supply

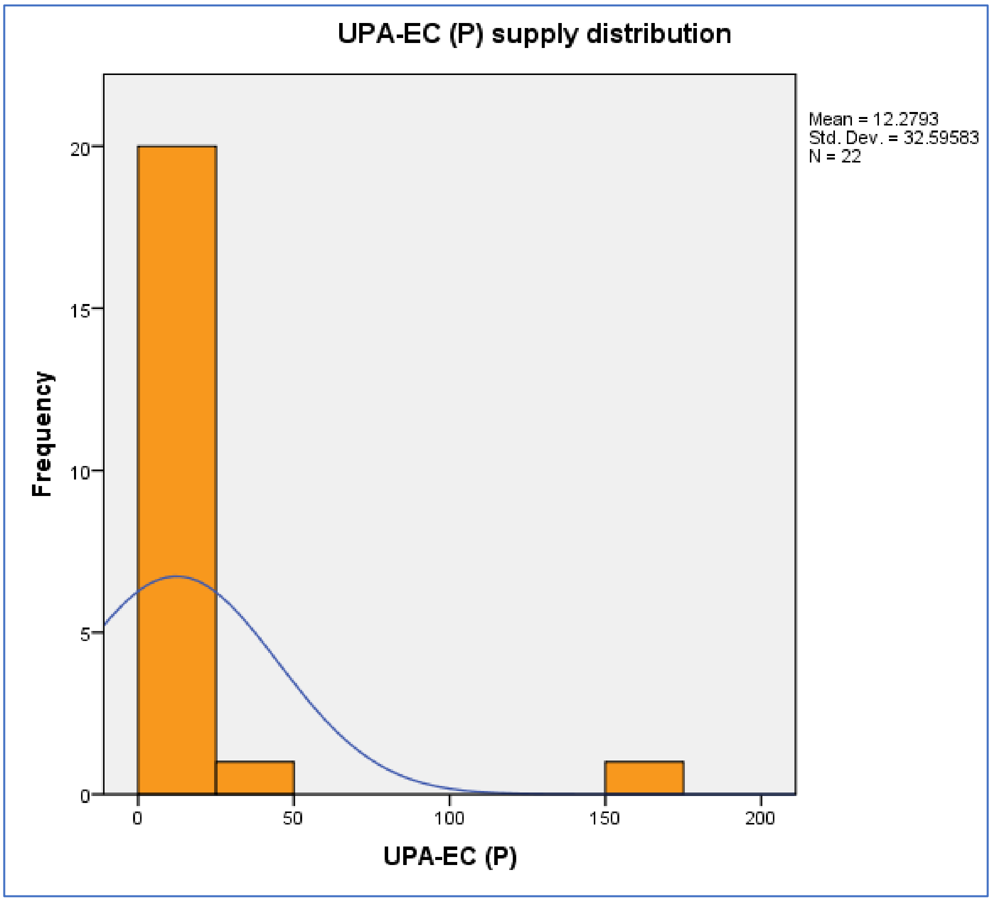
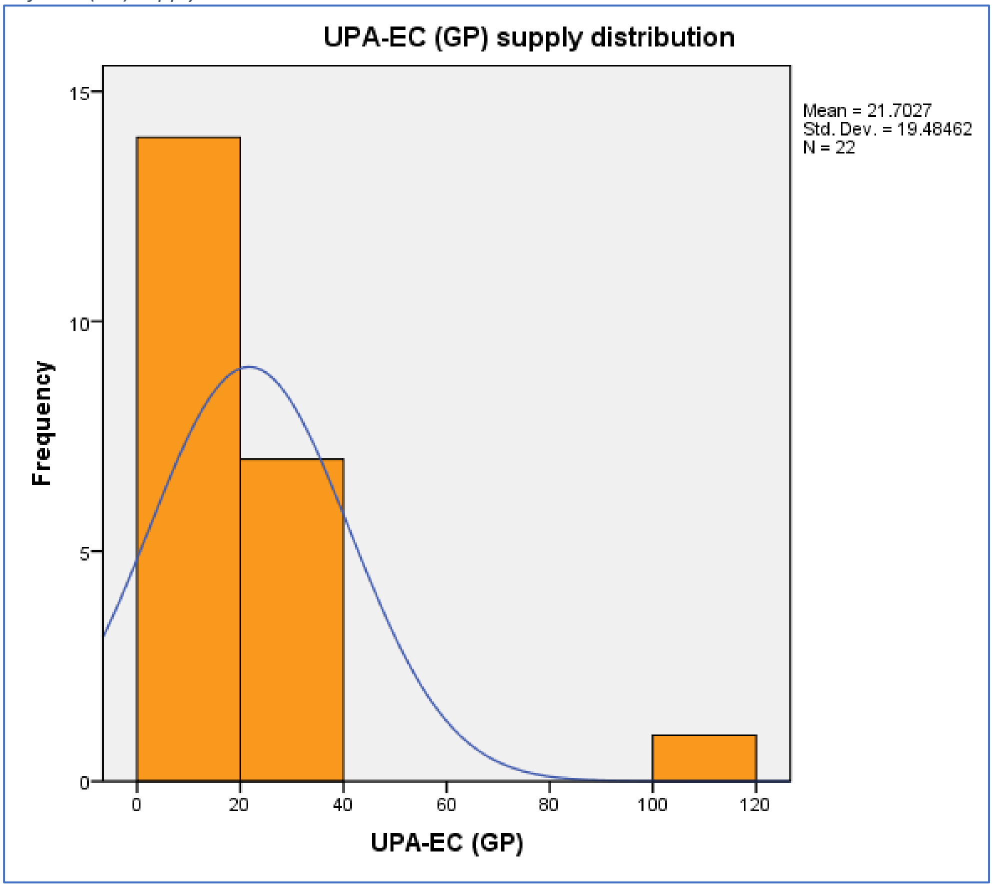


Figure 15 Distribution of UPA (GP) supply



7.2.3 Determining correlation

Scatter graphs were plotted of the dependent variables LNG-EC (GP) and UPA-EC (GP) supply rates against the independent variables, the corresponding pharmacy supply rates (LNG-EC (P) and UPA-EC (P)). Linear best fit lines were added and showed negative correlations for both (*Figure 16* and *Figure 17*). This suggests that increasing supply rates of community pharmacy EHC supply correlates to a decreased GP prescribing rate.

R^2 values were calculated for both LNG (GP) / LNG (Ph) and UPA (GP) / UPA (Ph) and were determined to be 0.174 and 0.015 respectively. This suggests 17.4% and 1.5% of the variation may be explained by this relationship.

Figure 16 Scatter chart, adding fit line. Dependent variable on y axis (LNG-EC (GP)), independent on x axis (LNG-EC (P))

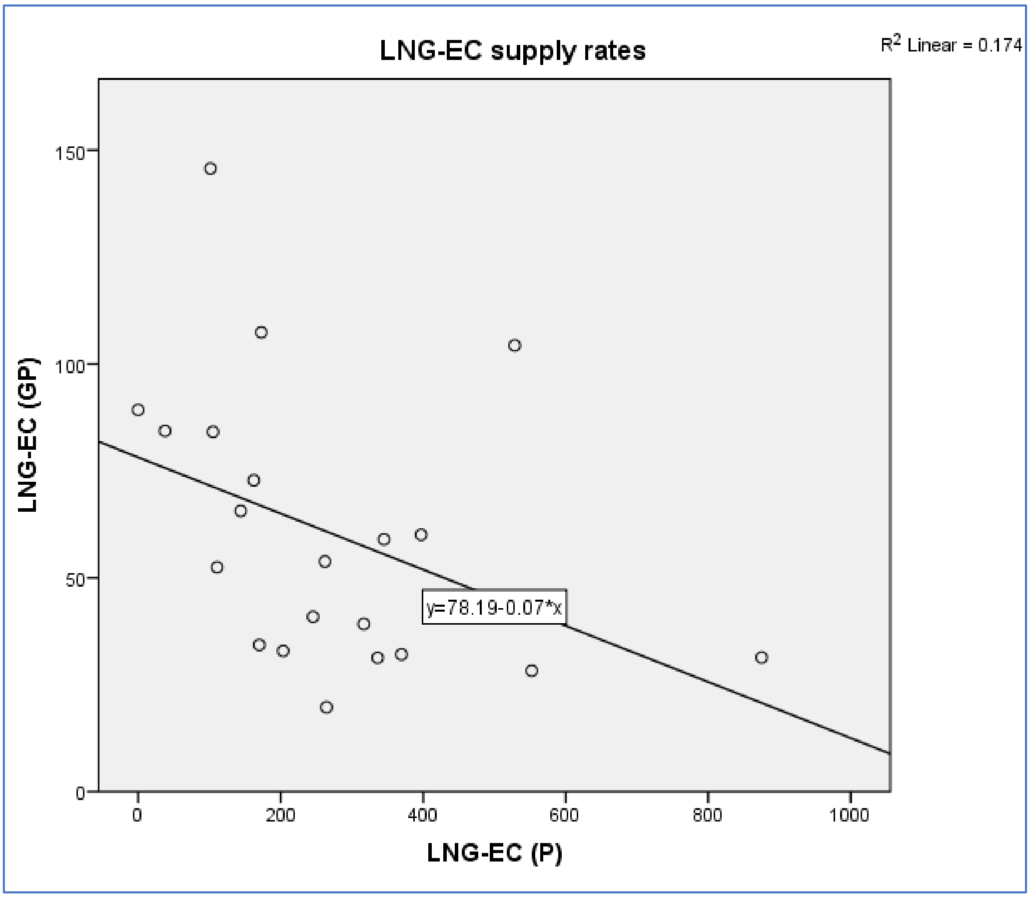
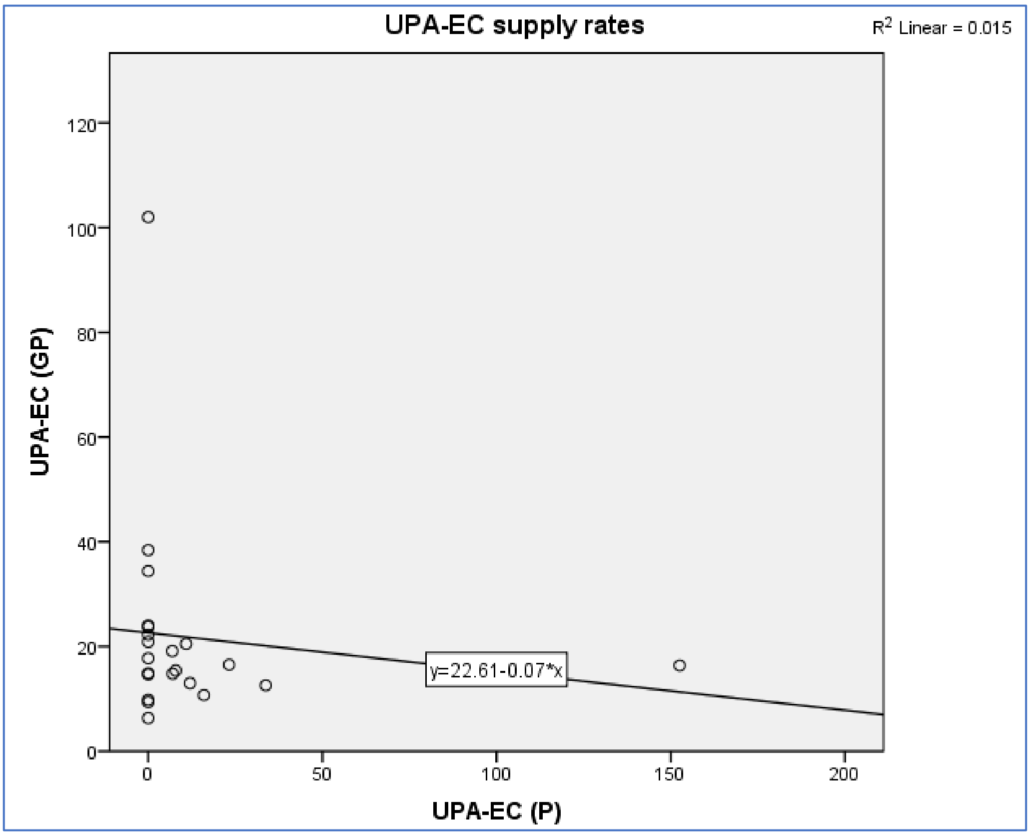


Figure 17 Scatter chart, adding fit line. Dependent variable on y axis (UPA-EC (GP)), independent on x axis (UPA-EC (P))



Two other independent variables were identified from the returned data. Firstly, the percentage of all community pharmacies within the Local Authority area that were reported as providing EHC services (regardless of the individual pharmacy activity) – % EC Supply (Ph). This figure indicates the percentage of community pharmacies who have a contract with the Local Authority to provide EHC services, not just those that provided EC, and therefore includes pharmacies that supplied 0 provisions i.e., demonstrated a lack of engagement with the contract. The other independent variable identified was mean consultation rate (per 10,000 population) for each commissioned community pharmacy, described as EHC (Ph) mv.

To allow these figures to be determined the LNG and UPA values were added together, therefore both these variables reflect the total EHC service provision. This necessitated combining GP prescription data, as a rate per 10,000 population, to provide an alternative dependent value – EHC (GP).

Similar scatter graphs were plotted for EHC (GP) supply and % EC Supply (Ph) and EHC (Ph) mv. Again, the R^2 value was determined. This can be seen in *Figure 18* and *Figure 19*, with R^2 values for EHC (GP) and % EHC Supply (Ph) (R^2 = 0.204) and EHC (GP) and EHC (Ph) mv (R^2 = 0.075).

Figure 18 Scatter chart, adding fit line. Dependent variable on y axis (combined rate of supply - EC (GP)), independent variable on x axis (% EC supply (P))

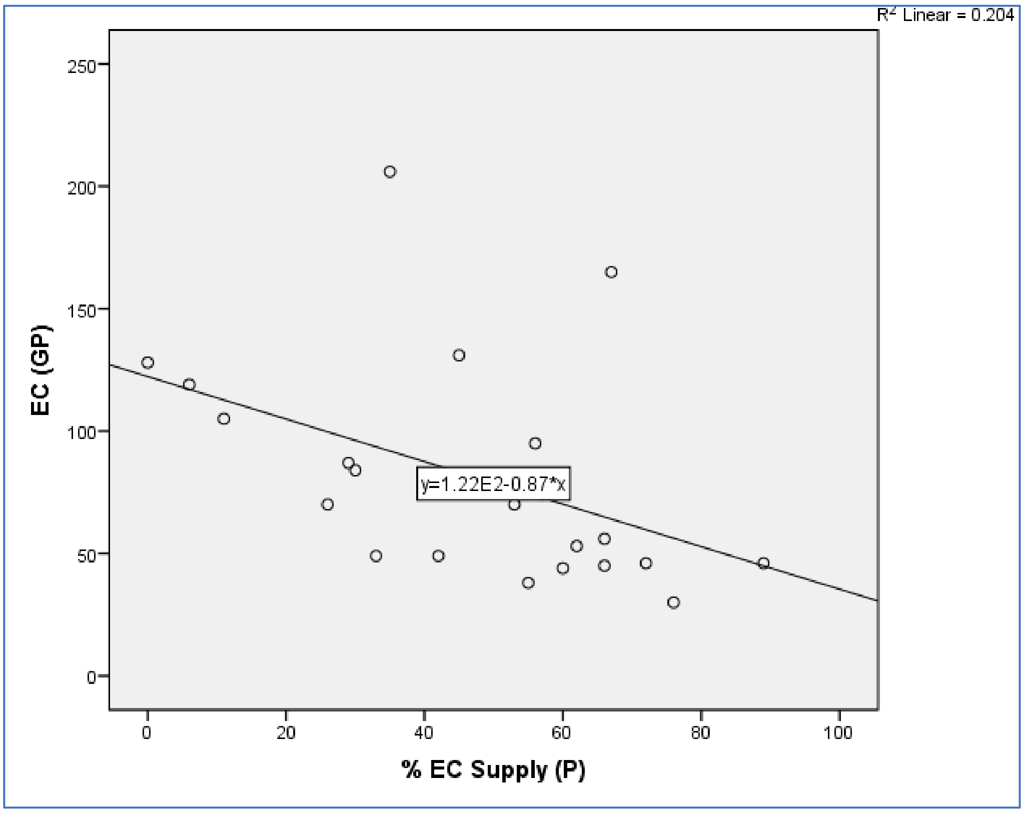


Figure 19 Scatter chart, adding fit line. Dependent variable on y axis (combined rate of supply - EC (GP)), independent on x axis (EC (P) mv)

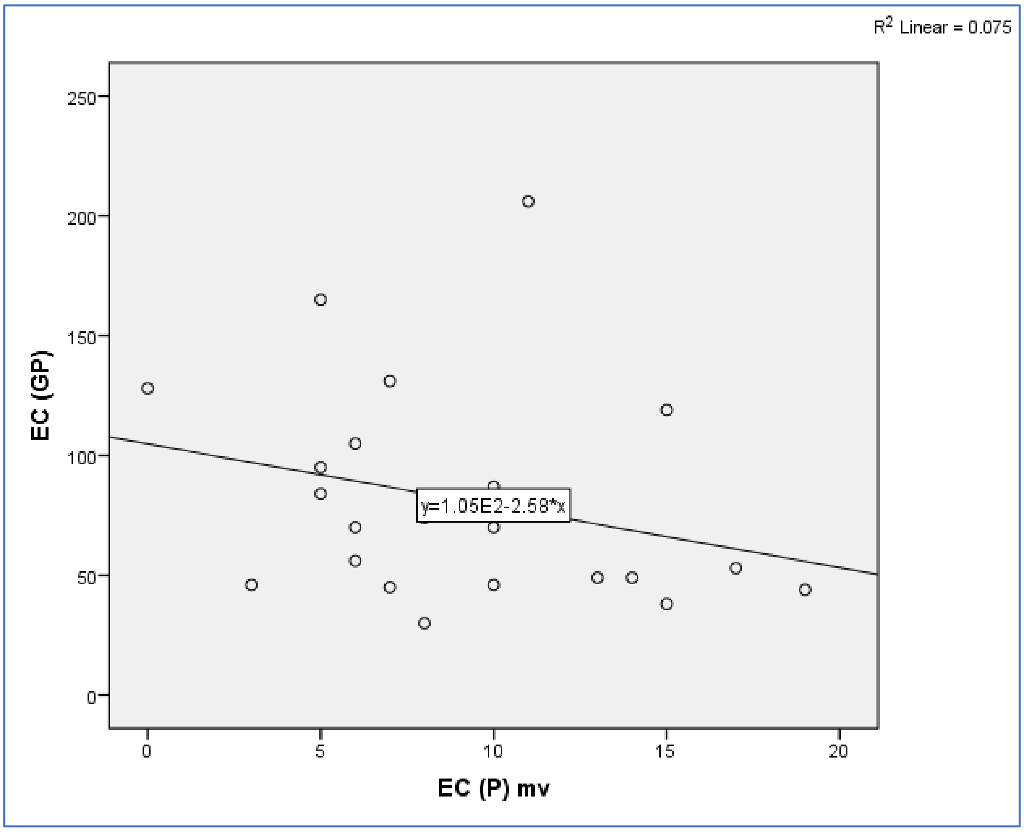


Table 7 R squared (R^2) values

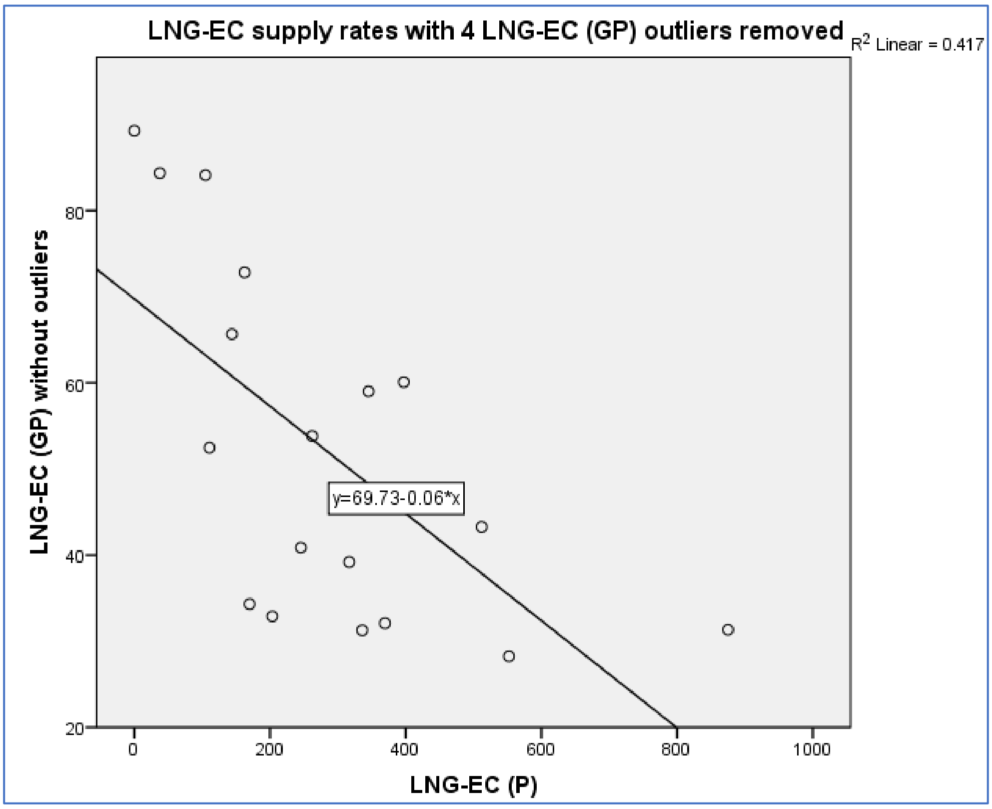
	LNG (Ph) R^2	UPA (Ph) R^2	% EHC Supply (Ph) R^2	EHC (Ph) mv R^2
LNG (GP)	0.174			
UPA (GP)		0.015		
EHC (GP)			0.204	0.075

All the calculated R^2 values for each scatter plot are displayed above in *Table 7.*

7.2.4 Removing outliers

Manual review of the scatter plot of LNG (GP) and LNG (Ph) supplies indicated 3 outlying results, with high LNG (GP) values (*Figure 16*). Data points greater than 1 standard deviation from the mean were removed (4 data points total) and the scatter plot was redrawn (*Figure 20*), the new R^2 value was calculated, 0.417.

Figure 20 Scatter chart, adding fit line. Dependent variable on y axis (LNG-EC (GP)) with 3 outliers removed, independent on x axis (LNG-EC (P))



7.3 Main study: Analysis of EHC service provision results (Local Authority)

The aim of this thesis was determining what influences EHC service commissioning and provision. One of the objectives (page 45) was to identify variables and then analyse their relationship to EHC activity. The feasibility study has already described the correlation between rate of community pharmacy EHC provision and GP EHC prescribing, but this section will repeat the analysis with a larger data set.

Furthermore, this section describes the correlation at a Local Authority level of analysis between GP prescribing rates of EHC and:

1. The rate of community pharmacy provision
2. Measures of deprivation
3. Rurality
4. The prevalence of commissioned community pharmacy providers

Following this, path analysis was used to describe the relationships between the variables.

As previously detailed, legal responsibility for commissioning public health services lies with Local Authorities, including sexual health provision. 97% of Local Authorities commission EHC services from community pharmacy, which in 2015 was commissioned from 5529 (47%) of all pharmacies in England (Mackridge, Gray and Krska, 2017). These services allow for the supply of either (or both) of two contraceptive drugs: Levonorgestrel (LNG) and Ulipristal (UPA), with no direct charge to patients. Pharmacies are reimbursed at a (locally agreed) rate and commissioned by the Local Authority. As a locally commissioned service, pharmacy contractors make an individual business decision whether to apply for and then provide this service. The policy review (page 18, chapter 2) explored some of the factors that may influence this. They must provide this service within any confides of the specification which details factors such as drugs available for supply (LNG, UPA or both), patient eligibility criteria, reimbursement and required training by pharmacists and teams. Conversely all GP surgeries provide this care through routine appointments, with no direct contractual restrictions.

The previous methods chapter (chapter 6) explains the rationale for the data collection process. As detailed, Freedom of Information (FOI) requests were used to obtain community pharmacy EHC provision data, which were combined with publicly available data.

7.3.1 Determining the data population

This study considered EHC provision from all of England, with an intention to gain data from the entire country allowing generalisation of the results. Data from outside England were not requested.

Data of Local Authority districts were obtained from the Office for National Statistics, resulting in 327 potential commissioners of community pharmacy services (Office for National Statistics, 2017a). These data were manually checked against online reference sources such as the Local Government Association. This revealed a hierarchy of authorities, with different responsibilities for different authority types (see *Figure 9*). District councils are not responsible for the commissioning of public health services, passing this responsibility to an-overarching county council. For example, Lancashire County Council commissions public health services on behalf of the populations of 11 district councils.

This system is not universal, with a combination of district/county council relationships, borough councils and metropolitan authorities. In many instances the provision of wider sexual health services is commissioned to an organisation, who in turn sub-contract community pharmacies. However, as primary commissioner the Local Authority remains responsible for responding to FOI requests.

Through direct questioning of council employees/helplines and reviewing council information available online, many of these responsibilities were clarified. Where there was doubt, a FOI request was sent to multiple authorities, and the response provided clarity (e.g., “This council does not have responsibility for public health commissioning, please refer your request to….”). In total, 206 of the original 327 potential commissioners were identified as councils for whom an overarching authority provided this function. During this data review an additional 26 authorities not included in the original data set were identified.

This resulted in a potential data set of 147 commissioners; to whom Freedom of Information (FOI) requests were sent in March and April of 2020. Most of these requests were made via email (appendix 2), although in some cases an online webform was completed. Councils have a legal requirement to respond within 20 working days. Where responses were not received, a follow up request was sent 5 weeks after the initial contact. This is summarised below:

$$327\ Local\ Authorities\ identified - 206\ Local\ Authorities\ that\ do\ not\ commission = 121\ Local\ Authorities$$

$$121\ Local\ Authorities + 26\ additional\ Local\ Authorities\ identified\ through\ FOIs = 147\ Local\ Authorities\ included\ in\ the\ dataset$$

Of these 147 commissioners, 34 (23%) were unable to supply data. Reasons provided included the pressures of the ongoing COVID-19 pandemic and corresponding prioritisation of resources, not holding the requested data (or available in a usable form), or sub-contracting arrangements that meant they were unable to provide the data.

There were 5 Local Authorities (3%) that confirmed that they did not commission an EHC service from community pharmacy during the specified period. In this instance councils provide EHC services through alternate routes (such as specialist sexual health clinics), but no details were provided. Data from Local Authorities that confirmed the absence of a service (i.e., zero provision) were included in the data set as this provides data on the rate of GP prescribing without any community pharmacy commissioning. The full flow of identified commissioners and subsequent exclusion is depicted in *Figure 21*.

7.3.2 FOI response data and sample size

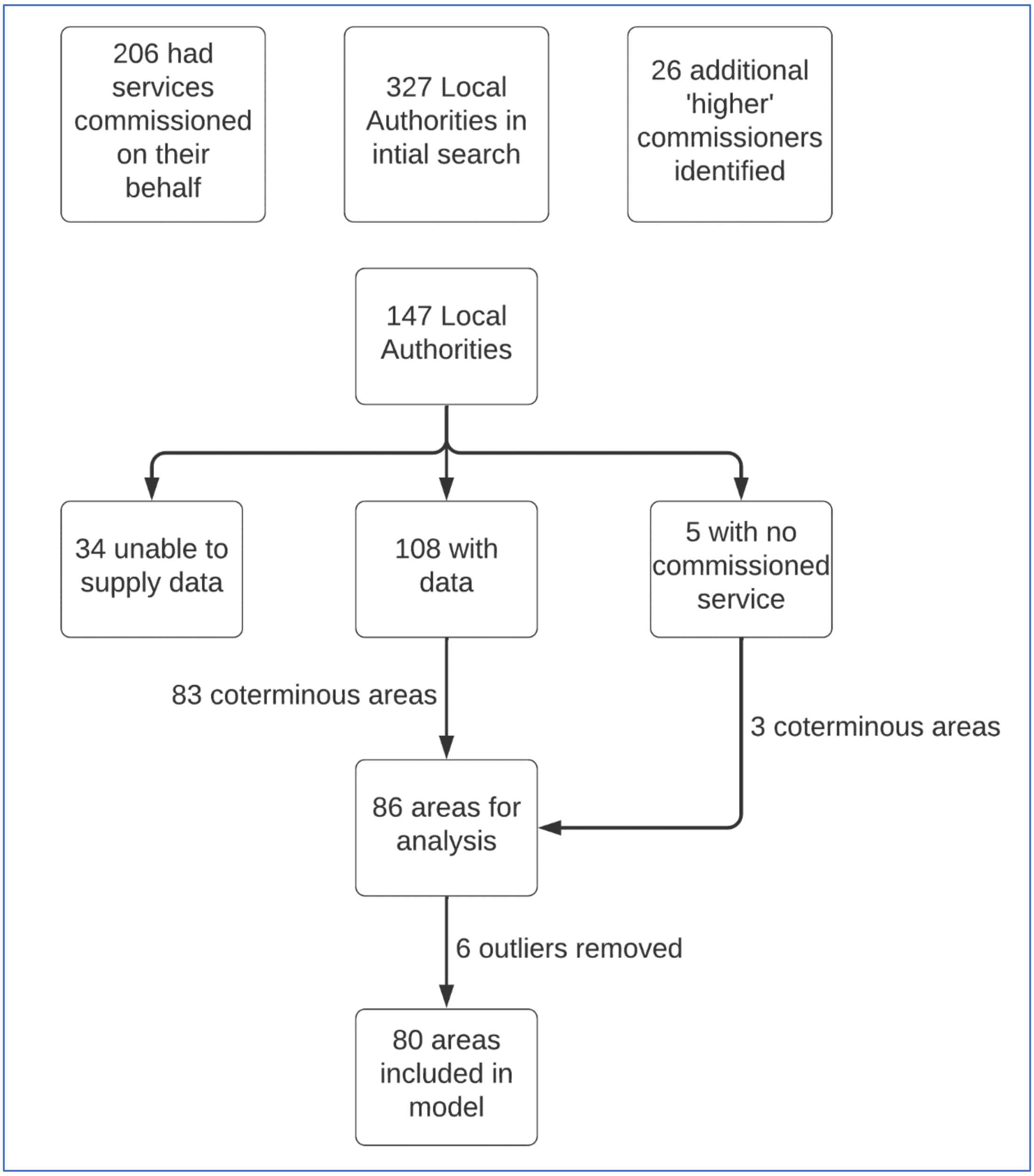
From the original 147 Local Authorities in the dataset, 108 (73%) councils provided data with a further 5 confirming no service was commissioned (3%). These FOIs provided data for 207,731 community pharmacy EHC consultations. The feasibility study highlighted an example where FOI null-return FOI responses were known to be incorrect (see page 142). Where FOI responses indicated no service was commissioned, this was confirmed through contact with the Local Pharmaceutical Committee and searching of both the PSNC services database and local public websites (PSNC, 2019). As explained in the methods, the Local Authority is the unit of analysis for this work, reflecting the contractual arrangements in community pharmacy. However, GP prescribing data is organised by CCG area. Reflecting a historic separation of work and responsibility, the geographies of these two organisation groups do not always match. This means in some cases the populations served and GP surgeries/community pharmacies included in the data are not comparable.

Accordingly, for each of these 108 councils, data from the Office of National Statistics was used to 'map' the Local Authority geography to that of the coterminous CCG (Office for National Statistics, 2017b). The proportion of overlapping geographical area was included in the public data set. Where there was greater than 95% geographical matching, it was determined that the two bodies were analogous. Where the matching was less than this, the Local Authority results were excluded from later analysis.

22 of these areas mapped to more than one CCG area meaning the data were excluded. In 19 cases multiple CCGs were coterminous to a single Local Authority. In these

instances, data collected later for each CCG were amalgamated to allow comparison to the single larger Local Authority. From the identified 147 Local Authority commissioners, data for analysis were available for 86 areas. Within the final data set there were 3 Local Authorities who had confirmed there was no community pharmacy service commissioned. These Local Authorities were mapped to 127 coterminous (greater than 95% overlap) CCGs.

Figure 21 Number of Local Authorities and those successfully mapped to CCGs and available for analysis



Data for prescribing numbers within CCGs were obtained from openprescribing.net, searching for prescribing of both Levonorgestrel and Ulipristal Acetate (OpenPrescribing.net, 2017). Data were available for all identified CCG areas. Searches were made for both LNG-EC (*Levonelle (0703050A0BC)*, *Levonorgest (Emergency Contracep) (0703050A0AA) and Levonorgest (Oral) (0703021L0AA))* and UPA-EC *(Ulipristal Acetate (Emergency Cont) (0703050B0))* for all data nationally. This returned the absolute numbers of LNG and UPA prescribed by all GP surgeries, mapped to CCGs, across England. The unit of analysis remains the Local Authority area.

The geographical area covered accounts for data relating to an estimated total female population (aged 12-55) of 9,380,153 (Local Authority mean 109,072, range 29,354 - 588,835) (Office for National Statistics, 2017c). The estimated total female population (aged 12-55) for all of England is 15,773,732 (Office for National Statistics, 2017b). Both values correspond to mid-year estimates in 2017 in line with the start of the investigated time period (financial year 2017-18).

The 86 areas for analysis were spread across England, with no obvious geographical concentration (e.g., between North and South). Similarly, there was no clear increased likelihood of data from areas of higher population concentration. The Office for National Statistics categorise the rurality of a Local Authority area in the *Rural Urban Classification* last updated in 2011 (Office for National Statistics, 2018b). This process classifies Local Authority areas in 6 categories:

- Major Urban: 100,000 people OR 50% of the population in an urban area with a population exceeding 750,000

- Large Urban: 50,000 people OR 50% of the population in an urban area with a population between 250,000 and 750,00
- Other Urban: fewer than 37,000 people OR less than 26% of the population in rural settlements/larger market towns
- Significant Rural: more than 37,000 people OR less than 26% of the population in rural settlements/larger market towns
- Rural-50: 50% - 80% of the population in rural settlements/larger market towns
- Rural-80: at least 80% of the population in rural settlements/larger market towns

Table 8 Rurality of Local Authorities eligible for analysis (i.e., outliers already removed)

Classification	**Number of Local Authorities**	**% of Local Authorities**	**% all of England**
1. Major Urban	43	49.4	21.5
2. Large Urban	16	18.4	12.7
3. Other Urban	3	3.4	15.5
4. Significant Rural	7	8.0	15.0
5. Rural-50	9	11.5	14.7
6. Rural-80	8	9.2	20.6

Table 8 indicates an over-representation of Major Urban Local Authorities (50% of Local Authority areas for analysis), when compared to Major Urban Local Authorities as a % of all England (21.5%). All other rurality types are lower than the % for all England data. The literature did not highlight any relationship between rurality an EHC usage. Highly rural areas may have lower access to healthcare due to greater distances between patients and healthcare settings. This should impact GP and community pharmacy data equally, negating the impact within the authority area. One of the co-variates explored in the data includes access to healthcare which may control for any influence of rurality.

Figure 22 Map highlighting Local Authority areas where data were collected and successfully mapped to CCG. The data are the number of females aged 12-55. Darker shades indicate greater population numbers.

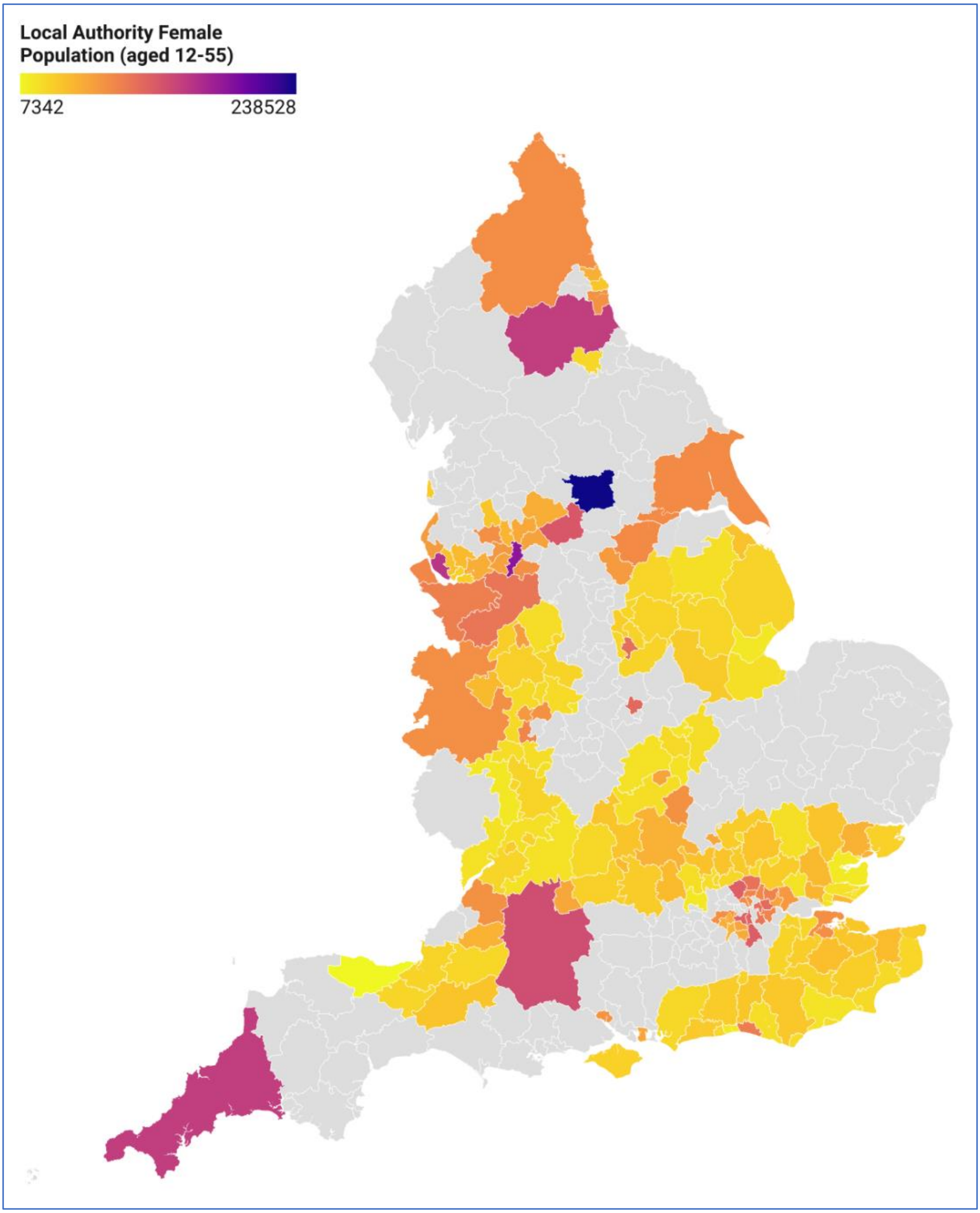


Figure 23 Map highlighting local authority areas where data were collected and successfully mapped to CCG. Darker shades of green indicate higher rates of community pharmacy provision.

