Quality and effectiveness of osteoporosis treatment decision aids: a systematic review and environmental scan

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Purpose

Decision aids (DA) are evidence-based tools that support shared decision-making (SDM) implementation in practice; this study aimed to identify existing osteoporosis DAs and assess their quality and efficacy; and to gain feedback from a patient advisory group on findings and implications for further research.

Methods

We searched multiple bibliographic databases to identify research studies from 2000 to 2019 and undertook an environmental scan (search conducted February 2019, repeated in March 2020). A pair of reviewers, working independently selected studies for inclusion, extracted data, evaluated each trial's risk of bias, and conducted DA quality assessment using the International Patient Decision Aid Standards (IPDAS). Public contributors (patients and caregivers with experience of osteoporosis and fragility fractures) participated in discussion groups to review a sample of DAs, express preferences for a new DA and discuss plans for development of a new DA.

Results

We identified 6 studies, with high or unclear risk of bias. Across included studies, use of an osteoporosis DA was reported to result in reduced decisional conflict compared with baseline, increased SDM and increased accuracy of patients' perceived fracture risk compared with controls. Eleven DAs were identified, of which none met the full set of IPDAS criteria for certification for minimization of bias. Public contributors expressed preferences for encounter DAs that are individualized to patients' own needs and risk.

Conclusions

Existing DAs for informing patient decisions about osteoporosis treatment fail to comprehensively meet international quality standards and patient needs, underpinning the need for new DA development.

Mini Abstract

Using a systematic review and environmental scan we identified 11 decision aids to inform patient decisions about osteoporosis treatment and 6 studies evaluating their effectiveness. Use of decision aids increased accuracy of risk perception and shared decision-making but the decision aids themselves fail to meet quality standards or patient needs.

Introduction

Despite the significant mortality and morbidity associated with fragility fractures, and the benefits of treatment, 85% of patients in need of fracture prevention treatment, such as bisphosphonates, do not receive it [1]. Furthermore, the number of women starting fracture prevention treatment is declining, despite the ageing population in need of treatment increasing [2]. The reasons for this decline are complex; however, the problem is not solely related to rates of identification of patients at risk: 25% of patients who are recommended bisphosphonates actively decide against starting treatment [3]. In those who do decide to start treatment, long term persistence is known to be poor [4]. Reasons for treatment non-initiation and non-persistence include skepticism over benefits and safety, lack of understanding of the consequences of non-treatment and/or fracture risk assessments and perceived or experienced side effects [5, 6]. The poor uptake of osteoporosis treatment globally has been described as the 'osteoporosis crisis', and it has been suggested that a major contributing factor to this situation is the failure of clinicians to adequately and accurately communicate risks such as the risk of poor disease outcome (prognosis) and the harms and benefits relating to treatment options [7]. Furthermore, patients have identified improving access to information from health professionals as the most important area for research in osteoporosis [8].

Decision aids (DAs) are tools that support the implementation of shared decision-making (SDM) in practice. SDM is an approach in which patients and clinicians work together to develop a treatment plan that responds well to the patient's situation. DAs may provide numerical estimates of risk/benefit and are a well-recognized mechanism to improve risk communication and support informed patient decision-making [9, 10]. Across a range of conditions, DAs have been demonstrated to increase patient knowledge, reduce decisional conflict, increase patient participation in decision-making, improve the accuracy of risk perception, and improve uptake of preventative treatments [9]. The UK National Institute for Health and Care Excellence (NICE) guidance recommends DAs to support SDM, if 'high quality' aids are available [11], and International Standards for Patient Decision Aids (IPDAS) readily facilitate such quality assessment [12].

SDM supported by use of DAs has the potential to improve the likelihood of each patient receiving and taking fracture prevention medication given their risk, informed preferences, and personal circumstances. In this way, implementing SDM can account for how different patients in different situations assign different value and priority to reducing their fracture risk, choosing from strategies such as the use of particular medications. To our knowledge, the impact of DAs to promote SDM in the care of patients with osteoporosis considering treatment has not been systematically summarized.

Our study had two aims. First, we conducted a systematic review to identify and summarize research studies which had assessed the efficacy of existing osteoporosis DAs. Second, we aimed to identify existing osteoporosis DAs and assess their quality. We assumed that not all existing DAs had been evaluated in scientific peer reviewed publications, so we supplemented the systematic review with a broader range of search methods to identify existing DAs using an environmental scan method. Additionally, we sought feedback from an advisory group of public contributors and discussed preferences for the design of a new DA, in line with international guidance on DA development [13].

Methods

An overview of the methods is shown in Figure 1.

Fig 1. Overview of study methods

Protocol and Registration

The protocol for the systematic review was previously published and registered in the International Prospective Register of Systematic Reviews (PROSPERO registration number CRD42019126787) [14]. This report adheres to the Preferred Reporting Items for Systematic Review and Meta-analysis (PRISMA) standards.

Eligibility criteria

We included DAs, and efficacy studies about DAs, relevant to people facing a decision about osteoporosis treatment or fracture prevention strategies in patients with osteoporosis. Identified DAs had to be sufficiently available to perform quality assessments i.e. the DA was either fully available or we had sufficient information on screenshots in papers included in the systematic review to be able to judge quality. We excluded DAs intended to help decide whether or not to perform a diagnostic test, those available in a language different than English, those intended only for education rather than clinical decision support, and those designed only for clinicians. For efficacy assessment, eligible studies were randomized or non-randomized trials that evaluated DAs impact on SDM outcomes (e.g. decisional conflict, knowledge), patient outcomes such as quality of life or anxiety and clinical outcomes such as adherence.

Information Sources and Search Strategy

For the systematic review, a comprehensive search of several databases was conducted from 2000 to 5th February 2019 (and subsequently repeated up to 24th March 2020), limited to English. The databases included Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed

Citations, and Daily, Ovid EMBASE, Ovid PsycINFO, Ovid Cochrane Central Register of Controlled Trials, Ovid Cochrane Database of Systematic Reviews, Web of Science, and Scopus. The search strategy was designed and conducted by an experienced librarian with input from one author (VTR). Controlled vocabulary supplemented with keywords was used to search for osteoporosis DAs. The search strategy is available in Supplementary Table 1.

The environmental scan was informed by the methodology employed by previous environmental scans about DAs [15, 16]. Three additional searches were conducted: a search of an existing DA database, social media and Google. Initially, in December 2017, a search of an international DA database (the Ottawa DA A-Z inventory) was conducted using the terms 'osteoporosis' and 'bisphosphonate'. In October 2019, and updated in March 2020, the search of the Ottawa database was repeated and we searched social media, namely Facebook, Twitter and Instagram using the terms 'osteoporosis', 'bone fracture', 'shared decision-making', and 'decision aid'. Terms were entered as words and '*hashtags'*. In addition, a Google search was conducted, using the terms 'osteoporosis' and 'decision aid' or 'decision tool' with the first 100 hits being screened (an approach used in a previous environmental scan [15].)

Study and DA Selection

Two reviewers independently screened all titles and abstracts. Full texts were retrieved and independently screened by two reviewers with acceptable reproducibility (weighted overall kappa = 0.69). Disagreements during title, abstract or full text screening were resolved by a third reviewer (JPB).

DAs were identified from the systematic review and social media search by VTR and MUS, and from the Ottawa database and google by AH and ZP. Two authors (VTR and ZP) agreed identified DAs met inclusion criteria.

Data Extraction and Quality Assessment

Data from eligible research studies was extracted in duplicate by 4 reviewers (VTR, MUS, GFT, and LM) on: study design, setting, target population, and characteristics of participants (e.g. age, sex, baseline risk of fracture). Risk of bias of included studies was assessed by 3 reviewers (VTR, MUS and GFT) using the 7-item Cochrane Collaboration's risk assessment tool.

Of the DAs identified in both the systematic review and environmental scan, data was extracted by two authors (AH and ZP) on: the availability (e.g. online or paper) and intended use, the target population the tool was designed for, the nature of the options, risks and benefits explained and the method of displaying these risks and benefits. Two authors (VTR and AH or LB) reviewed the

satisfaction of International Patient Decision Aids Standards (IPDAS) criteria for each included DA independently, using a binary yes/no scale, and resolved any disagreements by discussion with a third author (ZP). The 44-item IPDAS v4.0 checklist criteria were used, excluding the 9 items relating to diagnostic tests [12]. This checklist includes dimensions relating to the information provided, probabilities presented, values elicitation, guiding the patient through making a decision, development of the DA, the evidence underpinning the DA, disclosures, use of plain language and evaluation of the DA [12]. Six of the 44 items, described as 'qualifying' are considered essential for a DA to meet the classification of a DA with evidence of a further six 'certification' criteria required to reach certification standards [12]. The full list of criteria (35 items used), is available in Supplementary Table 2.

