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Review

Evaluating the content and development of decision aid tools for the management of menopause: A scoping review

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ABSTRACT

Objective: Decision-making during menopause (especially surgical menopause) can be complex given the variability in risk–benefit perceptions of menopausal treatments. Decision aid tools (DATs) help women participate in decision-making about options. Our objective is to identify and evaluate the content and development of DATs for managing menopause, with a special focus on surgical menopause.

Methods: We systematically searched electronic databases, including MEDLINE and EMBASE, from inception to March 2017 for relevant records. The principal inclusion criterion was that papers reported studies on DATs for managing menopause. Search terms were derived from two concepts: menopause and DATs. Data extracted were presented in written evidence tables and narrative summaries.

Results: Our search yielded 18,801 records. Of these, 26 records met our inclusion criteria, which gave rise to 12 DATs from peer-reviewed literature and 6 from grey literature. Seventeen DATs were focused on natural menopause and two targeted surgical menopause, both identified from grey literature. More than half were published before the Women's Health Initiative (WHI) publication and 70% before the release of the International Patient Decision Aid Standards (IPDAS). Very few studies reported the full development of the DAT involved, and less than half of DATs were informed by a needs assessment to identify the decisional needs of their target population. Most DATs focused on hormone therapy as a treatment option and did not provide a comprehensive overview of other options. None of the DATs reported the steps involved in finding, appraising and summarizing scientific content of the tool.

Conclusion: This review highlights several limitations in the content and development of DATs for managing menopause. No peer-reviewed DATs were identified for surgical menopause. A need for a complete, evidence-based DAT in the context of surgical menopause is identified.

1. Introduction

Decision-making at menopause can be complex given the variability in the risk-benefit perceptions of treatment options, such as hormone therapy (HT). The use of HT declined dramatically after the initial publication of the Women's Health Initiative (WHI) Estrogen-Progestin (EPT) trial showed an increased risk of coronary heart diseases (CHD), stroke, venous thromboembolism (VTE) and breast cancer with HT and raised concerns over its safety [1,2]. As participants in the WHI on average were in their 60 s and were not symptomatic, the same risks may not apply to younger symptomatic women [3]. Other treatment options are available for managing menopausal symptoms, however HT is the most effective treatment. In light of the controversy with HT, menopausal women are often challenged by the value-laden nature of the decision to manage their menopausal symptoms. Women who go through early surgical menopause (≤45 years) are specifically challenged as they may experience severe symptoms associated with the abrupt decline in hormones and may have long-term health sequelae.

Decision aid tools (DATs) are patient-targeted interventions to help patients facing value-laden decisions. DATs are shown to be superior to standard measures in improving patients' knowledge, expectations about treatment outcomes, decision quality, shared decision-making, and decisional conflict [4–6]. DATs support shared decision-making and informed, value-based decisions when developed based on a

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recognized quality criteria and valid evidence sources [7,8]. On the contrary, poorly developed DATs have the potential to cause harm and are less likely to advocate shared decision-making [9]. The International Patient Decision Aid Standards (IPDAS) provides a framework of evidence-based quality criteria that serves as a reference for developing and/or evaluating the quality of DATs [7].

In 2011, a systematic review of the effect of menopausal symptoms management decision aids reported several DATs created for managing menopause [10]. None of these DATs targeted surgical menopause. This review highlighted several inadequacies of identified DATs mostly related to the lack of completeness and currency of evidence on presented options [11–26]. However, this review did not include the grey literature, and focused only on trials evaluating the effectiveness of DATs in menopause. We decided to undertake a scoping review which would allow us to broadly examine the extent, range and nature of research activity associated with the development of DATs for menopause to identify gaps in existing literature, with no restrictions on the type and source of studies that can be incorporated (e.g. both peer-reviewed and grey literature) as opposed to a systematic review. The objectives of our scoping review were to identify and evaluate the development and content of DATs used for managing menopause in the published and unpublished literature, and specifically in the context of surgical menopause.

2. Methods

We conducted a scoping review based on the stages proposed by Arksey and O'Malley for performing scoping reviews [27]. The systematic approach involved in identifying, extracting and summarizing relevant scientific evidence in scoping reviews reduces the risk of introducing bias during any of these steps.

2.1. Eligibility criteria

Studies on the development and evaluation of DATs for managing natural or surgical menopause, with no restriction to the target population of women or treatment modalities discussed in the DAT were eligible for inclusion. Unpublished DATs for managing menopause, found in the grey literature also qualified for inclusion. We excluded: review papers; studies on DATs created for conditions other than menopause management; studies on determinants or predictors of decisions; and studies published in languages other than English.