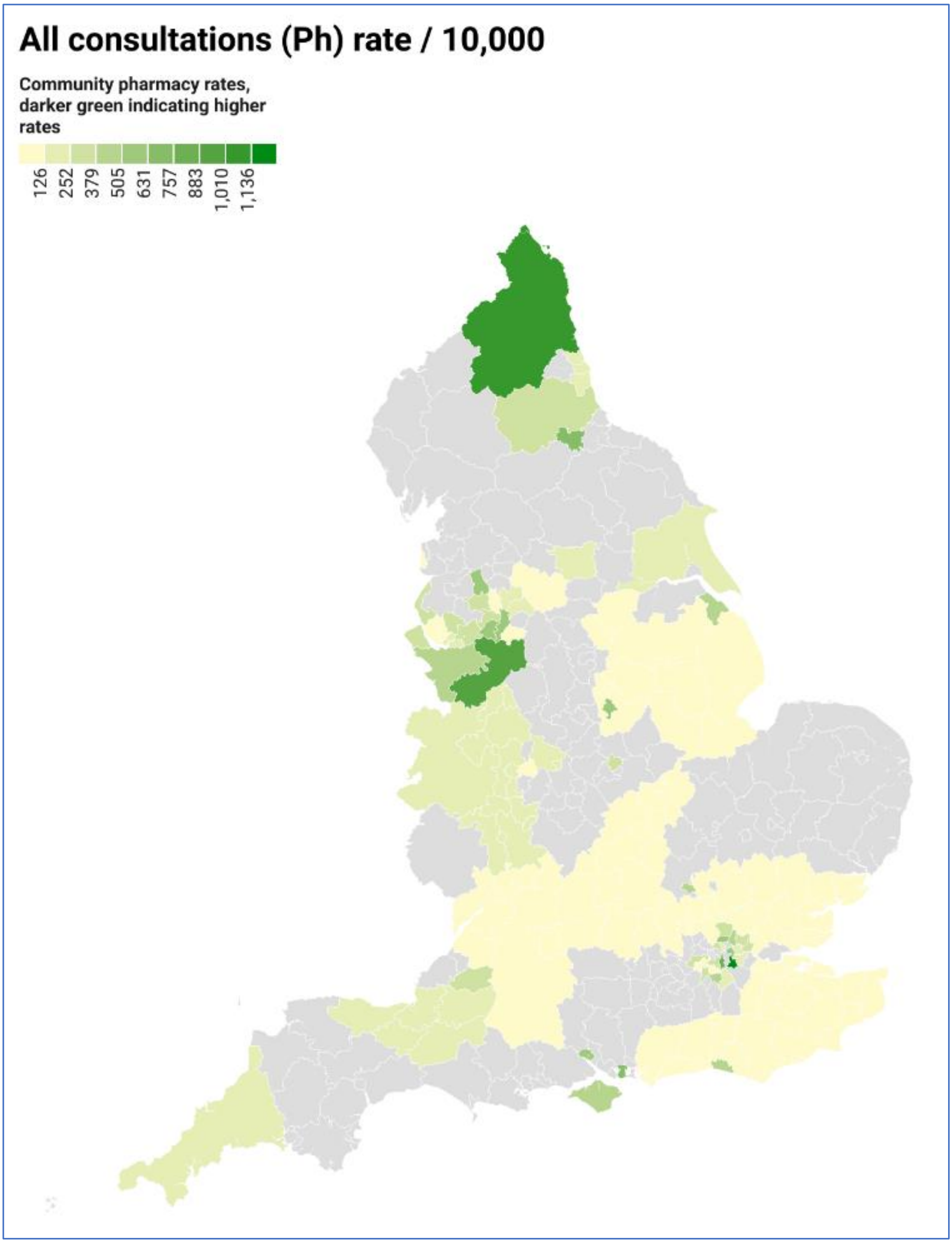


Figure 22 displays the availability of data for analysis. There is no clear geographical clustering which may indicate an additional co-variate or source of bias. The darker shades in the figure represent greater population numbers. It is important to note that high population density areas (such as London) appear as a lighter shade, as the population is split into many Local Authorities. The values represent numbers of eligible female population, rather than population density. Similar to geography, there is no clear clustering of high/low population density authority areas. *Figure 23* depicts the spread of community pharmacy consultation rates across the country. There is no obvious clustering of high or low values. As with the population density (*Figure 22*) no obvious geographical trends can be observed.

The collected data includes 54% of all Local Authority areas and a female (12-55) population of 9,380,153. This is 59% of the total eligible female population. Whilst there are some apparent gaps in the response rate, over 50% of the total sample size (geographic and population) are covered. The data is not dissimilar to the rural-urban proportions across the country, and the total number of data points meets the power calculations determined in the feasibility study (*page **Error! Bookmark not defined.***). This provides a strong indication that the analysis can be generalised across the country.

7.3.3 Description of the data - frequency

The unit of analysis throughout is the Local Authority. For each of the 86 local authorities, the rates (per 10,000 female population, aged 12-55) were calculated for LNG and UPA in both community pharmacy and GP settings. These are described as LNG (Ph) / 10,000 or

UPA (Ph) / 10,000 for community pharmacy and for GP, LNG (GP) / 10,000 or UPA (GP) / 10,000. The raw data were also combined to calculate a combined rate for all EHC consultations – all consultations (Ph) / 10,000 or all consultations (GP) / 10,000. All the calculated rates for all Local Authorities are available in appendix 3.

Table 9 details the frequency of the LNG, UPA and consultation rates calculated. The frequency indicates the number of Local Authority areas with that rate of consultations, per 10,000 female population. Reviewing the frequency table shows that the spread of data within community pharmacy is much greater than that of a GP setting. 12 of the LNG (Ph) and 12 of the All Consultation Rates (Ph) were higher than 511, 14% of the total. This contrasts sharply to the highest GP setting value of 206 consultations per 10,000.

There were 3 all consultations (Ph) values where there were 0 consultations, reflecting the 3 Local Authorities where no service was commissioned. There are 4 LNG (Ph) 0 values, as in one case an area provided only UPA. The 55 UPA (Ph) 0 values reflects the tendency in commissioning to restrict the service to LNG provision only – often as a cost control measure. No GP areas reported 0 consultations or prescriptions of either drug, likely reflecting the lack of restrictions highlighted during the policy review (page 18, chapter 2).

Table 9 Frequency of calculated EHC rates per 10,000 female population

Rate per 10,000 population	Frequency LNG (Ph)	Frequency UPA (Ph)	Frequency all consultations (Ph)	Frequency LNG (GP)	Frequency UPA (GP)	Frequency all consultations (GP)
0	4	55	3	0	0	0
1-30	8	20	7	9	72	1
31-60	11	5	8	35	13	22
61-90	4	1	5	31	0	30
91-120	7	1	5	9	1	22
121-150	5	0	9	2	0	8
151-180	7	1	6	0	0	2
181-210	3	2	4	0	0	1
211-240	3	0	3	0	0	0
241-270	7	0	5	0	0	0
271-300	3	0	5	0	0	0
301-330	2	0	2	0	0	0
331-360	2	0	3	0	0	0
361-390	3	0	2	0	0	0
391-420	2	1	4	0	0	0
421-450	2	0	2	0	0	0
451-480	0	0	0	0	0	0
481-510	1	0	1	0	0	0
511+	12	0	12	0	0	0

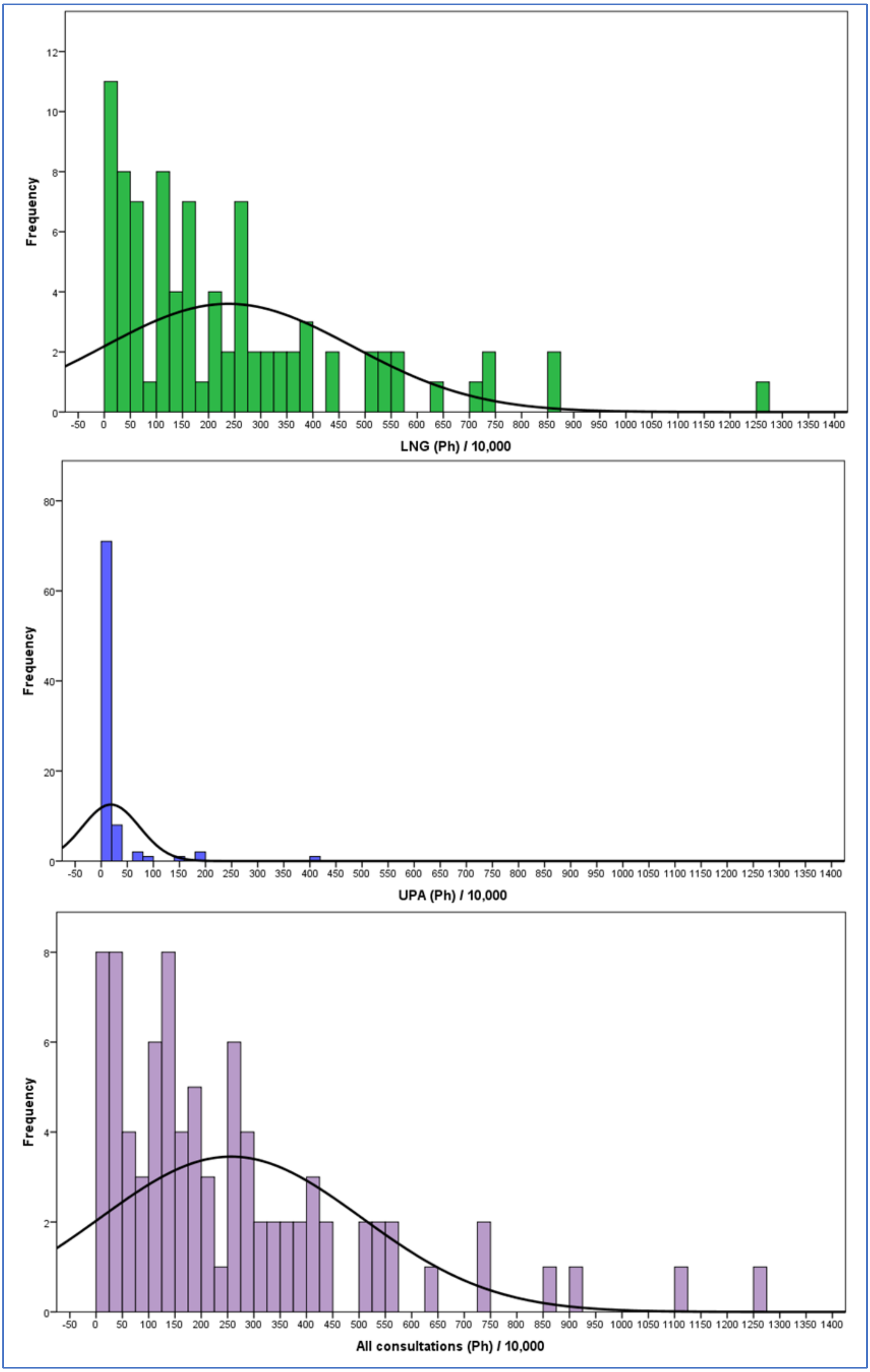
Table 10 shows the final data for the rates of LNG, UPA and combined consultations (all consultations). These data are expressed for both community pharmacy (Ph) and general practice (GP) consultations. The 'all consultations' values were determined by adding the number of LNG and UPA consultations and determining the rate per 10,000 population (as previously described). In all three scenarios the range was greater in the Ph variable, as was the standard deviation, skewness and kurtosis – reflecting the greater spread and lack of normality of community pharmacy data. These three values describe the 'shape' of the distribution. Skewness is a measure of symmetry in the distribution (left and right on the x-axis), and kurtosis the size of the tails and height of the peak (Field, 2018). The standard deviation indicates how spread the data is relative to its mean (Field, 2018).

In both GP and community pharmacy settings UPA is supplied at a lower rate than LNG. The skewness of the data illustrations that each value skews towards 0. The community pharmacy data is highly skewed as shown by the frequencies in *Table 9*. Whilst the bulk of the data are grouped near 0, there is a long range of data, reflected by the high standard deviations. The GP data is much less skewed, although also cannot be described as normal distribution. A similar pattern is visible when reviewing the kurtosis. Kurtosis defines how heavily the tails of a distribution differ from the tails of a normal distribution. High kurtosis values tend to have heavy tails, possibly indicating outliers. The kurtosis values are higher in the UPA results, as well as greater in Ph data compared with GP.

Table 10 Description of consultation rates

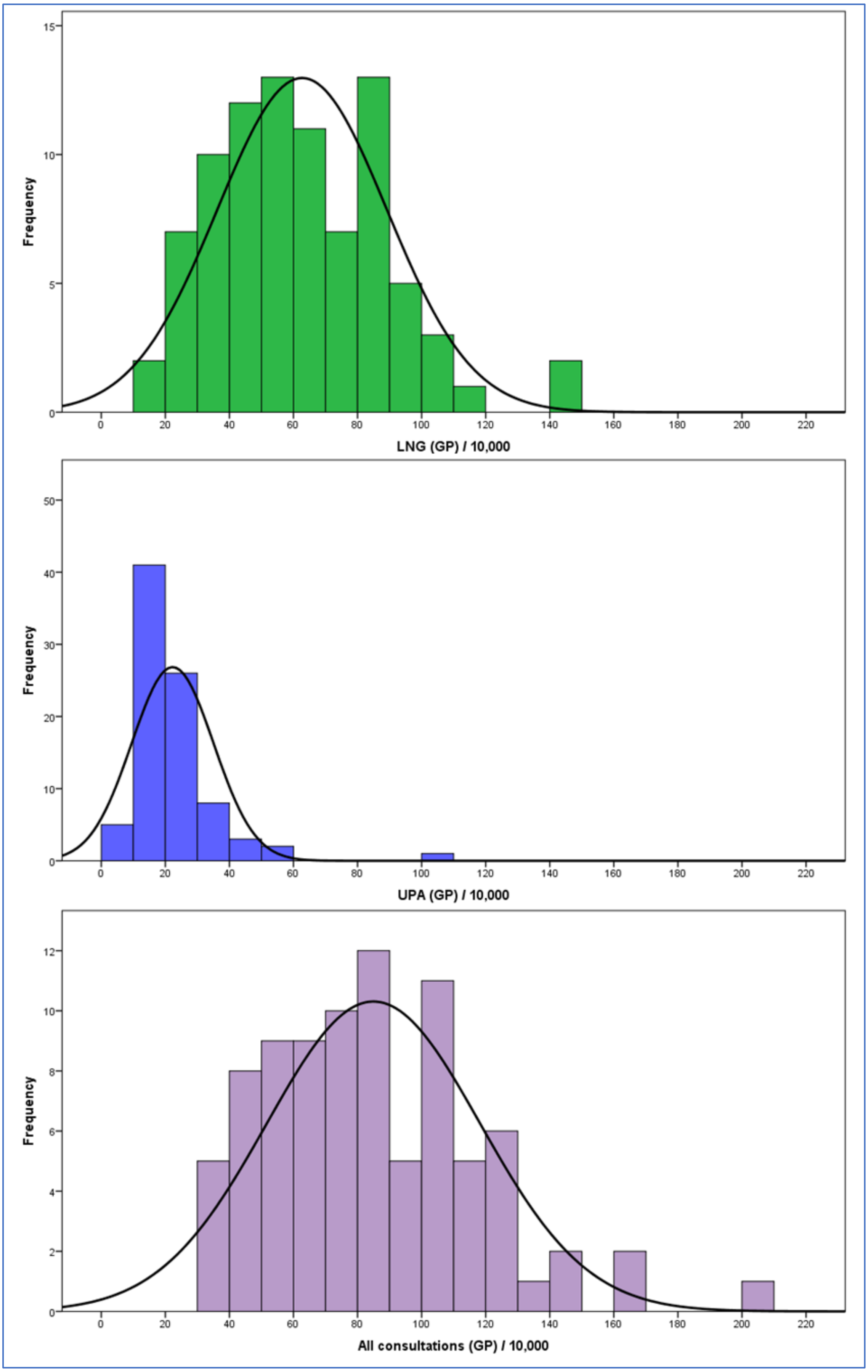
	LNG (Ph) / 10,000	UPA (Ph) / 10,000	All consultations (Ph) / 10,000	LNG (GP) / 10,000	UPA (GP) / 10,000	All consultations (GP) / 10,000
Number	86	86	86	86	86	86
Mean	237.9	18.6	256.4	62.7	22.3	85.0
Median	170.8	0.0	180.0	59.0	19.8	82.2
Std. Deviation	238.2	54.7	248.3	26.4	12.8	33.3
Skewness	1.7	5.1	1.7	0.6	3.3	0.8
Kurtosis	3.6	29.9	3.8	0.5	17.4	1.1
Range	1262.0	400.1	1262.0	128.4	95.7	176.0
Min	0.0	0.0	0.0	17.3	6.3	30.4
Max	1262.0	400.1	1262.0	145.7	102.0	206.4

Figure 24 Histograms of Community Pharmacy consultation rates (per 10,000 population)



Histograms were plotted of community pharmacy data. *Figure 24* displays the data for LNG, UPA and all consultations. The x axis (consultation rate) is the same for each graph to allow comparison. As indicated by the skewness values, and the normal curve added to the chart, none of the data exhibit normality. The graphs highlight several outliers in all 3 scenarios. The charts also highlight the concentration of UPA results towards 0.

Figure 25 Histograms of GP consultations rates (per 10,000 population)



Histograms were also plotted for the GP data (*Figure 25*). Again, the x axis has been fixed to allow comparison, however the scale is smaller than the community pharmacy data due to the lower rates. The degree of data skew is less in the GP data, demonstrated by the curve more closely resembling a standard distribution – although the data is not normally distributed. Similar to the community pharmacy data, the UPA data are clustered at the lower end of the scale.

The proportion of commissioned pharmacies ranges from 0% to 100%. The mean proportion of commissioned pharmacies is 48.1% (SD 26.8).

7.3.4 Description of the data – correlation

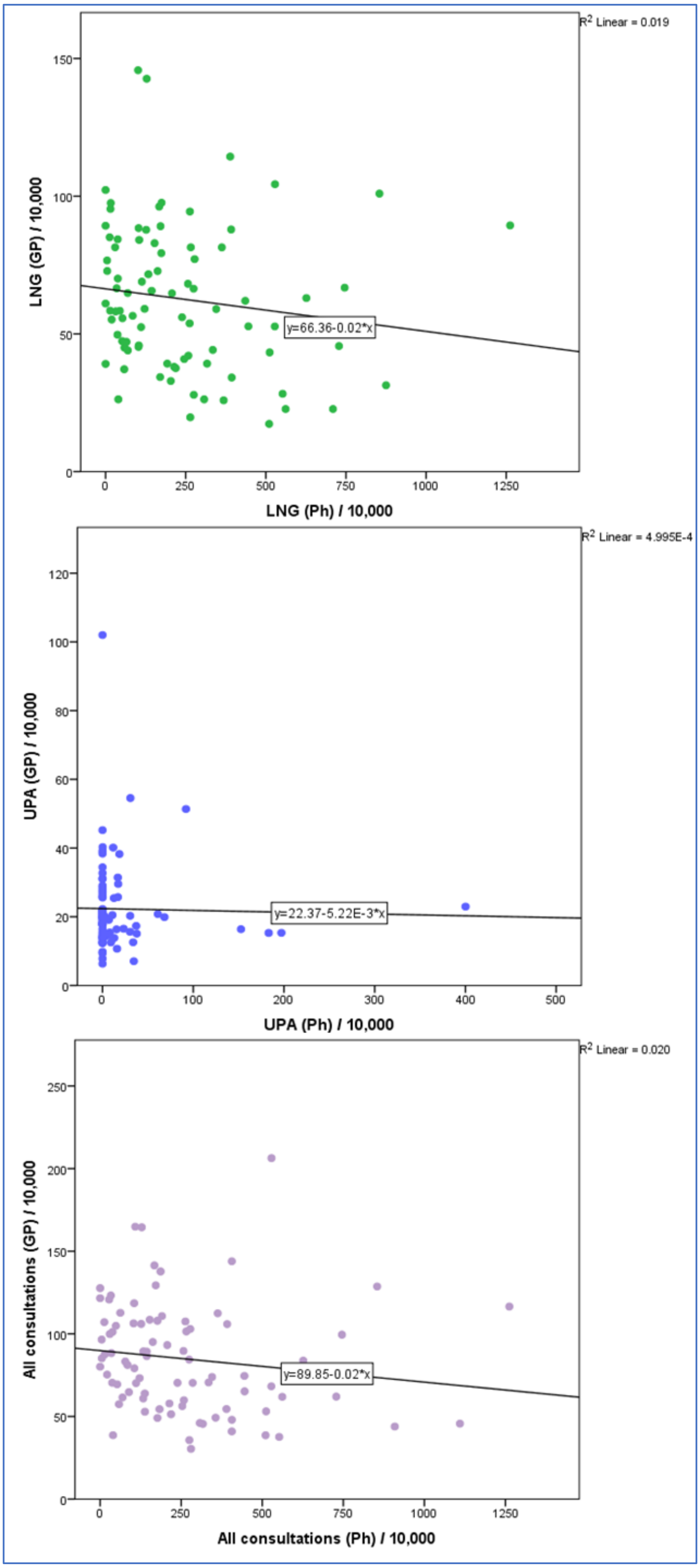


Figure 26 Scatter plots of community pharmacy and GP supply rates per 10,00 population. 1 – LNG, 2 – UPA, 3 - all consultations

Scatter graphs were plotted to determine the size of correlation between the corresponding community pharmacy and GP data. *Figure 26* displays the data for LNG, UPA and all consultations respectively – each with a linear best fit line added. From this the R^2 values can be determined which were 0.019 (LNG), 0.00 (UPA) and 0.020 (all consultations). This would indicate a low level of prediction by these variables, ranging from 1.9% to 2.0%. Whilst many studies do demonstrate a much higher value of R^2, this is very dependent on the setting of the correlation and the variable in question.

7.3.5 Removing Outliers

Given the clear presence of outliers in all the data groups, the data were reviewed to improve the fit of the established theoretical model. Box plots were plotted, and outliers were highlighted by SPSS. Data points outside 1.5 times the Inter Quartile Range from the 1st or 3rd quartile were removed. This exercise was repeated for each of the drugs and settings.

The updated data values are displayed in *Table 11*. For the community pharmacy data, rates above 600 (LNG), 30 (UPA) and 600 (all consultations) were removed totalling in 7 values being removed for each variable. With the GP data, rates above 100 (LNG), 40 (UPA) and 130 (all consultations) were removed totalling 6, 2 and 6 values being excluded. This exercise removed between 2% and 9% of the data, leaving over 90% of the data within each group.

In each scenario the mean decreased due to the removal of upper value outliers. For example, the mean of all consultations (Ph) decreased from 261.2 to 200.2. Similarly, the 'all consultations' (GP) mean decreased from 85.4 to 79.2. In each case the number and range of the GP outliers was lower than that of the community pharmacy data resulting in a smaller impact on the mean. Median values also decreased (all consultations (Ph) reduced from 183.1 to 167.2 once outliers were removed) but the difference was less pronounced. Within the GP data the change was even smaller, with the median remaining unchanged at 19.8 for UPA (GP) rates.

Both the skewness and kurtosis values dramatically reduced in all scenarios. Following the removal of outliers, the LNG and all consultation rates could be considered moderately skewed in community pharmacy and not significantly skewed in GP data. Both settings exhibited a high degree of skew (towards 0) with UPA provision.

Table 11 Descriptions of consultation rates with outliers removed

	LNG (Ph) / 10,000 - no outliers	UPA (Ph) / 10,000 - no outliers	All consultations (Ph) / 10,000 - no outliers	LNG (GP) / 10,000 - no outliers	UPA (GP) / 10,000 - no outliers	All consultations (GP) / 10,000 - no outliers
Number	79	79	79	80	84	80
Missing	7	7	7	6	2	6
Mean	185.5	5.6	200.2	58.5	20.9	79.3
Median	152.9	0.0	167.2	58.3	19.6	77.2
Std. Deviation	156.1	10.4	154.9	21.7	8.7	26.3
Skewness	0.8	1.9	0.7	0.0	1.2	0.1
Kurtosis	-0.2	2.4	-0.4	-1.0	1.5	-1.0
Range	561.6	37.7	561.6	80.3	45.8	99.0
Minimum	0.0	0.0	0.0	17.3	6.3	30.4
Maximum	561.62	37.69	561.62	97.63	52.11	129.36
Shapiro-Wilk	0.001	0.000	0.001	0.000	0.002	0.231

Following the removal of outliers, histograms were replotted (*figure 27 and 28)*. The clear outliers seen in *Figure 24* and *Figure 25* have been removed. The community pharmacy data did not appear to visibly indicate normal distribution, whereas the GP data are much closer to a normal distribution. Whether the data is normally distributed determines the most appropriate statistical tests. The Shapiro-Wilk test is a standard test, specifically for normality, and compares this to the standard deviation and mean (Field, 2018). Shapiro-Wilk tests confirmed non-normal distribution in the community pharmacy and GP data. All consultations (GP) exhibits normal distribution with a Shapiro-Wilk value of 0.231.

Figure 27 Histograms of Community Pharmacy consultation rates (per 10,000 population) - no outliers

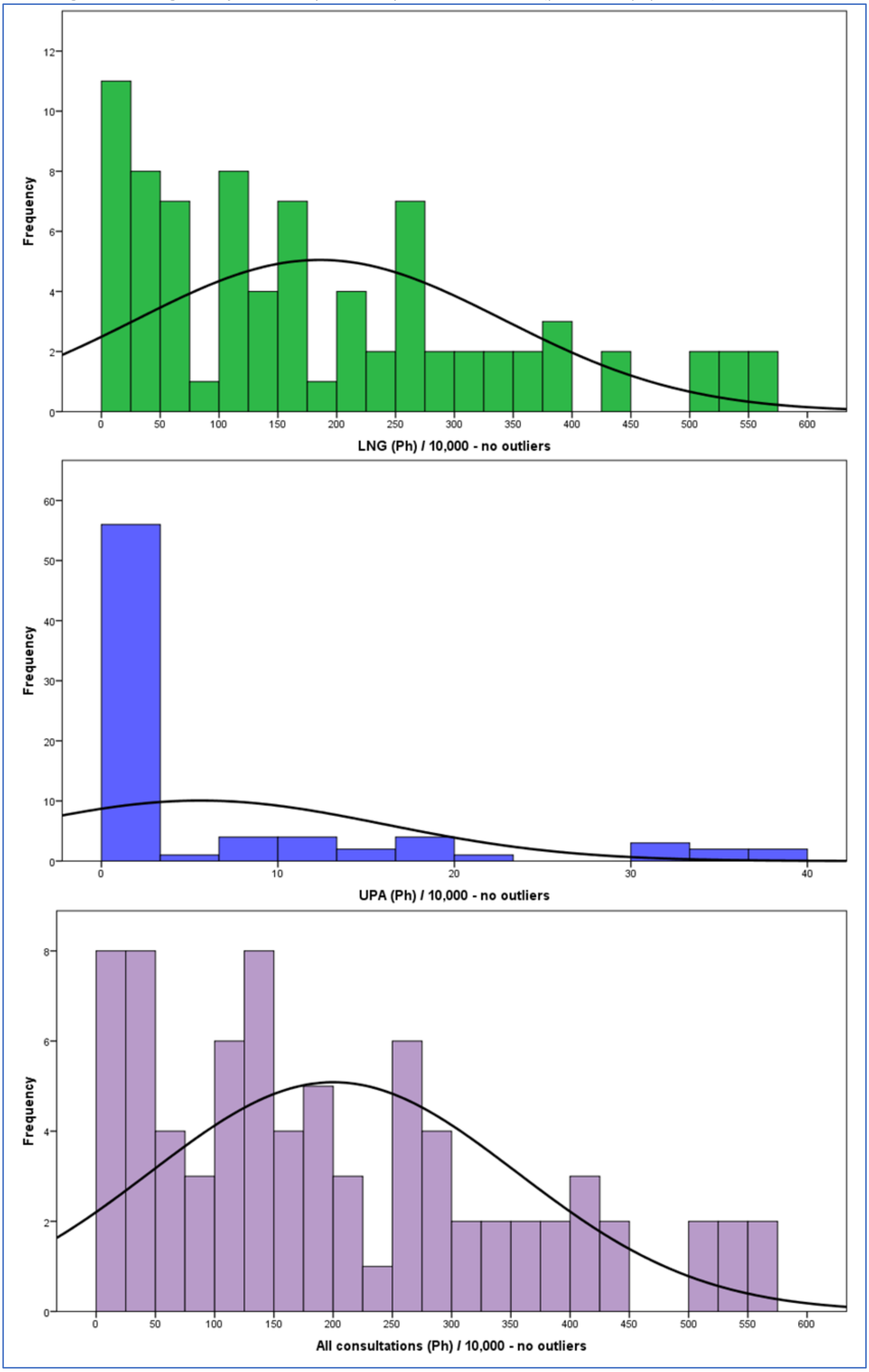
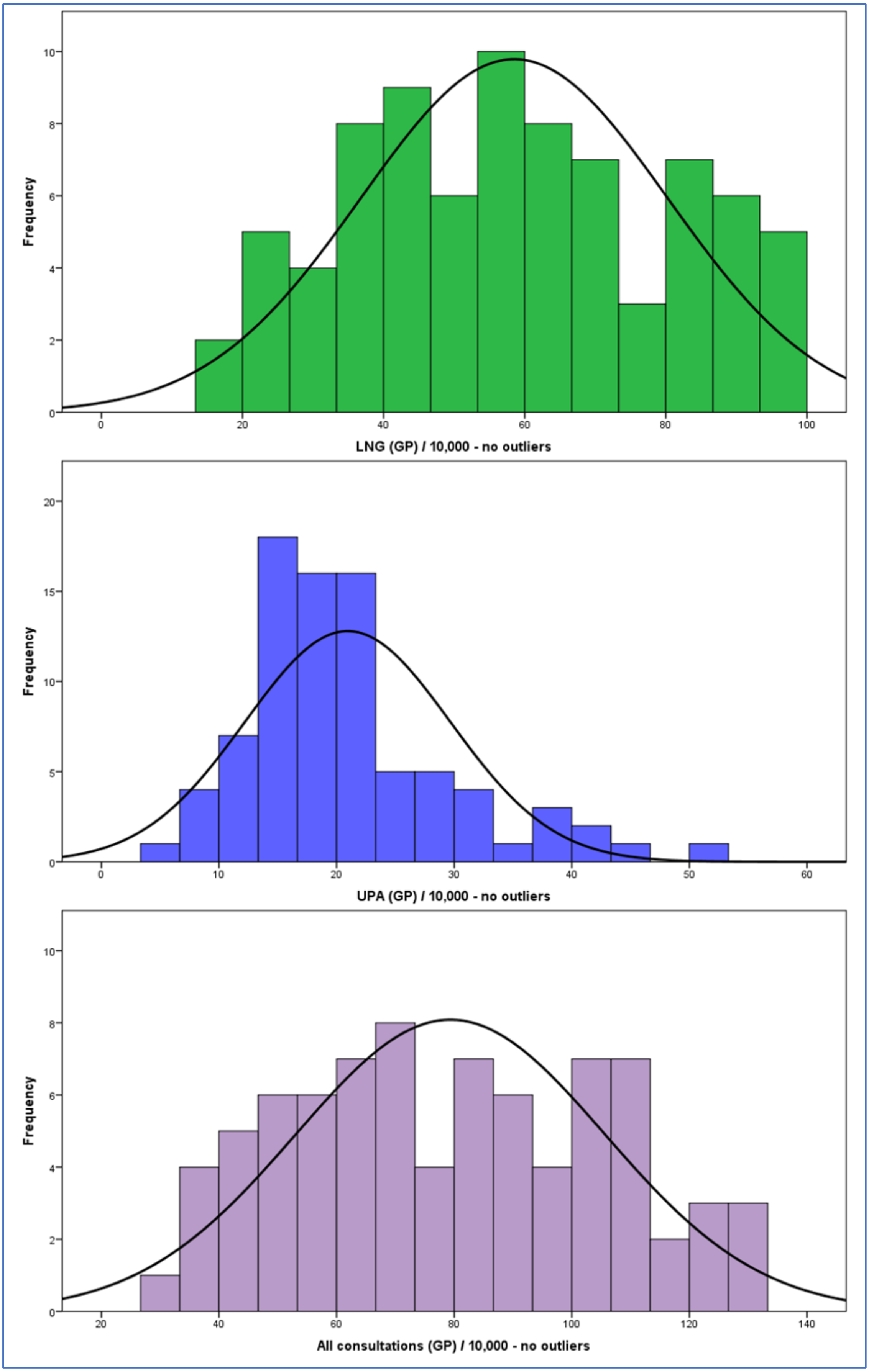


Figure 28 Histograms of GP consultations rates (per 10,000 population) - no outliers



As before, scatter graphs were plotted to determine the degree of correlation. R^2 values were found for LNG (0.13), UPA (0.017) and all consultations (0.21). The greater R^2 value of all consultations once outliers were removed (0.21 increased from 0.02) is suggestive that the manipulated data conforms much more strongly to the model. With over 90% of the original data points included in the scatter graph, this provides some strength to possible conclusions. *Figure 29* provides the scatter graphs and the line of best fit for each of the scenarios – LNG, UPA and all consultations. An R^2 value of 0.21 is indicative that 21% of the data is GP supply rate is explained by the independent variable - community pharmacy EHC rates.

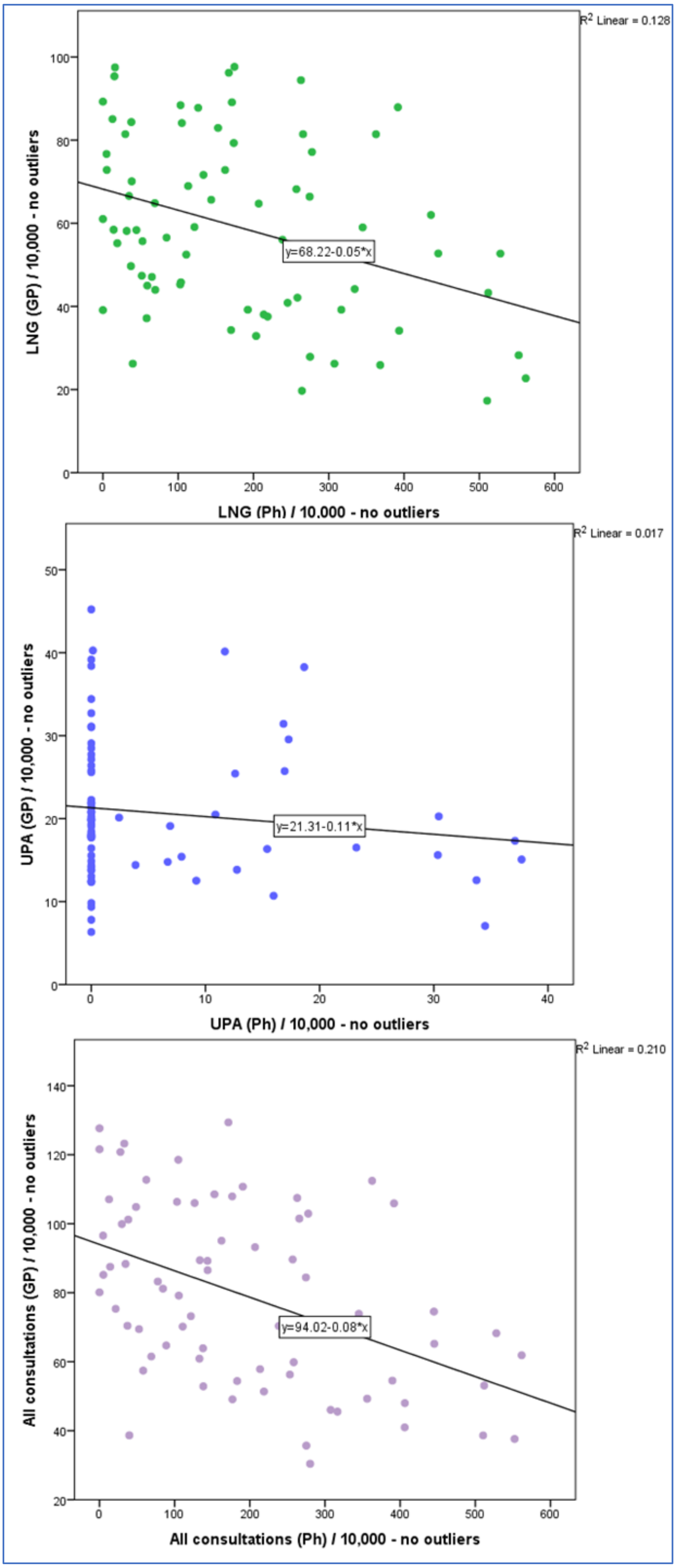


Figure 29 Scatter plots of community pharmacy and GP supply rates per 10,00 population (no outliers). 1 – LNG, 2 – UPA, 3 - all consultations

7.3.6 Determining correlation

During the policy review (page 18), feasibility study, and data collection several co-variates were identified. Where data were available bi-variate correlations were determined using 2-tailed Pearson's correlation coefficient. Correlations were determined between the key variables: community pharmacy and GP provision. Correlations were also determined for likely influences on EHC provision/demand – namely the measures used to determine the Index of Multiple Deprivation (IMD). Given the slight over-representation of Major Urban areas, correlations were also determined for the measure of local rurality. The full correlation matrix is presented in Appendix 4.

Significant correlations with the two key variables (all consultations (P) and (GP)) are displayed in *Table 12*. Significance is indicated at 0.01** and 0.05*. Community pharmacy and GP EHC provision rates (all consultations) were found to be strongly negatively correlated, $r(73) = -0.458$, $p<0.01$.

Significant correlations were also found between community pharmacy EHC provision rates and the % of pharmacies commissioned, $r(77) = 0.461$, $p<0.01$; rurality, $r(79) = -0.230$, $p<0.05$; Index of Multiple Deprivation $r(79)$, $= 0.287$, $p>0.05$; income deprivation $r(79) = 0.252$, $p<0.05$, health deprivation and disability $r(79) = 0.275$, $p<0.05$; crime $r(79) = 0.266$, $p<0.05$; living environment $r(79) = 0.331$, $p<0.01$; income affecting children $r(79) = 0.293$, $p<0.01$ and income affecting older people $r(79) = 0.321$, $p<0.01$.

Fewer significant correlations were found between GP data and the co-variates. Other than the strong correlation to community pharmacy provision, the only significant correlation was with living environment r(80) = 0.241, p<0.05. Whilst not statistically significant there is a trend between all consultations (GP) and the % of pharmacies commissioned (-0.195, p=0.089).