Synthesis

In the systematic review, we considered SDM outcomes such as decisional conflict, knowledge, patient participation in decision-making, preference in treatment decisions, risk expectations and perceptions, etc. Patient important and surrogate outcomes were also considered. We planned to synthesize outcome data quantitatively using random effects model. However, we reported data narratively due to heterogeneity in reporting across the 6 studies.

Patient and public involvement: advisory group

Public contributors were invited to attend an advisory group in December 2017 in which the DAs identified in the first search were reviewed. Discussion groups differ from focus groups. In focus groups with patients, patients are participants in qualitative research, designed to answer a research question. In advisory discussion groups, public contributors inform and advise the research process, e.g. project decision making and study design, in partnership with researchers. This emphasizes co-learning, multi-way communication and collaboration between the participants and facilitators [17]. The GRIPP2 guided the reporting of patient and public involvement (PPI) [18].

Public contributors in our osteoporosis Research User Group consist of men and women with experience of osteoporosis and/or fragility fractures and people with experience of caring for people with osteoporosis. Public contributors from the osteoporosis Research User Group were invited to attend, and asked to comment on general impressions towards the DAs appearance, the suitability of the DA for use in a clinical consultation and whether, or not, the information regarding fracture risk felt tailored or relevant to their individual characteristics. Additionally, they were asked their requirements and preferences for the development of a new DA. The advisory discussion group was facilitated by ZP and SC. Discussion notes were written with the intention of drawing on participants' expertise in order to inform decision-making in relation to future research [17].

Results

Systematic review: summary of included studies

We identified 2199 records which resulted in the inclusion of 15 studies [19–33] that referred to one or more eligible DAs (Figure 2). Six of the 15 studies evaluated DAs' impact on 8 outcomes and were included for data extraction; the other studies were used as complementary when assessing decision aid's quality using IPDAS in the environmental scan.

Fig 2. PRISMA Flow diagram

Six studies reporting impact on SDM and other relevant outcomes contributed 507 participants (Table 1) [19, 24, 26, 28, 31, 33]. Five were randomized controlled trials (RCTs) [24, 26, 28, 31, 33], the other was a pseudo-experimental before and after study [19]. Two RCTs evaluated the impact of the Osteoporosis Choice DA in the clinical encounter [28, 31], one RCT evaluated a multimedia tool and printed booklet for use in outpatients (but designed to be read alone) [24], and the remaining three evaluated DAs which are no longer freely available (the paper Healthy Bones DA used both before, and in the encounter [33], with the remaining two evaluating versions of the 'Making Choices' DA used before the encounter [19, 26]). Of note, the control arm in all but one study encompassed usual care or an existing educational booklet; however, in the study evaluating the multimedia tool, the control arm intervention received a booklet which was noted to contain similar information to the multimedia tool, and was also given to participants in the intervention arm [24]. Participants enrolled in these studies were all postmenopausal women with mean ages ranging 50-77 years old. Five studies specified educational status: in four studies, participants were predominantly educated, the majority completed high school or a greater degree [19, 28, 31, 33]. Only one study reported health literacy measured at baseline and reported 82% of the sample had acceptable health literacy [24]. Treatment status was variable; one study included only participants in treatment for osteoporosis [26], two studies included only participants with untreated osteoporosis [28, 31], and three studies included participants with osteoporosis irrespectively of their treatment status [19, 24, 33].

Risk of bias assessment

Among all studies, four trials received an "unclear" risk of bias using the Cochrane tool [24, 26, 28, 33], and two trials study received a "high" risk of bias (Figure 3) [19, 31]. Overall, absence or inadequate reporting of allocation concealment but especially blinding of participants, personnel and outcome assessors were important sources of potential bias among these studies.

Fig 3. Risk of bias of effectiveness studies

Effectiveness of decision aids.

The outcomes evaluated related to decisional quality (decisional conflict, realistic expectations, knowledge) decisional process (involvement in decision-making, preparation for SDM and SDM), quality of life and adherence (Table 2).

Four studies compared decisional conflict immediately after the encounter in intervention arm and controls, all studies found lower decisional conflict scores in the DA arms [24, 28, 31, 33], and two, evaluating the Healthy Bones DA and multimedia tool [24, 33] reported a statistically significant difference. Two studies compared decisional conflict before and after using the Making Choices DA and both reported statistically significant lower decisional conflict scores post-DA compared to baseline [19, 26]. The only trial to measure health literacy found that of the participants with limited health literacy, those in the control arm (receiving booklet only) had a greater (significant) reduction in decisional conflict at 6 months than those in the arm receiving a multimedia tool [24]. Both trials with Osteoporosis Choice found a significant difference in percentage of patients that identified correctly their risk category post-intervention [28, 31]. The results were consistent with the Making Choices before and after study [19]. The two Osteoporosis Choice RCTs [28, 31] and the Making Choices before and after study [19] measured knowledge immediately post-intervention using non-validated and validated questionnaires. Both trials found a significant difference when measuring knowledge specific to the DA, but no difference in generic knowledge [28, 31]. The results were consistent with the before and after study [19]. Furthermore, in the RCT of the multimedia tool compared with booklet, osteoporosis knowledge improved from baseline to all time points in both trial arms [24].

Two randomized trials measured involvement in decision-making using the OPTION score [28, 31]. Both trials found a significant higher involvement when using the Osteoporosis Choice DA.

One randomized trial measured quality of life at 6 months using the EURO QoL5d Health Thermometer tool [31]; with no difference in quality of life observed between intervention and controls.

Three randomized trials measured adherence at >4 months, using different measures [26, 28, 31]. Overall, no study found a difference in adherence when using a DA, although one Osteoporosis Choice study [31] found, more patients initiated treatment (filled the prescription) in the intervention arm compared with controls (80% compared with 43%, p=0.07).

Environmental Scan: summary of included decision aids

Eleven DAs were identified for evaluation (Supplementary Figure 1), of which 5 were identified in the systematic review with a further 6 identified in searches of Ottawa A to Z inventory and social media. The google search did not add any new DAs.

The characteristics of the 11 DAs identified are described in Supplementary Table 3. Two of the DAs identified are no longer available (Healthy Bones and Making Choices) but sufficient information was available within the related research studies to rate using the IPDAS criteria [19, 20, 33]. Of the 9 currently available DAs, three are interactive dynamic websites, two of which are designed for use in the encounter; individual risk factors are entered in order to calculate fracture risk (Osteoporosis Choice and HealthDecision). One of the interactive DAs not meant for the encounter includes a values clarification exercise (Healthwise). Five DAs are printable PDF files. Four of these have sections to complete about fracture risk (AACE/ACE) or values, decisions and knowledge (three Cochrane tools). Finally, one DA comprised a multimedia tool and associated printed booklet; the tool comprised learning modules with information on osteoporosis, its risk factors, prevention, and management, using a set of dramatized episodes recorded on video and viewed on a computer.

All DAs discussed treatment options relating to bisphosphonates, with AACE/ACE, Healthy Bones, Making Choices and the multimedia tool including information about other treatment options (including Teriparatide, denosumab, raloxifene, HRT and Calcitonin). Two DAs made reference to falls prevention (Osteoporosis Choice and multimedia tool). The Cochrane, Healthwise and Making Choices DA are explicitly for postmenopausal women only. Six DAs used Cates plots to demonstrate fracture risk with and without treatment (Cochrane tools, Osteoporosis Choice, HealthDecision and NICE). The remainder used either textual descriptions (Healthwise), descriptions of frequencies (Making Choices) or other visual methods e.g. ticks (AACE/ACE, Healthy Bones, multimedia tool) to show benefits of treatment. Side effects were mostly described using frequencies with the HealthDecision and Cochrane tools expressing side effects visually in a Cates plot.