2.2. Data sources

A systematic literature search was conducted by a librarian (TC) to identify all relevant published and unpublished studies. We searched electronic bibliographic databases including: Ovid MEDLINE (1946 to March 2017), Ovid EMBASE (1974 to March 2017), CINAHL (inception to March 2017), Ovid PsycINFO(1806 to March 2017), and HAPI (1985 to October 2015), to identify studies reporting the development of DATs for managing surgical or natural menopause (Additional file 1). Grey literature searches were conducted in SCOPUS, ProQuest Dissertations and Theses, and Google web from inception to March 2017. Search terms were searched as MeSH headings or keywords and were derived from two main concepts: menopause and DATs. We hand searched reference lists of relevant review papers and relevant articles for additional studies. We limited our search to English language and human.

2.3. Selection process

Search results from relevant sources were exported to one Refworks account and close duplicates were removed. Eligibility screening was completed independently by two reviewers (HS and LM) and disagreements were resolved by a third investigator (TS). Titles and abstracts were initially screened, followed by full-text review of articles to confirm eligibility.

2.4. Data extraction and synthesis

Data extraction was completed by two independent reviewers (HS and LM) and discrepancies were resolved by a third reviewer (TS). Data extracted included: manuscript characteristics, population characteristics, DAT characteristics and data on DATs content and development evaluation in reference to the IPDAS quality checklist [7]. We chose the IPDAS checklist as a judging criteria because it is comprehensive, evidence-based and developed by an international collaboration of experts in the field of DATs. IPDAS has also been used as a quality reference in several systematic reviews [28,29] and is currently embraced as a DAT evaluation criteria by the Ottawa Health Research Institute (OHRI). The OHRI aims at educating the public about DATs and promotes their use in different health decision contexts [30]. The IPDAS criteria address three dimensions of quality: content, development and effectiveness. Since DAT effectiveness was previously addessed by Carpenter et al., our scoping review focuses on the content and development dimensions [10]. Each DAT was evaluated with respect to four content quality criteria including: 1) provides information about options in sufficient detail for decision making; 2) presents probabilities of outcomes in an unbiased and understandable way; 3) includes methods for clarifying and expressing values; and 4) includes structured guidance in deliberation and communication. Development was evaluated with respect to five development quality criteria: 1) presents information in a balanced manner; 2) has a systematic development process; 3) includes up to date scientific evidence that is cited in a reference section or technical document; 4) discloses conflicts of interest; and 5) uses plain language. Descriptive analysis was used to describe the evaluation of the content and development of DATs. Peer-reviewed and grey literature were discussed separately. To determine the qualifying and certifying potential of identified DATs we screened them against features of qualification and certification as proposed by Joseph-Williams et al. [30]. The proposed "qualifying" criteria for an intervention to qualify as a decision aid [31] included: describes health condition or problem for which index decision is required; explicitly states decision under consideration; describes the options available for the index decision; and describes the positive and negative features of each option. Additionally the following DAT "certified" criteria were proposed to prevent harm to a patient: shows the negative and positive features of options in equal detail; provides citations to the evidence selected; provides a production/publication date; provides an update policy; provides information about the levels of uncertainty around event or outcome probabilities; and provides the funding source used for development. Each DAT must meet all of the proposed criteria to be classified as "qualified" and "certified".

3. Results

The results of our search and screening process are included in Fig. 1. Our search yielded 18,801 records, of which 44 full-text records were retrieved and assessed for eligibility. Of these, 26 were included in the review. Twenty articles were located in the peer-reviewed literature which discussed 12 unique DATs. The remaining 6 records were found in the grey literature each representing a unique DAT.

Table 1A lists the main characteristics of peer-reviewed articles discussing DATs for managing menopause. Articles were mainly from the US (55%), and Canada (40%). The majority were evaluation studies (85%), of which 88% were randomized controlled trials (RCTs). Only 3 of the studies were on DAT development and included data on evaluation [14,32,33]. Over 50% were published before the WHI publication, and 70% published before the release of IPDAS. All studies focused on natural menopause. One study targeted menopausal women with disabilities [19]. The age range of women across studies was 40–75 years and the mean sample size was 177 (range 24–463)