Table 12 Bivariate correlations (Local Authority)

**. Correlation is significant at the 0.01 level (2 tailed) *. Correlation is significant at the 0.05 level (2 tailed)		All consultations (Ph) / 10,000 - no outliers	All consultations (GP) / 10,000 - no outliers
All consultations (Ph) / 10,000 - no outliers	Pearson Correlation		**-.458****
	Sig. (2-tailed)		**.000**
	N	79	73
All consultations (GP) / 10,000 - no outliers	Pearson Correlation	**-.458****	
	Sig. (2-tailed)	**.000**	
	N	73	80
% of pharmacies commissioned	Pearson Correlation	**.461****	-.195
	Sig. (2-tailed)	**.000**	.089
	N	77	77
Local Authority Rurality	Pearson Correlation	**-.230***	.184
	Sig. (2-tailed)	.041	.103
	N	79	80
Index of Multiple Deprivation (IMD)	Pearson Correlation	**.287***	.026
	Sig. (2-tailed)	.010	.820
	N	79	80
Income Deprivation Domain	Pearson Correlation	**.252***	.017
	Sig. (2-tailed)	.025	.880
	N	79	80
Health Deprivation and Disability Domain	Pearson Correlation	**.275***	-.094
	Sig. (2-tailed)	.014	.404
	N	79	80
Crime Domain	Pearson Correlation	**.266***	.077
	Sig. (2-tailed)	.018	.497
	N	79	80
Living Environment Deprivation Domain	Pearson Correlation	**.331****	**.241***
	Sig. (2-tailed)	.003	0.031
	N	79	80
Income Deprivation Affecting Children Index (IDACI)	Pearson Correlation	**.293****	.034
	Sig. (2-tailed)	.009	.764
	N	79	80
Income Deprivation Affecting Older People Index (IDAOPI)	Pearson Correlation	**.321****	.101
	Sig. (2-tailed)	.004	.375
	N	79	80

7.3.7 Multiple regression

Multiple regression analyses were conducted to examine the relationship between all consultations (GP) / 10,000 – no outliers, and the variables listed in *Table 12*. Variables were removed using the backward method (see page 128), to create the 8 models described below (*Table 13*). Using a backward method creates a model of all variables identified in *Table 12*, and the contribution of each evaluated with the p-value of its t-test. The significance variables are compared against the removal criteria and removed if not making a significant contribution to the model. There were 10 independent variables originally included in the model, and these were removed sequentially – as depicted in *Table 13*. The model summary is presented in *Table 14*.

Table 13 Variables contained in each model (dependent variable: all consultations (GP) / 10,000 no outliers)

Variable	**Model number**							
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**
All consultations (Ph) / 10,000 - no outliers	✓	✓	✓	✓	✓	✓	✓	✓
Local Authority Rurality	✓	✓	✓	✓	✓	✓	✓	✓
Living Environment Deprivation Domain	✓	✓	✓	✓	✓	✓	✓	✓
Income Deprivation Affecting Older People Index (IDAOPI)	✓	✓	✓	✓	✓	✓	✓	
Crime Domain	✓	✓	✓	✓	✓	✓		
% of pharmacies commissioned	✓	✓	✓	✓	✓			
Index of Multiple Deprivation	✓	✓	✓	✓				
Income Deprivation Domain	✓	✓	✓					
Income Deprivation Affecting Children Index (IDACI)	✓	✓						
Health Deprivation and Disability Domain	✓							

Table 14 Model summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.659	.435	.341	21.19321	.435	4.615	10	60	.000
2	.659	.435	.351	21.02313	.000	.025	1	60	.875
3	.659	.434	.361	20.85869	.000	.034	1	61	.855
4	.656	.431	.367	20.75563	-.003	.379	1	62	.540
5	.655	.429	.376	20.61820	-.001	.155	1	63	.695
6	.651	.424	.380	20.55596	-.005	.608	1	64	.438
7	.645	.416	.380	20.54439	-.008	.926	1	65	.340
8	.639	.408	.381	20.52764	-.008	.891	1	66	.349

Linear regression plots determined an R^2 value for the correlation between all consultation (Ph) and (GP) as 0.21. The multiple regression models increase the R^2 to between 0.408 and 0.435. The adjusted R^2 provides an indication of how well the model(s) generalise. The adjusted R^2 values are slightly lower, indicating between 2% and 9% less explanation of GP EHC rates if generalising across the population. The adjusted R^2 values ranged from 0.341 to 0.381.

The F-test is a measure of how much a model has improved the prediction of the dependent variable, compared to the level of inaccuracy of the model (Field, 2018). In short, how good the model is and how useful the multiple regression is in describing the variance found (Field, 2018). F-tests are shown in *Table 15*. All the results are statistically significant ($p>0.01$). This demonstrates that the independent variables statistically significantly predict the dependent variable in each of the models. The regression models are a good fit of the data.

Table 15 Analysis of Variance (ANOVA)

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	20726.543	10	2072.654	4.615	.000
	Residual	26949.133	60	449.152		
	Total	47675.676	70			
2	Regression	20715.386	9	2301.710	5.208	.000
	Residual	26960.290	61	441.972		
	Total	47675.676	70			
3	Regression	20700.421	8	2587.553	5.947	.000
	Residual	26975.254	62	435.085		
	Total	47675.676	70			
4	Regression	20535.511	7	2933.644	6.810	.000
	Residual	27140.165	63	430.796		
	Total	47675.676	70			
5	Regression	20468.620	6	3411.437	8.025	.000
	Residual	27207.056	64	425.110		
	Total	47675.676	70			
6	Regression	20210.102	5	4042.020	9.566	.000
	Residual	27465.574	65	422.547		
	Total	47675.676	70			
7	Regression	19818.929	4	4954.732	11.739	.000
	Residual	27856.747	66	422.072		
	Total	47675.676	70			
8	Regression	19442.938	3	6480.979	15.380	.000
	Residual	28232.737	67	421.384		
	Total	47675.676	70			

The model with the best fit, model 8, found a significant regression equation ($F(3,67)=15.380$, $p<0.00$), with an R^2 of 0.408. This predicted the rate of all consultations (GP) / 10,000 is equal to 59.132 + -0.092 (all consultations (Ph) / 10,000) + 3.648 (Local Authority Rurality) + 1.283 (Living Environment Deprivation). All consultations (GP) / 10,000 decreased by -0.092 for every consultation / 10,000 population in community pharmacy, increased by 3.648 between increasing levels of rurality, and increased by 1.283 for each point increase in the living environment deprivation.

Local rurality was explained in *Table 8*, where Local Authorities are divided into 6 groups based on the urban/rural split. Moving from “urban with major conurbation” to “urban with city and town" increase the rate of all consultations (GP) / 10,000 by 3.648. This describes a positive correlation with increased rurality.

Living Environment deprivation considers both 'indoor' (the quality of housing) and 'outdoor' (air quality and road traffic accidents) environments. The scale of measurement, the indices, range from 4 – 66 across the 327 local authority areas. Higher values indicate greater deprivation, with an increased index increasing the rate of all consultations (GP) / 10,000 by 1.283.

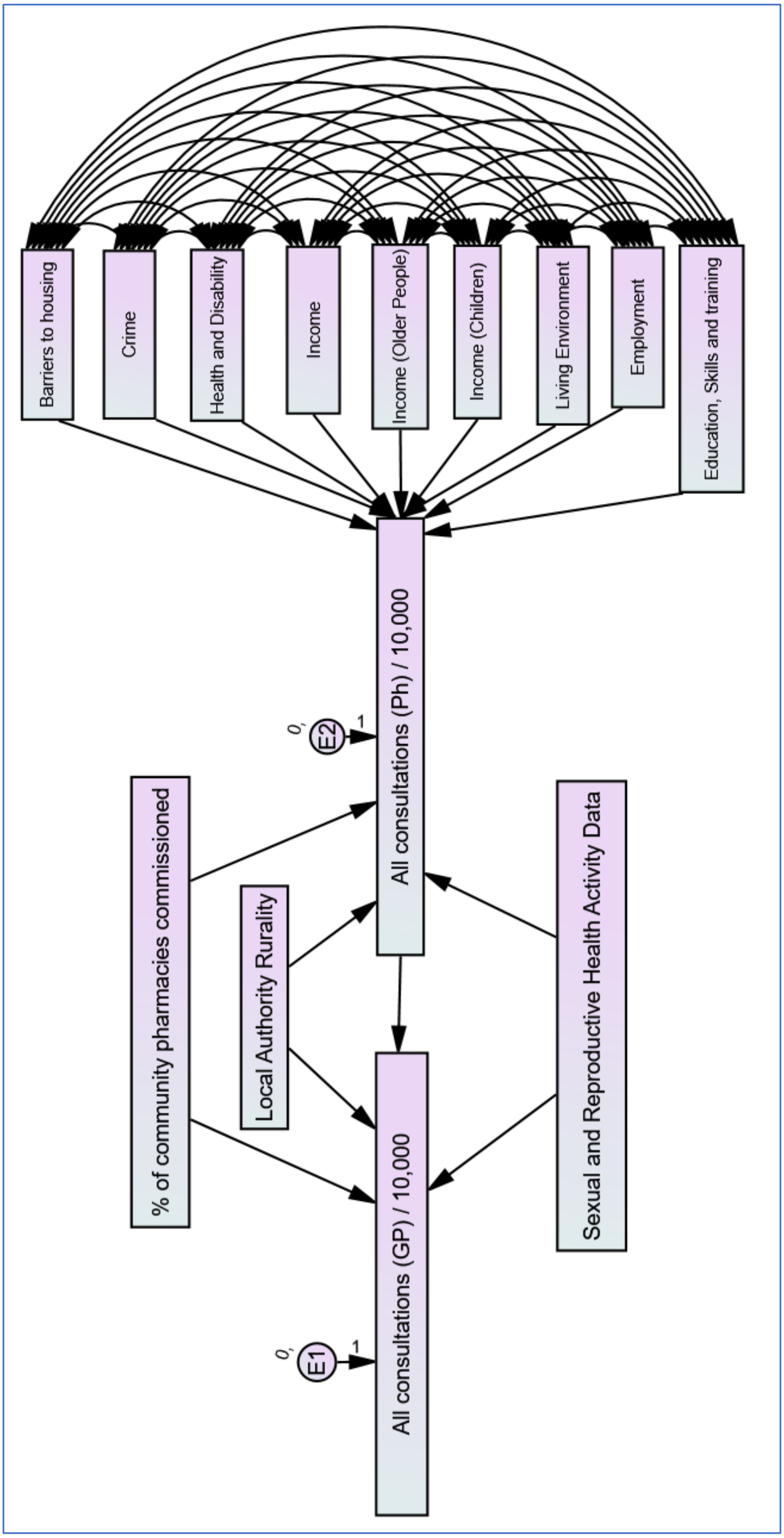
Finally, increasing the' all consultations' (Ph) / 10,000 rate of EHC consultations by 100 decreases the corresponding 'all consultations' (GP) / 10,000 rate by 9.2. The model variables are summarised in *Table 13*. The regression equation is displayed below.

7.3.8 Path analysis

It was predicted that the indicators of deprivation with statistically significant correlations would feature in the model. Additionally, population density / rurality was theorised to influence provision by impacting the number of sites and the total number of opening hours. Finally, patients who did not attend either GP or community pharmacy could also receive EHC treatment from sexual health clinics. Although not a high volume of provision (sexual health clinics are often referred to for more complex treatment), this may also account for patient behaviours. This theoretical model is displayed in *Figure 30*. As there are no unobserved variables, all the variables are depicted as rectangles (following standard practice). Single-headed arrows are regression pathways, double-headed arrows represent intercorrelations. Both all consultations (GP) and all consultations (Ph) are acting as dependent variables, i.e., they have variables that affect them. This means the theoretical model has an assumed unknown error for each dependent variable (all consultations GP and all consultations Ph), which are referred to as E1 and E2 respectively.

All the indices of deprivation are interdependent. This means they all act on each other and the lines, although difficult to pick out, represent double-headed arrows and intercorrelations between all the indices.

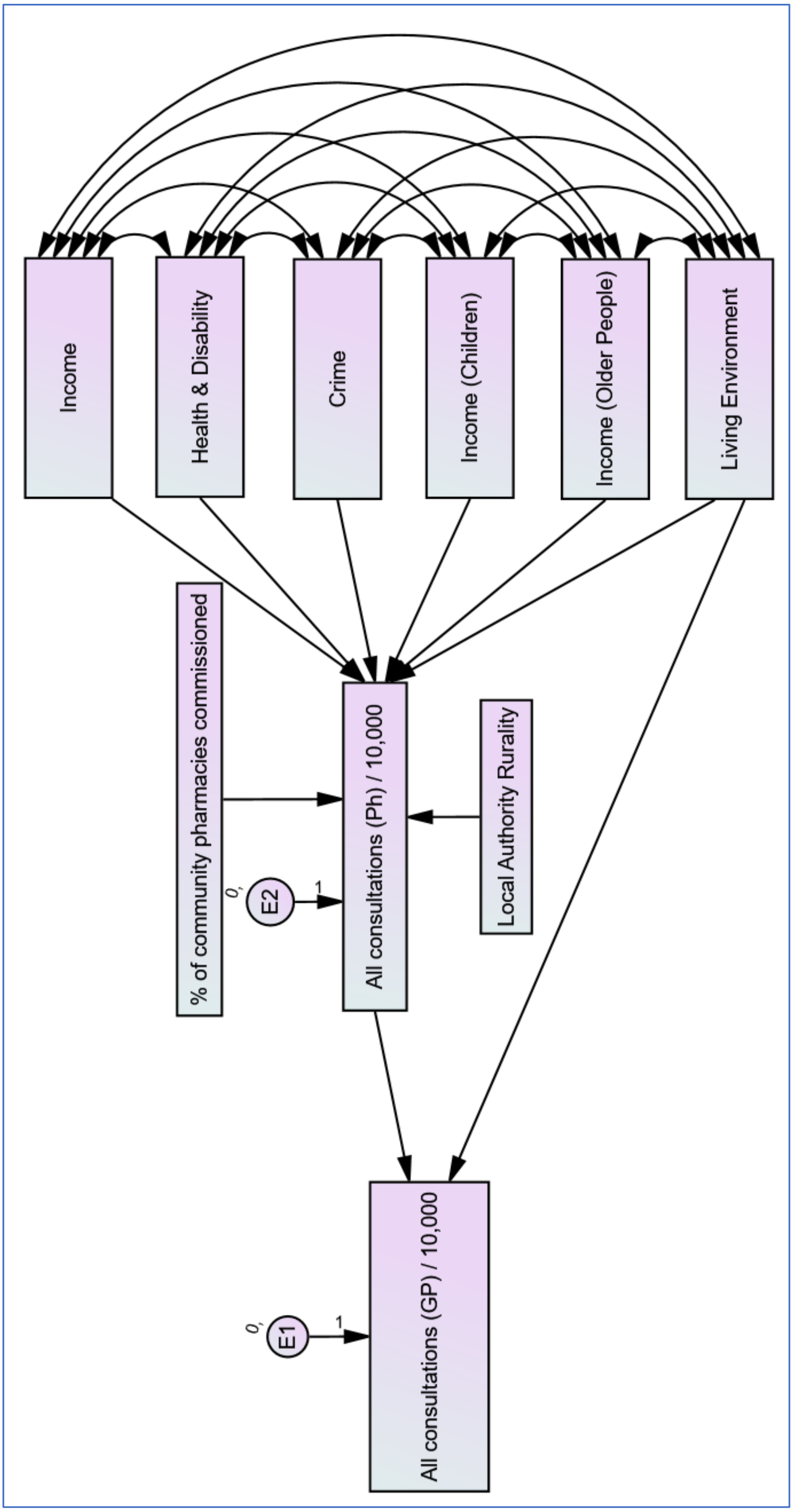
Figure 30 Theoretical path analysis of factors influencing all consultations (GP) rates of provision



This theoretical model demonstrates the wide range of factors influencing community pharmacy provision. This in turn influences the rate of GP EHC prescribing. Both sexual health clinics and rurality were also predicted to influence these two factors.

The data from *Table 12* showing correlations changes this, informing the variables for an updated model. Not all aspects of deprivation are significantly correlated to GP or community pharmacy EHC provision. No significant correlations were found between Sexual and Reproductive Health Activity Data and other variables. Accordingly, this was excluded from the model. As no significant correlation was determined between local authority rurality and all consultation rates (GP), this path was removed. The new model is depicted in *Figure 31*.

Figure 31 Updated path analysis of variables influencing all consultations (GP)



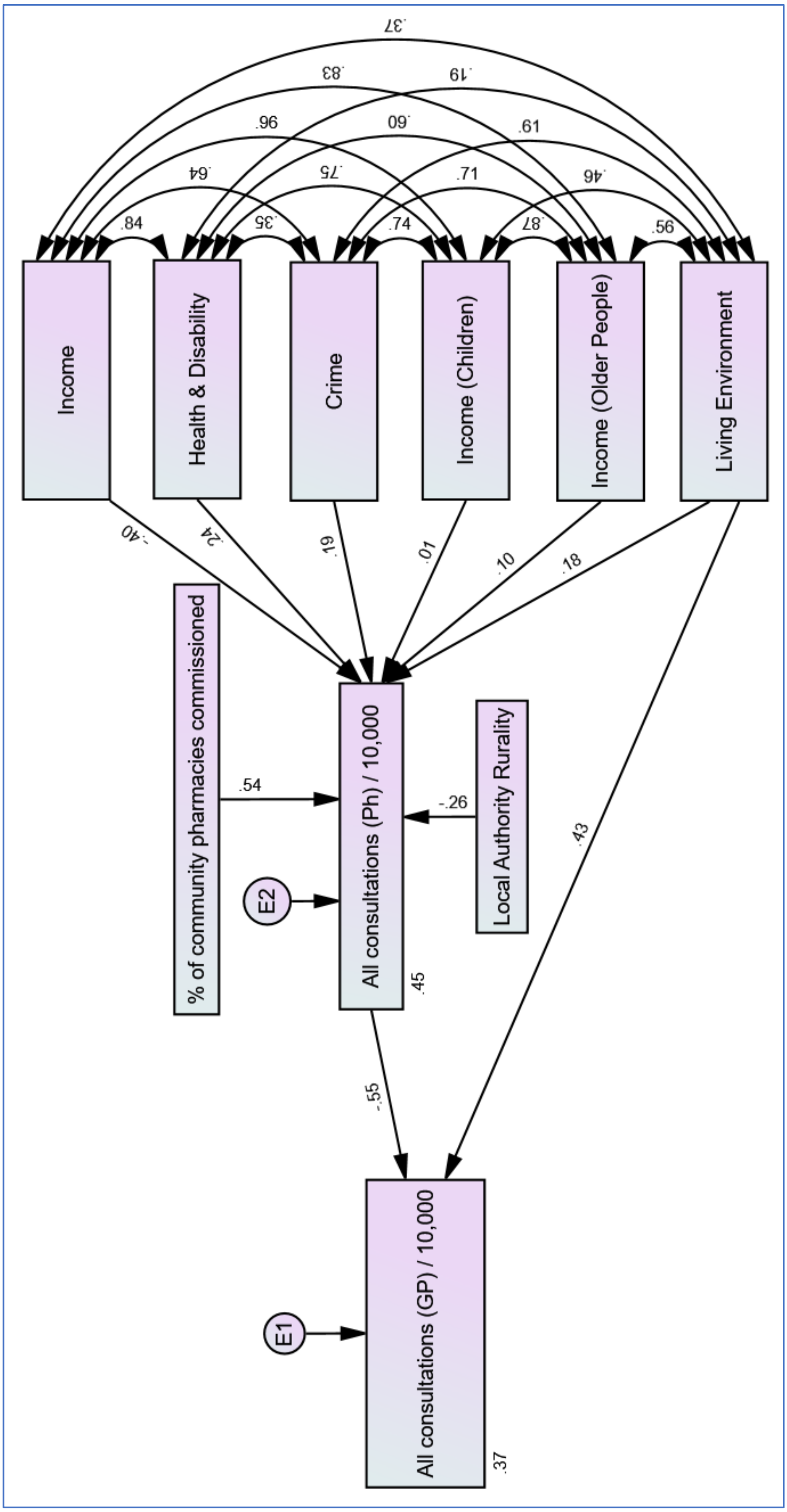
The collected data were imported into SPSS AMOS v27 and a maximum likelihood analysis was run. Standardisation estimates and squared multiple correlations are shown in *Figure 32*. One of the key outputs from a path analysis are regression weights. These are predictions of how much the dependent variable will change when the independent one does. Usually there are two ways of presenting this: *b* (unstandardised) where the data is used in its original units of measurements, and β (standardised) where each variable has been standardised to have a mean of 0 and an SD of 1 (Streiner, 2005). Standardised regression weight (β) are often more useful as variables can be directly compared and will be reported almost exclusively here.

The effect of all consultations (Ph) on all consultations (GP) was strong (β = -0.55) as predicted from the initial linear regression. It is notable that the percentage of pharmacies commissioned was equally strong in its effect on all consultations (Ph) (β = 0.54). In this instance, an increased proportion of the pharmacies within the local authority area providing EHC to patients increased the rate of consultations (Ph), but there was no significant correlation to all consultations (GP). Income is a known predictor of access to EHC services (both due to need and capacity to pay for treatment), and the strength of this relationship is also evident (β = -0.40). Local authority rurality also had a strong influence on all consultations (Ph), (β = -0.26). Rurality increases as the value increase (1 = urban with major conurbation, 6 = mainly rural). In this case greater rurality decreases the 'all consultation' (Ph) rate of provision.

The intercorrelations between the measures of deprivation (income, health and disability, crime, income (children), income (older people), and living environment) were predicted and expected by design. These linked measures combine to create the overall measure of the index of multiple deprivation. It is however of note that living environment was the only deprivation variable to influence all consultation (GP) (β = 0.43), whist they all influenced all consultations (Ph).

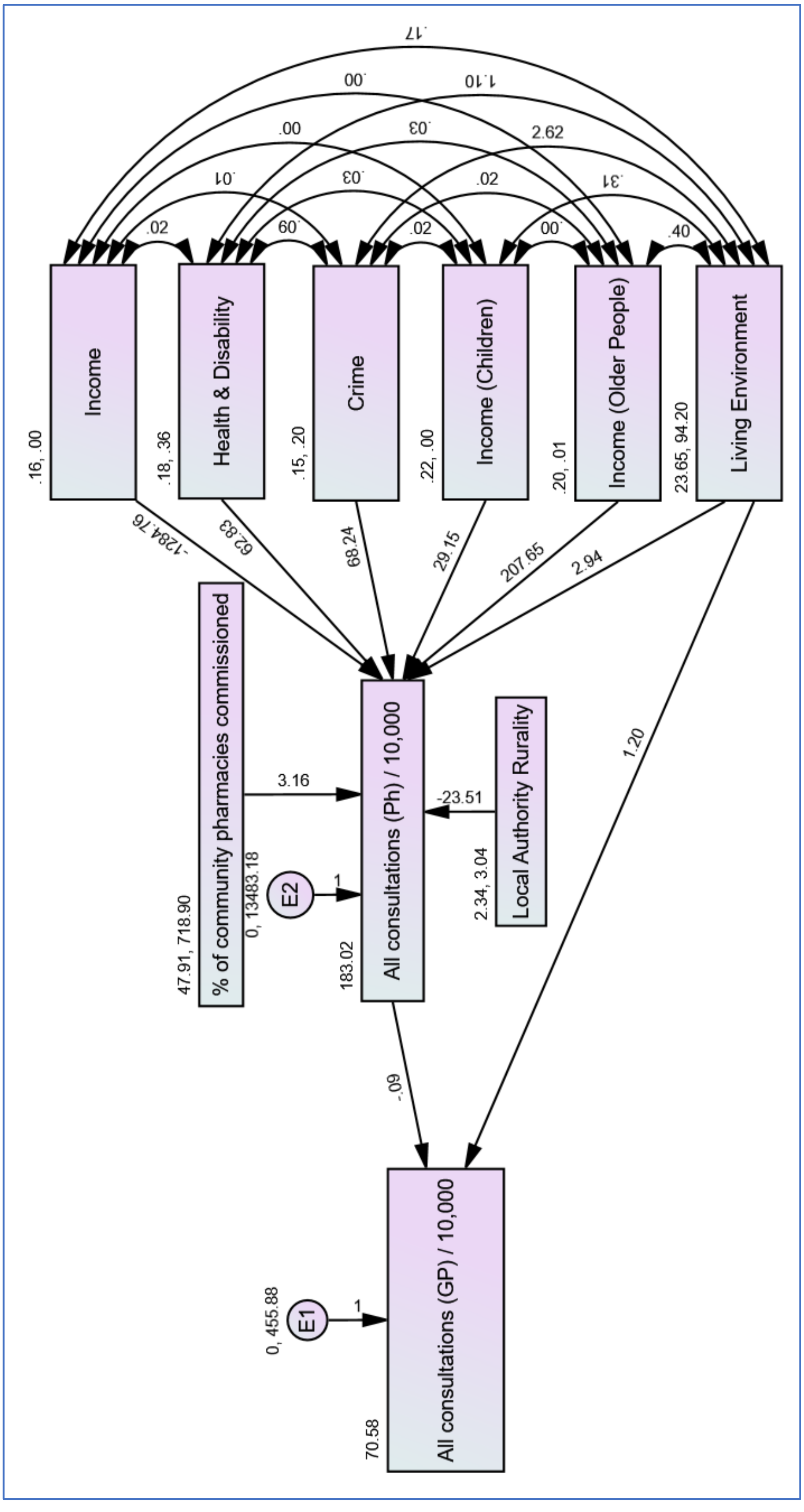
The path analysis was run in AMOS v27, and the results are presented here. The numbers next to the arrows show thew correlations (positive or negative) between the variables. The arrow shows which direction the correlation is acting. The diagrams below show the standardised results *(Figure 32)* and the unstandardised results *(Figure 33).*

Figure 32 Path analysis of variables influencing all consultations (GP) rates of provision (standardised estimates)



Goodness-of-fit statistics indicate the model has a poor fit. The fit statistics were as follows: chi-square = 81.562 (df=20, p = 0.00), RMSEA = 0.190, NFI = 0.891, CFI = 0.911.

Figure 33 Path analysis of variables influencing all consultations (GP) rates of provision (unstandardised estimates)



The fit statistics for the unstandardised model were as follows: chi-square = 38.238 (p = 0.00), RMSEA = 0.143, NFI = 0.949, IFI = 0.967, CFI = 0.965.

7.3.9 Interpreting Direct and Indirect effects

Regression models are useful for quantifying the direct relationships between variables and outcome measures; however, these typically study factors independently of each other. Path analysis is like multiple regression but allows for numerous dependent variables to be considered at once as well as describing the inter-relationships between them. Path analysis is particularly useful for understanding the competing variables in a health system, an approach not yet applied to community pharmacy services. Path analysis can be used to understand the relative strengths, and inter-linked relationships of many variables. For example, how the location of services, rurality, or impact of social factors influences service uptake and outcomes (Sk, 2020).

Path analysis demonstrates the relationships between the variables, beyond that of the multiple regression analysis. It also provides an indication of indirect relationships, i.e., the association variable A, may have on variable C *through* its impact on variable B.

The effects described in *Figure* 32 are displayed in *Table 16*. There are only two direct effects on all consultations (GP), living environment and all consultations (Ph). There are, however, numerous indirect effects on all consultations (GP) that are mediated through community pharmacy consultations. Living environment is the only variable that has both direct and indirect effects, and the total effect (determined by adding the direct and indirect) can be seen in the final column (0.334). The largest effect is the effect all consultations (Ph) has on all consultations (GP). However, the effect of % of commissioned pharmacies commissioned is also a notable effect.

Table 16 Path analysis standardised Direct, Indirect, and Total Effects

Variable	Direct Effect	P value	Indirect effect	Total effect
All consultations (Ph) / 10,000 - no outliers	-0.552	0.000	-	-0.552
% of pharmacies commissioned	-		-0.299	-0.299
Local Authority Rurality	-		0.144	0.144
Income	-		0.221	0.221
Health Deprivation and Disability Domain	-		-0.134	-0.134
Crime Domain	-		-0.107	-0.107
Living Environment Deprivation Domain	0.435	0.000	-0.101	0.334
Income Deprivation Affecting Children Index (IDACI)	-		-0.054	-0.054
Income Deprivation Affecting Older People Index (IDAOPI)	-		-0.007	-0.007

7.4 Main study: Analysis of EHC service provision results (community pharmacy)

The previous section described relationships and correlations influencing Local Authority data. The dependent variable was the rate of GP EHC prescribing. In this section the focus moves, and the unit of analysis is individual pharmacies. The dependent variable is now the rate of EHC provisions in community pharmacy.

The section aims to describe the correlations between the rate of community pharmacy EHC provision and:

1. Dispensed prescription volume (all prescriptions not just EHC)
2. National service provision (MUR, NMS, and Influenza)
3. Deprivation
4. Ownership type

This section draws heavily on the work of Jacobs *et al.* (2017) who described many of the correlations between the variables above and national service provision. This work of course focuses on a local service, local services were not considered by Jacobs *et al.* (2017).

7.4.1 FOI response data and sample size

As described earlier in the chapter (page 156), FOI requests were sent between March and April 2020. As detailed in *Figure 21,* 108 (73%) Local Authorities provided data. From these 108 Local Authorities, 76 were able to provide detail by individual pharmacy contract. Some authorities judged this information to be “commercially” sensitive or risked breaching patient confidentiality, and therefore refused release of data under section 40 of the FOI act. This section of the legislation exempts the normal requirements of disclosure if it would (amongst other things) contravene data protection principles. Other Local Authorities did not hold the data of individual pharmacy provisions.

From these 76 Local Authorities, data from 3195 community pharmacies were made available. To assist with future analysis and ensure accurate data, the pharmacies were matched to their NHS BSA F-code. The information provided varied widely, with some councils providing the F-code (as requested) and some providing partial address information, pharmacy trading name or just contractor information.

Many areas had numerous pharmacies from the same organisation, so without additional qualifying information identification of the individual pharmacy was impossible. Data cleansing to remove duplicates or remove those pharmacies unable to be identified reduced the data set to 3069 of the 3195 pharmacies (96%).

As the unit of analysis is individual pharmacy, not Local Authority there was no need to determine co-terminus areas. This means some of the data points may be different to the previous section. Data were excluded based on the ability to identify the pharmacies giving a different sub-set of the returned FOI responses.

These pharmacies collectively provided 21,976 Ulipristal and 154,087 Levonorgestrel, with a combined total of 180,478 consultations. The number of consultations is higher than Ulipristal and Levonorgestrel volumes combined, as some consultations resulted in no medication supply.

For each pharmacy additional data points were obtained. Using publicly held data from the NHSBSA, prescription numbers for each month were obtained (NHS Business Services Authority, 2022a). Some of the pharmacies dispensed no prescriptions in a month – likely due to opening/closure or a change in contract. To provide an accurate picture, the number of months where more than 0 prescription items were dispensed was used to calculate an accurate monthly average.

This data set also provided the total number of MURs, NMS, and Influenza vaccinations. The mean MUR and NMS values were calculated using the same process as the mean prescription volume. Finally, postcodes were used to determine the indices of deprivation from public datasets.

7.4.2 Description of the data

For this section, the unit of analysis is individual pharmacy premises (or ‘contracts’). As explained in the introduction, each pharmacy premises has a contract with NHS England. The organisation or business that owns the pharmacy premises and holds the contract with NHS England, is referred to as the ‘contractor’*. Table 17* details the frequency of LNG, UPA and all EHC consultations for each community pharmacy. As previously explored not all Local Authority services include the ability to provide UPA, accordingly the number of 0 returns for UPA is much higher than LNG.

Each of the pharmacies included in this data set have signed a contract with the Local Authority to provide EHC services when approached by patients. Despite this, 433 (14%) of pharmacies provided no consultations in the entire year. This may be due to a lack of demand but may also reflect operational/training issues within the pharmacy. Some of these challenges were explored in the policy review (chapter 2).

The data is clearly skewed towards 0, yet each consultation type exhibits long tails. LNG and EHC both have values over 1000 (10 and 14 respectively). For the UPA data 2158 (70%) of the pharmacies provided 0 provisions.

Table 17 Frequency of pharmacy EHC rates

Volume	UPA	LNG	EHC
0	2158	507	433
1-50	823	1884	1868
51-100	45	318	347
101-150	18	139	165
151-200	7	70	69
201-250	5	36	44
251-300	4	31	36
301-350	3	17	21
351-400	1	10	15
401-450		11	11
451-500	2	5	7
501-550		6	10
551-600		4	8
601-650		2	4
651-700		7	5
701-750		3	3
751-800	1	5	5
801-850		1	2
851-900			
901-950		1	1
951-1000		2	1
1000-2000	2	7	9
2000+		3	5

The data is summarised in *Table 18*. The mean values are presented for prescription volume (Rx), MURs (MUR) and NMS (NMS). The total volumes for the year 2017/18 are presented for MUR, NMS, and flu services.

The skewness and kurtosis for UPA, LNG, and EHC data were high reflecting the lack of normal distribution. Previous literature has suggested the presence of a 'double-peaked' distribution for MUR data which may be hidden within the below data (Jacobs et al., 2016). It is notable that the Standard Deviation of NMS is greater than the mean, as are all the EHC values.

Table 18 Description of individual pharmacy data

	UPA	LNG	EHC	Rx	MUR	Total MUR	NMS	Total NMS	Total Flu
Number	3,069	3,069	3,069	3,069	3,069	3,069	3,069	3,069	3,069
Mean	7.16	50.21	58.81	7,911	26	308	7	88	136
Median	0	13	17	7,170	32	380	5	57	110
Std. Deviation	39.97	153.69	172.06	4,048	10.33	124.51	8.41	100.96	131.64
Skewness	15.81	15.50	13.14	1.24	-1.12	-1.11	2.54	2.54	1.77
Kurtosis	333.75	403.23	282.16	2.44	0.05	0.02	11.09	11.12	4.77
Range	1020	5029	5029	34,544	58	696	87	1048	939
Min	0	0	0	23	0	0	0	0	0
Max	1020	5029	5029	34,567	58	696	87	1048	939

Figure 34 displays histograms of the pharmacy provision data, LNG, UPA, and combined EHC consultations. In all examples the majority of pharmacies provided small numbers of EHC, heavily skewing the distribution towards 0. There were 2,301 (75%) pharmacies

who provided less than 50 consultations in the year (fewer than one per week). There was no noticeable difference in the distribution of the three provision variables.