Quality of Decision Aids

Full IPDAS results for each DA are shown in Figure 4. The Making Choices DA was rated as meeting the most number of criteria (28/35, 80%), with the AACE/ACE tool rated as meeting the fewest (9/35, 25.7%). Of the currently available tools, the Osteoporosis Choice tool rated the best overall (27/35, 77%). Only HealthDecision and the multimedia tool met the minimum criteria to be classified as a DA (see supplementary Table 2 for definition of classification criteria and Figure 4 for results). This was because the remainder DAs did not state the decision to be considered (AACE/ACE) or, more commonly, did not describe the physical, social and psychological consequences of the options, particularly of having a fracture. No DA met the certification criteria; most commonly this

was because an update policy was not described or levels of uncertainty of the evidence were not described; however, 3/11 tools also did not describe benefits and harms of options in equal detail. Evidence that the DA was developed with review by patients or had been evaluated was only available for Osteoporosis Choice, the multimedia tool and the 2 DAs not currently available.

Fig 4. Quality of decision aids evaluated using IPDAS criteria

Public contributor views

6 DAs were identified in the first environmental scan search (December 2017), and were presented to public contributors (with the Cochrane alendronate tool shown to represent all 3 Cochrane tools due to similar content). Six (female) public contributors attended the advisory discussion group. Public contributors found aspects of three tools confusing and difficult to understand (Supplementary Table 4). The NICE decision support tool was not well received and felt to cause confusion rather than to enhance understanding, because the example risk scenarios were not personalized and difficult to interpret. Parts of the text in the Cochrane tool and the layout of Cates plots in the HealthDecision tool were reported as confusing. The visualization of risk of rare harms (atypical fracture and osteonecrosis of the jaw) was welcomed in the HealthDecision tool; however, it was felt this image (a Cates plot of 1000 or 10,000 people) was too complicated to interpret easily. Osteoporosis Choice was the preferred DA to its appearance and relatively simple content, although it was felt this tool was missing visual information on harm risks. The group noted that information on harms of medication varied greatly between tools causing them to question the accuracy of this information. Additionally, the group felt that the tools seemed to downplay the significance of potential side effects (especially gastrointestinal).

The public contributors felt their ideal DA would be computerized, web-based, suitable for use in a time-limited consultation, and include benefits and harms of drug treatment, both in written explanation and visual form. They suggested it would be helpful to have a print-out afterwards to study at their leisure and discuss with their general practitioner (GP). Public contributors stressed the need for a personalized risks as this meant they had more confidence in making an individualized and informed decision, based upon their own needs. They also felt the DA should give a brief overview of the information with an option for more in-depth evidence according to patient preference. Although Cates plot of 1000 people were felt to be too complicated, they liked the idea that rare harms could be presented alongside benefits in the same image and were positive about the suggestion to use alternative images for this, for example a football stadium infographic, which was felt to be an easily relatable image.

Discussion

We have conducted a comprehensive multifaceted review of the quality and effectiveness of DAs to support decision making about osteoporosis treatment, and gone beyond previous studies by embedding patient perspectives.

We identified only six studies of clinical effectiveness, relating to four DAs, of which only two DAs are currently available. In the context of osteoporosis, we have found low quality evidence that decisional conflict reduces after the use of a DA, and that DA use increases SDM and increases patients' accuracy of their perceived fracture risk. This finding is consistent with the Cochrane Systematic Review [9] which also found that DAs decrease decisional conflict, indecision about personal values, and the proportion of people who were passive in decision making. A subgroup analysis performed with the Cochrane review demonstrated use of DAs improved treatment initiation rates of preventative treatment to reduce risk of stroke in diabetes and hypertension. However, our review has not provided evidence that DAs improve treatment adherence in osteoporosis, although these results are limited by small numbers in the included studies and by different measures of treatment adherence across studies.

It is important that further research on the effectiveness of DAs attends to both the decision quality (eg as measured by decisional conflict) and the decision process components of SDM [34]. In our study, two studies did not attend to this latter measure [19, 26]. Furthermore, as the 'osteoporosis crisis', characterized by poor treatment uptake, has been blamed on a failure of effective SDM, it is essential that further studies evaluating effectiveness of DAs evaluate the impact on adherence, and ideally using measures of both compliance and persistence. Moreover, the ability of osteoporosis DAs to address barriers to adherence, specifically low perceived need or high concerns, needs to be addressed. We have also identified that health literacy is an important consideration that needs to be evaluated in any further research.

Our environmental scan identified 11 relevant DAs which varied from dynamic websites for use in the encounter to information leaflets with no interactive components that could be used pre- or post-consultation. Of 11 identified DAs, only the HealthDecision tool and the multimedia tool meet criteria to be classified as DA, but did not meet the full set of criteria for certification or quality. Across all the IPDAS criteria assessed, the Making Choices (Ottawa) and the Osteoporosis Choice DA performed best and also clearly report user involvement during development [19, 27, 28, 31] and it is therefore perhaps unsurprising that of the tools reviewed by the public contributors, the Osteoporosis Choice DA was viewed most favorably. Across the DAs, the IPDAS assessment identified that common deficiencies were found in describing the natural course of osteoporosis,

helping patients imagine the consequences of options, including the physical, social and psychological consequences of sustaining a fracture, and using the same denominator in probabilities. Few DAs had information about their development or any evaluation and few described an update policy or reported any uncertainty around reported risks. The DAs included in this review varied in complexity and interactivity; the only included study in this review that measured health literacy reported greater gains with a simple booklet than with a multimedia tool and booklet combined [24].

The discussion group with patient contributors added to our evaluation using IPDAS. For example, although the Osteoporosis Choice DA was rated by authors as describing benefits and harms in equal detail, our patient contributors felt this DA lacked a visual displays of harms which would add value. Furthermore, although the HealthDecision DA was only one of two tools meeting criteria to be described as a DA, our public contributors found the visual presentations of risks too complicated to understand, highlighting the importance of user involvement in development, testing and evaluation. Our public contributors also reported that paper based tools that could be used before the consultation, that aimed to present a range of, or 'average' fracture risk(s), rather than personalized risk, were felt to be confusing. Public contributors preferred tools which were web-based and could offer information that could be individualized to their needs; this is in line with evidence, albeit of low certainty, that DAs with these characteristics are more effective at promoting adherence [35]. A recent systematic review of encounter DAs only concluded that these are effective in improving patient knowledge, reducing decisional conflict and did not increase the length of time of the consultation [36].

Feedback from this discussion group informed a research proposal to design and evaluate a new DA to be used in the consultation when fracture prevention treatments are being considered. Subsequently, funding was secured to develop and evaluate a new DA, as part of a wider consultation intervention to improve informed decision-making regarding fracture prevention treatments (the iFraP study). A second public contribution group was convened in September 2018, in which plans for the co-production of the new DA were discussed, and the plans for public involvement in the overall research design in terms of needs assessment, user testing and design/refinement [13]. Public contributors expressed the importance of receiving consistent messages across primary and secondary care; thus, they advised that it was essential to involve primary care practitioners (GPs) as stakeholders in development of any new DA, despite the new DA being initially targeted specialist secondary care services. The group suggested that patients should provide informal feedback on early versions of the DA as part of iterative development. Members agreed to help interpret findings of 'think aloud' interviews used for more formal clinical testing of

the prototype, in order to advise DA refinements ahead of a pilot study. Public contributors expressed preferences to have active roles in the study management and also felt they should be involved in the scientific advisory group, which would decide on the evidence which would underpin the DA. Integrating public contribution throughout these study groups was felt to facilitate patient input in all aspects of the study. Working together with public contributors to plan research at the outset is a key UK Standard for Pubic Involvement [37]. However, a challenge remains to ensure we identify and address barriers to taking up public involvement in research, particularly in ensuring we involve a range of public with relevant experience and varied perspectives, particularly including those who have prominent concerns about medication. Continued recruitment of new members to our patient and public involvement group will be essential to provide a range of perspectives and avoid overburdening a small group of public contributors.