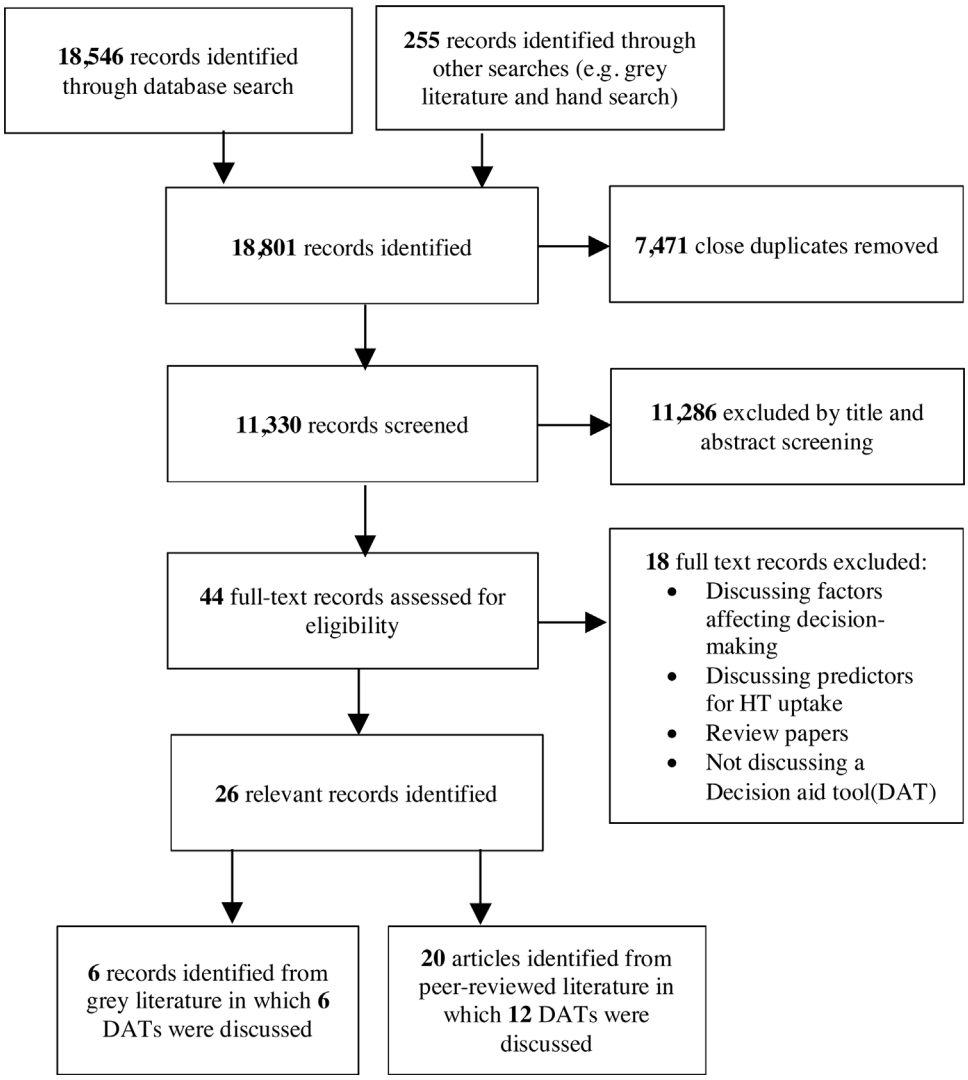

Fig. 1. Flow Chart of result of search results and screening for inclusion.

(Table 1B).

3.1. DATs characteristics

Characteristics of peer-reviewed and grey literature DATs are summarized in Tables 2A and B, respectively. Twelve unique DATs were identified from the peer-reviewed literature. None targeted women with surgical menopause. All DATs were patient-targeted interventions for women who had natural peri- or post menopause. The majority were developed to be administered before consultation with a health care provider (75%). Close to 60% were computer/web-based interventions, and 42% were paper-based. Most DATs discussed only HT as a treatment option (83%), and half were informed by the Ottawa Decision Support Framework (ODSF).

Six DATs were found in grey literature [34–39]. Of these, four were developed for natural menopause, one for both natural and surgical menopause [39], and one for surgical menopause only [37]. All 6 DATs targeted patients, and four were developed for prior consultation use [35–38]. All DATs were web/computer or smart-phone-based. All DATs in the grey literature were developed post-WHI and IPDAS except one [38]. Four of the DATs focused primarily on HT as a treatment modality.

3.2. DAT content evaluation

Table 3A describes the results of DATs' content evaluation.

Peer-reviewed DATs met most items listed under the quality criterion for "providing information in sufficient details for decision-making", yet only one-third included the option of doing nothing [12,18,22,26]. Only a few DATs met several aspects of the criterion about "presenting probabilities of outcomes in an unbiased and understandable way" [20,22,25,26]. In the criterion for "methods for clarifying and expressing values," less than half described the procedures & outcomes to help patients imagine the physical, emotional and social effects of the option for values clarification [14,17,20,25,26]. The criterion for "structured guidance in deliberation and communication" included very few DATs that explicitly presented the steps involved to make a therapy decision to support guidance in deliberation (17%) [12,14].

On a similar note, most DATs found in the grey-literature met several items under criteria for "providing information in sufficient details for decision-making", "methods for clarifying and expressing values" and "structured guidance in deliberation and communication". Yet, almost all failed to report many items for "presenting probabilities of outcomes" [35–37,39].