Figure 34 Histograms of Pharmacy data

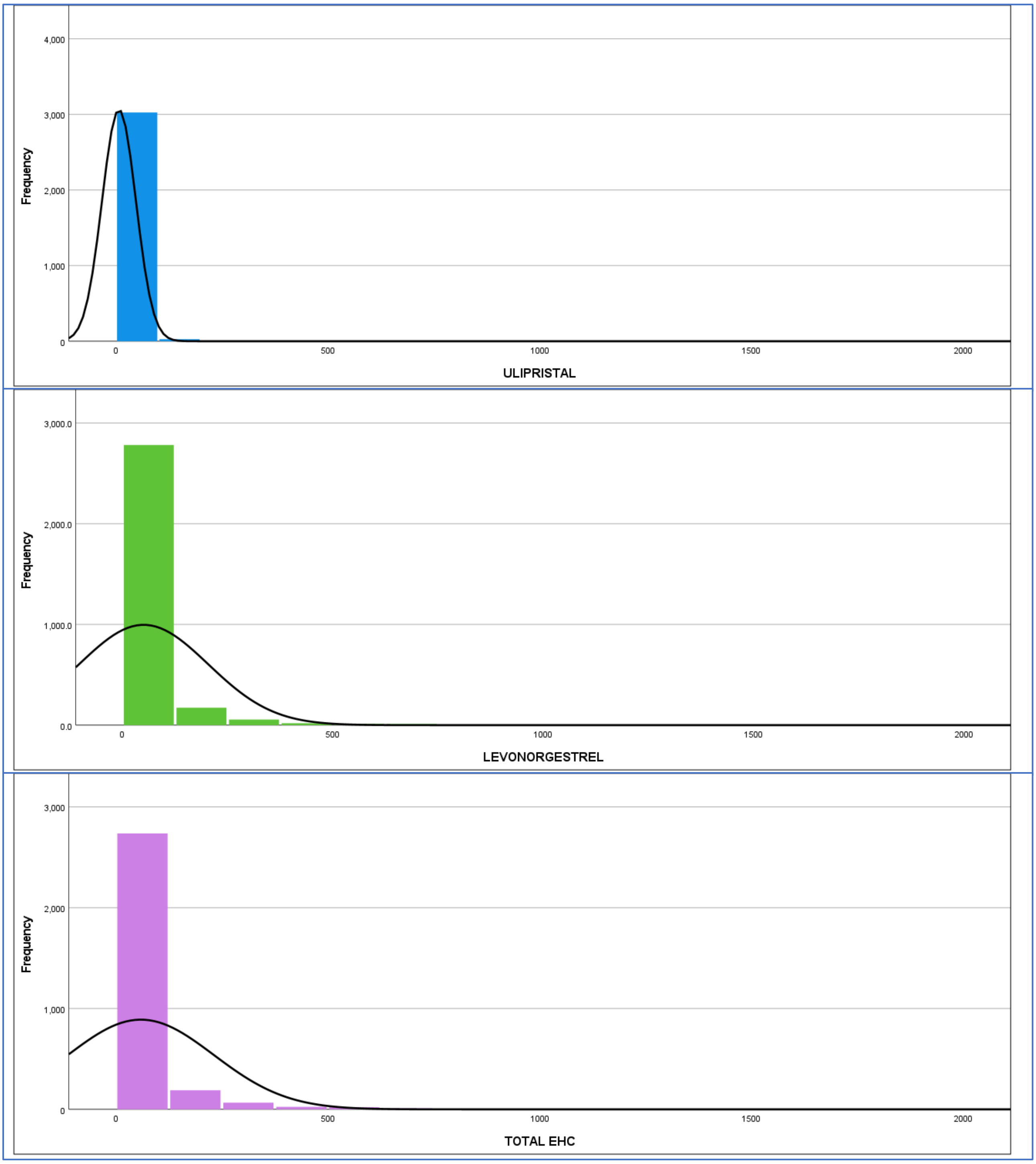
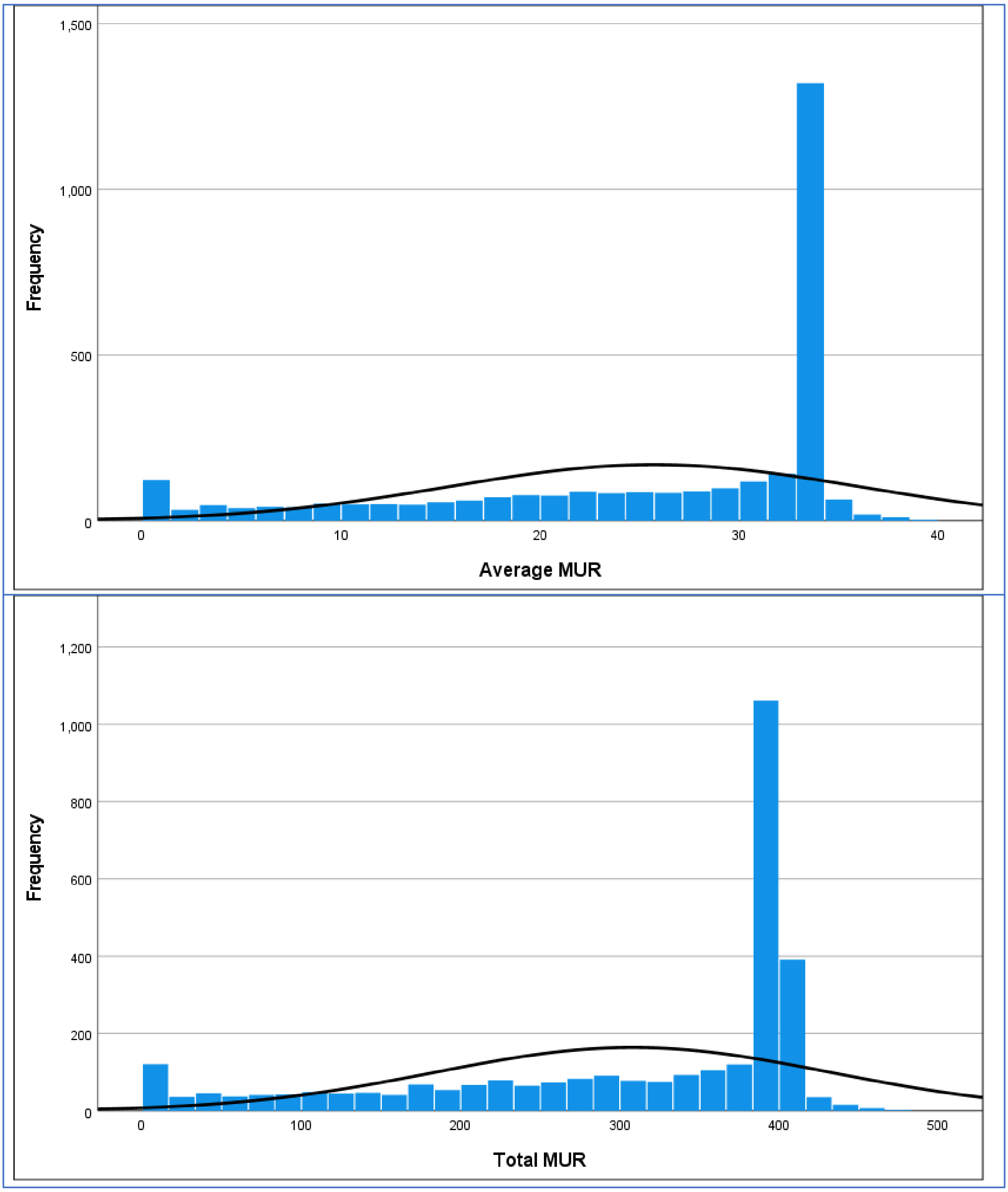


Figure 35 Histograms of mean and total MUR data

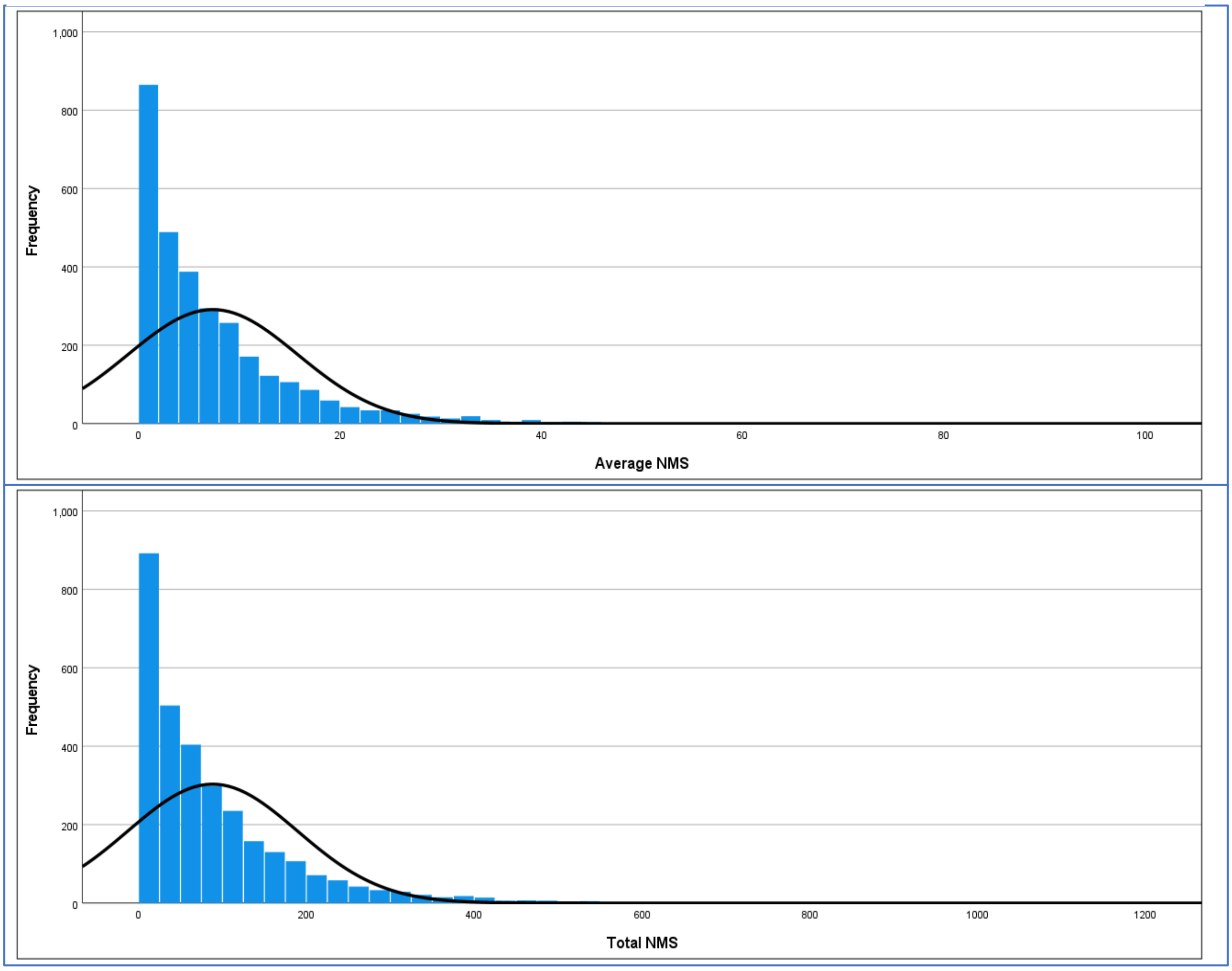


MUR data shows bimodal distribution (*Figure 35*). This is likely due to the cap in place, set at 400 MURs per year. Pharmacies providing 400 MURs each year would likely provide an average of 33 MURs per month. This is closely reflected in the mean (26) and medium (32).

The 400 cap is an annual one, but due to individual accounting arrangements, some individual pharmacies may appear to exceed this. This is because they must claim for a maximum of 400 MURs in a year but have no requirements on the timing within a year. Theoretically, one pharmacy could provide 400 MURs in March and 400 in April – providing 800 in a calendar year but only 400 in each financial year.

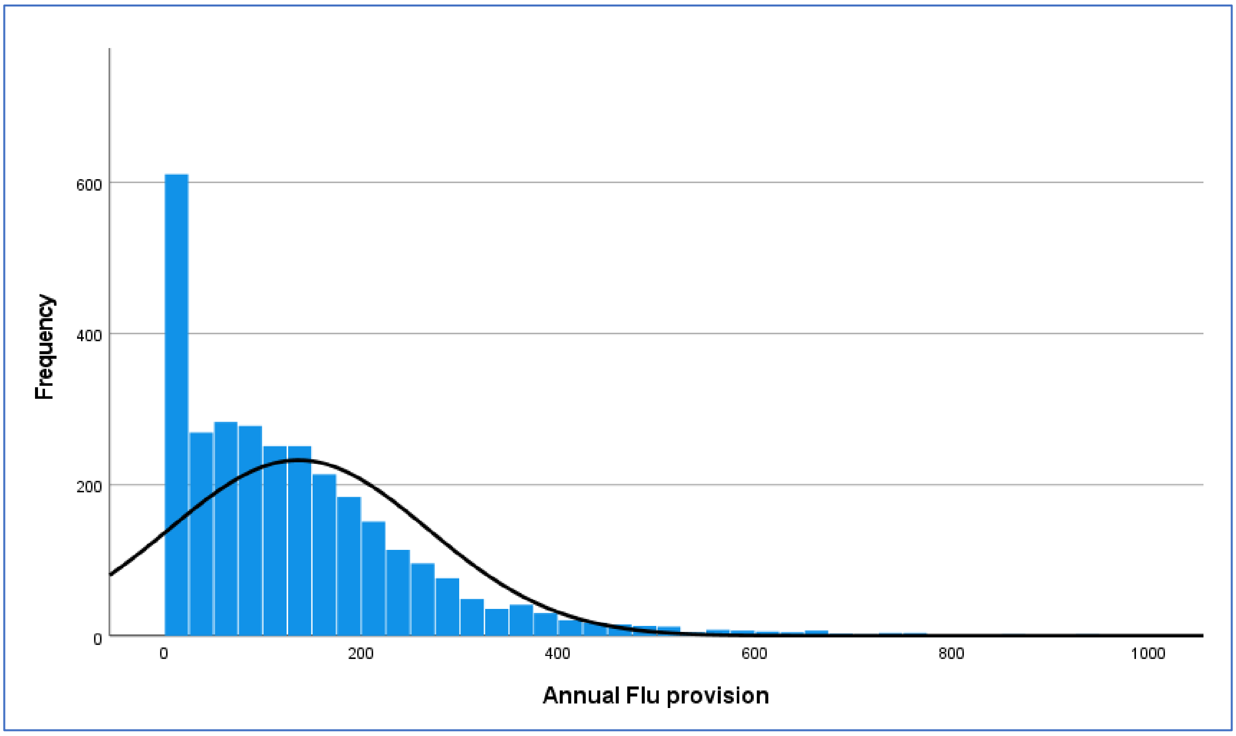
As MURs are an advanced service, provision is optional. There were 42 (1.4%) pharmacies that provided no MURs throughout the year.

Figure 36 Histograms of mean and total NMS data



The NMS provision is displayed in *Figure 36* and similar to EHC volumes it skews towards 0. Unlike MURs there is no cap for NMS services. There is no noticeable difference between the distribution and spread in the total volume for the year and the mean monthly volume.

Figure 37 Histogram of total Flu provision (annualised data)



Again, annual Flu provision (*Figure 37*) is distributed in a similar fashion to both NMS and EHC. The data is not normally distributed, but it does display a single peak.

Figure 38 Scatter plot of total EHC and Average Monthly Prescriptions (Rx)

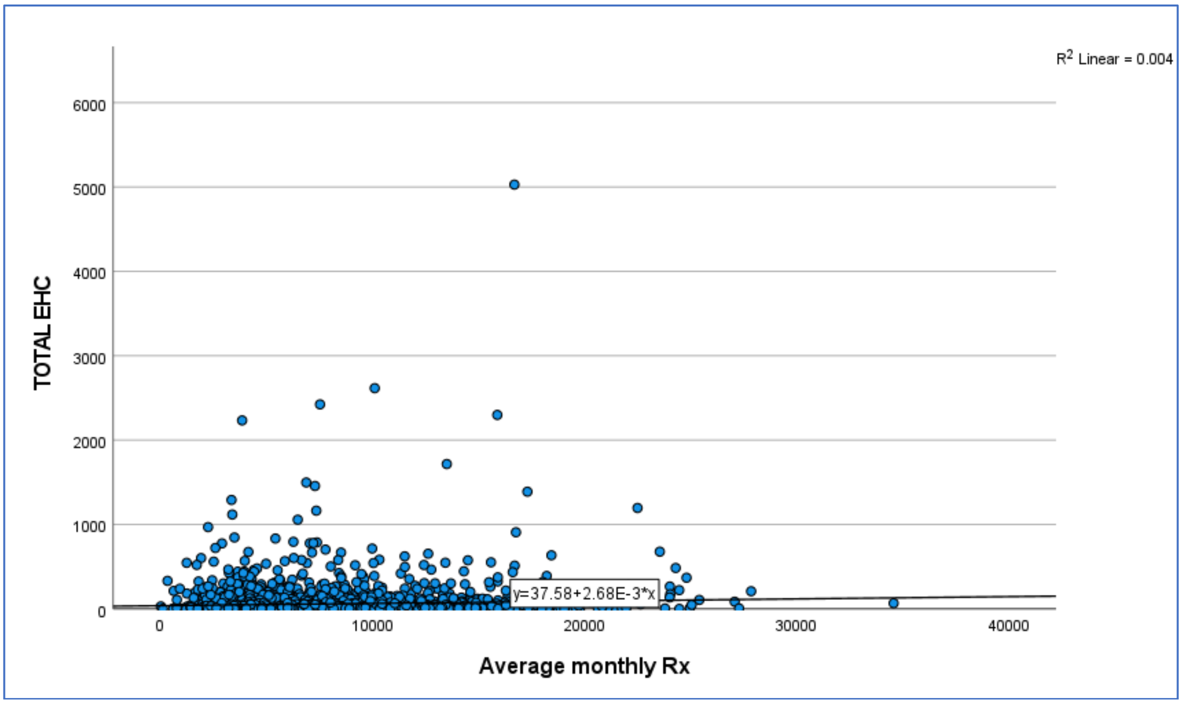


Figure 39 Scatter plot of total EHC and total (annual) MUR provision

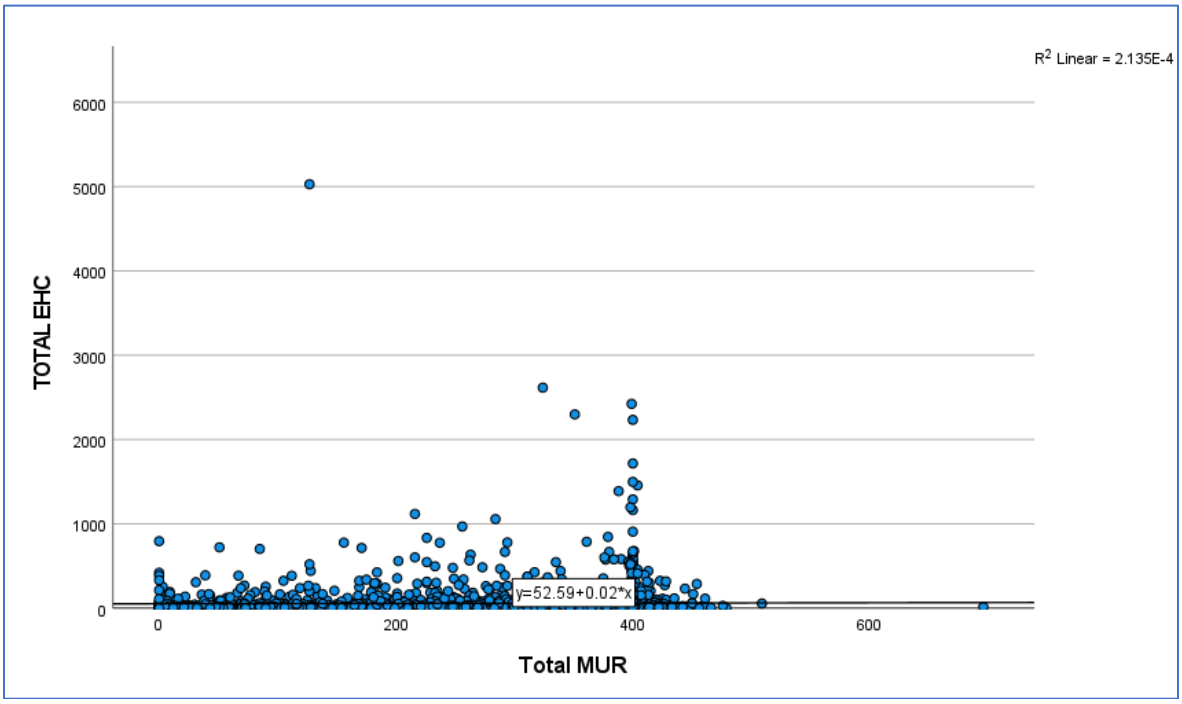


Figure 40 Scatter plot of total EHC and total (annual) NMS provision

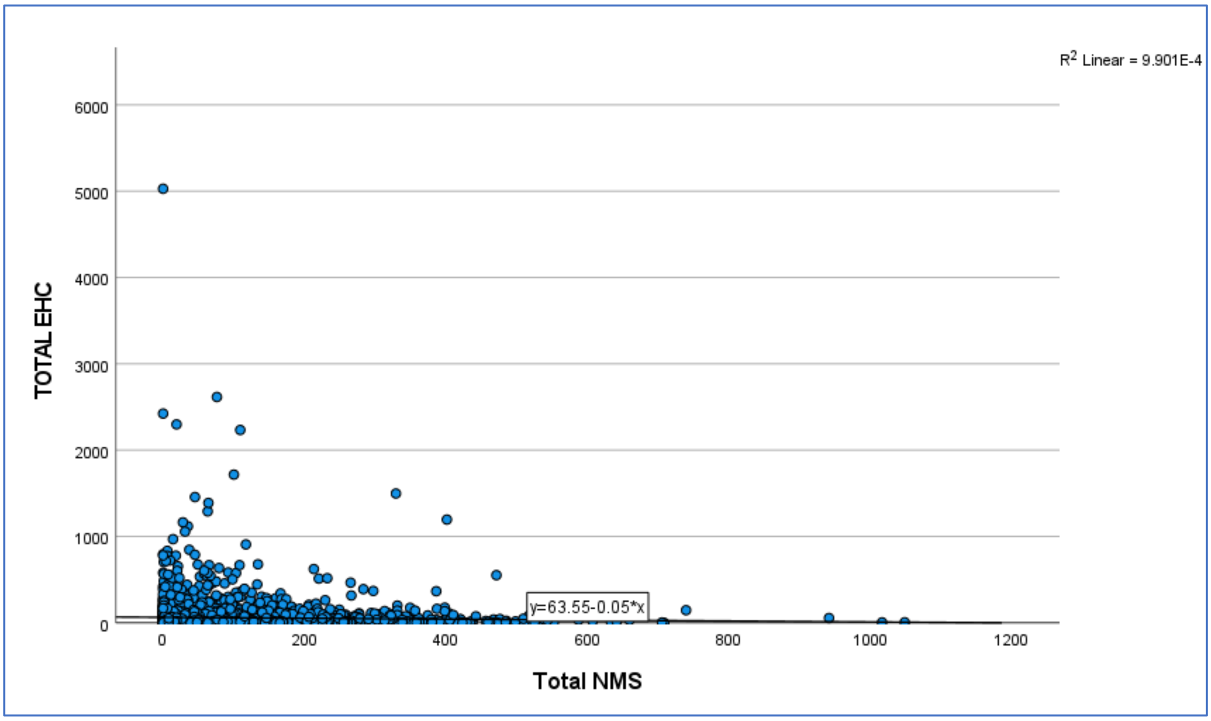
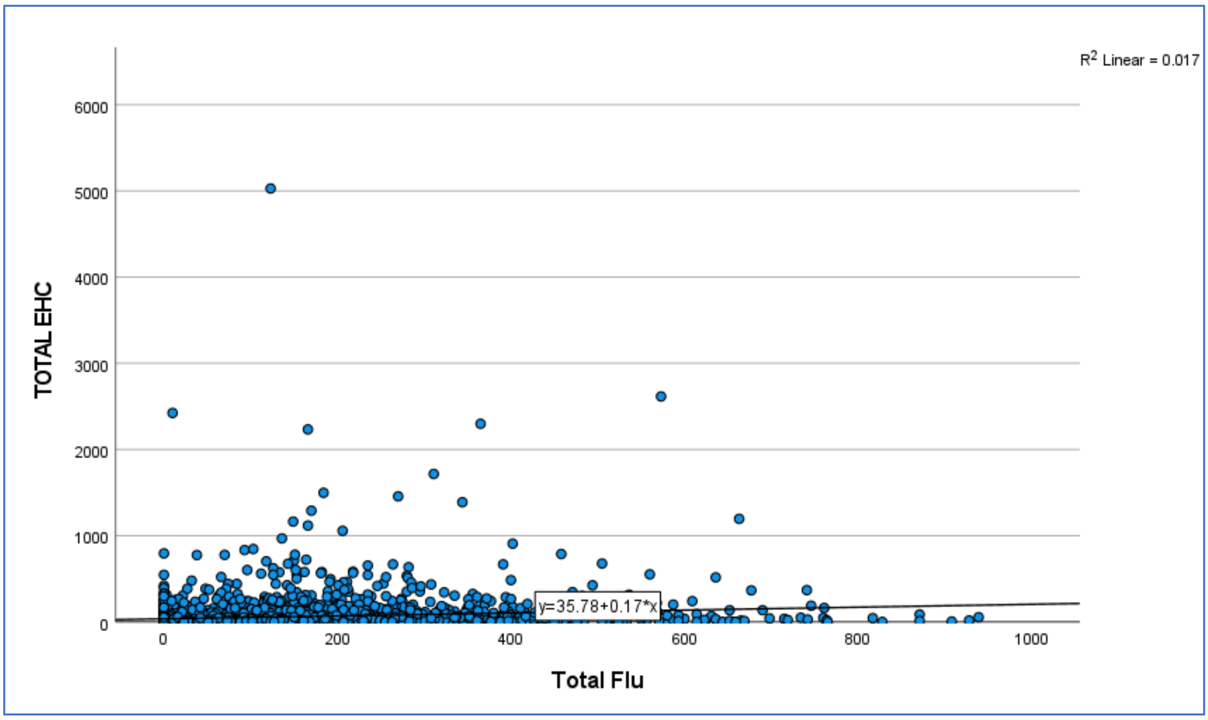


Figure 41 Scatter plot of total EHC and total (annual) flu provision



Scatter graphs were plotted to determine the size of correlation between total EHC supply and various markers of pharmacy activity. *Figures 38 – 41* display the graphs, with linear best fit lines added. Neither prescription volume nor the national services demonstrate a strong correlation. R^2 values were determined as 0.004 (prescription volume), 0.000 (MURs), 0.000 (NMS), 0.017 (flu). This would indicate a very low or negligible level of prediction from these variables with flu being the highest predictor at 1.7%.

7.4.3 Determining Correlation

As undertaken previously when considering Local Authority data, bi-variate correlations were determined using 2-tailed Pearson's correlation coefficient. Correlations were determined between community pharmacy provision and identified co-variates. The full correlation matrix is presented in Appendix 5 – Bi-variate correlations (individual pharmacy).

Significant correlations are displayed in *Table 19*. Significance is indicated at 0.01 (highlighted by **) and 0.05 (highlighted by *). Significant correlations were found between 8 of the 10 indicators of deprivation. There was no significant correlation between Income rank or Education and Skills rank. The indicators with the strongest correlation were Barriers to Housing and Services rank and Living Environment rank both, $r(3070) = -0.159$, $p<0.01$.

Significant correlation was also found between EHC and Rx, r(3070) = 0.063, p<0.01 and Total Flu, r(3070) = 0.129, p<0.01.

Table 19 Bi-variate correlations (individual pharmacy)

**. Correlation is significant at the 0.01 level (2 tailed) *. Correlation is significant at the 0.05 level (2 tailed)		EHC (n = 3070)
Rx	Pearson Correlation	.063**
	Sig. (2-tailed)	.000
Total Flu	Pearson Correlation	.129**
	Sig. (2-tailed)	.000
Index of Multiple Deprivation Rank	Pearson Correlation	-.074**
	Sig. (2-tailed)	.000
Employment Rank	Pearson Correlation	.046*
	Sig. (2-tailed)	.011
Health and Disability Rank	Pearson Correlation	-.062**
	Sig. (2-tailed)	.001
Crime Rank	Pearson Correlation	-.146**
	Sig. (2-tailed)	.000
Barriers to Housing and Services Rank	Pearson Correlation	-.159**
	Sig. (2-tailed)	.000
Living Environment Rank	Pearson Correlation	-.159**
	Sig. (2-tailed)	.000
Income Deprivation Affecting Children Index (IDACI) Rank	Pearson Correlation	-.061**
	Sig. (2-tailed)	.001
Income Deprivation Affecting Older People Index (IDAOPI) Rank	Pearson Correlation	-.149**
	Sig. (2-tailed)	.000

The bivariate correlations between TOTAL EHC, all the national services, and the Index of Multiple Deprivation rank are displayed in *Table 20*. As before significance is indicated at 0.01** and 0.05*.

It is notable that Rx displays significant correlation with TOTAL EHC (r(3069) = 0.063, p=0.000), all the national services and the IMD Rank (r(3069) = -0.074, p=0.000). Despite being statistically significant, the correlations are low. The three national services, MUR, NMS, and Flu all display significant correlation with each other.

TOTAL EHC does not exhibit significant correlation with either MUR and NMS volumes, but does with Flu ($r(3069) = 0.129$, $p=0.000$). The deprivation measure (IMD Rank) correlates with both TOTAL EHC ($r(3069) = -0.074$, $p=0.000$) and flu ($r(3069) = -0.040$, $p=<0.05$). This means that in areas of greater deprivation there is an increase in both rates of EHC provision and total volumes of flu vaccinations. IMD Rank does not display significant correlation with the other two national services – MUR and NMS.

Table 20 Bivariate correlations TOTAL EHC, national services and deprivation (individual pharmacy n=3069)

**. Correlation is significant at the 0.01 level (2 tailed) *. Correlation is significant at the 0.05 level (2 tailed)		TOTAL EHC	Rx	Total MUR	Total NMS	Flu annual	IMD Rank
TOTAL EHC	Pearson Correlation		.063**	.015	-.031	.129**	-.074**
	Sig. (2-tailed)		.000	.410	.082	.000	.000
Rx	Pearson Correlation	.063**		.219**	.406**	.215**	-.090**
	Sig. (2-tailed)	.000		.000	.000	.000	.000
Total MUR	Pearson Correlation	.015	.219**		.404**	.292**	-.027
	Sig. (2-tailed)	.410	.000		.000	.000	.139
Total NMS	Pearson Correlation	-.031	.406**	.404**		.259**	.008
	Sig. (2-tailed)	.082	.000	.000		.000	.664
Flu annual	Pearson Correlation	.129**	.215**	.292**	.259**		.040*
	Sig. (2-tailed)	.000	.000	.000	.000		.028
Index of Multiple Deprivation Rank	Pearson Correlation	-.074**	-.090**	-.027	.008	.040*	
	Sig. (2-tailed)	.000	.000	.139	.664	.028	

7.4.4 Reviewing organisation type

Following the correlations described above, bivariate correlations were undertaken for contractor type. Mirroring the methodology used in the literature (Jacobs *et al.*, 2017) the ownership of the pharmacies were grouped by the size of the company. The 5 groups were: Large Multiple (more than 200 pharmacies), Medium Chain (26 – 200 pharmacies), Small Chain (6 – 25 pharmacies), Independent (5 pharmacies or fewer), and Supermarkets. Details of the service provision are depicted in *Table 21.*

Table 21 Service provision data, grouped by ownership type

		TOTAL EHC	Rx	Total MUR	Total NMS	Flu annual
Large multiple (more than 200)	N	1471 (47.9%)				
	Mean (SD)	64.24 (174.901)	7,972.89 (3,988.158)	345.84 (86.831)	92.84 (86.556)	151.51 (122.768)
	Range	2,616	24,804	476	708	928
Medium (26 – 200)	N	268 (8.7%)				
	Mean (SD)	29.44 (48.812)	8,980.48 (3,901.415)	399.90 (99.516)	107.50 (113.419)	103.34 (113.485)
	Range	332	23,681	456	1,016	742
Small chain (6 – 25)	N	259 (8.4%)				
	Mean (SD)	37.05 (68.791)	8,368.86 (4,285.777)	294.50 (142.719)	96.38 (135.183)	113.91 (130.159)
	Range	543	33,124	461	1,048	939
Independent (5 or fewer)	N	909 (29.6%)				
	Mean (SD)	66.16 (216.467)	7,809.43 (4,162.381)	239.83 (150.456)	78.91 (111.043)	124.92 (148.200)
	Range	5,029	27,828	696	739	871
Supermarket	N	162 (5.3%)				
	Mean (SD)	51.60 (78.627)	5,414.35 (2,452.919)	317.30 (91.809)	57.41 (57.682)	154.06 (120.244)
	Range	497	13,740	367	338	734

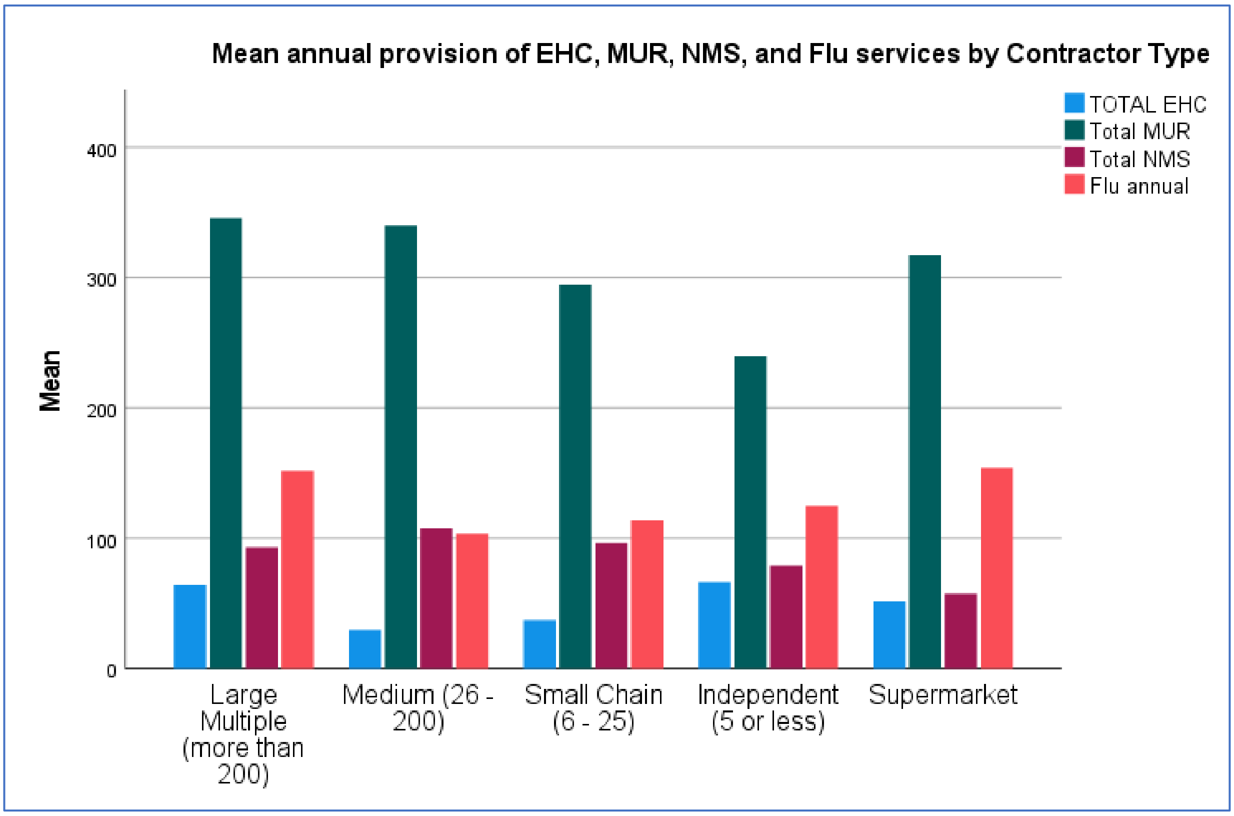
The data is displayed in *Table 21* grouped by ownership type, with the proportions of the entire data set indicated by parenthesis. The proportions are largely in line with national pharmacy ownership.

One-way ANOVA were calculated and are displayed in *Table 22*. Each of the four variables had statistically significant differences. From this we can determine that there is a significant difference between the groups for each variable, controlling for Type 1 errors. Annual service provision, grouped by contractor type is displayed in *Figure 42*.

Table 22 ANOVA of ownership type

		Sum of Squares	df	Mean Square	F	Sig.
TOTAL EHC	Between Groups	454672.358	4	113668.090	3.854	.004
	Within Groups	90368148.061	3064	29493.521		
	Total	90822820.419	3068			
Average monthly Rx	Between Groups	1385632326.477	4	346408081.619	21.712	.000
	Within Groups	48884065211.311	3064	15954329.377		
	Total	50269697537.788	3068			
Total MUR	Between Groups	6664382.556	4	1666095.639	124.833	.000
	Within Groups	40894039.404	3064	13346.619		
	Total	47558421.960	3068			
Total NMS	Between Groups	380805.982	4	95201.495	9.442	.000
	Within Groups	30894391.350	3064	10083.026		
	Total	31275197.332	3068			
Flu annual	Between Groups	930181.445	4	232545.361	13.640	.000
	Within Groups	52235955.347	3064	17048.288		
	Total	53166136.792	3068			

Figure 42 Mean provision of national services and EHC by contractor type



MUR provision appears to trend downwards as the company size decreases. There is a similar (although smaller) trend with NMS and flu provision. For EHC provision there does not appear to be a noticeable trend that changes with contractor type. Whilst medium and small chain pharmacies appear to provide fewer EHC, the other contractor types appear greater or comparable. As contractor type is ordinal data, Spearman's rho correlations were then determined, these are displayed in *Table 23*.

Table 23 Spearman's rho correlation (Contractor Type)

** Correlation is significant at the 0.01 level (2-tailed)			Contractor Type (n = 3069)
Spearman's rho with contractor type	TOTAL EHC	Correlation Coefficient	.027
		Sig. (2-tailed)	.128
	Total MUR	Correlation Coefficient	**-.274****
		Sig. (2-tailed)	.000
	Total NMS	Correlation Coefficient	**-.207****
		Sig. (2-tailed)	.000
	Flu annual	Correlation Coefficient	**-.147****
		Sig. (2-tailed)	.000

Contractor type was negatively correlated with annual provision of MUR (-0.274, p=0.000), NMS (-0.207, p=0.000), and Flu (-0.147, p=0.000). There was no significant correlation with EHC provision. This indicates that pharmacies part of larger groups are more likely to provide greater numbers of MUR, NMS, and flu services. However, there is no statistically significant trend in EHC provision.

The ANOVA displayed in *Table 22* show there a significant difference between different organisations for all the variables. The presence of supermarkets adds an additional level of complexity to the conclusions. Supermarket pharmacies operate as part of very large (often multinational) businesses. However, the size of the pharmacy portion of the business is small compared to the overall business. The actual number of pharmacies is much lower than other large multiples. As supermarket data only account for 5.3% of the data reviewed, they were excluded, and the ANOVA was repeated.

Table 24 1-way ANOVA of contractor type (excluding supermarket data)

		Sum of Squares	df	Mean Square	F	Sig.
TOTAL EHC	Between Groups	445786.531	3	148595.510	4.827	.002
	Within Groups	89372823.141	2903	30786.367		
	Total	89818609.672	2906			
Index of Multiple Deprivation Rank	Between Groups	7.333	3	2.444	1.343	0.259
	Within Groups	5282.515	2903	1.820		
	Total	5289.848	2906			
Average monthly Rx	Between Groups	319723121.207	3	106574373.736	6.457	.000
	Within Groups	47915358539.967	2903	16505462.811		
	Total	48235081661.174	2906			
Total MUR	Between Groups	6649857.976	3	2216619.325	162.755	.000
	Within Groups	39536975.626	2903	13619.351		
	Total	46186833.602	2906			
Total NMS	Between Groups	216342.039	3	72114.013	6.896	.000
	Within Groups	30358714.060	2903	10457.704		
	Total	30575056.099	2906			
Flu annual	Between Groups	876814.546	3	292271.515	17.001	.000
	Within Groups	49908110.847	2903	17191.909		
	Total	50784925.393	2906			

Repeating the 1-way ANVOA does not change the significance, except for EHC which is slightly lower (p=0.002 rather than p=0.004). All the variables still display significance, indicating removing the supermarket data has not dramatically changed the findings from the data.

Post-hoc tests are useful for understanding the nature of the differences between groups. Fisher's LSD post-hoc tests were completed to see the difference between the groups and are displayed in *Table 25*. The difference between EHC provision does not follow the organisation size, with two groups forming. Multiples and independents displayed no difference between each other, but a significant difference to small chains and mediums chains. Similarly, small chains and medium organisations EHC provisions were not significantly different from each other.

Table 25 1-way ANOVA post-hoc LSD tests for EHC, MUR, and NMS provision by organisation (excluding supermarket data)

Pharmacy ownership type		Total EHC		Total MUR		Total NMS	
		Mean difference	Sig.	Mean difference	Sig.	Mean difference	Sig.
Large Multiple (more than 200)	Medium (26 - 200)	**34.797***	.003	5.933	.444	**-14.656***	.031
	Small Chain (6 -25)	**27.187***	.022	**51.334***	.000	-3.539	.608
	Independent (5 or less)	-1.923	.795	**106.009***	.000	**13.938***	.001
Medium (26 - 200)	Large Multiple (more than 200)	**-34.797***	.003	-5.933	.444	**14.656***	.031
	Small Chain (6 -25)	-7.610	.619	**45.401***	.000	11.118	.212
	Independent (5 or less)	**-36.720***	.003	**100.076***	.000	**28.595***	.000
Small Chain (6 -25)	Large Multiple (more than 200)	**-27.187***	.022	**-51.334***	.000	3.539	.608
	Medium (26 - 200)	7.610	.619	**-45.401***	.000	-11.118	.212
	Independent (5 or less)	**-29.110***	.019	**54.675***	.000	**17.477***	.015
Independent (5 or less)	Large Multiple (more than 200)	1.923	.795	**-106.009***	.000	**-13.938***	.001
	Medium (26 - 200)	**36.720***	.003	**-100.076***	.000	**-28.595***	.000
	Small Chain (6 -25)	**29.110***	.019	**-54.675***	.000	**-17.477***	.015

The national services exhibit a different trend. MUR provision is not significantly different between large multiple and medium pharmacies. However, both these larger organisations provided significantly more MURs than small chains, all of whom provided more than independents. There is a trend with larger organisations providing greater volumes of MURs.

This is not exhibited as clearly with NMS consultations. Independents again provide significantly fewer NMS consultations than all other larger organisations. However, the trend does not follow organisation size with the pharmacy chains. Medium chains provided significantly more NMS than large multiples.

7.4.5 Controlling for deprivation

The analysis described above indicate a relationship between both organisation type and deprivation on EHC provision. However possible interaction between these variables makes it difficult to draw conclusions or predict future EHC provision.

An analysis of variance compares means between different groups, to determine if there is a significant difference between the groups. However, this only considers the influence of a single variable, and the correlations displayed in *Table 20* indicate that other variables influence EHC provision. Deprivation is one such variable displaying a negative correlation with EHC provision (-0.074, p=0.000), although the correlation is low. There are greater numbers of EHC consultations in areas of greater deprivation. This is also supported by the literature, which indicates that deprivation plays a substantial role in EHC need and therefore provision (Morgan and Liu, 2017; Wellings *et al.*, 2013).