A strength of this study is the use of multiple methods to bring together evidence about effectiveness and quality, and the views of public contributors to further our understanding. By supplementing the systematic review with an environmental scan and additional novel search methods, we were able to identify a comprehensive range of decision aids for quality assessment. However, this study is subject to a number of limitations. First, the real impact of DAs on SDM remains uncertain due to high or unclear risk of bias of all included studies. Lack of allocation concealment and blinding may have introduced significant bias favoring the intervention arm. However, decisional conflict was reduced consistently across trials and measured using the same validated scale, which decreases subjectivity and raises confidence in the results. We only sought feedback from public contributors about the DAs identified in the initial search, although of the currently available tools, the AACE/ACE, multimedia and Healthwise were excluded, none of which contain visualizations of risks, which the group preferred. The NICE DA was updated between the review by public contributors and the IPDAS assessment; however, the Cates plots were not altered meaning that the comments from the group relating to risk presentation and helpfulness are still relevant to the second version. A further limitation of this study relates to the fact that the IPDAS standards do not involve assessment of the quality of the evidence underpinning the DAs [12]; given the wide variation in frequencies of gastro-intestinal side effects reported, it is likely the tools were drawing on different sources of evidence. Furthermore, we did not directly assess readability of the DAs.

Overall, our findings demonstrate that of the existing available tools, the Osteoporosis Choice tool best meets IPDAS criteria and has evidence of effectiveness, and, that paper based DAs which do not individualize risk should be used with caution, due to the confusion reported by our public contributors. However, the findings also underpin the need for a new DA that meets both IPDAS

criteria and patient needs. Guidance on the development of DAs, derived from a systematic review and expert consensus, recommends five stages of development, overseen by a steering group from start to finish [38]. The stages involve i) scoping the need for the DA, ii) determining the design, by reviewing needs of patients and clinicians and reviewing the appropriate evidence, iii) designing a prototype, and iv) alpha and v) beta testing (usually in the field). Patients are recommended to be involved in the design, the testing phases and in the overseeing steering group. Our experience has demonstrated that reviewing existing tools has been an effective way of scoping the function of our proposed tool and a first step in determining patient decision needs. Further steps to determine patients' needs will include qualitative research using focus groups, evidence synthesis of guidelines and patient information leaflets, and review of findings from a previous systematic review [39] and ongoing public collaboration throughout. A recent systematic review of user-involvement in DA development [13] has identified that more involvement of users in advisory and partnership roles is needed; our example demonstrates that public contributors are keen to be involved in advisory roles and have positively contributed to development of a new DA by advising on the format of DA printouts, and methods of informal alpha testing.

At present, fracture prevention/osteoporosis DAs are not being widely used in routine practice. Furthermore, across a range of conditions, DA implementation in general is low with less than half of authors of trials included in the original Cochrane review reporting that the tested DA was being used in clinical practice [40]. Therefore, any new DA development needs to ensure barriers and facilitators to implementation in clinical practice are considered from the outset. The public contributor group were insightful here, suggesting early involvement of relevant stakeholders, including those from primary care, in development work, which we have already actioned.

Conclusion

In summary, by using a combined approach of a systematic review, environmental scan and consultation with public contributors, we have identified that existing osteoporosis decision aids show promise in increasing the accuracy of risk perception and shared decision-making, yet fail to comprehensively meet international quality standards and patient needs, suggesting a need for a new DA to address these deficits. Public contributors identified that DAs for osteoporosis need to be used in the consultation and individualized to their own needs and risk. We have briefly described planned public contribution in a new study to develop, design and evaluate a new DA.

Declarations

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Conflict of Interest: Juan P Brito, Victor D Torres Roldan, Meritxell Urtecho S, Nataly R. Espinoza Suarez, and Lisdamys Morera work at the Knowledge and Evaluation Unit at the Mayo Clinic where the Osteoporosis Choice tool was developed. Zoe Paskins, Ashley W Hawarden, Laurna Bullock, Gabriel F Torres, Anne Worrall, Steven Blackburn, Stephen Chapman, and Clare Jinks declare that they have no conflict of interest.

Ethical approval: This article does not contain any studies with human participants or animals performed by any of the authors.

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Fig 1. Overview of study methods

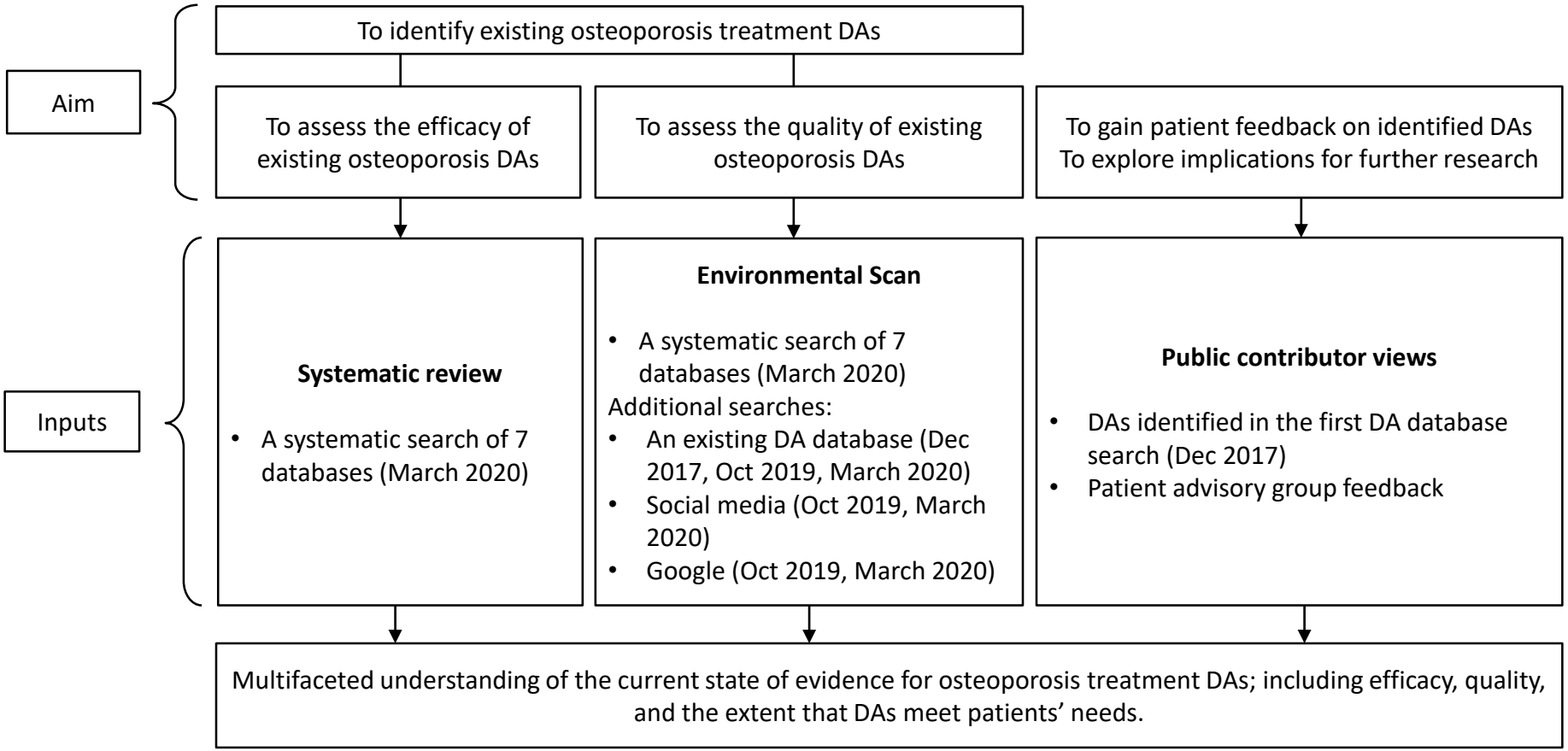
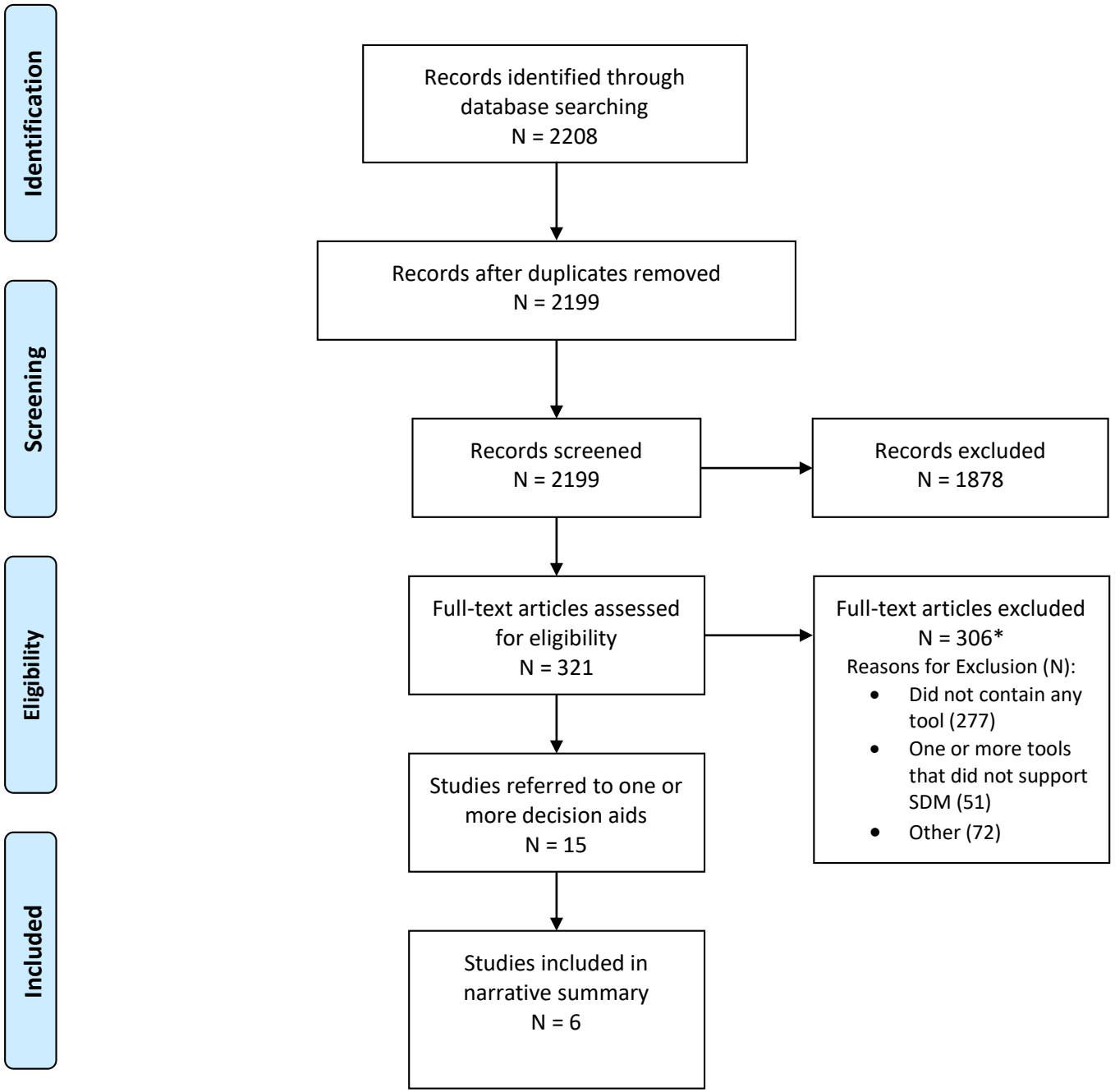