A 2-way ANOVA allows an appreciation of the interaction between two independent variables, which both act on the dependent variable. The data has shown that both pharmacy organisation and deprivation influence EHC provision. Using this method can identify if deprivation and pharmacy organisation interact and affect each other. From this the effect of deprivation can be understand and accounted for when considering the impact of pharmacy organisation.

Continuing with the data set with supermarkets excluded, a 2-way ANOVA was completed. This is shown in *Table 26*. In this instance the dependent variable is EHC provision, and the two independent variables are Pharmacy ownership type (excluding supermarkets) and the Index of Multiple Deprivation Rank (IMD). To allow a 2-way ANOVA to be undertaken with IMD rank data, the data were grouped into 5 groups (rank 1+2, 3+4, 5+6, 7+8, and 9+10).

Table 26 2-way ANOVA of EHC provision and Pharmacy ownership type and deprivation (excluding supermarket data)

Tests of Between-Subjects Effects					
	Type III Sum of Squares	df	Mean Square	F	Sig.
Pharmacy ownership type	306435.094	3	102145.031	3.347	**.018**
Index of Multiple Deprivation Rank	396651.357	4	99162.839	3.250	**.011**
Pharmacy ownership type x Index of Multiple Deprivation Rank	401937.007	12	33494.751	1.098	.357
R^2 = .019 (Adjusted R^2 = .013)					

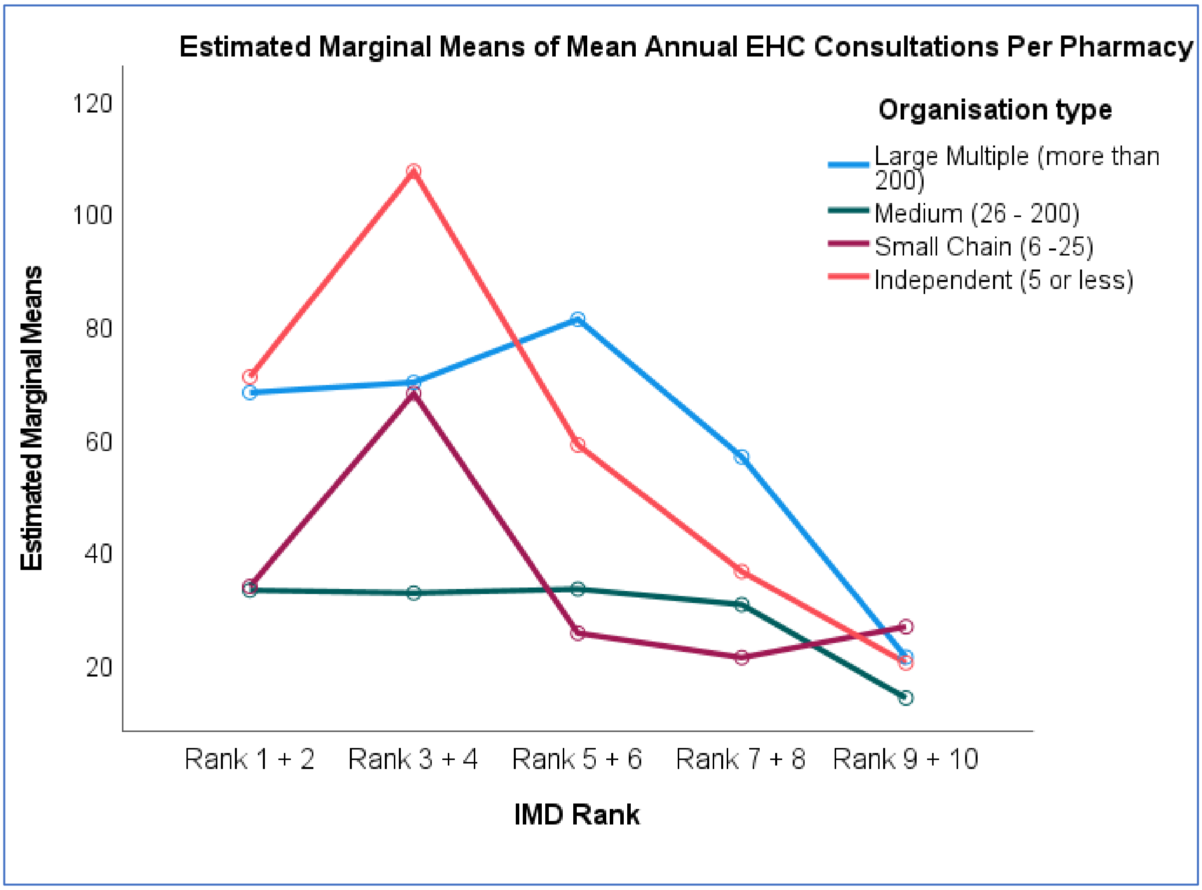
From the 2-way ANOVA it can be seen that there is a significant difference in both the Pharmacy ownership type and deprivation groups. Post-hoc Fisher's LSD tests provides clarity in what these differences are.

Table 27 2-way ANOVA post-hoc LSD tests for EHC consultations by IMD rank (excluding supermarket data)

Deprivation	Deprivation	Mean Difference	Sig.
IMD Rank 1 + 2	IMD Rank 3 + 4	-16.52	.065
	IMD Rank 5 + 6	-2.49	.791
	IMD Rank 7 + 8	17.81	.090
	IMD Rank 9 + 10	**41.88***	.000
IMD Rank 3 + 4	IMD Rank 1 + 2	16.52	.065
	IMD Rank 5 + 6	14.03	.146
	IMD Rank 7 + 8	**34.33***	.001
	IMD Rank 9 + 10	**58.40***	.000
IMD Rank 5 + 6	IMD Rank 1 + 2	2.49	.791
	IMD Rank 3 + 4	-14.03	.146
	IMD Rank 7 + 8	20.30	.067
	IMD Rank 9 + 10	**44.37***	.000
IMD Rank 7 + 8	IMD Rank 1 + 2	-17.81	.090
	IMD Rank 3 + 4	-**34.33***	.001
	IMD Rank 5 + 6	-20.30	.067
	IMD Rank 9 + 10	24.07	.056
IMD Rank 9 + 10	IMD Rank 1 + 2	**-41.88***	.000
	IMD Rank 3 + 4	**-58.40***	.000
	IMD Rank 5 + 6	**-44.37***	.000
	IMD Rank 7 + 8	-24.07	.056

As described, the IMD ranks were grouped into 5 groups. The areas of least deprivation (IMD Rank 9 + 10) provided significantly fewer EHC consultations than the most deprived areas. There is also a similar pattern between IMD Rank 3 + 4 and IMD Rank 7 + 8. It is surprising that the differences in means are not significant in every category, given the evidence of greater EHC need in more deprived areas. Barring IMD Rank 1 + 2, the other ranks do appear to follow the trend of increasing consultations with greater deprivation. The differences do not reach a significance of $p<0.05$ though. There may be several reasons for the different behaviours in the most deprived areas, some of which were explored in the policy review (page 18). Reasons linked to the most deprived areas may include reduced awareness of EHC services, reduced engagement with healthcare, financial challenges to accessing healthcare.

Figure 43 Interaction between Pharmacy organisation type and Deprivation



The interaction graph (*Figure 43*) depicts the interactions between the deprivation rank groups and organisation type. There are some instances of interaction such as between small chain and medium organisation, or large multiples and independents. This again follows the pattern of the post-hoc tests, creating two groups: large multiples and independents, and medium and small chains. The only interaction outside this pattern is at IMD Rank 9 + 10, the least deprived areas.

7.4.6 Multiple Regression

Regression analysis is the process of fitting a linear model to data, to predict an outcome (dependent) variable from a predictor (independent variable) (Field, 2018). In this section, the dependent variable is community pharmacy EHC provision. With one predictor the technique may be called simple regression, but several predictors is referred to as multiple regression (Field, 2018). Unless the regression is a perfect fit to the data (which is almost impossible), then only some of the variation is explained by the identified variables. Multiple regression adds further predictors to attempt to explain more of the dependent/outcome variable's variation.

Multiple regression analyses were conducted to determine the relationship between EHC provision, and the variables listed in Appendix 5. These indicate the 9 measures of deprivation and service provision data. Variables were removed using the backward method, to create the model listed in *Table 28.* The model summary shows the two variables (MUR and Health and Disability Rank) removed from the model (*Table 29*).

Table 28 Variables contained in each model (dependent variable: TOTAL EHC)

Variable	**Model number**		
	1	**2**	**3**
Rx	✓	✓	✓
Total MUR	✓		
Total NMS	✓	✓	✓
Flu annual	✓	✓	✓
Income Rank	✓	✓	✓
Employment Rank	✓	✓	✓
Education and skills Rank	✓	✓	✓
Crime Rank	✓	✓	✓
Barriers to Housing/services Rank	✓	✓	✓
Health and Disability Rank	✓	✓	
Living Environment Rank	✓	✓	✓
Income Deprivation Affecting Children Index (IDACI) Rank	✓	✓	✓
Income Deprivation Affecting Older People Index (IDAOPI) Rank	✓	✓	✓

Table 29 Model summary - TOTAL EHC

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	0.394	0.156	0.152	158.448	0.156	43.277	13	3055	0.000
2	0.394	0.156	0.152	158.422	0.000	0.010	1	3055	0.920
3	0.394	0.155	0.152	158.439	0.000	1.629	1	3056	0.202

There was not a large value for the R^2, the largest being between EHC provision and flu provision (R^2 = 0.017). The multiple regression did increase this 10-fold to 0.156 (adjusted R^2 = 0.152). The F-tests are presented in *Table 29*, showing the differences between groups are statistically significant. The model with the best fit found a significant regression equation ($F(11,3068)=51.003$, $p=0.000$), with an R^2 of 0.155.

The multiple linear regression equation is:

TOTAL EHC = (0.005 * Rx) + (-0.123 * Total NMS) + (0.161 * Flu annual) + (0.025 * Income Rank) + (0.001 * Education and skills Rank) + (-0.002 * Crime Rank) + (-0.001 Barriers to Housing/Services Rank) + (-0.001 * Living Environment Rank) + (-0.009 * IDACI Rank) + -0.011 * IDAOPI Rank) + 74.70.

The results of the regression show that the identified variables explained 15.2% of EHC variation, but that model 3 was a significant predictor of EHC variation. Rx (B=0.005, p=0.000) and Flu services (B=0.161, p=0.000) positively contributed significantly to the model, increasing EHC provision. NMS (B=-0.123, p=0.000) however, negatively contributed to the model decreasing EHC provision. Of the 9 measures of deprivation, 8 contributed to the final model. Standardised and unstandardised contributions can be seen in *Table 30.*

Table 30 Multiple regression coefficients - Model 3

Variable	**Coefficients**		
	Unstandardised (B)	**Standardised (β)**	**Sig.**
(Constant)	74.700		0.000
Rx	0.005	0.107	0.000
Total NMS	-0.123	-0.072	0.000
Flu annual	0.161	0.124	0.000
Income Rank	0.025	1.266	0.000
Employment Rank	-0.007	-0.350	0.000
Education and skills Rank	0.001	0.060	0.042
Crime Rank	-0.002	-0.080	0.000
Barriers to Housing/services Rank	-0.001	-0.050	0.009
Living Environment Rank	-0.001	-0.050	0.007
Income Deprivation Affecting Children Index (IDACI) Rank	-0.009	-0.479	0.000
Income Deprivation Affecting Older People Index (IDAOPI) Rank	-0.011	-0.552	0.000

The standardised values displayed in *Table 30* provide more insight into the relative strength of the variables. The effect of income on EHC provision (β=1.266, p=0.000) dwarfs any of the other variable listed. Income specifically affecting children (β=-0.479, p=0.000) and older people (β=-0.552, p=0.000) are strong negative effects, and this may be due to the age profile of the local population. Areas with greater older people deprivation may have fewer women aged 12-55 in need of EHC services.

Similarly, employment (β=-0.350, p=0.000) may reflect differing populations as indicated by the wide raging social influences on EHC uptake explored in the literature.

7.5 Main study: Modelling of findings if applied to current practice results

The previous sections described the results of the FOIs and subsequent analysis at both Local Authority and individual pharmacy level. The path analysis derived from the local authority analysis is key to meeting the aims of this thesis (page 44). The path analysis describes the influences on EHC service commissioning and provision. It may also provide a useful tool for commissioners when making commissioning decisions. This approach could be applied to other services, both commissioned from community pharmacy and elsewhere, provided data are available. To consider the practical benefit of the analysis undertaken, possible future predictions have been made using the relationships previously described.

7.5.1 Predicting changes to GP EHC prescribing rates

One variable that is potentially simple to practically influence is the proportion of EHC service commissioned pharmacies. Unlike population deprivation, commissioners can take discrete steps to change this such as speaking to individual pharmacy owners. Increasing the proportion of contracted pharmacies does not require changes to legislation, practice, or patient care. The proportion of commissioned community pharmacies was highlighted by the path analysis as one of the larger total effects (*Table 16*). The linear regressions allow predictions of the effect of changing variables. For instance, the proportion of community pharmacies commissioned to provide EHC services is 48%, closely matched to the 47% in the literature (Mackridge, Gray and Krska, 2017). The data available in this research is reflective of 60% of the eligible population. Using these values and estimated means, the impact of changing this (for instance to all pharmacies in England) can be estimated.

The linear regressions provide equations of the gradient. This can allow predictions to be made. Firstly, the change in community pharmacy EHC provision rates by increasing the proportion of commissioned pharmacies. As the data from Mackridge *et al.* (2017) had a higher FOI response rate, then the 47% value will be used. Then the correlation between GP EHC prescribing rates and community pharmacy EHC provision rates can be estimated with the new value. Finally, using the data collected the proportional change can be applied and the overall impact on GP prescribing can be estimated.

Current values (calculated means)	Increase % of commissioned pharmacies
$Mean\ consultation\ rate\ (Ph)$	$Mean\ consultation\ rate\ (Ph)$
$= 80.36 + 2.66$	$= 80.36 + 2.66$
$*\ \%\ commissioned\ pharmacies\ (47)$	$*\ \%\ commissioned\ pharmacies\ (100)$
$= 205.38$	$= 346.36$
$Mean\ consultation\ rate\ (GP)$	$Decreased\ mean\ consultation\ rate\ (GP)$
$= 94.02 - 0.08$	$= 94.02 - 0.08$
$*\ Mean\ consultation\ rate\ (Ph)(205.38)$	$*\ Mean\ consultation\ rate\ (Ph)\ (346.36)$
$= 77.59$	$= 66.31$
This is a reduction in the mean GP consultation rate	$77.59\ (original) - 66.31\ (reduced\ )$ $= 11.28$ $(15\%\ decrease)$
The current data represents 60% of the English population. The current total GP consultations (82,822) needs to be 'scaled up' to represent 100% of the English population.	$\frac{82{,}822}{0.60}$ $= 138{,}037\ consultations\ anually$
Therefore, the potential decrease in GP appointments can be determined.	$138{,}037 \text{ x } 0.85\% = 117{,}331$ $\underline{Reduction\ of\ 20{,}706\ consultations\ anually}$

The proportion of EHC service commissioned pharmacies affords an opportunity for policy change. If this were increased to 100%, the mean rate of consultation (community pharmacy) could increase from 205.38 / 10,000 to 346.36 / 10,000. An increase of this magnitude could decrease mean GP EHC prescribing rates by 11.28 / 10,000 (15%). This could equate to a reduction in 20,706 GP consultations per year, without any additive increases likely from patient awareness of a national / wider service offering.

7.5.2 Considering current practice across Great Britain

Reports from the Welsh government provide details on the number of commissioned community pharmacies, and their provision across the country (Statistics for Wales, 2018). Similar to England, detailed prescribing data is available publicly, providing information on EHC prescriptions from GPs (NHS Wales Shared Services Partnership, 2018). Again, both data types (pharmacy and GP) are available from public datasets from the Scottish government (Public Health Scotland, 2018). Using this data key facets of community pharmacy EHC commissioning across Great Britain can be compared.

To provide context of the differing commissioning environments, both the total number of pharmacies and the number (and rate) of abortions are also provided. In England the ratio of pharmacies to female population is 1 pharmacy for every 1,464 female aged 12-55. Both Scotland and Wales have lower ratios (Scotland - 1 pharmacy for every 1,221 female aged 12-55, Wales – 1 pharmacy for every 1,184 female aged 12-55). However, the geographies are also different, with both Scotland and Wales being generally more rural. This makes direct comparison difficult.

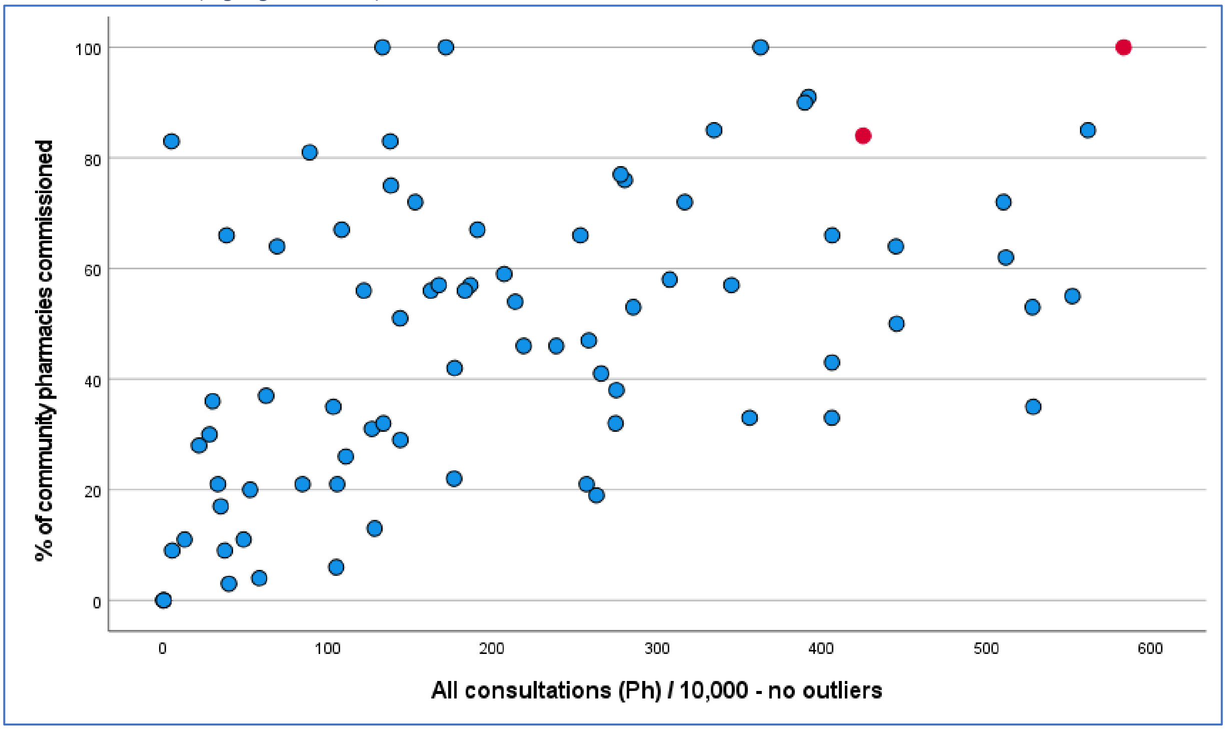
The data show a much higher rate of community pharmacy EHC provision in Wales and Scotland. All the values presented are mean values, in the case of Scotland and Wales estimated by national aggregated figures. There is no consideration of the local variation highlighted throughout the research.

Table 31 Comparing EHC provision across Great Britain for 2018/19

Country	England (in sample)	Wales	Scotland
Number of pharmacies (total)	6,409	716	1,269
Commissioned Pharmacies	2,851	574	1,269
% of total pharmacies commissioned	48%	84%	100%
Number of pharmacy EHC provisions	202,072	36,031	90,420
Number of GP prescriptions	82,822	3,286	57,088
Total female population (12-55)	9,380,153	847,599	1,549,991
Rate of EHC provision per 10,000 female population (Ph)	215.425	425.095	583.358
Rate of EHC provision per 10,000 female population (GP)	88.295	38.768	433.744
Number of abortions	191,555	9053	13,286
Rate of abortions per 10,000 female population	204	107	86

A scatter plot of the rate of community pharmacy EHC provision and proportion of commissioned community pharmacies is presented in *Figure 44*. The data for Scotland and Wales are highlighted in red, showing them to be amongst the higher end of the community pharmacy provision rates. They also broadly sit in the positive correlation trend seen with the English only data.

Figure 44 Scatter plot of the proportion of commissioned pharmacies and all consultations (Ph) - including data for Wales and Scotland (highlighted in red)

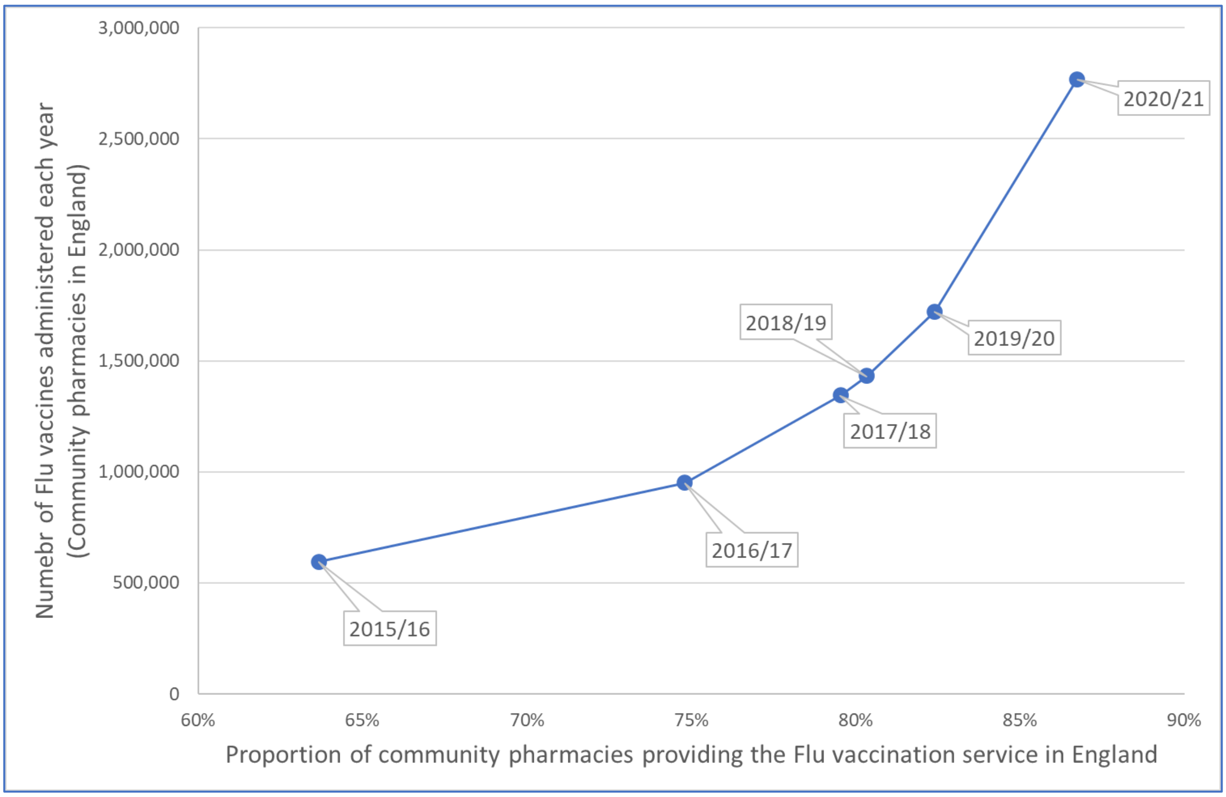


7.5.3 Comparisons with other community pharmacy service activity (influenza)

It may be possible to predict the influence of national commissioning in England by considering a local service that (relatively) recently became nationally commissioned. In September 2015, community pharmacies in England were able to provide flu vaccination as part of a national service for the first time (Rai and Wood, 2018). Before the national service, there were several examples of local commissioning, proving the patient receptiveness of the service. A service commissioned across Birmingham had 376 (57.7%) pharmacies commissioned to provide the service, although 61 (16%) of them did not provide any vaccinations (Rai and Wood, 2018). Similar to EHC, a large proportion (but not the majority) of community pharmacies provided the service. Flu vaccinations are also available from alternate providers (e.g., GP surgeries) like EHC. These similarities make comparisons useful.

In the 2018/2019 financial year, 73.5% of community pharmacies provided flu vaccinations through the national service (NHS Business Services Authority, 2022a). This number has been steadily increasing each year since national commissioning, starting at 7,195 and increasing to an all-time high of 9,800 in 2020 (Connelly, 2021). This increase in the proportion of commissioned pharmacies loosely trends with provision rates, increasing from 595,467 vaccines in 2015/16 to 2,766,332 in 2020/21 (Connelly, 2021).

Figure 45 Change in English community pharmacy Flu vaccine provision numbers over time, as the proportion of pharmacies providing the service changes (NHS Business Services Authority)



Chapter 8: Discussion

8.1 Introduction

This thesis aimed to determine what influences EHC service commissioning and provision, through the use of quantifiable, routinely collected data. EHC services have been primarily considered due to the noted variation across England, and GP EHC prescribing was used as a proxy for service outcomes. Using the data may provide a way to evaluate the factors and predict the impact on a community pharmacy commissioned service. Various data types have been identified and data successfully obtained either from open-source databases, or through FoI requests. The subsequent analysis was then presented.

In this chapter the role of the literature in guiding the analysis is discussed before considering the results found. Following the pattern of previous chapters, the discussion is split into sections – local authority analysis, then individual pharmacy analysis. Each section ends by considering the implications for practice.

8.2 Examples from the literature

There were two literature sources that guided this thesis. Mackridge, Gray and Krska (2017) informed a Local Authority level of analysis followed by the work of Jacobs *et al.* (2017) which guided the individual pharmacy level analysis.

The results of the CFIR analysis (page 68) show the importance of evidence strength and quality in commissioning decisions (*Figure 6*). Other key priorities were patient needs and resources, external policy and incentives, and organisational incentives and rewards. The literature reported a frustration expressed by commissioners and pharmacists about the lack of evidence guiding commission decisions. This was presented in two ways, a frustration due to commissioning services based on local policy alone, and a lack of commissioning services believed to have a strong evidence base.

The analysis presented in this thesis begins to highlight some of the data points that describe the impact of commissioning, and act as possible evidence to inform decisions. In this case GP EHC prescribing was used as a proxy measure for EHC service success. Commissioners will likely wish to consider appropriate dependent variables or alternative proxy measures for different services.

It is interesting that despite incentives being emphasised in the CFIR results (page 73), the review of community pharmacy EHC remuneration in the feasibility study (page **Error! Bookmark not defined.**) did not influence EHC provision. Accordingly, this was not explored in the main analysis. This may reflect a disconnect between contractual incentives (i.e., how much a company is paid) and individual incentives (i.e., how much the pharmacist is paid or otherwise incentivised). Incentives to provide services have not been found to enhance service quality, but this may warrant further consideration as a greater number of services are provided by community pharmacies (Elvey *et al.*, 2006). Evidence also discussed the importance of pharmacy location. Reviewing the proportion of commissioned community pharmacies is a proxy for this, with a greater proportion of commissioned pharmacies inferring greater access. This factor was also discussed during the feasibility study (page **Error! Bookmark not defined.**), which informed the later analysis.

Another factor was the proposed interplay between national and local services in community pharmacy, reported in the study by Jacobs *et al.* (2017). Reviewing these services between individual pharmacies formed another key theme of the analysis. This also considered the role of pharmacy ownership, again a factor highlighted in the literature as something reported to influence both commissioning decisions and provision.

Finally, the literature reported a lack of correlation between community pharmacy EHC services and the local health outcome, under-18 pregnancy rates. From this it was theorised that patient's move their care, accessing services from alternate locations. This was the main reason GP EHC prescribing was selected as a primary dependent variable. Evidence showed a relationship between GP EHC prescribing and community pharmacy EHC provision. Quantifying this relationship was important to better understanding how community pharmacy services act within a health system.

From these themes, the key data points were identified using routinely collected data. The analysis reflected the form of data and considered the topic from two units of analysis, Local Authorities, and individual pharmacies.

8.3 Feasibility Study

8.3.1 Value of the feasibility study in meeting the aims and objectives

The value of the feasibility study was in determining whether the chosen methodology would support answering the aims of the thesis. This thesis aimed to determine what influences EHC service commissioning and provision, through the use of quantifiable, routinely collected data. It was predicted that community pharmacy EHC data would be a valuble variable and is routinely collected by commissioners. What was not known was whether these data were available, and if they would be of sufficient quality to allow subsequent analysis.

When considering the methods of this study, it was recognised that secondary data collection relies on both the actions of others and the accuracy of data collection potentially outside of the usual rigour of scientific research. The purpose of this feasibility study was to determine both the availability of the data and its quality. It was an observational study which had a 100% response rate and a 96% data return rate, across a large section of England's footprint. When reviewing the literature a similar study methodology highlighted a 96% response rate from FOIs submitted across England (Mackridge, Gray and Krska, 2017). The comparable rates of data return were highly encouraging for determining feasibility of data collection across England.

The objectives of this thesis included quantifying the variables influencing a Local Authority commissioning EHC community pharmacy service. Specifically, this included determining the correlation between rate of community pharmacy EHC activity and the rate of GP EHC prescribing, as well as identifying other data driven variables. The feasibility study played a key role in achieving these objectives. Firstly, the data were of sufficient quality to allow determination of the correlation. Secondly, the feasibility study provided a small data set to explore the merits of different variables from which key variables were identified for later analysis.

8.3.2 Reviewing data collection – Are FOIs a suitable data collection tool?

Evidence discussed in the policy review (page 18, chapter 2) identified 152 Local Authorities in 2014/15, and restructures may have changed this number since then (Mackridge, Gray and Krska, 2017). However, this represented a sixfold increase in the feasibility study sample size, which assuming the response rate of both the feasibility study and previous studies is duplicated, should result in 146 separate data points for analysis (Mackridge, Gray and Krska, 2017). The high response rate, matching that of the literature, gives confidence in the use of FOIs. It is likely that FOI requests across England provide the data needed for this type of study.

It was difficult to gain assurance on the quality of the data without a form of direct data collection to provide comparison. However, the range of values supplied were of a similar order of magnitude from each Local Authority, this consistency of data gives some reassurance to the quality. Furthermore, contractual agreements between pharmacies and Local Authorities include requirements for accuracy, and routine audit processes to validate the information provided and subsequent payments made.

The data from both the FOIs and the open-source datasets provided absolute numbers of EHC supply to women. There is however a slight difference in the numbers. GP prescriptions are the number of prescriptions written (either electronically or on paper) and recorded on the GP clinical record. This may not directly translate to medicines taken by patients. Although exact numbers are unavailable, not all prescribed medications are dispensed by pharmacies leading to a possible inaccurately high value for both LNG-EC (GP) and UPA-EC (GP). However, due to the immediate need of the treatment (i.e., to prevent pregnancy post unprotected sexual intercourse) it was assumed to be unlikely that this value would be significant.

Additionally, it has been found that 20.1% of patients have waste medication (i.e. medication they have collected from a pharmacy but have not administered/used) (Trueman *et al.*, 2010). Similar to prescription numbers this is less likely to impact this treatment pathway and any discrepancy is likely to impact both GP and community pharmacy data equally.

There is no way to account for this potential variation without restricting the data collected to allow individual patient follow-up to determine end outcomes (i.e., taken within required efficacy time-limit, taking outside this recommended period, or not taking the provided EHC at all). Therefore, it was recognised as a potential confounding factor that is likely to affect both GP and community pharmacy data. This was possibly off set by the breadth of the data collected (n (total of all supplies) = 80,830) across 22 local authorities.

The difference in scale of provision between GP and community pharmacy rates was substantial. Despite this the FOI data was sufficiently comprehensive to allow calculation of the rate of community pharmacy EHC provision and GP EHC prescribing.

8.3.3 Correlation – Did the collected data allow for the intended analysis?

The feasibility study was undertaken in part to determine if the collected data were of sufficient quality to allow calculation of correlation, and from that the value of the statistical methods could be considered.

The R^2 value represents the "proportion of variance in the outcomes variable which is explained by the predictor variables" (Miles, 2014). R^2 is known to increase "monotonically as regressors are added to the model". This effectively means the R^2 value increases when additional variables are added, and this happens regardless of the true relationships. This value will not give an accurate indication of correlation for multiple independent variables (Ricci, 2010).

The dependent variables, LNG-EC (GP) and UPA-EC (GP), were plotted against community pharmacy supply, LNG-EC (P) and UPA-EC (Ph), and the R^2 value determined. This value provides useful insight into the value of determining the correlation between GP and community pharmacy activity. The correlation shows that GP EHC prescribing rates are negatively correlated with community pharmacy service EHC supply rates. It indicates some of this variation can be explained by the community pharmacy supply rate.

The R^2 values of LNG and UPA linear regressions (GP and community pharmacy supply rates) were determined as 0.174 and 0.015 respectively (*Figure 16* and *Figure 17*). These results indicate that 17% of LNG-EC (GP) and 1.5% of UPA-EC (GP) rates can be explained by the corresponding community pharmacy supply rates. Comparative work conducted across Europe (Gilchrist *et al.*, 2011) investigated patient groups accessing substance misuse services in different settings and found comparable R^2 values, ranging from 0.163 – 0.252. The variance explained here is not high, but it is comparable to other epidemiological studies. From this, correlation was judged a useful metric in later statistical analysis.

The much lower R^2 value for UPA supply, may have been a result of the lower volume of UPA data points. 59% of the Local Authority areas did not allow provision of UPA from community pharmacy and this may reduce the reliability of analysis. For clarity these are not zero supplies – which could reflect a lack of patient need. They are Local Authority areas where UPA could not be obtained from community pharmacy due to commissioning arrangements. Often these are financially driven, as UPA is more expensive than LNG. In these circumstances it is probable either LNG is provided to the patient, or the patient attends/is referred elsewhere.

Correlation was also determined between all EHC (GP) and % EC Supply (Ph) (R^2 = 0.204). This higher value indicates that greater proportions of community pharmacies providing EHC services may influence the rate of GP EHC prescribing. The policy review (page 18, chapter 2) highlighted reasons women choose different routes to care. Greater numbers of commissioned locations may help cater to these different reasons. The proportion of commissioned pharmacies is a useful factor to include in later analysis.

The R^2 value for EHC (GP) and EHC (Ph) mv ($R^2 = 0.075$) indicated the mean consultation rate explained little of the variance in GP EHC prescribing. This may be that mean volume is not a useful metric, given variation in provision between pharmacies. The actual provision rate for individual pharmacies is likely more dependent on geographical factors, or the more individual patient factors previously highlighted.

Increased access to EHC from community pharmacies negatively correlates to GP EHC prescribing rates. A greater mean supply of EHC from community pharmacy does not have a significant influence.

Histogram plots of the EC supply rates (LNG-EC (GP), LNG-EC (P), UPA-EC (GP) and UPA-EC (P)) suggested an approximate normal distribution to the results with a single peak (*figures 14 – 16*). However, the scatter plot of LNG-EC (GP) and LNG-EC (P) manually identified possible outliers in the LNG-EC (GP) data. Removing data points great than 1 standard deviation from the mean, removed 4 data points.

The higher R^2 value of 0.417 does indicate a much higher explanation of the LNG-EC (GP) dependent variable by the community pharmacy supply. However, this is to be expected by removing data that is not close to the regression line. No conclusions can be drawn by the increased R^2 value, other than a possibility that increasing number of data points may decrease variation in the data and accordingly provide a greater R^2 value.

From the regression completed there are a few conclusions. Firstly, the FOI data allows for calculation of correlation between GP prescribing and community pharmacy EHC provision. Secondly, the proportion of commissioned community pharmacies is an important data point that influences the provision of commissioned services. Finally, the mean rate of provision is not a useful data point.

8.3.4 Identifying covariates – What are the possible data points that could influence commissioning decisions?

A key element of determining the strength of population-based correlations is identifying confounding factors or covariates. Confounders can result in bias both positively - increasing the correlation, or negatively - decreasing it (McNamee, 2003). Identifying confounding factors can be difficult, since "causality cannot be established from data alone" (McNamee, 2003). There are two types of evidence of confounding, internal statistical and external evidence from prior research and beliefs or knowledge (McNamee, 2003). Determining if a factor is causally related to an outcome rather than associated with factors that are truly causal is key to determining the validity of the primary hypothesis (Smith and Phillips, 1992). Confounders and covariates are occasionally used interchangeably, but can be described as variables that are related to both the intervention and outcome but not causal (confounder) or explain part of the variability (covariate) (Field-Fote, 2019).

Determining linear regression assumes the data are independent of each other. Clustering of data may indicate confounding factors linking the dependent and independent variable in unexpected ways. An example of this may be socioeconomic, it was found that knowledge of EHC differed with socioeconomic backgrounds (Kosunen, Sihvo and Hemminki, 1997). This is likely an important factor in commissioning decisions. The high level of data return suggests data will be available for multiple Local Authorities allowing comparison. The Index of Multiple Deprivation statistics published nationally can be used to capture this covariate and multivariate analysis will help understand the relationship.

Other factors linked to the study population are likely to include basic descriptors of a population including variation in age. Variation in age has already been accounted for in the analysis by determining rates of EHC provision by 10,000 female population. Population descriptors that will be much more difficult to quantify or access include factors such as the presence of planning with a spouse, knowledge of contraception and previous use of EHC (Agyei and Migadde, 1995; Free, Lee and Ogden, 2002).

A possible confounding factor identified in the preparation work for this study was supply of EHC through alternative settings. An example of this is a bespoke, dedicated sexual health clinics or a school nurse clinic. If these clinicians are based in a GP surgery and are registered as prescribing under the practice prescribing budget, then their activity will be included in the openprescribing.net data (OpenPrescribing.net, 2017). However, in other circumstances this third EHC supply route is not accounted for in the data collected. Further investigation revealed an additional, publicly accessible database, the Sexual and Reproductive Health Activity Data Set (SRHAD) (NHS Digital, 2019c). This database accounts for many alternate sources of EHC access. For EHC services, it is predicted that the primary relationship is between community pharmacy and General Practice.

Accounting for these alternative supply routes may be important in understanding this relationship and will formed part of the later analysis.

One of the objectives of the feasibility study was to identify data that may inform commissioning decisions. Two key data points have been identified here, deprivation and alternate access routes. Both were accounted for in the full analysis.

8.3.5 Service design – Are there any factors within the community pharmacy contracts that may inform commissioning decisions or outcomes?

A manual review of the PGDs and service specifications underpinning the community pharmacy supplies revealed little difference that could be contribute to the variation described. It was expected that there would be differences in: non-clinical age exclusions, restriction by patient home address (e.g. no supply to patient's resident outside the Local Authority boundaries) and the reimbursement received by the community pharmacies.

Not all the documentation was publicly available and additional FOI requests would have been required to obtain these. However, of the 18 Local Authorities where the information was available, none of them placed any restrictions on resident/non-resident access. One Local Authority restricted the service to children aged 13 and above, but this was not considered significant as the available data sets do not list values for children under 14 but aggregate the data. This is likely because whilst the minimum age of conception is estimated to be 11, the vast majority of conceptions occur from 13 onwards (Balgir, 1994).