Fig 2. PRISMA Flow diagram



*Reasons for exclusion are not mutually exclusive

Fig 3. Risk of bias of effectiveness studies

Fig 4. Quality of decision aids evaluated using IPDAS criteria

	Items	1	2	3	4	5	6	7	8	9	10	11	n (%)
Information	Describes condition	✓	✓	✓	✓		✓		✓	✓	✓	✓	**9 (81.8)**
	States the decision		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	**10 (90.9)**
	Describes options	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	**11 (100)**
	Positive features	✓					✓				✓	✓	**11 (100)**
	Negative features	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	**11 (100)**
	Equal details	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	**8 (72.7)**
	Natural course	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	**4 (36.4)**
	Fair comparison		✓	✓	✓	✓		✓	✓		✓		**9 (81.8)**
Probabilities	Outcome probabilities		✓	✓	✓	✓	✓	✓	✓	✓	✓		**9 (81.8)**
	Reference class		✓	✓	✓	✓	✓		✓	✓	✓		**8 (72.7)**
	Event rates		✓	✓	✓	✓			✓	✓	✓		**7 (63.6)**
	Same time period		✓	✓	✓	✓			✓	✓	✓		**7 (63.6)**
	Same denominator		✓	✓	✓	✓			✓				**5 (45.5)**
	Viewing probabilities	✓	✓	✓	✓	✓			✓	✓	✓		**8 (72.7)**
Values	Describes what it is like	✓					✓					✓	**3 (27.3)**
	What matter most		✓	✓	✓		✓	✓	✓				**6 (54.5)**
DG	Step-by-step decision		✓	✓	✓	✓	✓	✓	✓		✓		**8 (72.7)**
	Worksheets		✓	✓	✓		✓		✓				**5 (45.5)**
Development	Patients' needs										✓		**1 (9.1)**
	Professionals' needs										✓		**1 (9.1)**
	Review by patients							✓	✓		✓	✓	**4 (36.4)**
	Review by professionals						✓		✓	✓	✓		**4 (36.4)**
	Tested with patients							✓	✓		✓	✓	**4 (36.4)**
	Tested with doctors							✓	✓		✓		**3 (27.3)**
Evidence	Provides citations	✓	✓	✓	✓	✓	✓		✓	✓	✓		**9 (81.8)**
	Publication date		✓	✓	✓	✓	✓		✓	✓	✓		**8 (72.7)**
	Update policy					✓				✓			**2 (18.2)**
	Levels of uncertainty		✓	✓	✓			✓					**4 (36.4)**
	Evidence synthesis		✓	✓	✓				✓	✓	✓		**6 (54.5)**
	Quality of evidence		✓	✓	✓				✓				**4 (36.4)**
Discl	Funding source		✓	✓	✓	✓		✓	✓		✓	✓	**8 (72.7)**
	Credentials		✓	✓	✓	✓	✓	✓	✓		✓	✓	**9 (81.8)**
PL	Readibility evaluated												**0 (0)**
Eval	Better choices							✓	✓		✓	✓	**4 (36.4)**
	Improves knowledge							✓	✓		✓	✓	**4 (36.4)**
	IPDAS score, n (%)	**9 (25.7)**	**23 (65.7)**	**23 (65.7)**	**23 (65.7)**	**18 (51.4)**	**17 (48.6)**	**17 (48.6)**	**28 (80.0)**	**15 (42.9)**	**27 (77.1)**	**14 (40.0)**	

1 AACE/ACE 2 Cochrane Alendronate 3 Cochrane Etidronate 4 Cochrane Risedronate 5 HealthDecision - Osteoporosis Shared Decision-Making tool 6 Healthwise - Osteoporosis: Should I Take Bisphosphonate Medicines? 7 Healthy bones (AHRQ) 8 Making Choices: Osteoporosis Treatment Options (Cranney) 9 NICE 10 Osteoporosis Choice (Mayo Clinic) 11 Multi-media tool (Lopez Olivo)

Table 1. Characteristics of included studies examining effectiveness of decision aids

First author (year)	Design	Country	Sample size	Target population	Sex	Mean age	Level of education	Risk of fracture	Decision Aid Tested	Delivery	Control
Lopez-Olivo et al. (2019)	Randomized Controlled Trial	USA	225	Postmenopausal women with osteoporosis or osteopenia	F	Intervention: 63.1 Control: 64.7	Intervention: Bachelor's degree or higher: 31.5% Control: Bachelor's degree or higher: 34.2%	Not specified	Multimedia patient education tool	Not specified/self-administered	Written booklet
Smallwood et al. (2016)	Randomized Controlled Trial	USA	50	Postmenopausal women with osteoporosis or osteopenia (treated or untreated)	F	Intervention: 68.8 Control: 67.8	Intervention: High school, 10.3%; Post-secondary, 89.7% Control: High school, 19%; Post-secondary, 80.9%	Not specified	Healthy Bones (modified)	Before and within encounter/self-administered	Educational web-page
LeBlanc et al. (2015)	Randomized Controlled Trial	USA	79	Postmenopausal women with untreated osteoporosis	F	Intervention: 69 Control: 66	Intervention: High school or less, 25%; Post-secondary, 75% Control: High school or less, 24%; Post-secondary 76%	Intervention: <10% in 10 years, 31%; >20% in 10 years, 19%; FRAX mean, 14% Control: <10% in 10 years, 47%; >20%, 15%; FRAX mean: 13%	Osteoporosis Choice	Within encounter/with clinician	FRAX calculator/ Usual Care
Montori et al. (2011)	Randomized Controlled Trial	USA	100	Postmenopausal women with untreated osteoporosis	F	Intervention: 67 Control: 67	Intervention: Less than high school, 4%; High school or greater, 96% Control: Less than high school, 4%; High school or greater, 96%	Intervention: <10% in 10 years, 3.9%; >30%, 19% Control: <10% in 10 years, 8%; >30%, 31%	Osteoporosis Choice	Within encounter/with clinician	Educational booklet
Oakley et al. (2009)	Randomized Controlled Trial	Not specified	33	Postmenopausal women with osteoporosis in treatment	F	Intervention: 77 Control: 77	Not specified	Intervention: previous fracture, n(%): 13(81) Control: previous fracture, n(%): 11(65)	Ottawa decision aid (modified)	Before encounter/self-administered	Usual care
Cranney et al. (2002)	Before and After Study	Canada	20	Postmenopausal women with osteoporosis (treated or untreated)	F	61.4	Less than high school, 11%; Post-secondary, 89%	BMD (T score), -3.03 (0.74)	Making Choices (Ottawa decision aid)	Before encounter/self-administered	Single arm

Table 2. Effectiveness of decision aids

	Author (year) & Decision Aid tested					
Outcomes	**Lopez-Olivo et al. (2019)** **Multimedia patient education tool**	**Smallwood et al. (2017)** **Healthy Bones (modified)**	**LeBlanc et al. (2015)** **Osteoporosis Choice**	**Montori et al. (2011)** **Osteoporosis Choice**	**Oakley et al. (2006)** **Ottawa decision aid (modified)**	**Cranney et al. (2002)** **Making Choices (Ottawa decision aid)**
Decisional Conflict	They used a low literacy version of the Decisional Conflict scale. Decisional conflict decreased in both the multimedia (Post intervention: 16.0 (25.9), 3 months: 33.7 (33.5), 6 months: 27.9 (30.4)). and printed booklet (Post intervention: 17.9 (28.2), 3 months: 32.5 (32.8), 6 months: 28.2 (32.1)) groups ($p < 0.05$).	They used the Decisional Conflict validated scale. Immediately post-intervention, there was a statistical significant lower decisional conflict in the decision aid arm (mean, 17.8) than controls (mean, 47.1). At 3 months: lower decisional conflict in the decision aid arm (mean, 11.2) compared to controls (mean, 25.5).	They used the Decisional Conflict validated scale. Immediately post intervention, not statistically significant difference between decision aid arm (median, 10.9; IQR, 25) and controls (median, 22.7; IQR, 20.7)	They used the Decisional Conflict validated scale. Immediately post intervention, not statistically significant difference between decision aid arm (median, 10.9; IQR, 52) and controls (median, 13.3; IQR, 58)	They used the Decisional Conflict validated scale. It was only assessed in the intervention group. Immediately post-intervention, they found a significant difference compared to baseline (median, 2.5; IQR, 1.6 vs median, 2; IQR, 1.4; respectively).	They used the Decisional Conflict validated scale (0-100). Immediately post-intervention, there was a statistical significant lower decisional conflict (mean, 37.4; SD, 14.2) than baseline (mean, 50.1; SD, 15.9).
Adherence	N/A	N/A	Immediately post-intervention, they measured the % of patients that filled their prescription; they found that more patients in the decision aid arm (83%) filled their prescriptions when compared to controls (40%). At 6 months, they measured the % of days covered; they found no difference between intervention arm (median, 47; IQR, 7.5) and controls (median, 85; IQR, 37.3).	They measured the % of days covered. At 6 months, they found no difference between participants in the decision aid arm (median, 100; IQR, 14) and controls (median, 98; IQR, 100). When they dichotomized at 80% days covered, they found a significant difference (100 vs 74, respectively)	They used the Medication Adherence Report Scale (MARS) validated scale and reported % of "compliant" patients. At 4 months, there were no differences between the decision aid arm (median, 100; IQR, 50) and controls (median, 100; IQR, 100).	N/A

Knowledge	They used the modified version of the Osteoporosis Patient knowledge Questionnaire. 17-item questionnaire. Knowledge improved from baseline to all evaluation time points in both the multimedia (Post intervention: 12.8 (3.2), 3 months: 12.3 (3.1), 6 months: 11.9 (3.1)) and printed booklet groups (Post intervention: 12.4 (3.2), 3 months: 11.9 (3.3), 6 months: 11.8 (3.4)) ($p < 0.0001$).	N/A	13-item questionnaire. Immediately post-intervention, they found a significant difference in knowledge specific to the decision aid -9 questions- between the intervention arm (median, 6; IQR, 3) and controls (median, 4; IQR, 3), but no difference in knowledge not specific to the DA -4 questions- (median, 1.5; IQR, 3; and median, 1.5; IQR, 3, respectively)	13-item questionnaire. Immediately post-intervention, they found a significant difference in knowledge specific to the decision aid -9 questions- between the intervention arm (median, 6; IQR, 9) and controls (median, 4; IQR, 8), but no difference in knowledge not specific to the DA -4 questions- (median, 2; IQR, 4; and median, 1.5; IQR, 4, respectively)	N/A	27-item questionnaire and reported % of correct answers. Immediately post-intervention, they found a significant difference in overall knowledge (mean, 82; SD, 18.9) compared to baseline (mean, 46.7; SD, 25.9).
Realistic expectations	N/A	N/A	They reported the % of patients who answered correctly their risk category. Immediately post-intervention, they found a significant difference in the proportion of patients that understood their risk without medication between the intervention arm (69%) and controls (35%). Also, more people understood their post-treatment risk reduction in the decision aid arm (79%) than the controls (30%).	They reported the % of patients who answered correctly their risk category. Immediately post-intervention, they found a significant difference in the proportion of patients that understood their risk without medication between the intervention arm (49%) and controls (43%). Also, more people understood their post-treatment risk reduction in the decision aid arm (28%) than the controls (16%).	N/A	They used a 5-item questionnaire and reported % of correct answers. Immediately post-intervention, they found a significant difference in overall knowledge (mean, 56.3; SD, 26.6) compared to baseline (mean, 17.5; SD, 16.7).
Involvement in decision making	N/A	N/A	They used the validated tool OPTION score. During the encounter, they found significantly higher involvement in the decision aid arm (mean, 57; SD, 3.5) than controls (mean, 43; SD, 3).	They used the validated tool OPTION score. During the encounter, they found significantly higher involvement in the decision aid arm (median, 48; IQR, 81) than controls (median, 27; IQR, 73).	N/A	N/A

Quality of life	N/A	N/A	Measured at 6 months. They used the validated tool EURO QOL5d Health Thermometer. At 6 months, they did not observe any difference between the decision aid arm (median, 85; IQR, 15) and controls (median, 85; IQR, 17).	N/A	N/A	N/A
Preparation for SDM	N/A	They used the Preparation for Decision-Making validated scale. Immediately post-intervention, they found a significant difference between subjects in the decision aid arm (mean, 68.1; SD, 23.4) and controls (mean, 39; SD, 29.4).	N/A	N/A	N/A	N/A
Shared decision-making	N/A	They adapted 4 binary items from the DECISIONS study (assessed patient perceptions of any follow-up discussions with a primary care physician, including whether the subject was provided with alternative treatment options, discussed reasons for and against taking medication, and was asked what she wanted to do regarding treatment). At 3 months, not statistically significant difference between those in the decision aid arm (mean, 3.19; SD, 1.2) compared to controls (mean, 2.9; SD, 1.3).	N/A	N/A	N/A	N/A

Supplementary Table 1. Search strategy

Ovid

Database(s): PsycINFO 1806 to January Week 4 2019, EBM Reviews - Cochrane Central Register of Controlled Trials December 2018, EBM Reviews - Cochrane Database of Systematic Reviews 2005 to January 30, 2019, Embase 1974 to 2019 February 04, Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily 1946 to February 04, 2019

Search Strategy:

#	Searches	Results
1	exp Osteoporosis/	176948
2	("age-related bone loss*" or osteoporoses or osteoporosis or osteoporotic* or "pathologic decalcification*").ti,ab,hw,kw.	244588
3	1 or 2	244842
4	*Decision Making, Computer-Assisted/	10437
5	*Decision Support Techniques/	18858
6	*Decision Support Systems, Clinical/	5939
7	*decision support system/	12343
8	*patient decision making/	1996
9	(((decision* or decid*) adj2 (support* or aid* or tool* or instrument* or technolog* or technique* or system* or program* or algorithm* or process* or method* or intervention* or material*)) or (decision adj2 (board* or guide* or counseling)) or "adaptive conjoint analys*" or "decision making").ti,ab,hw,kw.	775951
10	4 or 5 or 6 or 7 or 8 or 9	775951
11	3 and 10	2994
12	limit 11 to english language [Limit not valid in CDSR; records were retained]	2793
13	limit 12 to yr="2000 -Current"	2570
14	remove duplicates from 13	2038

Scopus

1	TITLE-ABS-KEY("age-related bone loss*" or osteoporoses or osteoporosis or osteoporotic* or "pathologic decalcification*")
2	TITLE-ABS-KEY(((decision* or decid*) W/2 (support* or aid* or tool* or instrument* or technolog* or technique* or system* or program* or algorithm* or process* or method* or intervention* or material*)) or (decision W/2 (board* or guide* or counseling)) or "adaptive conjoint analys*" or "decision making")
3	PUBYEAR AFT 1999 AND LANGUAGE(english)
4	1 and 2 and 3
5	INDEX(embase) OR INDEX(medline) OR PMID(0* OR 1* OR 2* OR 3* OR 4* OR 5* OR 6* OR 7* OR 8* OR 9*)
6	4 and not 5

Web of Science

1	**TOPIC:** (("age-related bone loss*" or osteoporoses or osteoporosis or osteoporotic* or "pathologic decalcification*")) *AND* **TOPIC:** ((((decision* or decid*) NEAR/2 (support* or aid* or tool* or instrument* or technolog* or technique* or system* or program* or algorithm* or process* or method* or intervention* or material*)) or (decision NEAR/2 (board* or guide* or counseling)) or "adaptive conjoint analys*" or "decision making")) *AND* **LANGUAGE:** (English) Indexes=SCI-EXPANDED, ESCI Timespan=2000-2019
2	PMID=(0* or 1* or 2* or 3* or 4* or 5* or 6* or 7* or 8* or 9*)
3	1 NOT 2

Supplementary Table 2. IPDAS criteria used

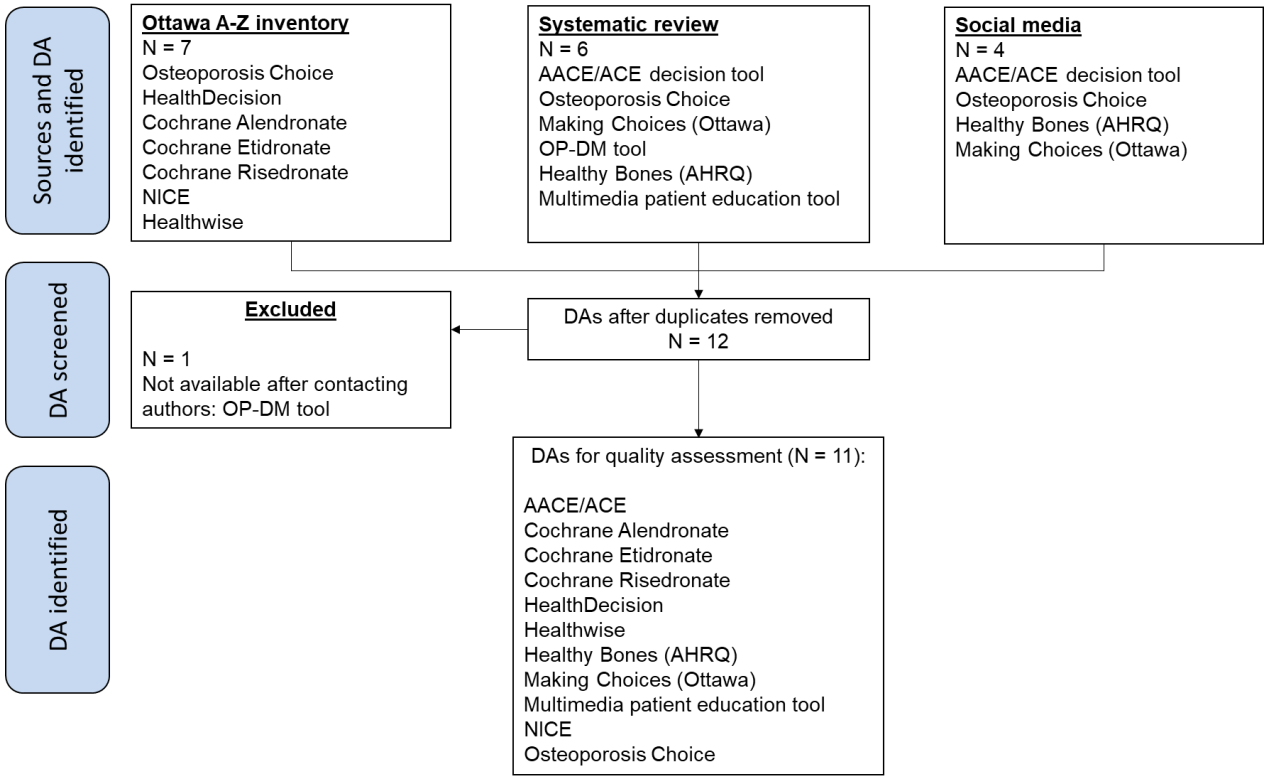
Item Dimension	Criteria	Type of criteria (qualifying, certification or quality)
Information	The patient decision aid describes the health condition or problem (treatment, procedure, or investigation) for which the index decision is required.	Qualifying
	The patient decision aid shows the negative and positive features of options with equal detail (e.g., using similar fonts, sequence, presentation of statistical information).	Certification
	The patient decision aid describes the natural course of the health condition or problem, if no action is taken (when appropriate).	Quality
	The patient decision aid explicitly states the decision that needs to be considered (index decision).	Qualifying
	The patient decision aid makes it possible to compare the positive and negative features of the available options.	Quality
	The patient decision aid describes the options available for the index decision.	Qualifying
	The patient decision aid describes the positive features (benefits or advantages) of each option.	Qualifying
	The patient decision aid describes the negative features (harms, side effects, or disadvantages) of each option.	Qualifying
Probabilities	The patient decision aid provides information about outcome probabilities associated with the options (i.e., the likely consequences of decisions).	Quality
	The patient decision aid specifies the defined group (reference class) of patients for whom the outcome probabilities apply.	Quality

	The patient decision aid specifies the event rates for the outcome probabilities.	Quality
	The patient decision aid allows the user to compare outcome probabilities across options using the same time period (when feasible).	Quality
	The patient decision aid allows the user to compare outcome probabilities across options using the same denominator.	Quality
	The patient decision aid provides more than 1 way of viewing the probabilities (e.g., words, numbers, and diagrams).	Quality
Values	The patient decision aid describes what it is like to experience the consequences of the options (e.g., physical, psychological, social).	Qualifying
	The patient decision aid asks patients to think about which positive and negative features of the options matter most to them (implicitly or explicitly).	Quality
Guidance	The patient decision aid provides a step-by-step way to make a decision.	Quality
	The patient decision aid includes tools like worksheets or lists of questions to use when discussing options with a practitioner.	Quality
Development	The development process included a needs assessment with clients or patients.	Quality
	The development process included a needs assessment with health professionals.	Quality
	The development process included review by clients/patients not involved in producing the decision support intervention.	Quality
	The development process included review by professionals not involved in producing the decision support intervention.	Quality

	The patient decision aid was field tested with patients who were facing the decision.	Quality
	The patient decision aid was field tested with practitioners who counsel patients who face the decision.	Quality
Evidence	The patient decision aid (or associated documentation) provides citations to the evidence selected.	Certification
	The patient decision aid (or associated documentation) describes how research evidence was selected or synthesized.	Quality
	The patient decision aid (or associated documentation) provides a production or publication date.	Certification
	The patient decision aid (or associated documentation) describes the quality of the research evidence used.	Quality
	The patient decision aid (or associated documentation) provides information about the update policy.	Certification
	The patient decision aid provides information about the levels of uncertainty around event or outcome probabilities (e.g., by giving a range or by using phases such as ‘‘our best estimate is...’’).	Certification
Disclosure	The patient decision aid (or associated documentation) provides information about the funding source used for development.	Certification
	The patient decision aid includes authors’/developers’ credentials or qualifications.	Quality
Plain Language	The patient decision aid (or associated documentation) reports readability levels (using 1 or more of the available scales).	Quality
Evaluation	There is evidence that the patient decision aid improves the match between the preferences of the informed patient and the option that is chosen.	Quality