Reimbursement also did not exhibit great variation, with 9 of the 18 Local Authority specifications detailing fees of £10. Excepting one outlier, all the prices were within one standard deviation and did not show enough variation that it was expected there would be no influence on either LNG-EC (GP) and LNG-EC (P). Scatter plots displayed no correlation between reimbursement and either LNG-EC (GP) or LNG-EC (P).

Due to the lack of variation the specifics of the contractual arrangements between commissioners and pharmacies were not considered in the full analysis.

8.3.6 Statistical significance – what data are needed for analysis?

The full analysis extended the sample size to all Local Authorities in England. This was predicted to provide a 6-fold increase in sample size. To determine a statistically significant correlation (a significance of 0.05), with an assumed R value of 0.417 (from current LNG-EC correlations) a sample size of 43 would be required. To achieve a regression power level of 0.8, with an anticipated effect size of 0.17 (R^2 as found in LNG-EC correlations), the minimum sample size would need to be 48 data points to achieve statistical significance. The later data collection provided a larger sample size than this increasing the likelihood of statistically significant results.

The data analysed in the feasibility study showed that FOIs provide data of sufficient quality, allowing the rate of community pharmacy EHC provision to be determined. This data can also be used to determine correlations between GP EHC prescribing rates and community pharmacy EHC provision and activity. There is a previously identified relationship between GP EHC prescribing and community pharmacy EHC provision, confirmed by the correlations described here (Lloyd and Gale, 2005).

When considering data points that support an understanding of EHC commissioning, community pharmacy provision and GP prescribing are clearly important. Data on population estimates is publicly available, allowing calculation of rates of provision by female population aged 12-55, controlling for differences in population between areas. The proportion of commissioned community pharmacies is also impactful, but the mean provision rate is not. Other data points for consideration in any modelling include deprivation within the Local Authority area and alternate access points. Both were included in the analysis within the main study and the subsequent modelling.

However, community pharmacy service specifics, such as remuneration, did not prove to be a useful data point. This was surprising as the literature suggested contractual features such as costs incurred had an influence on commissioning (Mills *et al.*, 2017). The literature on this is qualitative and may reflect a difference between opinion and behaviour. The strength of the quantitative approach taken here is that opinions can be objectively tested. Factors such as remuneration may influence perceptions by commissioners and pharmacy employees, but this has not been shown to influence community pharmacy provision.

8.3.7 Summary

The feasibility study determined three key things which informed the main study. Firstly, that community pharmacy EHC provision data are available through FOI requests to local authorities. Secondly, that the data returned is of sufficient quality and completeness to allow analysis; and that this data allows calculation of a negative linear correlation between GP EHC prescribing and community pharmacy EHC supply. Finally, several data points were identified to be included in any future modelling.

These additional data points included the proportion of commissioned community pharmacies, but not the mean provision rates. Other factors included alternate access routes to EHC, such as family planning clinics. What was not judged to be a powerful factor was specific aspects to the commissioned service, such as remuneration levels, which were not explored further.

The analysis seemed to support the relationship between GP EHC prescribing and community pharmacy EHC provision. The data set in the feasibility study is underpowered to generalise this relationship across the country. This relationship was treated as a proxy for successful EHC commissioning. Using the identified data points there was a need to build a statistical model that could be used to inform future commissioning decisions. This was the path analysis, described on page 129.

8.4 Main study: Analysis of EHC service provision (Local Authority)

The introduction (chapter 1) set out the complexity of community pharmacy commissioning. This is particularly evident with EHC services. Being a public health service, the responsibility for commissioning EHC services sits with Local Authorities. Each Local Authority has the freedom to commission services according to local need and processes. This creates variation in approach, intention, and design. Despite being commissioned by 97% of Local Authorities, only 47% of community pharmacies are commissioned. This varies widely from 4% to 99% of the pharmacies in a Local Authority (Mackridge, Gray and Krska, 2017).

Previous research by Mackridge, Gray and Krska (2017) demonstrated there was no significant correlation between community pharmacy public health commissioning and local health outcomes (such as under 18 pregnancy rates and EHC, deaths from substance use and needle and syringe exchange programmes, and diabetes prevalence and NHS health checks) (Mackridge, Gray and Krska, 2017). This included EHC services where there was no significant correlation between under 18 pregnancy rates and the proportion of commissioned pharmacies (Mackridge, Gray and Krska, 2017). A conclusion that could be drawn from this, is that community pharmacy EHC services do not provide the benefits to health that may be justifiably expected from the expenditure. Indeed, the authors suggest:

"*there is a need to re-visit the benefit of local commissioning of these service, which may be influenced by a range of factors other than identified need*" (Mackridge, Gray and Krska, 2017).

Other research has demonstrated the impact community pharmacy commissioned services can make. A study of the introduction of EHC services in North Yorkshire reported high uptake in community pharmacy, increased overall provision, and a shift of activity from GP prescribing to community pharmacy supply (Lloyd and Gale, 2005). These facts could be considered contradictory – with commissioning not linked to health need or outcomes, yet community pharmacy services increasing access and provision.

What neither of these two examples can do (with the data collected), is consider both the variation in commissioning across the country, nor how community pharmacy services sit within a broader health network. An apparent assumption in the Mackridge *et al.* (2017) conclusion is that community pharmacy services operate in isolation and that a lack of correlation to health outcomes suggests a lack of benefit (Mackridge, Gray and Krska, 2017). The Lloyd and Gale (2005) study reviews a single region in England, preventing generalisable conclusions or the identification of any trends or correlations (Lloyd and Gale, 2005).

It is hypothesised that community pharmacy EHC provision influences GP EHC prescribing, and that the relationship between these two clinical settings is dependent on the commissioning actions of the Local Authority. This suggests there is a need to consider the way in which these services are judged. What is their purpose and how can this be measured? From this, data can be identified and analysed to inform the required commissioning decisions.

8.4.1 Meeting the aims and objectives

The objective of this part of the analysis was to quantify the variables influencing a Local Authority commissioned EHC community pharmacy service. The data collected and subsequently analysed here articulated several variables based in routinely collected data. A key objective (page 44) was to determine the correlation between the rate of community pharmacy EHC activity and its association with the rate of GP EHC prescribing. This correlation is depicted in *Figure 29* and discussed later in this chapter (page 254).

Other objectives included identifying data-driven variables and analysing their relationships to EHC activity and creating a path-analysis model to represent these relationships. The feasibility study identified many of these variables, and the subsequent analysis across Local Authorities articulated and quantified the relationships. Using the correlations determined in the analysis (page 178) the path-analysis was created to represent these relationships. From this understanding of the variables, the influences on EHC service commissioning and provision can be better understood.

8.4.1 The effectiveness of FOIs as a means of data collection

Previous research and the feasibility study (page **Error! Bookmark not defined.**) both showed the validity of using FOI requests to obtain community pharmacy service data (Mackridge, Gray and Krska, 2017). Despite the need to review the list of possible commissioners in response to the tiered structure of local government, a complete list of 147 potential commissioners was found. A response rate of 76% was lower than the 96% response rate observed in both the initial study and the literature (Mackridge, Gray and Krska, 2017). It was surprising that the response to routine and legally obligated information requests differed across local authorities – with some providing data within the 20 days required, some requesting a delay and some refusing or unable to provide data. It is impossible to know the reasons but may reflect the respective capacity within different organisations. Responses from Local Authorities varied, but two common themes appeared in the null returns. These were either a lack of data, often due to complex sub-commissioning arrangements, or the pressures of the COVID-19 pandemic.

Despite this, a response rate of 76% provided a large data set for analysis. The feasibility study determined that a minimum sample size of 48 data points would be needed to achieve statistical significance (page 242). The FOIs returned data from 108 councils with a further 5 confirming no service was commissioned. This means 96% of the Local Authorities confirmed the presence of a commissioned service. This matches the literature, which also found in 2015 that 97% of Local Authorities commissioned an EHC service (Mackridge, Gray and Krska, 2017). Reflecting 60% of the eligible English female population and 59% of all English Local Authorities, the data set is likely large enough to allow some later generalisation.

The unit of analysis was determined to be the Local Authority geography. This was due to the commissioning of community pharmacy being undertaken by Local Authorities. Other units of analysis were considered however, not all Local Authorities were able (or willing) to provide individual pharmacy data which would have allowed more detailed analysis – for example at ward level. Wards are small geographical areas, linked to the electoral process. These areas vary, but often consist of approximately 7,000 people. Many population indicators, such as markers of deprivation, are often calculated at ward level.

Analysis at ward level was considered, but ultimately rejected. The number of FOIs not containing pharmacy identifying information would have led to a much-reduced data set. Furthermore, the policy review (page 18, chapter 2) set out many of the factors influencing EHC access. These included perceived privacy, location, and opening hours (Seston *et al.*, 2007). It can be reasonably assumed that women cross ward boundaries when accessing EHC services – particularly in preference to these influences. Population descriptions of the ward may not accurately describe the patients or patient volumes accessing EHC services. This factor is also relevant to Local Authority analysis, but the much larger geography and population size likely makes intra-authority travel a smaller confounder.

Correlating the Local Authorities to co-terminus CCGs excluded 27 local authority areas. Data for GP prescribing was only available by CCG boundaries due to their commissioner. Community pharmacy is commissioned by Local Authorities, but GPs are commissioned within a national NHS framework by CCGs. As these geographies are not parallel, there is no way to compare the data from different commissioners – except where they are co-terminus. Despite this loss of 24% of the local authorities, the remaining 86 areas for analysis represented 60% of the English female population (12-55). This is a large proportion of the population and *Figure 22* depicts the spread across the country. There is no obvious geographical divide or clustering of the areas. This gave some confidence in the generalisation of any conclusions.

The co-terminus areas did over-represent Major Urban local authorities (*Table 8*). There is no indication in the literature that rurality plays a role in patient choice, or preference to accessing community pharmacy services. A study based in California compared rural and urban community pharmacy provision, and found no difference between the proportions of pharmacies providing EHC (Bigbee *et al.*, 2007). There was a reported higher volume of provision in urban areas, but this is likely off-set by greater populations (Bigbee *et al.*, 2007). The variables used in the analysis are EHC rates, (per 10,000 female population) to counter differences in population and allow direct comparison between areas. Whilst no comparable study has been found within England, there is evidence that community pharmacy EHC services are well used in rural locations (Pearce and Jolly, 2020).

8.4.2 Assessing the results of the FOI requests

Following data collection, the data were described. The range of community pharmacy data was much greater than GP data. Community pharmacy rates varied from 0 to over 511 per 10,000 (the highest rate was 1,262). The GP rates ranged from 6 to 206. The 0 values for community pharmacy represent 4 areas where there was no commissioned service. There were also 54 areas where community pharmacy supplied no UPA. This is probably due to the commissioning structure of community pharmacy. Supply requires the use of PGDs and a Local Authority commissioner decision to fund interventions (described in chapter 2, page 30). During the period investigated UPA was more expensive than LNG (UPA=£14.05, LNG=£5.20 (NHS Business Services Authority, 2022b)). Guidance from The Faculty of Sexual and Reproductive Healthcare was updated in 2017 to indicate many examples when UPA is a preferred treatment choice over LNG (The Faculty of Sexual and Reproductive Healthcare, 2017). Prior to this, the position was less clear likely permitting a more financially conservative commissioning decision.

The historic lack of evidence or guidance indicating treatment preference for either treatment combined with the price difference has led to anecdotal evidence commissioners do not always follow best practice due to cost restraints (All Party Parliamentary Group on Sexual and Reproductive Health in the UK, 2020).
All the community pharmacy data skewed towards 0, reflecting the high number of 0 and very low rates. There was a similar pattern in the GP data, although much less pronounced. Scatter plots of the dependent variable (GP EHC prescribing rates) and the independent variable (community pharmacy provision rates) indicated a small degree of correlation. R^2 rates were particularly low, ranging from 0.00 (UPA) to 0.020 (all consultations). Both the histograms and the scatter plots highlighted outliers.

It is notable that in both GP and community pharmacy settings UPA is supplied at a lower rate than LNG. This likely reflects a combination of clinical guidelines/service specifications, ingrained practice (LNG has been in use for longer) and the respective costs of the two drugs.

8.4.3 Identifying and removing outliers

To remove the outliers box plots were plotted and the highlighted outliers were removed. SPSS determines outliers as data points outside 1.5 times the Inter Quartile Range from the 1st or 3rd quartile. This value is termed the “upper fence” (or “lower fence” if below) (Kwak and Kim, 2017). This was repeated until no data points were highlighted as outliers for each scenario (LNG, UPA, all consultations) for pharmacy and GP settings.

The causes for outliers can be wide ranging and there is little consensus about when (or if) to remove them from data sets. Certainly, removing outliers may lead to smaller sample sizes potentially compromising the reliability of study results (Kwak and Kim, 2017). Ultimately, there is a need to understand the data collection process, identify possible rationale for outliers, and justify decisions to remove them.

In the case of the data presented here, there are many co-variates influencing the data points. Socio-demographic predictors are difficult to quantify, often influenced by many individual population or group characteristics making summaries or generalisations difficult (Metcalfe *et al.*, 2016). Despite an expectation for a low R^2 value, the calculated values (0.00 – 0.02) were extraordinarily low. Crucially this did not match the available literature which indicated a strong relationship (Lloyd and Gale, 2005).

To determine a justification for removing or otherwise adjusting for outliers requires a hypothesis for the cause (Kwak and Kim, 2017). For this data there were two likely types of factors: the known variation between commissioning frameworks, and local geographic variations. It has been highlighted previously that Local Authorities do not regularly commission UPA PGDs from community pharmacy – accounting for the lower UPA / higher LNG seen in community pharmacy. Other factors not captured here include the remuneration for service provision, local engagement and training, and service restraints, such as excluded patient groups. Local geographical factors possibly influencing individual data points include intra-professional relationships, the number of pharmacies, and individual patient choice. There are several different factors not explored here that may well account for single data points, outside the trend exhibited by the data. For example, Metcalfe et al. (2016) have previously articulated the extraordinarily complex interactions between patient social factors and circumstances, which may skew individual data points (Metcalfe *et al.*, 2016).

Given this rationale for removing outliers, it was judged reasonable to do so, provided the data set remained of a similar size. The final data set represented over 90% of the original model, making minimal changes to the generalisation of any results. Despite the small number of data points excluded (a maximum of 7 for any variable) the R^2 values increased markedly.

Removal of outliers increased the R^2 value from 0.02 to 0.13 (LNG), 0.017 (UPA) and 0.21 (all consultations). Despite the removal of a small number of outliers, the increase in R^2 was substantial.

The scatter plot (*Figure 29*), and subsequent best fit line is an important part of describing the community pharmacy / GP EHC relationship. The negative correlation indicates that increasing community pharmacy EHC activity decrease GP EHC prescribing. The best fit line (all consultation (GP) = 94.02 -0.08 x all consultations (community pharmacy)) indicates that an increase in the community pharmacy rate of 100 / 10,000, would decrease the GP rate by 8 / 10,000. The implications of this are considered later in the discussion (page 254).

8.4.4 Possible implications of the correlation found

The data included 202,072 community pharmacy consultations. Of these, 91% (184,183) were for LNG. Initial data description and regressions were determined for both LNG and UPA separately to identify any different patterns or trends. Nothing was observed, except for a weaker relationship than with the combined data. Accordingly, the data were combined, and 'all consultations' are discussed from this point forward.

A key outcome of linear regression is the R^2 value, which indicate the percentage of the dependent variable explained by independent variable(s). There is no universal value indicating what R^2 should be, but rather it is informative as part of the investigation being undertaken. Additionally, the subject being measured will affect the R^2 expected. Simple direct relationships may be expected to have high R^2 values, such as a person's weight and height.

The correlations being analysed here are not simple, nor being measured in a controlled environment. Work by Mecalfe *et al.* (2016) in Canada previously attempted explain the complex interactions between access to (and use of) EHC (Metcalfe *et al.*, 2016). In that example regression modelling was used to understand the relationships between the method of contraception and socioeconomic factors. The study highlighted a R^2 value of 0.20 when modelling unwanted pregnancies and 0.02 for contraception use (Metcalfe *et al.*, 2016). This low value reflects that the “use of contraception is a complex issue” with many interacting factors, including socio-economic, relationship, knowledge, and **access** (Metcalfe *et al.*, 2016). This issue of access is a key objective of community pharmacy commissioning. Given the inter-woven factors, it would not be expected that the relationships described here would result in a high R^2 value.

Notwithstanding the low predictive results of this study design, there is value in establishing the presence of these low correlations. Multiple regression modelling of suicide predictors by Schaik *et al.* (2019) provides a useful insight into the value and application of low R^2 values. The model highlighted expressed R^2 values ranging from 0.44 for emergency hospital admission to 0.09 for the level of carers’ social contact (van Schaik *et al.*, 2019). The complex nature of population behaviour means many independent variables have low prediction values. However, where statistically significant there is a need to apply a theoretical framework to the regression model (van Schaik *et al.*, 2019).

In short, an explanatory approach is needed, where the use of substantive knowledge can guide the selection of variables and the ultimate change in practice based on the findings. Some factors may only explain a small element of variation, but if they are controllable then change may be enacted to influence the dependent variable. This is determined by combining theory and data. This is how the analysis can support commissioning decisions.

By identifying the controllable factors that influence service provision, they can be considered when making commissioning decisions.

In this case the theoretical rationale, that increased community pharmacy uptake correlates to decreased GP provision, is established in the policy review of this thesis (page 18). From this literature and framework, the theoretical path analysis was developed, and then refined with the correlations found. Applying this knowledge and the results of the path analysis allows the generation of recommendations for commissioners. From this, path analysis, the correlations found, and a commissioners' knowledge, appropriate routine data can be identified and used to inform commissioning and service provision.

For EHC services a dependent variable of GP EHC prescribing per 10,000 female population (aged 12-55) was chosen as a proxy-measure for community pharmacy service outcomes. The primary independent variable is community pharmacy EHC provision per 10,000 female population (aged 12-55). For both these variables bi-variate correlations were undertaken. The difference in the number of significant correlations is notable.

GP consultations were significantly negatively correlated with community pharmacy consultations, and positively correlated with the living environment deprivation domain. GP consultations did not significantly correlate with any of the other markers of deprivation. This contrasts with community pharmacy consultations, which correlated with 7 of the 10 measures of deprivation. It could be assumed that these correlations support the “inverse care law” and the “positive pharmacy law” (Hart, 1971; Todd A *et al.*, 2014).

The “inverse care law” states that access to healthcare is inverse to deprivation, where the areas of greatest need have the least access to care (Hart, 1971). Whilst this original finding is quite dated, no literature has disproved the original findings. Indeed, the impact of the recent pandemic has re-enforced this trend. Analysis of diagnosis and treatment commencement in General Practice has shown this is lower in areas of high deprivation, accented by the pandemic (Carr *et al.*, 2021; Williams *et al.*, 2020).

Patient need (and demand) has been shown to be greater in areas in greater deprivation, including in areas such as sexual health (Smith, 1993; Ashworth *et al.*, 2007). For example, women in the most deprived areas were more than twice as likely to have an abortion than those in the least deprived (Department of Health and Social Care, 2018). There were no negative correlations between deprivation and GP EHC prescribing, so GP prescribing does not appear to be less frequent in areas of greater deprivation. However, the increased need creates an expectation of positive correlation – if GP activity was responding to this demand. It should be noted that the non-significant correlations were positive (i.e., greater EHC with greater deprivation). The lack of significant correlation demonstrated here supports the “inverse care law”.

Conversely, the “positive pharmacy law” demonstrates that there is a “positive trend between community pharmacy accessibility and deprivation decile – with the highest access in the most deprived areas” (Todd A *et al.*, 2014). This is broadly supported by the significant correlations found. The Index of Multiple Deprivation (IMD), Income, Health and Disability, Crime, Living Environment, Income affecting children, and income affecting older people all positively correlated to all consultations (community pharmacy). Of the 10 measures of deprivation, 7 were significantly positively correlated – indicating there is greater community pharmacy EHC provision in areas of greater deprivation. The other three deprivation measures, also positively correlated to 'all consultations' (community pharmacy), but these were not statistically significant.

Correlations alone cannot provide a complete insight into the role of deprivation on the community pharmacy and GP EHC relationship. However, it is potentially important that in the areas of greatest need (increased deprivation) there is greater community pharmacy activity. This finding supports the health strategy set out in policy and commissioning objectives (see page 22) (Depatment of Health, 2013).

The only deprivation measure significantly correlating to GP EHC prescribing is the index of Living Environment. The Living Environment domain measures the quality of the local environment both indoors (quality of housing) and outdoors (air quality and road traffic accidents) (Ministry of Housing Communities and Local Government, 2019a). It is not clear from the description of the domain or the literature, why this one domain would display significant correlation. The correlation between Living Environment with GP prescribing (0.241, $p<0.05$) is smaller than with Ph provision (0.331, $p<0.01$). This is in line with the trend of deprivation strongly correlating to community pharmacy activity rather than GP prescribing.

The rurality of the Local Authority area may be of more relevance to GP prescribing. 'All consultations' (community pharmacy) negatively correlate to rurality (-0.230, $p<0.05$). This means more rural areas have lower rates of community pharmacy EHC provision. Whilst not statistically significant, the 'all consultations' (GP) correlation was positive (0.184, $p=0.103$). A recent review of the indices of deprivation in rural settings raised questions of their validity (Burke and Jones, 2019). The nature of the assessment process is arguably subjective, with the experience of deprivation differing between urban and rural settings (Burke and Jones, 2019; Commins, 2004). Furthermore, the aggregated nature of the deprivation measures may overlook isolated houses / people, a feature more likely in rural areas (Burke and Jones, 2019).

Burke and Jones have proposed an alternative approach to calculating deprivation in rural settings, but this has not yet been adapted (Burke and Jones, 2019). It does, however, highlight the different needs of rural populations – which in turn may partially explain the rurality correlations.

Another important factor in explaining the role of rurality and deprivation is the business models underpinning general practice and community pharmacy. The overwhelming majority of community pharmacy funding comes from the NHS, via the national contract (The King's Fund, 2020a). This is primarily through fees linked to dispensing prescriptions, described in chapter 1 (page 2). Areas of greater deprivation and population density are known to correlate with greater volumes of prescribing (Local Government Association, 2021; Covvey *et al.*, 2014). Accordingly, community pharmacies have a financial incentive to locate and cluster in areas of high deprivation and more dense populations.

Furthermore, opening a new pharmacy can be complex. Entry to the market is regulated, meaning opening a new pharmacy must be approved by NHS England. The decision to permit new pharmacy openings, or changes in location, are assessed alongside a Pharmaceutical Needs Assessment (PNA) for an area (Pharmaceutical Services Negotiating Committee, 2021). The PNA for an area considers the pharmaceutical services within a local authority area and determines if the population needs are met (Department of Health, 2013b). Deprivation is a key measure of these needs (Department of Health, 2013b).

Unlike community pharmacy, general practice is contracted for a geographical area or population area, without specific consideration of deprivation (The King's Fund, 2020b). Community pharmacy is paid by activity, whereas general practice operates on a patient-list basis, being paid a flat fee for registered patients (NHS England, 2020). The primary aim of the contract is to ensure complete coverage of the population.

This fundamentally different approach to funding may well play a role in the correlation found between both rurality and deprivation, and EHC provision. Community pharmacies have a clear financial incentive outside of any EHC need or activity, to locate their business in areas of greatest deprivation and high volumes of activity. Conversely, GPs are incentivised to spread their premises geographically to ensure coverage.

This would result in greater pharmacy access in areas of greater deprivation and greater EHC need. It could also result in greater GP access in more rural areas, and no strong correlation to deprivation. There is little direct evidence on this, beyond the previously highlighted “positive pharmacy law” and “inverse care law” (Todd A *et al.*, 2014; Hart, 1971). It would however explain the correlations found.

8.4.5 How multiple regression contributes to the data analysis

Following bivariate correlations, multiple regression was undertaken. The dependent variable was the rate of GP EHC prescriptions per 10,000 female population (aged 12-55) – all consultations (GP). The predictor (independent) variables were the variables with identified correlations, as depicted in *Table 12.*

The eventual multiple regression model contains three independent variables, community pharmacy activity, rurality, and the living environment domain. This matches the previous simple regression correlations, where community pharmacy EHC provision (-0.458, p=0.000) and living environment (0.241, p<0.05) both significantly correlated to GP EHC prescribing. The correlation was not significant between GP EHC prescribing and rurality but there was a positive trend (0.184, p=0.103). The change in R^2 and adjusted R^2 can be seen in *Table 14.*

As discussed earlier (page 254), the R^2 value is an indication of the proportion of the variance that can be explained by the independent variable(s). In the case of the multiple regression model the R^2 is 0.408, indicating the three variables explain 41% of all consultations (GP). This is also sometimes referred to as a ‘goodness-of-fit summary’, an R^2 of 1 would indicate the variables completely explain any change in the dependent variable (Cameron and Windmeijer, 1997). However, R^2 is known to systematically overestimate the amount of variance explained in a population (Karch, 2020). The adjusted-R^2 value is an unbiased estimator of the population effect (Ricci, 2010).

Access to healthcare is difficult to describe, given the multiple variables impacting patient journeys. This can vary from the physical environment (location, transport/access, perceived cleanliness), to the people providing care (perceived competence, existing relationships), and promotion (word-of-mouth, perceptions about the setting) (Mosadeghrad, 2014). The policy review (page 18) set out many of the specific influences of EHC access, including income, age, marital status, and English language ability (Metcalfe *et al.*, 2016).

Metcalfe *et al*. (2016) attempted to quantify the relative strengths of socio-demographic predictors of contraception use and failure (Metcalfe *et al.*, 2016). They found 20% of the unintended pregnancy variance (R^2=0.020) can be attributed to socio-demographic factors, with approximately 1% of contraception use explained by these factors (Metcalfe *et al.*, 2016). Similar work to quantify these relationships considered the role of education, religion, wealth, and age on the use of contraception (Singh *et al.*, 2020). This study was in India, which has a quite different social and health system to England. However, the methods used were similar to this study. Singh *et al.* (2020) took pre-collected data, aggregated by 'zones' and undertook linear regression (Singh *et al.*, 2020). Singh *et al.* (2020) reported a pseudo R^2 of 0.182, much less than that reported in this study (Singh *et al.*, 2020).

The data presented here describes a R^2 value of 0.408, and an adjusted-R^2 value of 0.381. Comparisons with the literature demonstrate that this is a high value, suggesting a strong relationship and a model that explains a great deal of a complex variable.

8.4.6 Applying correlation and regression to commissioning

This study aimed to determine if analysis of routine data can yield insights into factors that influence local service commissioning. This has been explored using the example of EHC services. The complex web of variables that influence the routes of EHC access were described earlier as well as how regression models struggle to quantify these relationships (page 31 and 261). GP prescribing is a frequent and common route of EHC access, but literature has also identified the important role of community pharmacy services in influencing this patient pathway (Lloyd and Gale, 2005). Quantifying this relationship is an objective which supports a broader understanding of factors influencing commissioning.

The policy review (page 18) considered the commissioning of local healthcare services (page 36). The findings described many of the challenges and considerations possibly influencing decisions made and the subsequent service provision. What was evidence from the literature is that commissioning is not determined by or designed on data analysis. There are assumptions about the value gained from new patient pathways, and there is little evidence of published work to quantify benefits, that can later be applied across geographies. This is evident particularly in community pharmacy where there are no examples of quantified relationships between community pharmacy and GP EHC provision.

The linear regression has already quantified for the first time the impact of community pharmacy EHC services on GP EHC prescribing. Namely, that increasing the rate of community pharmacy prescribing by 100 per 10,000 female population (aged 12-55), could be expected to decrease GP EHC prescribing by 9 per 10,000 female population. This understanding gives commissioners the ability to critically evaluate the cost of commissioning and make informed decisions about best use of the public purse.

In this case, activity in one setting/location influences activity in another. Similar relationships between linked care settings have been identified previously, such as GP surgeries and Accident and Emergency (A&E) departments (Bankart *et al.*, 2011; Cowling *et al.*, 2016). Patient care in GP surgeries can be predicted to influence demand for care in A&E departments. However, even factors that affect only GP surgeries then have a ‘knock on’ effect on A&E departments.

Factors such as deprivation or age can logically be expected to increase the rate of A&E attendances given the likely increased healthcare needs and this was explored in the literature (Bankart *et al.*, 2011). What may have been of interest to commissioners is the influence of access (or perceived access) to GP surgeries. A 5% increase in patient reports of being able to consult a particular GP was estimated to decrease A&E appointments by 3.5% (Bankart *et al.*, 2011). By understanding this relationship, commissioners can balance the cost of changing variables (in this case GP access) against the expected benefits (A&E attendance).

Similar to the multiple regression reported in this thesis, this relationship describes how one (or several) variables account for the variance in a single outcome variable. In the case of Bankart *et al.* (2011) it was A&E attendances, in the case of this study it was rate of GP EHC prescribing. Regression models are useful to quantify direct relationships between independent and dependent variables. More complicated models have more paths, or paths that lead through more variables (Streiner, 2005). These more complicated models are needed for a more complete understanding of the relationship, especially when there are identified additional influences.

Path analysis is “an extension of multiple regression”, allowing examination of more complicated relationships (Streiner, 2005). This is particularly useful when considering health systems, and patient behaviours – given the knowledge of the wide range of competing influences on behaviours. A review of the literature has not shown this approach applied to community pharmacy service provision before. Examples often centre around education (Siracuse *et al.*, 2004) or patient experiences and expectations (Sabater-Galindo *et al.*, 2017; Nitadpakorn, Farris and Kittisopee, 2017). The results and implications of the path analysis are discussed next.

8.4.7 Reviewing the results of the path analysis

Previous literature has demonstrated the factors influencing an individuals' decision to access EHC (page 31). The data collected here considers the combined patient pathways, rather than individual decisions. Therefore, the variables are those that are applicable to the relevant population of the whole local authority. The variables influencing across populations could be considered in terms of their impact on the healthcare 'system'.

Deprivation is known to correlate to EHC access, and accordingly is a likely co-variate (Wellings *et al.*, 2013; Morgan and Liu, 2017). The government measures deprivation through the Index of Multiple Deprivation, consisting of seven domains (and two sub-domains) (Ministry of Housing Communities and Local Government, 2019a). These are available for several levels of aggregation, including the Local Authority unit of analysis. Similarly, rurality is known to impact both population needs and EHC uptake (Burke and Jones, 2019; Bigbee *et al.*, 2007). These data are also available for each Local Authority.

The focus of this work was to determine if data can yield insights into factors influencing local service commissioning. One the ways this was assessed was through consideration of community pharmacy EHC services, using GP EHC prescribing as a proxy for the desired commissioning outcome. Quantifying the relationship between GP and community pharmacy EHC activity was a key objective.

It was important to consider alternate routes for women to access EHC – namely A&E departments (and alternate 'urgent care settings') and family planning centres.

Segregated data are not available for A&E departments, preventing comparison between Local Authority areas. Data were available for the Sexual and Reproductive Health Activity Data Set (SRHAD) which collects information on community based sexual and reproductive health services (NHS Digital, 2019c). Previous literature has suggested that community pharmacy EHC provision does not have a relationship with either setting (Lloyd and Gale, 2005).

Provision of EHC through community services (family planning centres) was incorporated in the theoretical path analysis, as it was originally assumed that there would be a likely impact on both community pharmacy and GP EHC activity. The bi-variate correlations demonstrated that there was no significant correlation with either all consultations (community pharmacy) (0.020, p=0.864) or all consultations (GP) (0.037, p=0.745). This finding fully supported the literature, that community pharmacy EHC activity acts independently to family planning centre provision (Lloyd and Gale, 2005). A&E provision data were not available. Although not certain, the data supported finding regarding family planning centres lends confidence to the argument that community pharmacy EHC activity is not correlated with A&E activity.

Combining these identified 'system' variables created the theoretical path analysis, depicted in *Figure 30*. Bivariate correlations were used to identify the relationships deemed to be impactful (i.e., significance correlations were retained). This led to the creation of the updated path analysis, *Figure 31*. The number of indices of deprivation have reduced and the SRHAD data have been excluded. Notably, both the % of community pharmacies commissioned, and the local authority rurality were only found to correlate with community pharmacy. Therefore, the pathways were amended to reflect this direct, singular relationship.

As mentioned earlier, the value of path analysis is its ability to demonstrate inter-linked relationships. Crucially it provides an indication of indirect relationships, i.e., the association variable A may have on variable C *through* its impact on variable B. The easiest way to compare the relative importance of these variables is through standardised effects (β). Standardised rates (β) are standardised to have a mean of 0 and an SD of 1. This allows variables to be directly compared to determine the relative strength of their relationships. More detail on the use of standardised rates was detailed in the methods and results sections (pages 129 and 192).

The web of pathways may mean that a variable has a direct effect on the dependent variable, and an indirect variable mediated through a third variable. It is entirely possible to have contrary direct and indirect effects, and the total effect (the sum of direct and indirect effects) can facilitate understanding the complete impact of a variable (Palese *et al.*, 2019).

The path analysis shows the standardised squared multiple correlation (R^2) value for all consultations (GP) (0.37) and all consultation (community pharmacy) (0.45). These values indicate 45% of the community pharmacy rate and 37% of the GP rate can be explained by the variables identified. The multiple regression describes a R^2 value of 0.408, and an adjusted-R^2 value of 0.381. These figures are consistent with the path analysis model, suggesting the model is a good description of the relationships. This relatively high R^2

value may well be due to incorporating organisational factors, such as % of commissioned community pharmacies.

The key aspect that the path analysis adds to the evaluation of these variables are the indirect effects. Due to the elimination of outliers, the path analysis was run with some missing data. This means indirect and total effects are estimated and significance levels are not available. Despite this, what can be seen are the indirect effects on GP EHC prescribing mediated through 'all consultations' (community pharmacy) (*Table 16*).

The all consultations (community pharmacy) and living environment directly impacted on all consultations (GP). An increased rate of consultations (community pharmacy) decreased the rate of consultations (GP) (β=-0.552, p=0.000), and greater levels of living environment deprivation increased the rate of consultations (GP) (β=0.435, p=0.000). The relationship between community pharmacy and GP EHC activity is expected. The direct effect between living environment and all consultations (GP) also reflects the correlations explored previously. In addition to the direct effect, living environment has a further indirect effect on the GP rate, negatively mediated by the community pharmacy rate (β=-0.101).

What this all means is that deprivation influences GP EHC provision, through the effect it has on community pharmacy provision. Similarly, the proportion of pharmacies commissioned has an effect through community pharmacy provision and this is one of the largest influences. Without the path analysis, none of these influences would have been identified.

8.4.8 Factors influencing commissioning and provision – the role of rurality

In the path analysis (*Table 16*) the direct effects on all consultations (community pharmacy) reflect the correlations discussed earlier (page 254). Decreasing rurality (i.e., more urban areas) corresponded with an increased rate of ‘all consultations’ (community pharmacy) (β=-0.262, $p<0.05$). Rurality was also positively mediated by ‘all consultations’ (community pharmacy), with increased rurality increasing ‘all consultations’ (GP) (β=0.144). This means that rurality itself did not have a significant effect on rates of GP EHC prescribing the effect was only indirectly detected through that of the effect on community pharmacy. In urban areas pharmacy provision rates were greater, in rural areas GP rates were greater.

The relationship with rurality matches that found in the literature (Bigbee *et al.*, 2007). A 2007 study from California investigated EHC provision and rurality, for purchased EHC (Bigbee *et al.*, 2007). It was reported that community pharmacy provision was lower in rural areas due to “perceived community attitudes”, as well as a lack of training and perceived lack of patient demand (Bigbee *et al.*, 2007). The data in this study reflects commissioned EHC services, therefore training is a pre-requisite of commissioning. Despite this pre-requisite, training is known to be a barrier to community pharmacy service provision, especially with the requirements changing between commissioning areas (Mills *et al.*, 2017; Eades, Ferguson and O'Carroll, 2011; Aly *et al.*, 2020).

Rurality is known to impact community pharmacy service provision across a range of therapeutic areas. Within the United States, supply of naloxone (used in the immediate treatment of opioid overdoses) is a service often commissioned from community pharmacies. It has been found that rurality increased the levels of naloxone provision (greater provision in less urban / more rural areas) (Green *et al.*, 2020). However, rural pharmacies are also associated with other barriers to care, such as a lack of privacy and increased stigma (Green *et al.*, 2020). This is because the smaller population can result in reported reduced privacy ("everyone knows everyone's business") (Browne *et al.*, 2016). Questionnaires supplied to patient's accessing community pharmacies in Australia also reported privacy concerns, amplified in rural locations "in smaller towns with only one pharmacy … pharmacy customers tend to know each other" (Hattingh *et al.*, 2016). This is an interesting facet that is likely to apply to EHC services as discussed in the policy review (page 31). Research by Seston *et al.* (2007) studied women's preferences in EHC provision, and determined that privacy was the second most important factor in determining service-use (both whether they would seek care and the chosen location), with a 'willingness-to-pay' value of £19.96 (Seston *et al.*, 2007). This means that women would be willing to pay approximately £20 to ensure the consultation was conducted in private, rather than in (for instance) the pharmacy shop floor (Seston *et al.*, 2007).

A systematic review of the literature did not find differences in the care / service provided in rural and urban community pharmacies (Howarth, Peterson and Jackson, 2020). The literature suggested that rural patients were more likely to ask questions of the pharmacy teams, but notably not in the area of contraception (Howarth, Peterson and Jackson, 2020). There was no difference in the willingness of pharmacists in rural or urban areas to diagnose, provide advice, or treatment in the area of sexual health (Howarth, Peterson and Jackson, 2020). Norman *et al.* (2015) explored pharmacist attitudes to contraception services and found no reported difference between rural and urban areas but theorised that opening hours (a critical factor in service uptake) may be reduced in rural areas, reducing the likelihood the service is used (Norman *et al.*, 2015).

The data in this study do not explore individual patient factors, but considering existing literature, it could be concluded that the perceived lack of privacy in a rural location explains this relationship. Previous research has found that community pharmacy is viewed positively due to its 'discrete' and 'anonymous' service (Bissell and Anderson, 2003). The data here, and the literature highlighted, are suggestive that this experience is more likely to apply in urban areas. The increased number of pharmacies in urban areas indicates a possible transient nature of patients (i.e., a patient can access any commissioned community pharmacy regardless of previous use, rather than their own registered GP).

Combining the direct and indirect effects is suggestive that in more rural locations, patients are more likely to access EHC from GP services, rather than community pharmacy. Exploring the exact reasons for this, perhaps through qualitative work, would be a useful extension of this work. In particular, considering perceptions of privacy in rural and urban settings, and how to change this, could be useful.

8.4.9 Factors influencing commissioning and provisions – pharmacy access

In the path analysis (*Table 16*) a greater proportion of commissioned pharmacies increased the rate of community pharmacy EHC provision (β=0.542, p=0.000).