There is evidence that the patient decision aid helps patients improve their knowledge about options' features.	Quality

Supplementary Figure 1. Identification of DAs in environmental scan



Supplementary Table 3. Characteristics of included decision aids

Decision aid	Availability and intended use	Target population~~Population~~	Nature of options, and risks and benefits described	Methods of displaying risks and benefits
Multimedia patient education tool	Freely available multimedia video and information leaflet. Video included: an overview of osteoporosis; description of the treatment options, including the harms/risks and benefits. Patient testimonials were included throughout. Evaluated for use in outpatients but designed to be read alone	Post-menopausal women over 50 years old with a diagnosis of osteoporosis or osteopenia	Risk of osteoporotic fracture with/ without treatment was not provided. Benefits and side effects of bisphosphonates (alendronate, ibandronate, risedronate, zoledronic acid), denosumab, hormones (estrogen, estrogen plus progestin, calcitonin, teriparatide), and raloxifene described.	Effect of each drug on fracture risk reduction at 'spine' and 'hip and other bones' expressed by tick (evidence that the drug can prevent fracture) or question mark (unknown). Side effects described.
Osteoporosis Choice (Mayo clinic).	Freely available interactive (dynamic) website. Final results can be printed or emailed. Intended for use during the clinical encounter with a clinician. Details about fracture risk are entered.	Adults aged 45-95 years.	Risk of osteoporotic fracture with and without bisphosphonates and side effects of bisphosphonates.	Two Cates plots (100 people "like you") demonstrate fracture risk for those who take and those who do not take bisphosphonates. Side effects are textually presented using denominators of 4 and 10,000.
HealthDecision Osteoporosis Shared Decision-Making Tool.	Freely available interactive (dynamic) website. Final results can be copied and pasted into a word processor for printing. States best used by patients and clinicians together. Details about fracture risk are entered.	Adults aged 40-90 years.	Risk of osteoporotic fracture with and without bisphosphonates (alendronate, risdedronate, zoledronic acid) and side effects of bisphosphonates.	A risk summary of major fracture and hip fracture is presented as a percentage over ten years. Cates plots (100, 1000 or 10000 people "like you") demonstrate fracture risk for those who take and those who do not take bisphosphonates. Fracture risk is separated by type (hip or - wrist, upper arm and spine) within the same Cates plots. Side effects are presented within the same cates plots.
Cochrane Musculoskeletal Decision Aids for alendronate (Fosfomax), etidronate (Didronel) and risedronate (Actonel).	Freely available online as a PDF that can be downloaded and printed. States 'a DA to discuss options with your doctor'. Includes sections to complete about values, decisions and knowledge.	Post-menopausal women with a diagnosis of osteoporosis, osteopenia or low bone density that have sustained a recent fracture.	Risk of osteoporotic fracture with and without bisphosphonates (alendronate, etidronate and risedronate) and side effects of bisphosphonates.	Two Cates plots (100 women) showing 'best estimate' hip fracture risk with a placebo drug and with a bisphosphonate. Two Cates plots (100 women) showing the number of people who stop treatment due to the side effects of bisphosphonate and with a placebo drug. Serious harms are presented textually using denominators of 10,000. A grading system is used to grade the accuracy of the estimates.

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NICE bisphosphonate for treating osteoporosis patient decision aid.	Freely available online as a PDF that can be downloaded and printed. States the DA will help clinicians explain the pros and cons.	Women aged 65 and over, men aged 75 and over, and other people who could be at higher risk of fractures.	Risk of osteoporotic fracture with and without bisphosphonates and side effects of bisphosphonates.	Three Cates plots (100 individuals) represent the risk of spinal fracture with and without bisphosphonates for a baseline fracture risk of 10, 20 and 30%. Three Cates plots (100 individuals) represent the risk of hip fracture with and without bisphosphonates for a baseline fracture risk of 10, 20 and 30%. Side effects are presented textually as "common", "less common but serious", "rare", "very rare" and using a denominator of 100.
Healthwise Osteoporosis: Should I Take Bisphosphonate Medicines?	Freely available interactive (dynamic) website. Final results can be printed. States the 'information will help you understand what your choices are so that you can talk to your doctor about them'. Includes sections to complete about values, decisions and knowledge.	Post-menopausal women.	Risk of osteoporotic fracture with and without bisphosphonates and side effects of bisphosphonates (mentions alendronate, risedronate, ibandronate and zoledronic acid).	The DA indicates that the FRAX tool may be used to predict fracture risk and explains bisphosphonates lower fracture risk. Risk of rare side effects are presented using a denominator of 1000. No visual displays of fracture risk or harms
AACE/ACE Osteoporosis Treatment Decision Tool.	Freely available online as a PDF that can be downloaded and printed. Includes sections to complete about fracture risk No information about intended use.	Not clearly specified.	Risk of osteoporotic fracture described as low medium or high. Side effects and efficacy of bisphosphonates (alendronate, risedronate, ibandronate, zoledronic acid), denosumab, raloxifene, calcitonin, teriparatide, calcium, vitamin D and exercise described.	Efficacy of drugs expressed using a "tick" based system. Five ticks represent maximum efficacy. The tool uses a bar chart to present an example of the 10-year fracture risk (with and without treatment) for an eighty-year-old with a T score of -3.0, maternal history of hip fracture and a history of previous fracture. Extremely rare side effects are presented using denominators of 10,000 and 100,000.
Healthy Bones (AHRQ)	No longer available. Originally designed to be embedded in patient record and used with clinician. Screenshot in associated paper used for quality assessment	Unknown	Side effects and efficacy of bisphosphonates (alendronate, risedronate, ibandronate, zoledronic acid), denosumab, raloxifene and teriparatide described.	Effect of each drug on fracture risk reduction at hip, back and other sites expressed by tick (some protection), cross (no protection) or unknown.
Making Choices (Ottawa)	No longer available. Originally paper based decision aid accompanied by patient booklet.	Post-menopausal women with osteoporosis	Risk of osteoporotic fracture with and without bisphosphonates (alendronate and etidronate), hormones and raloxifene.	Three Cates plots (100 individuals) represent low, medium or high risk of spinal fracture at baseline. Text describes number of women with fewer broken hips if they are low/medium or high risk over a lifetime. Side effects described (no frequencies).

Supplementary Table 4. Summary of public contributor discussion relating to each decision aid

Decision aid	Ease of Understanding	Information about harms	Helpfulness	Implications for new DA/research
Osteoporosis Choice (Mayo Clinic)	Attractive layout Vertical layout of images in Cates plot preferred Seemed easy to understand	Information (side effects) on abdominal problems not consistent with other resources	Does not help prioritize values Does help understand treatment benefit	Provides a useful model of displaying risk A new DA needs more information on treatment benefit
HealthDecision Osteoporosis Shared Decision-Making Tool	The colors were not considered appealing Too much information on each plot	Only tool to visualize risk of common side effects and rare harms Side effect information not believable about gastrointestinal side effects (too few) and not understandable as about placebo rather than drug itself	Too complicated to make sense of The Cates plots of 10,000 deemed the most potentially helpful (due to inclusion of rare harms) – but information too small to see	Useful to visualize harms and benefits together, but alternative methods of displaying this need to be explored
NICE bisphosphonate for treating osteoporosis patient decision aid[a]	Caused apprehension Implies the drugs don't work Difficult to understand due to complicated terms and cates plots not interpretable Felt it was written for health professional rather than patient	Text description of side effects clear	Unclear how should be used Doesn't help to understand purpose of drug Too complicated to make sense of Not practical for use in the consultation	DAs need to demonstrate individual rather than 'average' fracture risk

Cochrane Decision Aid for alendronate	Some language perceived as confusing – e.g. 'by chance', but generally simple language	Cates plots for common side effects Compared side effects with placebo (although some found this confusing)	Long, not suitable for consultation Section to check knowledge liked by some, while others found it patronizing	Comparing outcomes in treatment vs placebo is confusing for some

[a] Note NICE DA updated between public contributor discussion and IPDAS rating – comments relate to version 1