Additionally, the relationship between the proportion of EHC service commissioned pharmacies and all consultations (GP) was negatively mediated by all consultations (community pharmacy) (β=-0.299). This means increasing the proportion of commissioned pharmacies indirectly decreased the rate of GP EHC prescribing through its effect on community pharmacy provision. This was the largest indirect effect and larger than many direct effects.

This result is quite interesting. If it was assumed that the number of patients in an area accessing EHC is static, then increasing the proportion of commissioned community pharmacies would be expected to have no impact on the rate of community pharmacy EHC provision. It may reduce the mean provision from each pharmacy. This example would result in the same number of individuals 'spread' across a greater number of locations. In that instance we would not expect a significant positive correlation. Given that there is a positive correlation, this suggests that increasing the proportion of commissioned community pharmacies increases the demand for the service in community pharmacy.

This is further supported by the indirect effect where an increased proportion of commissioned pharmacies decreases the rate of GP EHC prescribing. That there was no direct effect shows the benefit of utilising a path analysis approach as this relationship would not have been clear through linear regression alone. Although the direct correlation was not significant, the trend does support the indirect effect: $r(77) = -0.195$, $p=0.089$.

A key influence in the design of this research was previous work by Mackridge, Gray and Krska (2017). The research conducted in 2014/15 used FOIs to determine that EHC was the most frequently commissioned Local Authority service (47% of all community pharmacies in England) and the proportion of commissioned pharmacies varied from 4% to 99% within Local Authorities (Mackridge, Gray and Krska, 2017). This matched the data reported here, where the proportion of EHC service commissioned pharmacies varied from 3% to 100% between Local Authority areas.

Mackridge *et al.* (2017) compared service provision to key local health outcome metrics (Mackridge, Gray and Krska, 2017). In the case of EHC, the proportion of pharmacies commissioned to provide EHC did not correlate to the local under 18 pregnancy rate (Spearmans correlation, r(140)=0.161, p=0.057) (Mackridge, Gray and Krska, 2017). It was acknowledged that the data could not account for provision of similar services by other agencies, meaning health needs could be met by other providers (Mackridge, Gray and Krska, 2017). Mackridge *et al.* (2017) investigated the relationship between community pharmacy provision and local health outcomes in isolation. This research attempted to compare its impact within the local health system and a relationship has been found and quantified.

8.4.10 Using path analysis to describe and assess the factors influencing commissioning of services

The approach in the literature suggests an underlying assumption as to the purpose of community pharmacy local commissioning. Namely that it is often intended to meet a specific patient need. The analysis presented here suggests otherwise. Minor ailments, EHC, or smoking cessation services all offer patient care that is replicated elsewhere. Therefore, the benefit of the service is not necessarily a particular therapeutic outcome – i.e., if the service was not commissioned the patient would (presumably) receive treatment elsewhere. The key benefit to these pharmacy services (of which EHC is a prime example) is to either increase access through greater numbers of service locations or to move patients and so increase capacity elsewhere.

If the service purpose / outcome is to move patient care or increase access to simplify patient journeys – how is this best described or measured? Numbers of patient interactions won't reveal success. Nor will correlations with population health metrics as this is influenced by existing healthcare provision. The literature did not reveal a widely recognised method for defining or judging commissioning success.

What is needed is a method of estimating numbers of patients accessing community pharmacy, over another possible option, or accessing community pharmacy where previously they would have 'gone without'. This is sometimes collected in service evaluation but relies on patient self-reporting and is subject to response bias and social desirability bias (where respondents are more likely to report what they believe the questioner wants to hear). The path analysis presented here may go some way towards solving this problem.

The direct and indirect effects from the path analysis imply a scenario where patients are more likely to choose community pharmacy for EHC care, *where it is available*. However, when a service is not commissioned (either at all, or in pharmacies close to and known by the patient) they will choose alternate routes to care. This will likely be GP care, since there was no significant correlation between community pharmacy EHC provision and other providers. Considering the impact of community pharmacy services on local health outcomes in isolation, fails to account for the natural flex in healthcare provision – where alternate settings will provide care in the absence of commissioning.

Providing EHC to women following unprotected sex (in turn reducing unwanted pregnancies) is the primary 'medical' aim of any community pharmacy service (Depatment of Health, 2013). However, correlating pharmacy activity and pregnancy rates does not necessarily provide a clear indication of commissioning success. Similarly, whilst the rate of provision is a good indication of demand it is difficult to determine if this is meeting all demand in an area. Lower community pharmacy provision rates may indicate patients are not receiving EHC or are accessing EHC elsewhere – not that there is lower demand.

What this research offers, is a method of reviewing the impact community pharmacy services have on local healthcare systems. The use of path analysis, to highlight direct and indirect effects, shows what is influencing patient access and how to potentially change this. This method would allow predictions of the impact of new commissioning or changes to services. For example, an area without an EHC service could predict how patient access would change between family planning, and GP services. This could theoretically be applied to any service type across community pharmacy or any part of healthcare.

The path analysis methodology presented here provides a tool for commissioners looking to enact change. Understanding the interdependencies both within and between settings allows predictions of impact. Then success can be defined and measured. For example, if a new service is commissioned the activity in another setting can be measured and the impact inferred through correlation. The path analysis allows an understanding of all the various influences on this relationship. Then action can be taken to influence the provision.

A theoretical understanding of any service and path analysis could be applied across commissioning activities. This could consider where patients access care (as in the EHC example), or potentially how preventative treatment influences later acute interventions, or how public awareness of a public health issue influences behaviours. This relies on the data being available to allow the analysis shown in this study, and a theoretical justification for the relationships found.

8.4.11 Accounting for bias

As discussed in the policy review (page 18, chapter 2) community pharmacy supplies EHC through both Local Authority commissioned services, and through private sales.

There is no visibility of the scale or geographical distribution of these private sales although evidence highlighted in the literature indicates that the price is a barrier to access (Killick and Irving, 2004). It is impossible to determine the impact this may have on the rate of EHC supply within individual Local Authorities. It is possible that private sales will be lower where commissioned services are available (as patients are probably more likely to access free services over private sales), however, this may not be the case where there is a greater perception of ease or privacy from private sale. It is likely that deprivation plays a role in this relationship.

Additionally, the literature has highlighted issues with the availability of trained healthcare staff in community pharmacy influencing access and provision (Mills *et al.*, 2017). Where trained staff are not available, then a private sale is the only means of access to EHC within the pharmacy. Alternatively, patients may choose alternate routes to free contraception, such as GP or sexual health services.

Accordingly, whilst private sales will undoubtably have an impact on community pharmacy service provision, it is impossible to predict to what extent, how it will influence the rate of supply within a population, nor determine this from national available data.

8.5 Main study: Analysis of EHC service provision (Community pharmacy)

Following consideration of EHC provision at a Local Authority level of analysis, further analysis was conducted at an individual pharmacy aggregation. EHC services are often provided confidentially in community pharmacies. Coupled with the data collection process in this study means that there is no way to identify patients. The implications of this are that there is no way to assess whether the EHC provisions in an individual pharmacy are linked to regular patients, or patients from any specific GP surgery.

Accordingly, correlations cannot be determined between individual community pharmacies and GP surgeries as were undertaken at the Local Authority aggregation.

However, research by Jacobs *et al.* (2018 has previously identified how organisational factors can influence the provision of services (Jacobs et al., 2018). Organisational factors reflect how a pharmacy business is structured and managed. Focussing solely on national service provision, organisational culture, staffing and skill mix, and ownership type were found to affect the provision of services (Jacobs *et al.*, 2017).

What has not been considered is the influence (if any) of organisational factors on local service provision. In this case EHC services. There are several external factors that may influence EHC provision, such as descriptors of the population (i.e., deprivation) and contractual measures. The literature search (page 30) highlighted the role of culture and process in pharmacies and suggests reviewing the national services alongside EHC services may provide helpful context.

It is possible that pharmacies providing greater volumes of national services will have greater rates of EHC provision. Some of the factors identified in the literature (culture, skill-mix, and staffing) are suggested to be favourable to service delivery. These factors may translate to all services (including EHC). Given the relationships, trends, and correlations established in the literature, national service volume may act as a proxy-measure for these intangible factors such as pharmacy culture.

8.5.1 Meeting the aims and objectives

The literature clearly demonstrated that pharmacy organisation type (large multiple, medium, small chain, independent, and supermarket pharmacy) influences service provision and commissioning. From this it was important to describe the role of pharmacy organisation in influencing EHC service commissioning, as per the thesis aims.

The objective addressed through this analysis was quantifying the variables influencing EHC provision from an individual pharmacy. The data collected and described here clearly articulate the role of organisation type, but also how this differs for EHC services. What is also clear is the much more impactful role of local deprivation on EHC provision.

8.5.2 Variation in FOI data and its implications for commissioning

Local Authorities were asked to provide the FOI data separated by individual pharmacy premises. Unfortunately, not all Local Authorities were able or willing to do this. The variation in Local Authority response is interesting, with no standard approach used. Each Local Authority had an individual process and determination criteria. This provides some difficulties in collecting data through this route.

FOI requests are seen as a valuable tool for investigative journalists, yet their use in research has not been fully embraced (Savage and Hyde, 2014). This research has confirmed their value in pharmacy local service analysis, previously established by Mackridge *et al.* (2017). However, it is possible that their infrequent use may explain the variation. One Local Authority expressed concern that provision of this information could be used for commercial benefit. This is despite the information being historical, and evidence being provided of the intended research use. This lack of understanding, and limited need for Local Authorities to develop processes to manage FOI requests of this nature, may explain this variation in response. Of the 108 local authorities able to provide data, 76 (70%) were able to provide individualised data. Some of the Local Authorities were unable to provide individualised data, as these data were not collected by the commissioner.

The literature has highlighted individual pharmacy factors influencing service success (explored earlier page 79) (Jacobs *et al.*, 2018). This analysis was designed to explore if routine data could provide insights into these organisational factors, which in turn may support commissioning decisions. Individual pharmacy factors are known to effect national service provision and were reported to influence commissioning decisions (Jacobs *et al.*, 2018). That some Local Authorities did not have data aggregated to individual pharmacy is a possible point of concern. The commissioner's ability to accurately determine service provision and its ability to meet patient/population need within their commissioned area likely relies in part on this information.

All Local Authorities were also asked to provide individual identifiers (preferably the NHS 'F-code'). This F-code (detailed on page 132) allows for comparisons to be drawn with several pharmacy features, such as prescription volume, and service provision. This was not provided by many of the Local Authorities and there was a need for manual data review. By using some provided information (pharmacy internal codes, post codes, street names etc.), the pharmacies could be linked to their F-code in 96% of cases.

That this data was not available from Local Authorities, is suggestive that there is no comparison of pharmacy provision within the broader environment. For example, it seems unlikely that the prescription volume of pharmacies is being considered in the commissioning process if the F-code is not readily available (prescription volume is only available via the NHS Business Services Authority (NHSBSA) which lists pharmacies by F-codes).

Whilst not conclusive, this supports the findings from the policy review (page 18) that local commissioning does not appear to be data based. Many Local Authorities do not appear to have identified and mapped their commissioned pharmacies, which raises questions about how decisions about ongoing commissioning are made.

8.5.3 Cleansing FOI data and describing the data

Once the FOI responses had been received, the data were cleansed. This meant removing duplicates and unidentifiable pharmacies, after which they were matched to NHSBSA data. There was a need to make several judgements on how the variables were quantified. For instance, 47 (1.5%) of the 3070 pharmacies did not dispense any prescriptions during one or more months of the year in question. The EHC data was not provided by month (unlike the NHSBSA data) but aggregated for the year. It is highly likely that a pharmacy that dispenses no prescriptions is not open to the public. The 0 data likely reflected a pharmacy opening (registered with the NHS but not yet open to the public) or in the process of closing (closed to the public but still able to submit any final claims for payment). Accordingly, it was decided to determine the mean monthly prescription volume (Rx) for the months where prescriptions were recorded.

Other key variables were the national service provision – MURs, NMS, and Flu. These services are provided throughout the year, with data available for each month. Due to seasonal variation (similar to EHC), the decision was taken to use annualised values (rather than monthly means) as the independent variables.

As expected, the data followed the skew towards zero identified during the Local Authority analysis. It is difficult to explain why 434 (14%) of the pharmacies provided no EHC during an entire year. Local Authorities were asked to provide details of commissioned pharmacies (i.e., pharmacies who have signed a contract to provide EHC services). It is possible some non-contracted pharmacies may have been included in error. However, each Local Authority area contains other pharmacies not included in the returned data suggesting a refined data set.

This skew toward zero reflects some of the challenges to commissioning highlighted in the literature. The financial focus on national contractual requirements is reported to overwhelm local service needs (Nazar and Nazar, 2019). This is compounded by a lack of pharmacy team 'engagement' (Carlisle, Fleming and Berrigan, 2016). Even of those pharmacies recording EHC provisions, there were 713 (23%) who provided less than 10 EHC consultations in the year.

The variation in provision (from zero to over 2,000 provisions per year) demonstrates a need to understand the factors influencing service activity. Understanding what variables increase provision can only be beneficial to commissioners aiming to meet contraceptive needs (United Nations Population Fund, 2020; Depatment of Health, 2013).

National services exhibit a different distribution to that exhibited by EHC provision. MURs are no longer commissioned by NHS England, having been discontinued on 31st March 2021. However, at the time of these data all pharmacies were permitted to provide (and claim) up to 400 MURs per year. Unlike the EHC provision, MURs display a bimodal distribution with peaks at 400 and 0. This corresponds with previous research demonstrating this trend of either providing the maximum allowed volume, or not providing the service at all (Jacobs *et al.*, 2017). The distribution of NMS and Flu provision are closer to EHC, skewing towards zero.

No literature has been found comparing local and national community pharmacy service provision. However, the distribution of the services is interesting, perhaps reflecting the different design of the services. MURs involve pharmacy recruitment of existing patients, with a cap (or target) for activity. NMS and EHC both rely on external 'referrals' whether that be new prescriptions presented by patients, or women attending for EHC. There is arguably limited opportunity for pharmacy teams to influence maximum provision levels (although the previous issues around service priorities still apply) (Nazar and Nazar, 2019). Flu could be described as a middle ground between the two, with patients both presenting and being recruited by pharmacy teams.

The scatter plots (*Figure 38* to *Figure 41*) revealed little correlation between EHC provision and prescription volume or national service provision. The R^2 value for the correlation between EHC provision and mean prescription volume (Rx) was 0.004. Earlier in this discussion (page 270) patient concerns about privacy were explored, and the possible implications on choice of pharmacy (or clinical setting). This was considered alongside rurality. A possible extension of this reasoning is that pharmacies with greater prescription volumes (and therefore serving greater numbers of patients) would be proactively chosen by patients. If privacy is determined by the volume of patients, being 'lost in a crowd', there would be a positive correlation between Rx and EHC provision. Similarly, if patients choose their regular pharmacy, you may also expect this positive correlation due to simple volumes of eligible patients.

The lack of strong correlation indicates two possible conclusions. Clearly how 'busy' a pharmacy is does not explain much of the variance in EHC provision. For example, polypharmacy can be considered being prescribed 5 or more medicines, and this is more common in elderly patients (i.e., those over 65) (Masnoon *et al.*, 2017; Roughead *et al.*, 2011), which means that prescription volume could merely be a poor indication of the eligible EHC female population (12-55 years). Pharmacies with greater prescription volume may serve patients with an age skewed towards the elderly.

Alternatively, patients may choose their location for EHC provision based on privacy-related factors that are not related to perceived 'busyness'. Research by Seston *et al.* (2007) found that women who are "dissatisfied with aspects of the EHC service", such as privacy, they may choose not to visit it and risk unwanted pregnancy (Seston *et al.*, 2007).

The literature highlights the importance of consultation rooms in ensuring privacy (Anderson and Blenkinsopp, 2006).

This is unlikely to be a significant factor in this study, as subsequent to the findings of Anderson and Blenkinsopp contractual changes have been agreed within England (Anderson and Blenkinsopp, 2006). As part of the current contractual arrangement, from 1st January 2020, all pharmacies in England must have a consultation room (National Health Service England, 2020). Whilst not a requirement at the point of data collection, this was well known by pharmacies. Previous data has indicated over 90% of pharmacies in England had a consultation room in 2017 (Public Health England, 2017). Furthermore, all national services in the data set required a consultation room. Only 24 (0.8%) of pharmacies did not provide any national service, meaning all other pharmacies must have a consultation room for private consultations. It has been reported by patients that there is a low awareness of the availability of consultation rooms (Hindi, Schafheutle and Jacobs, 2018; Rodgers *et al.*, 2016). Given the change in consultation room availability and corresponding service provision increase, there is likely scope for further work on privacy-related concerns and EHC in community pharmacy to determine if patient and public perceptions have shifted.

The linear regression show that the three national services, MUR, NMS, and flu explain almost none of the variation in EHC provision. The largest R^2 value is that of flu (0.017) suggesting it may explain 1.7% of the variation. MUR and NMS have R^2 values of effectively 0. Following the experience of preparing the Local Authority data, efforts were made to reduce outliers. This made no noticeable difference to the data and therefore all the data remains in the analysis. The small R^2 numbers are suggestive that national and local service provision (in this case commissioned EHC services) do not meaningfully influence each other. Commissioners interviewed by Jacobs *et al.* (2018) reported a belief that provision of other services would be a factor influencing commissioning, but the data here are suggestive this is not the case (Jacobs *et al.*, 2018).

8.5.4 Identifying possible influences on commissioning – prescription volume

All the bivariate correlations at the individual pharmacy aggregation are available in Appendix 4. However, the significant correlations with EHC provision are shown in *Table 20*. TOTAL EHC can be seen demonstrate significant correlation with Rx, flu, and 8 measures of deprivation. The positive correlation between TOTAL EHC and Rx, whilst significant (r(3069) = 0.063, p=0.000) is not large but indicates greater EHC provision in pharmacies with greater volumes of prescriptions. The negative correlation between TOTAL EHC and deprivation (r(3069) = -0.074, p=0.000) demonstrates a similar relationship, with pharmacies in more deprived areas providing greater volumes of EHC.

The literature highlights that deprivation and prescription numbers are linked. For instance, people prescribed 10 or more medications are more likely to live in deprived areas (Guthrie *et al.*, 2015). There are however, differing conclusions about the nature of this relationship. Analysis of Scottish primary care prescribing also found an increasing prescription burden in more deprived populations, but this effect was insignificant compared to other variables. Age has a strong impact on prescription numbers, as does the incidence of particular clinical conditions – such as cardiovascular health (Payne *et al.*, 2014).

This complicated relationship between deprivation and prescribing may be better explained when considered by therapeutic area. The medication used in conditions such as depression, pain and diabetes are significantly correlated with deprivation (McLean *et al.*, 2014). Opioids are a particularly strong example of prescribing trends varying by deprivation (greater prescribing in more deprived areas) (Chen *et al.*, 2019).

A possible interpretation of this correlation between Rx and EHC provision is that both are impacted by deprivation rather than each other. The weak association is reflective of the higher volume of prescribing in more deprived areas and the greater EHC demand in these same areas (Guthrie *et al.*, 2015; Wellings *et al.*, 2013).

8.5.5 Identifying possible influences on commissioning – national services

There is no significant correlation between EHC provision and either MUR or NMS service provision. There is however, significant correlation between TOTAL EHC and flu provision, $r(3069) = 0.129$, $p=0.000$. All three of these are national services. There is some research exploring barriers to service provision in community pharmacy. Contractor type (whether the pharmacy business is part of a large company or smaller independent) is known to influence national service provision (Thayer, Willis and Jacobs, 2017; Jacobs *et al.*, 2015). A possible difference between MURs, NMS, and flu, is public awareness and perception. Research by Rodgers *et al.* (2016) found that only 18.2% of the public had heard of the

MUR service, and only 8.6% for NMS (Rodgers *et al.*, 2016). Conversely influenza vaccination programmes are well established and widely recommended as the most effective mechanism for minimising the impact of influenza (Mowbray *et al.*, 2016). This difference in public perception and knowledge may begin to explain why MURs and NMS are different to flu provision. Regardless the correlations do not suggest that national service provision is a strong factor influencing local service commissioning or provision.

8.5.6 Identifying possible influences on commissioning – deprivation

What is perhaps most interesting are the correlations exhibited between deprivation (measured by the Index of Multiple Deprivation – IMD Rank) and the services explored here. Both the literature and the analysis in this research have shown the relationship between EHC provision (and need) and deprivation. Where deprivation is greater, EHC service uptake in community pharmacy is greater.

Conversely age-sex standardised analysis has shown that flu vaccination uptake is reasonably consistent across the range of deprivation (Coupland *et al.*, 2007). In the data here deprivation is significant positive correlated to flu ($r(3069) = 0.040$, $p<0.05$) but a smaller correlation than the negative corelation with EHC ($r(3069) = -0.074$, $p<0.01$).

There is some evidence in the literature that people choose community pharmacy flu services over alternate venues (mainly GPs) (Anderson and Thornley, 2014). Before flu vaccinations were commissioned by the NHS from community pharmacy, private vaccinations were available. Evidence at the time demonstrated that people eligible for free NHS services, would pay community pharmacy for vaccination. The most common reasons for this were convenient location, opening hours, a preference for the pharmacy environment or staff, and inconvenience of getting to the GP surgery (Anderson and Thornley, 2014). Once commissioned, people accessing community pharmacy for NHS free flu vaccinations including those in the most deprived areas (Anderson and Thornley, 2016). The community pharmacy flu service was particularly attractive to those of working age, including healthcare and social care workers (Anderson and Thornley, 2016). The data here are from 3 years after Anderson and Thornley, and patient behaviours may have since changed.

This does not adequately explain the differing correlations exhibited between deprivation and flu, MURs, and NMS services. A possible conclusion from the correlations is that service provision in community pharmacy is greater in more deprived areas. This is not present in MURs and NMS, possibly making them outliers. When determining the likeliness of this conclusion, it is useful to consider other community pharmacy services. Minor ailments is a commonly commissioned service, now nationally commissioned in Scotland and Wales. In these services, community pharmacists are commissioned to provide free treatment for urgent yet low-acuity conditions. Research investigating the uptake of minor ailments services in Scotland found that provision was positively correlated with deprivation (higher in more deprived areas), rurality (greater in more urban areas), and higher proportions of under 16s in the local population (Wagner, Noyce and Ashcroft, 2011).

These inferences all tally with literature detailing the “inverse care law” and the “positive pharmacy care law” (Hart, 1971; Todd A *et al.*, 2014). Namely that community pharmacies are more populous in areas of greater deprivation; with 99.8% of the population in the most deprived areas being within a 20 minute walk of a community pharmacy (Todd A *et al.*, 2014). This contrasts with much of the rest of healthcare, where care is less likely in more deprived areas (Hart, 1971).

What is impossible to determine from the literature and data available in this research are the causes for these relationships. Does the greater demand for care in more deprived areas increase provision in community pharmacy through volume of need? Is it the location of community pharmacies, more populous in deprived areas, that increases provision through ease of access? Or are there other more personal reasons people choose community pharmacy care, and are these distinct to deprived populations? Regardless, deprivation appears to be a factor influencing the provision of EHC services, and likely plays a role in other services.

8.5.7 The role of pharmacy ownership

Previous literature has indicated ownership type is a strong predictor of national service provision (Jacobs *et al.*, 2017). Research by Jacobs *et al.* (2017) grouped pharmacies based on the size of the company they were part of (Jacobs *et al.*, 2017). Following this example, the same grouping sizes were used – large multiple (more than 200 pharmacies in their company), medium (26 – 200 pharmacies), small chain (6 – 25 pharmacies), independent (5 or fewer pharmacies), and supermarkets. It has been previously theorised that the ‘practical’ method of providing pharmaceutical services will vary between national companies (chains), supermarkets, and small independents. This means that different business priorities, company cultures, and ways of working will influence service provision (Jacobs *et al.*, 2017). To allow comparison with the literature the same groupings were used in this study.

Previous research had determined that contractor type had a strong association with MUR, and NMS provision but not prescription volume (where there was no association) (Jacobs *et al.*, 2017). Other key variables influencing MUR and NMS provision included increased staff, the presence of a pharmacy technician or accuracy checker, or increased opening hours – which were all positively associated (Jacobs *et al.*, 2017). Both these services must be provided by a pharmacist; therefore, the suggested underlying reason why increased staff or additional roles would lead to greater provision is that they increase pharmacist capacity. Pharmacy technicians and accuracy checkers can offer greater levels of responsibility to the pharmacy processes, potentially allowing pharmacist involvement in patient care, away from dispensing activity (Bradley *et al.*, 2013). The data available for this research does not provide the level of detail to understand staffing arrangements or opening hours. However, previous evidence from both quantitative analysis and qualitative interviews, is that MUR and NMS provision are influenced by ownership type, perhaps as a result of the influence of staffing models or opening hours (Jacobs *et al.*, 2017).

The qualitative work of Jacobs *et al.* (2017) revealed the importance of culture in service provision (Jacobs *et al.*, 2017). Some pharmacists believed that the presence of activity targets influenced behaviours, increasing service provision. Some superintendent pharmacists cited the centralised operations, performance management, policy development and off-site dispensing as key influences in service provision. Another key theme of the study was the role of “centralised decision making”, where a head office made decisions of what (and how) activity would be undertaken, to maximise efficiencies (Jacobs *et al.*, 2017).

The data collected in this research were grouped by ownership, using the same categories as the work by Jacobs *et al.* (2017). *Figure 42* highlights the difference in service provision within the data collected for this research. MUR provision shows the clearest trend, with decreasing company sizes decreasing the service volume. The large multiples (more than 200 pharmacies) provided a mean of 345.84 MURs, whereas independent pharmacies (5 or fewer pharmacies) provided 239.83 MURs in a year. This trend is seen to a lesser degree with NMS (large multiples, 92.84 down to independents, 78.91) and flu (large multiples, 151.51 down to independents, 124.92). EHC provision does not follow this trend. Whilst there are differences in provision these do not follow pharmacy numbers linked to ownership type.

Supermarkets appear to be an outlier to the trends displayed by other pharmacy types. Whilst having fewer pharmacies within their businesses, they operate as part of extremely large companies. This contradiction in structure may partially explain why their provision is an outlier. For example, both Flu and MUR provision in supermarkets matches that of large multiples, whereas their NMS provision is the lowest of all groups. There may also be an influence in the type of patient accessing supermarket-based services, due to an increased tendency to be located out of town (Bush, Langley and Wilson, 2009).

From these relationships it could be concluded that pharmacy ownership may be a factor in service commissioning and provision. Certainty, the evidence from Jacobs *et al.* (2017) included reports from commissioners that it is viewed as such (Jacobs *et al.*, 2017). However, the relationship may not be clear for all services. The introduction (chapter 1) set out some of the differences between national and local services. This may change the impact of this factor and is explored further in the next section.

8.5.8 Is organisation type an influencing factor to EHC provision?

The trend in service provision (larger companies providing greater volumes of services) is not displayed with regard to EHC. Bush *et al.* (2009) discussed the 'corporatisation' of community pharmacy and its influence on service provision in 2009 (Bush, Langley and Wilson, 2009). This work has now been overtaken by changes in the landscape (such as the reduction in community pharmacy funding in 2017) but describes a trend of increasing multiple pharmacies, replacing independent pharmacies (Ridge and Cavendish, 2015; Bush, Langley and Wilson, 2009). Bush *et al.* (2009) used questionnaires to assess attitudes to service provision in different pharmacy types as well as assessing reported service provision (Bush, Langley and Wilson, 2009). Crucially, this work did not capture actual service provision – just whether the service was offered but determined that larger companies had an advantageous position for attracting commissioned activity. Conversely, supermarkets were determined to be less likely to provide pharmacy services

(Bush, Langley and Wilson, 2009). A particular reason suggested for this was the risk to corporate reputation – particularly with regard to EHC provision, which has historically been culturally stigmatised (Murphy and Pooke, 2019; Bush, Langley and Wilson, 2009).

There are examples of this in EHC provision. In 2002 Tesco (the then largest supermarket group) decided to stop supplying EHC to customers under 16 without a prescription responding to concerns expressed by some customers (Pharmaceutical Journal, 2002). This was suggested to be a response to shareholder concern, a responsibility not present with smaller companies (Bush, Langley and Wilson, 2009). This restriction included PGD supplies (such as those collected in this research) and resulted in Tesco pharmacies being removed from the service by commissioners. A similar incident occurred in 2017, where Boots (the largest multiple) was criticised for high prices of EHC (for private purchase) which were maintained to prevent 'misuse' of EHC (Murphy and Pooke, 2019). Following pressure from MPs and public reaction, this position was reversed, and this also highlights the relationship between larger companies and public opinion at large.

Whilst an interesting view of the balance large companies engaged in healthcare must maintain, the data in this research does not show any evidence of reduced multiple service provision. There is an apparent trend of increased MUR provision (a national service) by larger companies, but no pattern for EHC, a local service. Two conclusions could be drawn from this, either the reported advantages offered to multiples do not apply to EHC, and / or the main determinants of EHC provision are external to the pharmacy organisation.

There are different business models in healthcare which have been predicted to impact on service provision, and this has been explored across the globe (Feletto *et al.*, 2010). Not all countries permit ownership of several pharmacies, and several such as Australia, France and Germany require ownership of the pharmacy business to be restricted to registered pharmacist (Hattingh, 2011). Where multiple ownership is not permitted, there are some examples of countries that permit 'networking' between pharmacies (Feletto *et al.*, 2010). A networked pharmacy connects two or three pharmacies closely located through a shared ownership model, allowing sharing of workload (Feletto *et al.*, 2010).

A review of service provision in Australia found that community pharmacy businesses generally react to their local environment rather than anticipate it, but that networked pharmacies able to share a "strategic approach to managing product and service integration" are better able to respond, through a concept of "operational flexibility" (Feletto *et al.*, 2010). This matches previous research from the UK which highlight the advantages of multiples such as, operational capability, purchasing power, and other economies of scale (Gidman, 2010; Bush, Langley and Wilson, 2009).

What is rarely acknowledged in the literature is the source of the evidence base. All the literature explored here, gains views, insights, and opinions often from pharmacists, both employed and pharmacy owners. Whilst perception and opinion are undoubtedly important to behaviours and ultimately service provision, the data collected here does not bear out many of the conclusions of previous literature. A perceived reduced autonomy to make professional decisions about service provision experienced by pharmacists in corporate environments is theorised to translate into a possible detriment in patient care (Dobson and Perepelkin, 2011). A common thread from the existing literature is that corporate businesses are more likely to make purely financial decisions, resulting in compromised patient care, potentially through 'rationalised' service provision (Dobson and Perepelkin, 2011; Gidman, 2010; Bush, Langley and Wilson, 2009).

The data presented in this research shows no correlation between EHC provision and company size. Accordingly, the actual service provision (rather than pharmacist reported perception) is that service delivery is not significantly between different ownership types. It could be concluded that the advantages of larger business operations only apply to national services (MUR/NMS/flu), but also that at a local level there is neither an advantage for one group, nor a deliberate decision not to provide services. Accordingly, in the case of EHC ownership type is likely not a factor influencing provision and should probably not form part of the commissioning decision making process. Whether this applies to other local services cannot be determined without further investigation of these services.

8.5.9 Controlling for deprivation

The predictive role of deprivation in EHC provision has been explored from numerous angles. Both between local authorities, but also between individual pharmacies, the deprivation of the population has a significant correlation to EHC provision. More deprived areas have greater rates of EHC provision.

Given this relationship, when considering organisation type any confounding influence of deprivation is important to consider. The 2-way ANOVA provides an opportunity to not only understand the influence of deprivation and organisation type on EHC provision (both of which were significant), but also the interaction between the two. There may be a circumstance where different organisation types are skewed to more or less deprived areas. This would mean that although organisation type would appear to be a significant factor, deprivation was the true reason behind the variation.

The 1-way ANOVA post-hoc tests (*Table 25*) indicate two groups forming, large multiples and independents, and small and medium chains. The estimated marginal means plot (*Figure 43*) also suggest this grouping. By controlling for deprivation, it can be seen that an increasing organisation size does not have a significant influence on EHC provision. The degree of interaction seen (despite not being statistically significant) emphasises the large role of deprivation on EHC provision.

Whilst there are some significant differences between different organisation types, these are not linked to size. It is difficult to predict the reasons for this. It may be that small businesses are more aware of local business opportunities or patient need, and very large companies have the organisation efficiency of scale to capitalise on opportunities. Small and medium chains have the benefit of neither.

The literature has described how pharmacy ownership type is correlated to national service provision. The data presented here suggests that deprivation is a strong predictor of EHC service provision, regardless of ownership type. When identifying data to provide insights into service commissioning and provision, deprivation is likely a stronger factor than ownership type.

8.5.10 Using multiple regression to understand the factors influencing EHC provision

Following the bivariate correlations, a backwards multiple regression was determined, with TOTAL EHC as the dependent variable. The R^2 values determined from the linear regressions earlier *(figures 34 – 37)* were very low, indicating the national services and prescription volume explained very small amounts of the variation. The multiple regression increased the R^2 to 0.155 (adjusted R^2 0.152) indicating all the identified variables explained 15.5% of the variation.

This figure is quite low, although as acknowledged previously in earlier chapters (page 254), predictors of social situations often result in low R^2 values (van Schaik *et al.*, 2019). This is due to the complex nature of human decision-making being influenced by many factors. Literature considering patient decision-making, considered 6 different individual factors that may influence a woman's decision to access emergency contraception. These included income, education, and maternal age, yet only resulted in an R^2 of 0.20 (Metcalfe *et al.*, 2016). Given that the research here collected no individual patient factors, the R^2 of 0.155 is potentially valuable in understanding the relationships explored here. Additionally, it is reported that pharmacy specific factors such as location and opening hours effect service provision and these were not available either (Jacobs *et al.*, 2017).

It is interesting to compare the multiple regression of individual pharmacies (dependent variable - TOTAL EHC), and the multiple regression of pharmacy provision in different local authority areas (dependent variable – 'all consultations' (community pharmacy)). The regression model of individual pharmacies (*Table 28*) highlights the importance of deprivation in determining EHC service provision. Of the 9 indices of deprivation, 8 of them were retained in the model. This contrasts with the local authority model, where only 1 index was retained (*Table 13*).

The deprivation index that was excluded from the multiple regression was Health and Disability Rank, which "measures the risk of premature death and the impairment of quality of life through poor physical or mental health" (Ministry of Housing Communities and Local Government, 2019a). Individual markers of Health and Disability rank include years of potential life lost, hospital episode data, and numbers of people claiming illness or disability related benefits (Ministry of Housing Communities and Local Government, 2019b). It is not immediately obvious why this index of deprivation was excluded from the regression model, but there is little direct connection between these markers and EHC need.

An understanding of the literature would suggest that national service provision may correlate to local service provision, in this case EHC. The lack of correlation between MURs, NMS, and Flu, combined with the deprivation indices in the multiple regression model suggest otherwise. It was thought that building on the work of Jacobs *et al.* (2017) that culture, attitudes, behaviours, and organisation would determine the provision of EHC services (Jacobs *et al.*, 2017). It is reported that these factors correlate to national service provision, and if these national services correlate to EHC provision, assumptions could be made about other local service provision. The lack of these strong relationships suggests two things: that national and local service provision have different influences, and deprivation plays a much stronger role in EHC provision than it does in national services.

Deprivation is important as this appears to be of more relevance to EHC provision at the individual pharmacy aggregation, than Local Authority aggregation. The high number of deprivation indices retained in the regression model is suggestive that the population accessing individual pharmacies is important to service delivery. The 'hyper-localised' population not just the generalised deprivation of the commissioning areas needs to be considered. It is the population immediately in the vicinity of the pharmacy and accessing the pharmacy that is important. This feature is masked or muted when conducting Local Authority aggregated analysis. The advent of ICS organisations, with larger commissioning geographical footprints, may make this distinction even more important.

This potentially impacts commissioning decisions. Reviewing the existing evidence, there is a temptation to consider both previous service provision (success) and other factors such as ownership type when deciding how and where to commission services. The data explored here suggests that commissioners should not consider other service provision when making their determinants, and that the hyper-localised population is of more significance. What may be more difficult to judge, particularly for community pharmacy, is the population that access pharmacies. The literature has shown that 90.2% of the population have access to a community pharmacy within a 20 min walk, greater than that of General Practice (Todd A et al., 2014; Todd et al., 2015). It is reported that some patients choose pharmacies for their anonymity and this may well extend to choosing pharmacies away from their living environment, further complicating this relationship (Bissell and Anderson, 2003).

8.6 Applying the analysis to future commissioning decisions

The thesis has so far identified a gap in the literature, namely a lack of data to influence commissioning decisions and provision. Using the example of EHC services, routinely available data has been used to identify factors that could influence EHC provision and therefore commissioning decisions. The path analysis and supporting analysis, have shown how routine data can be used to inform decisions, and predict how these decisions will change population behaviours or outcomes.

Next the discussion considers the limitations in this approach, before considering how the analysis undertaken could be applied to practice. This section also highlights examples from recent changes to community pharmacy practice, that appear to support some of the key themes of the analysis. For instance, the role of the proportion of commissioned pharmacies which is a factor more easily influenced by commissioners that deprivation levels.

8.6.1 Limitations

This thesis has used FOI data, combined with other data points to identify and analysis factors influencing the commissioning and provision of EHC services. Several conclusions have been drawn, particularly about the value of using path analysis to inform and predict the effect of commissioning decisions. This has been undertaken within the context of community pharmacy EHC services, with the proxy outcome of GP EHC prescribing rates.

Whilst the data have successfully described population behaviours via two different units of analysis (Local Authority and individual pharmacy) it did not capture individual factors. These include those influencing patient choice, or specific organisation factors of GP surgeries or community pharmacies. In part this was a conscious decision, recognising the wealth of qualitative literature exploring individual patient attitudes and actions. Additionally, any barriers to pharmacist service provision (e.g., refusal to supply EHC on ethical/religious grounds) have not been accounted for. This did not feature heavily in the literature, and whilst being a confounding factor, is unlikely to have a significant impact given the size of the data sample.

It is important to note that a portion of the variation in EHC provision is likely to be accounted for by private EHC sales. This data is not available, and being commercially sensitive, is not subject to FOI requests. This is a likely contributing variable to EHC provision.

It is important to note that the data obtained through FOR requests could not be independently verified. However, contractual agreements between pharmacies and Local Authorities include requirements for accuracy, and routine audit processes to validate the information provided and subsequent payments made. As the data forms a critical part of service remuneration, both community pharmacies and commissioners are incentivised to accuracy.

The analysis is based on the complex commissioning landscape of Local Authorities in England, and application outside this setting should be done with care. The modelling exercise has used data from Scotland and Wales to make some predictions, but the commissioning structure of England is different. The path analysis is presented as a tool for use in numerous commissioning environments, and testing this using alternate settings would help validate the process and analysis undertaken.

Finally, the research was undertaken and contextualised using experience gained as a practitioner. In line with professional doctorates, the research subject is embedded in the work and expertise of the student. This does of course guide the research, both in the methodology and the conclusions. Approaching the subject through a different lens may elicit different emphasis to the conclusions.

8.6.2 Implications for EHC commissioning

The findings of this study suggest the relationship between community pharmacy and GP EHC activity is a negative correlation. Greater EHC provision rates in community pharmacy decreases the GP EHC prescribing rate. Furthermore, there are several quantifiable factors that influence this, most notably deprivation and the proportion of commissioned pharmacies.

The influence of the proportion of commissioned pharmacies presents an opportunity for policy change, for instance by commissioners. By encouraging (or mandating) greater numbers of pharmacies to offer EHC services the rates of GP EHC prescribing can be further influenced. Using the quantified relationship, the effect of increasing the proportion of commissioned pharmacies was estimated (page 223). The literature indicates that the proportion of commissioned pharmacies across England is 47%, and this matches the 48% found in the collected data (Mackridge, Gray and Krska, 2017).

The modelling described on page 139 (results on page 223) estimates that a change from the literature mean proportion of commissioned pharmacies (47%) to 100% (the theoretical maximum) would reduce the rate of GP EHC prescribing by 15%. Applied across the country, this suggests a decrease of 20,706 GP consultations a year. This number is a small fraction of the 307 million GP appointments each year (NHS Digital, 2022). However, given ever present pressures on GP appointments and the backlog of care created by the pandemic this is likely to be of interest to commissioners and policy makers (Carr *et al.*, 2021).

Local commissioners wishing to predict the effect of (for instance) commissioning a community pharmacy EHC service where one currently does not exist could repeat the calculation and estimate the likely change to GP prescribing rates. Similarly, if commissioners wished to embark on a local initiative to increase the proportion of commissioned pharmacies, they could use this quantified relationship to predict the likely change. This can then inform commissioning decisions, the local priorities, and feed into pharmacoeconomic analysis.

8.6.3 An argument for national commissioning

The literature review (chapter 4) set out many of the barriers and considerations to commissioning. These include aspects such as a perceived priority of national services over local ones, variation in service expectations, a lack of evidence, and concerns/challenges with training of staff (Aly *et al.*, 2018; Miller, Cumming and Lewis, 2018; Nazar and Nazar, 2019).

A possible conclusion to draw when considering the barriers highlighted in the literature is that a national commissioned service, or some other nationally structured system would tackle these. An example of a national framework, with local commissioning, is the recent Covid-19 vaccination programme. Within the community pharmacy aspect of the programme, the vaccination service was commissioned as an enhanced service. This means the service specification (detailing the payment, contractual terms and conditions, expectations, and training requirements) was agreed nationally (NHS England and NHS Improvement, 2021). The local NHS regional teams were then able to commission a standardised service in locations and volumes dictated by their local needs.

If commissioners were trying to increase the provision through community pharmacy, then increasing the proportion of commissioned pharmacies is desirable, regardless of the exact method of commissioning. Both Wales and Scotland commission EHC services, through slightly different mechanisms. Within both Wales and Scotland there is no separation between public health (local authorities) and healthcare (NHS). NHS boards are responsible for all community pharmacy commissioning. Wales commission this as an 'enhanced service', like the local commissioning within England. In Wales every health board commission this so the variation is reduced as there are no areas without a commissioned service. This is likely to change further in the future with the new contractual framework agreed in Wales, further standardising requirements. Scotland commission EHC as a 'core service', meaning all community pharmacies provide the service.

This study has described the relationship between GP EHC prescribing and community pharmacy EHC provision, showing that in England increasing community pharmacy activity decreases GP prescribing. Furthermore, increasing the proportion of commissioned pharmacies further increases this effect. Theoretically, when taken to a logical conclusion (i.e., all community pharmacies commissioned) the commissioning outcome will be maximised. As both Wales and Scotland have national services, this theory can be tested using publicly available data. The key data points are compared to the dataset collected for England in *Table 31*.

The local variation analysis completed on the collected English data was not done with the Welsh and Scottish data and the modelling on page 226 compares nationally aggregated data only. Despite this, the rates of community pharmacy EHC provision in Wales and Scotland are at least double the English value. The conclusion drawn from the linear regression undertaken previously is that increasing the proportion of commissioned pharmacies increases the community pharmacy EHC provision rate. The data from Wales and Scotland support this with the greater proportions of commissioned pharmacies collectively providing greater rates of EHC provision. This should be taken with an element of caution given the different environments (e.g., different health systems, NHS commissioning of EHC etc.) but it is indicative of the real-world result.

If this were to hold true with national commissioning in England (or other methods to increase the proportion of commissioned pharmacies) the estimations in the modelling could be greatly underestimating the impact. The data presented earlier (page 223) suggested increasing the proportion of commissioned pharmacies in England to 100% would result in an increase in the rate of 140.98 / 10,000 female population (from 205.38 to 346.36). This would be an increase of 67%. Comparisons with Scotland and Wales suggest this may be even higher. *Figure 44* depicts a scatter plot of the proportion of commissioned pharmacies and the rate of community pharmacy EHC provision.

It is also of note that the rate of abortions in Scotland and Wales are much lower than England. Research by Mackridge *et al.* (2017) did not find correlation between community pharmacy EHC provision and under-18 abortion rates (Mackridge, Gray and Krska, 2017). Proving causation through regression analysis is extremely difficult, but the lower abortion rates (in Scotland and Wales) with greater rates of community pharmacy EHC provision is a contradictory finding to the literature.

The analysis by Mackridge, Gray and Krska (2017) would suggest that abortion rates in Scotland and Wales should be unaffected by the community pharmacy EHC provision (which may be the case, and this could be a coincidence). The data in *Table 31* indicates the total number of abortions, not the under-18 figure as cited by Mackridge *et al.* (2017). It may be the case that community pharmacy plays a greater role in preventing abortions in adult women.

This would be a useful point of investigation for future research. The literature has indicated the diverse reasons for accessing community pharmacy EHC services, as well as the cost barrier of purchasing EHC (Killick and Irving, 2004). It is possible that patients' behaviours have changed in Scotland and Wales following national commissioning – resulting in a stronger relationship between abortion rates and community pharmacy EHC provision. Alternatively, the relationship between community pharmacy EHC provision and abortion rates is present across the UK, but only in adult women, and not in under-18s.

8.6.4 The commissioning of other community pharmacy services

This study has used EHC services as a prime example of the variation in local commissioning and described and quantified some of the factors influencing this. However, EHC services are not unique in their design. Indeed, influenza vaccination historically mirrors many of the EHC commissioning properties. It was a local commissioned service, with a limited number of patient interventions (either vaccination or referral) and was a service available elsewhere (General Practice).

The data presented on page 228 describes a local service that was eventually commissioned nationally. The case for a nationally commissioned EHC service has been set out above, and influenza vaccination may present an historic example of the effects of a change from local to national commissioning in community pharmacy.

There are differences between the services but the principle of increased proportion of commissioned pharmacies increasing the rate of provision seems to apply again. In 2020/21 when the proportion of community pharmacies providing influenza vaccines was 87% the number of vaccines was at its highest. This adds further weight to the suggestion that national commissioning of EHC would increase the rate of provision. This increase is plotted in *Figure 45*. There will inevitably be a host of factors influencing this trend (not least of which being the COVID-19 pandemic). However, the overall picture supports the findings here, that increasing the proportion of pharmacies providing a service increases the provision rate.

Whether considering the data presented here, the calculations from UK comparisons, or the evidence of recent local to national commissioning changes there is a clear trend. Increasing the proportion of community pharmacies providing a service makes a marked difference on the rate of provision.

This has implications for policy makers keen to maximise the benefit of their services as well as tackle the backlog of the pandemic. There is a known inverse relationship between healthcare access and deprivation (Hart, 1971). This has been compounded by COVID-19, which has widened health inequalities, with implications for General Practice capacity to meet demand in deprived areas (Carr *et al.*, 2021).

Studies have demonstrated lower rates of diagnosis and treatment commencement in General Practice - particularly in areas of high deprivation, because of the pandemic (Williams *et al.*, 2020; Carr *et al.*, 2021). This is likely to translate into increased demand for GP care for years to come. This study found a negative correlation between community pharmacy EHC provision and GP EHC prescribing. Combining the path analysis conclusions and the bivariate correlations, the relationship between GP and community pharmacy activity appears clear. Understanding similar relationships for other services, may help identify and quantify the influences of service commissioning and provision.

The path analysis has been shown as a useful method of assessing commissioned service outcomes. It also provides a method to evaluate the potential significance of changes, identifying modifiable variables that will make the greatest impact. It would be valuable for policy makers to reflect on methods of increasing the proportion of commissioned community pharmacies in England to directly support GP capacity, whilst ensuring patient access to EHC. Reflecting on the data from Wales and Scotland, a nationally commissioned service may achieve that objective.

8.6.5 Applying these learnings across commissioning decisions

The literature review highlighted reports from commissioners and pharmacists, that commissioning decisions are not always decided by data or evidence (page 61). For instance, local relationships or policy can determine what is commissioned and where. It was reported that there was a lack of audit or other data review, to determine the success of commissioning. This was supported by the study which compared community pharmacy services to local health outcomes (e.g., EHC and under 18 pregnancy rates) (Mackridge, Gray and Krska, 2017). It is entirely reasonable to expect correlation between EHC services and under-18 pregnancy rates, given that EHC services (including those in community pharmacy) are presented as an avenue to support this health need (United Nations Population Fund, 2020; Depatment of Health, 2013).

The lack of readily available data points to base commissioning decisions on, may explain the reported opinions and actions in the literature. The study here has attempted to identify routine data-points, that can bridge that gap. By identifying the data, and demonstrating how it can be applied, it is hoped that commissioners can use the findings here.

The modelling has provided a few examples of how the analysis presented in this thesis could be used practically by commissioners. The correlations describing key relationships as well as the path analysis provide powerful tools to use data to inform decisions.

Commissioners can determine a primary outcome metric (for example appointments in a setting) and predict how commissioning decisions may change this. Through identification of all the variables influencing the outcome variable the effect of their actions can be predicted.

A key addition that this study also adds is the introduction of the path analysis. This allows commissioners not only to model multiple independent variables and their influences on the dependent variable, but also identify the indirect effects. It was seen in

EHC services that the proportion of commissioned pharmacies does not influence GP EHC prescribing rates directly. Without path analysis this relationship would have been lost.

Using path analysis to identify all the direct and indirect effects on the dependent variable, will allow commissioners to identify all routes to influence their goal. Once all the variables are identified and quantified, commissioners can predict the likely effect from decisions made. For instance, what is the likely effect of commissioning a service in one setting or directing resources to increase patient provision in a setting. Through this methodology commissioners can be more confident in the likely result of their decisions, and ultimately ensure best use of the public purse.

8.6.6 The impact of COVID-19

The data collection and analysis of this thesis was undertaken during the COVID-19 pandemic. All the data collected was from prior to the pandemic which means the pandemic itself has not impacted the analysis (e.g., there are no specific pandemic related variables). It was noted in the results (page 247) that the response rate of the FOI requests was slightly lower than the feasibility study (page 142). Whilst there were likely many reasons for this, several commissioners specifically cited the pandemic as impacting their ability to provide data. Without the pandemic, the response rate, and thus the generalisability of the data, would have been higher.

Many aspects of healthcare practice changed during the pandemic, and at the time of writing it is uncertain how many of these will lead to long lasting change. Many aspects of healthcare promoted a “digital first" approach to healthcare, defaulting to telephone or video consultations before face-to-face consultations. Several Local Authorities changed the EHC service specification to allow telephone consultations, followed by either collection or delivery of LNG/UPA.

One of the prime relationships described in this thesis is that between community pharmacy EHC provision and GP EHC prescribing. A change in patient expectations and default means of accessing healthcare (i.e., patients choosing to ring doctors or pharmacists first) may have fundamentally altered this relationship. It is possible this decreases the importance of physical access, making the correlation weaker.

Alternatively, many patients report challenges accessing GP services. This is further amplified by the “COVID backlog". The COVID backlog is the estimated large number of patients who did not access healthcare during the pandemic (as instructed by government guidance), who now need to access healthcare (Carr *et al.*, 2021; Williams *et al.*, 2020). This may act to disincentivise patients to attend general practice, and therefore skew the EHC relationship towards community pharmacy.

Unfortunately, this effect cannot be understood with the data available in this thesis. However, the great advantage of the methodology presented here is that replicating the analysis is relatively simple. FOIs to Local Authorities to update the variables with new data, would quickly allow any changed relationships to be quantified. There may be advantages to repeating this analysis regularly as public opinions and behaviours change as a result of government policies.

Chapter 9: Conclusions

9.1 Main findings

The aim of this thesis was to determine what influences EHC service commissioning and provision, through the use of quantifiable, routinely collected data. The literature did not reveal examples of a standard approach to commissioning decisions, and the only available literature and data raised questions of how these services should be appraised. EHC services have been highlighted as a prime example of this challenge, with evidence showing these services do not correlate to local health outcomes.

This thesis has identified routinely collected data and through analysis has described many of these influences. Using correlation and path-analysis the influences on both GP and community pharmacy EHC provision were described. Using the path-analysis and subsequent modelling, predictions were made on how changes could influence EHC provision. In this way the influences on commissioning are better understood.

The available data also allowed for analysis of the impact of community pharmacy EHC services. The literature described qualitative data reporting views on the role of pharmacy organisation type on commissioning decisions. The analysis presented here has added a quantitative view to this facet of commissioning.

Combining the results of all the analysis, several conclusions can be drawn:

1. Increased rates of EHC provision from community pharmacy services appear to correlate to a reduced EHC prescribing rate from General Practice.
2. EHC provision from community pharmacy seems to have little impact on provision from other sexual health services, such as family planning.
3. The proportion of community pharmacies providing EHC services appears to be a strong influence on the rate of community pharmacy EHC provision.
4. National services and their provision levels do not seem to be good predictors of EHC activity provided by an individual pharmacy.
5. Unlike suggested trends seen with national services, pharmacy organisation type does not seem to be a good predictor of EHC provision.
6. Deprivation appears to be one of the most important factors in determining likely community pharmacy EHC provision.

Previous literature has documented perceived influences on community pharmacy commissioning success, and frustrations expressed by commissioners trying to achieve service goals. Contrary to possible expectations, and current understanding in the literature, individual pharmacy EHC service provision is dependent on localised populations rather than the pharmacy's characteristics. If it is assumed this applies to other local services, commissioners should consider the localised population of a pharmacy (or the known customer base) and commission according to that – rather than previous provision through other services.

Additionally, a key determinant of EHC provision rates is the proportion of commissioned pharmacies. Changing patient behaviours seems to require increasing the number of locations to access a service. This may well be due to a combination of opportunity and awareness. It is likely, although not proven, that a national commissioned service would further increase the provision through community pharmacy. This would bring benefits to both patients, and General Practice – currently struggling with capacity.

Finally, the use of path analysis to assess the influences and benefits of EHC services demonstrated a new approach to service evaluation. Given the complexity of patient behaviours, understanding routes of access and their impact on local health outcomes is difficult. Services commissioned to duplicate care provided elsewhere are difficult to assess in isolation.

The correlations between GP and community pharmacy provision rates suggest commissioning EHC services successfully move activity from one location to another. If this is a primary objective of the service, then this cannot be assessed by comparing community pharmacy activity with local health outcomes. The ‘health-system’ adapts to patient needs, meaning there is little difference to overall outcomes. By considering the relationships (both direct and indirect) between multiple variables, then a better picture of service value can be established.

9.2 Implications of the study for practice and future research

By using the analysis presented here, commissioners can critically evaluate decisions. Once interventions are proven to be effective (through analysis of patient outcomes or similar) quantitative data can be used to objectively guide future decisions. Regardless of the service or provider, where data are available commissioners can adapt the techniques presented here to predict the benefit and impact of commissioning decisions. This will ultimately lead to a better use of the public purse, and limited health budgets.

Future research would be beneficial to determine if the findings reported here are true across different local services. Minor ailments services for example are commonplace, with variation in both provision and service offering. Some attempt was made to consider comparisons with Welsh and Scottish services. A more formal analysis of comparable data would be helpful. Similarly, although there are differences in form and function, understanding the influences on health board led services – compared to national ones would likely prove fruitful.

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Appendix 1 – Consolidated Framework for Implementation Research Constructs

Consolidated Framework for Implementation Research Constructs		
CFIR Website		
Construct		**Short Description**
I. INTERVENTION CHARACTERISTICS		
A	Intervention Source	Perception of key stakeholders about whether the intervention is externally or internally developed.
B	Evidence Strength & Quality	Stakeholders' perceptions of the quality and validity of evidence supporting the belief that the intervention will have desired outcomes.
C	Relative Advantage	Stakeholders' perception of the advantage of implementing the intervention versus an alternative solution.
D	Adaptability	The degree to which an intervention can be adapted, tailored, refined, or reinvented to meet local needs.
E	Trialability	The ability to test the intervention on a small scale in the organization, and to be able to reverse course (undo implementation) if warranted.
F	Complexity	Perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement.
G	Design Quality & Packaging	Perceived excellence in how the intervention is bundled, presented, and assembled.
H	Cost	Costs of the intervention and costs associated with implementing the intervention including investment, supply, and opportunity costs.
II. OUTER SETTING		
A	Patient Needs & Resources	The extent to which patient needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritized by the organization.
B	Cosmopolitanism	The degree to which an organization is networked with other external organizations.
C	Peer Pressure	Mimetic or competitive pressure to implement an intervention; typically because most or other key peer or competing organizations have already implemented or are in a bid for a competitive edge.
D	External Policy & Incentives	A broad construct that includes external strategies to spread interventions, including policy and regulations (governmental or other central entity), external mandates, recommendations and guidelines, pay-for-performance, collaboratives, and public or benchmark reporting.
III. INNER SETTING		
A	Structural Characteristics	The social architecture, age, maturity, and size of an organization.
B	Networks & Communications	The nature and quality of webs of social networks and the nature and quality of formal and informal communications within an organization.
C	Culture	Norms, values, and basic assumptions of a given organization.

D	Implementation Climate	The absorptive capacity for change, shared receptivity of involved individuals to an intervention, and the extent to which use of that intervention will be rewarded, supported, and expected within their organization.
1	Tension for Change	The degree to which stakeholders perceive the current situation as intolerable or needing change.
2	Compatibility	The degree of tangible fit between meaning and values attached to the intervention by involved individuals, how those align with individuals' own norms, values, and perceived risks and needs, and how the intervention fits with existing workflows and systems.
3	Relative Priority	Individuals' shared perception of the importance of the implementation within the organization.
4	Organizational Incentives & Rewards	Extrinsic incentives such as goal-sharing awards, performance reviews, promotions, and raises in salary, and less tangible incentives such as increased stature or respect.
5	Goals and Feedback	The degree to which goals are clearly communicated, acted upon, and fed back to staff, and alignment of that feedback with goals.
6	Learning Climate	A climate in which: a) leaders express their own fallibility and need for team members' assistance and input; b) team members feel that they are essential, valued, and knowledgeable partners in the change process; c) individuals feel psychologically safe to try new methods; and d) there is sufficient time and space for reflective thinking and evaluation.
E	Readiness for Implementation	Tangible and immediate indicators of organizational commitment to its decision to implement an intervention.
1	Leadership Engagement	Commitment, involvement, and accountability of leaders and managers with the implementation.
2	Available Resources	The level of resources dedicated for implementation and on-going operations, including money, training, education, physical space, and time.
3	Access to Knowledge & Information	Ease of access to digestible information and knowledge about the intervention and how to incorporate it into work tasks.
IV. CHARACTERISTICS OF INDIVIDUALS		
A	Knowledge & Beliefs about the Intervention	Individuals' attitudes toward and value placed on the intervention as well as familiarity with facts, truths, and principles related to the intervention.
B	Self-efficacy	Individual belief in their own capabilities to execute courses of action to achieve implementation goals.
C	Individual Stage of Change	Characterization of the phase an individual is in, as he or she progresses toward skilled, enthusiastic, and sustained use of the intervention.
D	Individual Identification with Organization	A broad construct related to how individuals perceive the organization, and their relationship and degree of commitment with that organization.
E	Other Personal Attributes	A broad construct to include other personal traits such as tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, and learning style.

V. PROCESS		
A	Planning	The degree to which a scheme or method of behaviour and tasks for implementing an intervention are developed in advance, and the quality of those schemes or methods.
B	Engaging	Attracting and involving appropriate individuals in the implementation and use of the intervention through a combined strategy of social marketing, education, role modelling, training, and other similar activities.
1	Opinion Leaders	Individuals in an organization who have formal or informal influence on the attitudes and beliefs of their colleagues with respect to implementing the intervention.
2	Formally Appointed Internal Implementation Leaders	Individuals from within the organization who have been formally appointed with responsibility for implementing an intervention as coordinator, project manager, team leader, or other similar role.
3	Champions	"Individuals who dedicate themselves to supporting, marketing, and 'driving through' an implementation", overcoming indifference or resistance that the intervention may provoke in an organization.
4	External Change Agents	Individuals who are affiliated with an outside entity who formally influence or facilitate intervention decisions in a desirable direction.
C	Executing	Carrying out or accomplishing the implementation according to plan.
D	Reflecting & Evaluating	Quantitative and qualitative feedback about the progress and quality of implementation accompanied with regular personal and team debriefing about progress and experience.

Appendix 2 – FOI Request Letter

Dear Information Manager,

Please can I request information under the Freedom Of Information scheme.

Please can you confirm if you commission any Emergency Hormonal Contraception services from community pharmacy providers (either directly or through prime providers/secondary commissioning models). If so, please provide details of each community pharmacy commissioned to provide the Emergency Hormonal Contraception service, including (for each pharmacy individually) the number of treatment incidents/consultations and the numbers of levonorgesterel and/or ulipristal acetate supplied.

Please provide all relevant data for the financial year April 1 2017 – March 31 2018.

Please provide this information electronically, preferably in a Microsoft Excel file format.

This information is likely held by the Public Health Commissioning Lead.

Thanks
Nick Thayer
12 Middlewich Road
Nantwich
CW5 6HL

Appendix 3 – Rates of EC provision in Local Authorities

Ref code	Female pop. (12-55)	LNG (Ph) / 10,000	UPA (Ph) / 10,000	Consultations (Ph) / 10,000	LNG (GP) / 10,000	UPA (GP) / 10,000	Consultations (GP) / 10,000
1	143,504	334	0	334	44	26	71
2	29,354	746	0	746	67	33	99
3	81,447	709	400	1110	23	23	46
4	57,000	103	30	133	45	16	61
5	41,274	219	0	219	38	14	51
6	77,797	214	0	214	38	20	58
7	42,754	512	0	512	43	10	53
8	37,757	0	0	0	89	38	128
9	79,996	345	0	345	59	15	74
10	53,569	111	0	111	52	18	70
11	100,190	875	34	909	31	13	44
12	92,507	393	13	406	34	14	48
13	35,848	170	7	177	34	15	49
14	43,433	101	7	108	146	19	165
15	151,100	105	0	105	84	34	119
16	180,085	528	0	528	104	102	206
17	66,473	162	0	162	73	22	95
18	62,299	144	0	144	66	21	87
19	74,636	245	8	253	41	15	56
20	71,444	204	153	356	33	16	49
21	48,982	317	0	317	39	6	46
22	80,023	38	11	49	84	20	105
23	67,259	552	0	552	28	9	38
24	58,878	264	16	280	20	11	30
25	86,590	262	23	285	54	17	70
26	83,890	69	68	138	44	20	64
27	43,339	392	0	392	88	18	106
28	83,895	38	0	38	70	31	101
29	72,264	122	0	122	59	14	73
30	58,287	32	31	62	58	55	113
31	123,364	59	19	78	45	38	83
32	238,528	85	92	177	57	51	108
33	109,610	263	0	263	94	13	107
34	105,694	562	0	562	23	39	62
35	48,164	670	0	670	68	52	120
36	80,191	174	17	191	79	31	111
37	70,746	104	34	138	46	7	53

38	49,576	175	12	186	98	40	138
39	87,980	239	0	239	56	14	70
40	79,130	0	0	0	102	19	122
41	73,894	0	183	183	39	15	54
42	63,064	436	9	445	62	13	75
43	50,706	40	0	40	26	12	39
44	83,000	257	0	257	68	21	90
45	87,472	528	0	528	53	16	68
46	82,944	167	0	167	96	45	141
47	113,233	854	0	854	101	28	129
48	100,581	1262	0	1262	89	27	117
49	108,114	127	0	127	88	18	106
50	104,908	626	0	626	63	21	84
51	65,591	308	0	308	26	20	46
52	116,853	0	0	0	61	19	80
53	117,994	128	0	128	143	22	164
54	102,296	266	0	266	81	20	101
55	88,911	134	0	134	72	18	89
56	74,008	58	0	58	37	20	57
57	80,723	275	0	275	28	8	36
58	54,365	275	0	275	66	18	84
59	64,650	53	0	53	56	14	69
60	90,726	258	0	258	42	18	60
61	61,031	368	38	406	26	15	41
62	85,902	445	0	445	53	12	65
63	93,740	389	17	406	114	30	144
64	33,931	192	197	390	39	15	55
65	78,584	30	0	30	81	18	100
66	64,510	728	0	728	46	16	62
67	77,398	510	0	510	17	21	39
68	54,699	278	0	278	77	26	103
69	143,554	171	0	172	89	40	129
70	63,389	35	0	35	67	22	88
71	130,976	15	13	28	95	25	121
72	222,112	65	4	69	47	14	62
73	207,826	13	0	13	85	22	107
74	197,201	5	0	5	77	20	97
75	141,067	153	0	153	83	26	109
76	232,326	113	30	144	69	20	89
77	155,886	207	0	207	65	28	93
78	248,186	52	37	89	47	17	65

79	402,519	19	2	22	55	20	75
80	224,504	14	0	14	58	29	88
81	192,971	103	0	103	88	18	106
82	588,835	45	61	105	58	21	79
83	148,976	5	0	5	73	12	85
84	138,775	16	17	33	97	26	123
85	342,094	69	15	84	65	16	81
86	116,071	363	0	363	81	31	112

Appendix 4 – Bi-variate correlation (local authorities)

		All consultations (Ph) / 10,000 - no outliers	All consultations (GP) / 10,000 - no outliers	% of pharmacies commissioned	Local Authority Rurality	Sexual and Reproductive Health Activity Data	Index of Multiple Deprivation (IMD)	Income Deprivation Domain	Employment Deprivation Domain	Education, Skills and Training Domain	Health Deprivation and Disability Domain	Crime Domain	Barriers to Housing and Services Domain	Living Environment Deprivation Domain	Income Deprivation Affecting Children Index (IDACI)	Income Deprivation Affecting Older People Index (IDAOPI)
All consultations (Ph) / 10,000 - no outliers	Pearson Correlation	1	-.458**	.461**	-.230*	.020	.287*	.252*	.170	.074	.275*	.266*	.137	.331**	.293**	.321**
	Sig. (2-tailed)		.000	.000	.041	.864	.010	.025	.133	.518	.014	.018	.228	.003	.009	.004
	N	79	73	77	79	78	79	79	79	79	79	79	79	79	79	79
All consultations (GP) / 10,000 - no outliers	Pearson Correlation	-.458**	1	-.195	.184	.037	.026	.017	-.075	-.017	-.094	.077	.093	.241*	.034	.101
	Sig. (2-tailed)	.000		.089	.103	.745	.820	.880	.510	.882	.404	.497	.414	.031	.764	.375
	N	73	80	77	80	79	80	80	80	80	80	80	80	80	80	80
% of pharmacies commissioned	Pearson Correlation	.461**	-.195	1	.269*	-.205	.103	.073	.130	.137	.211	-.187	.012	.044	.093	.063
	Sig. (2-tailed)	.000	.089		.014	.064	.352	.514	.243	.217	.056	.090	.913	.695	.404	.571
	N	77	77	83	83	82	83	83	83	83	83	83	83	83	83	83
Local Authority Rurality	Pearson Correlation	-.230*	.184	.269*	1	-.376**	-.399**	-.459**	-.290**	.015	-.302**	-.590**	-.029	-.304**	-.467**	-.502**
	Sig. (2-tailed)	.041	.103	.014		.000	.000	.000	.007	.888	.005	.000	.794	.004	.000	.000
	N	79	80	83	86	85	86	86	86	86	86	86	86	86	86	86
Sexual and Reproductive Health Activity Data	Pearson Correlation	.020	.037	-.205	-.376**	1	.521**	.507**	.494**	.179	.502**	.331**	-.149	.339**	.464**	.439**
	Sig. (2-tailed)	.864	.745	.064	.000		.000	.000	.000	.101	.000	.002	.174	.002	.000	.000
	N	78	79	82	85	85	85	85	85	85	85	85	85	85	85	85
Index of Multiple Deprivation (IMD)	Pearson Correlation	.287*	.026	.103	-.399**	.521**	1	.975**	.886**	.712**	.880**	.656**	.045	.448**	.938**	.813**
	Sig. (2-tailed)	.010	.820	.352	.000	.000		.000	.000	.000	.000	.000	.679	.000	.000	.000

	N	79	80	83	86	85	86	86	86	86	86	86	86	86	86	86
Income Deprivation Domain	Pearson Correlation	.252*	.017	.073	-.459**	.507**	.975**	1	.891**	.669**	.844**	.642**	.055	.368**	.955**	.834**
	Sig. (2-tailed)	.025	.880	.514	.000	.000	.000		.000	.000	.000	.000	.617	.000	.000	.000
	N	79	80	83	86	85	86	86	86	86	86	86	86	86	86	86
Employment Deprivation Domain	Pearson Correlation	.170	-.075	.130	-.290**	.494**	.886**	.891**	1	.772**	.924**	.342**	-.302**	.112	.766**	.558**
	Sig. (2-tailed)	.133	.510	.243	.007	.000	.000	.000		.000	.000	.001	.005	.303	.000	.000
	N	79	80	83	86	85	86	86	86	86	86	86	86	86	86	86
Education, Skills and Training Domain	Pearson Correlation	.074	-.017	.137	.015	.179	.712**	.669**	.772**	1	.733**	.221*	-.322**	.002	.566**	.313**
	Sig. (2-tailed)	.518	.882	.217	.888	.101	.000	.000	.000		.000	.041	.003	.989	.000	.003
	N	79	80	83	86	85	86	86	86	86	86	86	86	86	86	86
Health Deprivation and Disability Domain	Pearson Correlation	.275*	-.094	.211	-.302**	.502**	.880**	.844**	.924**	.733**	1	.353**	-.284**	.188	.751**	.596**
	Sig. (2-tailed)	.014	.404	.056	.005	.000	.000	.000	.000	.000		.001	.008	.083	.000	.000
	N	79	80	83	86	85	86	86	86	86	86	86	86	86	86	86
Crime Domain	Pearson Correlation	.266*	.077	-.187	-.590**	.331**	.656**	.642**	.342**	.221*	.353**	1	.388**	.608**	.741**	.714**
	Sig. (2-tailed)	.018	.497	.090	.000	.002	.000	.000	.001	.041	.001		.000	.000	.000	.000
	N	79	80	83	86	85	86	86	86	86	86	86	86	86	86	86
Barriers to Housing and Services Domain	Pearson Correlation	.137	.093	.012	-.029	-.149	.045	.055	-.302**	-.322**	-.284**	.388**	1	.335**	.205	.369**
	Sig. (2-tailed)	.228	.414	.913	.794	.174	.679	.617	.005	.003	.008	.000		.002	.058	.000
	N	79	80	83	86	85	86	86	86	86	86	86	86	86	86	86
Living Environment Deprivation Domain	Pearson Correlation	.331**	.241*	.044	-.304**	.339**	.448**	.368**	.112	.002	.188	.608**	.335**	1	.465**	.558**
	Sig. (2-tailed)	.003	.031	.695	.004	.002	.000	.000	.303	.989	.083	.000	.002		.000	.000
	N	79	80	83	86	85	86	86	86	86	86	86	86	86	86	86
Income Deprivation Affecting Children Index (IDACI)	Pearson Correlation	.293**	.034	.093	-.467**	.464**	.938**	.955**	.766**	.566**	.751**	.741**	.205	.465**	1	.872**
	Sig. (2-tailed)	.009	.764	.404	.000	.000	.000	.000	.000	.000	.000	.000	.058	.000		.000
	N	79	80	83	86	85	86	86	86	86	86	86	86	86	86	86

Income Deprivation Affecting Older People Index (IDAOPI)	Pearson Correlation	.321**	.101	.063	-.502**	.439**	.813**	.834**	.558**	.313**	.596**	.714**	.369**	.558**	.872**	1
	Sig. (2-tailed)	.004	.375	.571	.000	.000	.000	.000	.000	.003	.000	.000	.000	.000	.000	
	N	79	80	83	86	85	86	86	86	86	86	86	86	86	86	86

**. Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

Appendix 5 – Bi-variate correlations (individual pharmacy)

Correlations

		TOTAL EHC	Average monthly Rx	Total MUR	Total NMS	Flu annual	Index of Multiple Deprivation	Income Rank	Employment Rank	Education and Skills Rank	Health and Disability Rank	Crime Rank	Barriers to Housing and Services	Living Environment Rank	IDACI Rank	IDAOPI Rank
TOTAL EHC	Pearson Correlation	1	.063**	.015	-.031	.129**	-.074**	.004	.046*	.033	-.062**	-.146**	-.159**	-.159**	-.061**	-.149**
	Sig. (2-tailed)		.000	.418	.081	.000	.000	.832	.011	.069	.001	.000	.000	.000	.001	.000
	N	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069
Average monthly Rx	Pearson Correlation	.063**	1	.219**	.406**	.215**	-.090**	-.119**	-.145**	-.118**	-.128**	-.060**	.149**	.131**	-.091**	-.057**
	Sig. (2-tailed)	.000		.000	.000	.000	.000	.000	.000	.000	.000	.001	.000	.000	.000	.002
	N	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069
Total MUR	Pearson Correlation	.015	.219**	1	.404**	.291**	-.027	-.036*	-.046*	-.035	-.041*	-.039*	.057**	.009	-.013	-.014
	Sig. (2-tailed)	.418	.000		.000	.000	.137	.049	.012	.051	.023	.031	.002	.614	.484	.431
	N	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069
Total NMS	Pearson Correlation	-.031	.406**	.404**	1	.259**	.008	-.018	-.025	-.035	-.004	.027	.099**	.063**	.003	.014
	Sig. (2-tailed)	.081	.000	.000		.000	.665	.330	.162	.055	.805	.128	.000	.000	.880	.448
	N	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069
Flu annual	Pearson Correlation	.129**	.215**	.291**	.259**	1	.040*	.046*	.051**	.045*	.050**	.008	-.051**	.000	.042*	.042*
	Sig. (2-tailed)	.000	.000	.000	.000		.028	.011	.004	.013	.005	.647	.005	.990	.021	.021
	N	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069
Index of Multiple Deprivation Rank	Pearson Correlation	-.074**	-.090**	-.027	.008	.040*	1	.946**	.913**	.807**	.878**	.709**	.218**	.277**	.892**	.859**
	Sig. (2-tailed)	.000	.000	.137	.665	.028		.000	.000	.000	.000	.000	.000	.000	.000	.000
	N	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069
Income Rank	Pearson Correlation	.004	-.119**	-.036*	-.018	.046*	.946**	1	.947**	.791**	.821**	.591**	.131**	.148**	.919**	.851**
	Sig. (2-tailed)	.832	.000	.049	.330	.011	.000		.000	.000	.000	.000	.000	.000	.000	.000
	N	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069
Employment Rank	Pearson Correlation	.046*	-.145**	-.046*	-.025	.051**	.913**	.947**	1	.789**	.848**	.537**	.002	.057**	.829**	.724**
	Sig. (2-tailed)	.011	.000	.012	.162	.004	.000	.000		.000	.000	.000	.932	.002	.000	.000
	N	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069
Education and Skills Rank	Pearson Correlation	.033	-.118**	-.035	-.035	.045*	.807**	.791**	.789**	1	.720**	.443**	.013	.015	.774**	.615**
	Sig. (2-tailed)	.069	.000	.051	.055	.013	.000	.000	.000		.000	.000	.480	.415	.000	.000
	N	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069

Health and Disability Rank	Pearson Correlation	-.062**	-.128**	-.041*	-.004	.050**	.878**	.821**	.848**	.720**	1	.588**	.002	.095**	.762**	.750**
	Sig. (2-tailed)	.001	.000	.023	.805	.005	.000	.000	.000	.000		.000	.907	.000	.000	.000
	N	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069
Crime Rank	Pearson Correlation	-.146**	-.060**	-.039*	.027	.008	.709**	.591**	.537**	.443**	.588**	1	.184**	.276**	.581**	.621**
	Sig. (2-tailed)	.000	.001	.031	.128	.647	.000	.000	.000	.000	.000		.000	.000	.000	.000
	N	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069
Barriers to Housing and Services Rank	Pearson Correlation	-.159**	.149**	.057**	.099**	-.051**	.218**	.131**	.002	.013	.002	.184**	1	.289**	.183**	.289**
	Sig. (2-tailed)	.000	.000	.002	.000	.005	.000	.000	.932	.480	.907	.000		.000	.000	.000
	N	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069
Living Environment Rank	Pearson Correlation	-.159**	.131**	.009	.063**	.000	.277**	.148**	.057**	.015	.095**	.276**	.289**	1	.159**	.315**
	Sig. (2-tailed)	.000	.000	.614	.000	.990	.000	.000	.002	.415	.000	.000	.000		.000	.000
	N	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069
IDACI Rank	Pearson Correlation	-.061**	-.091**	-.013	.003	.042*	.892**	.919**	.829**	.774**	.762**	.581**	.183**	.159**	1	.784**
	Sig. (2-tailed)	.001	.000	.484	.880	.021	.000	.000	.000	.000	.000	.000	.000	.000		.000
	N	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069
IDAOPI Rank	Pearson Correlation	-.149**	-.057**	-.014	.014	.042*	.859**	.851**	.724**	.615**	.750**	.621**	.289**	.315**	.784**	1
	Sig. (2-tailed)	.000	.002	.431	.448	.021	.000	.000	.000	.000	.000	.000	.000	.000	.000	
	N	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069	3069

**. Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

Appendix 6 – Ethics Approval

Keele University FMHS Faculty Research Ethics Committee
health.ethics@keele.ac.uk

02 March 2020

Dear Nicholas,

Project Title:	The provision and commissioning of Community Pharmacy local services in England – a mixed method study
REC Project Reference:	MH-200114
Type of Application	Programme of Work

Keele University's Faculty of Medicine and Health Sciences Research Ethics Committee (FMHS FREC) reviewed the above programme of work.

Favourable Ethical opinion
The members of the Committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion
The favourable opinion is subject to the following conditions being met prior to the start of the programme.

1.	If any data is to be accessed from outside of England, an amendment to the ethics form must be submitted prior to access.

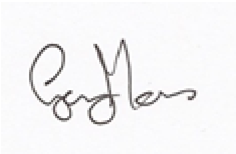
Reporting requirements
The University's standard operating procedures give detailed guidance on reporting requirements for studies with a favourable opinion including:

- Notifying substantial amendments
- Notifying issues which may have an impact upon ethical opinion of the study
- Progress reports
- Notifying the end of the study

Approved documents
The documents reviewed and approved are:

Document	Version	Date
All documents submitted with MH-200114	-	03 Feb 2020

Yours sincerely,



Dr Gary Moss
Chair