Table 1A
Manuscript Characteristics (Peer-reviewed articles).

Manuscript Characteristic	N (%) (N = 20)
Year of Publication	
1995–1999	4 (20%)
2000–2004	8 (40%)
2005–2009	7 (35%)
2010–2014	1 (5%)
Country of origin	
USA	11 (55%)
Canada	8 (40%)
UK	1 (5%)
Setting of recruitment	
Community-based	6 (30%)
Clinic Based	10 (50%)
Both	4 (20%)
Study design	
Development & evaluation	3(15%)
Qualitative (Focus groups)	2 (67%)
Decision analysis model	1 (33%)
Evaluation only	17 (85%)
RCT	15 (88%)
Other (e.g. pre-post)	2 (12%)
Timing of study relative to WHI	
Before	11 (55%)
During/After	5 (25%)
Unknown	4 (20%)
Timing of study relative to IPDAS	
Before	14 (70%)
After	3 (15%)
Unknown	3 (15%)

Table 1B
Population Characteristics (Peer-reviewed articles).

Population Characteristic	N (%) or mean (N = 20)
Age Range	40–75 years
Average Sample size	177 (Range 24–463)
Type of menopause	
Natural (Peri and/or post)	19 (95%)
Natural and surgical	1 (5%)
Special population	
Mobile disability	1(5%)

3.3. DAT development evaluation

Table 3B summarizes the results of DATs' development evaluation

For peer-reviewed DATs, only 3 reported the full development process of the corresponding DAT [14,32,33]. Less than half of DATs performed a needs assessment to identify the decisional needs of their target population and their health providers [12,14,20,22,25]. Only one DAT was field tested with practitioners [15]. None of the DATs reported the steps involved in finding, appraising and summarizing the scientific evidence included in DAT. Similarly, none reported how often the tool is updated.

Several quality features of development were lacking in DATs found in the grey literature. For example, all DATs failed to report steps for finding and appraising scientific data, and evidence on needs assessments and field-testing were lacking for all identified DATs.

3.4. Qualification and certification standards of DATs from grey literature

Table 4 summarizes the results of DATs screening for qualification and certification. Of the 6 available DATs, only 3 met all qualification standards and therefore were classified as "qualified" DATs. However, none of the DATs were considered "certified" and fully met the proposed certification criteria. It's important to note that only 6 DAT's were available for us to evaluate and these were all from grey literature. None of the DATs from the peer review literature were available for

Table 2A
DAT Characteristics (Peer-reviewed literature).

DAT Characteristic	N (%) N = 12
Target population	
Patient	11(92%)
Patient and clinician	1 (8%)
Nature of DAT	
Paper based/paper + audio	5 (42%)
computer-based/web-based	7 (58%)
Decision coach with aid	1 (8%)
Treatment modality presented	
HT	10 (83%)
HT and other available menopausal treatments	1 (8%)
Natural health products	1 (8%)
Timing of administration	
Prior to consultation	9 (75%)
Prior and during consultation	3 (25%)
Theoretical framework informing development[a]	
Ottawa decision support framework (ODSF)	6 (50%)
Decision analysis risk model (e.g. Markov model and MAU model)	4 (33%)
International patient decision-aid standards (IPDAS)	1 (8%)
Comprehensive Health Enhancement Support System (CHESS)	1 (8%)
Foundation for Informed Medical Decision Making	1 (8%)

[a] An aid can have more than 1 informing theory, hence proportions do not add up to 100%).

Table 2B
DAT characteristics (Grey Literature).

DAT Characteristic	N (%) N = 6
Type of menopause targeted	
Natural	4 (67%)
Natural and surgical	1 (17%)
Surgical only	1 (17%)
Timing of DAT update relative to WHI	
Post	5 (83%)
Pre	1 (17%)
Timing of DAT update relative to IPDAS	
Post	5 (83%)
Pre	1(17%)
Target population	
Patient	5 (83%)
Patient and clinician	1 (17%)
Nature of DAT	
Web-based	4 (67%)
Tablet/mobile application	1 (17%)
Video-based	1 (17%)
Treatment modality presented	
HT	4 (67%)
HT and other available menopausal treatments	2 (33%)
Timing of administration	
Prior to consultation	4 (67%)
Prior and during consultation	2 (33%)
Theoretical framework informing development[a]	
Ottawa decision support framework (ODSF)	2 (33%)
International patient decision-aid standards (IPDAS)	2 (33%)
Foundation of informed decision-making (FIDM)	1 (17%)

[a] An aid can have more than 1 informing theory, hence proportions do not add up to 100%.

Table 3A
DAT content evaluation based on IPDAS quality criteria.

Content Criterion	N(%) N = 12 (Peer-reviewed)	N(%) N = 6 (Grey-literature)
Provide information about options in sufficient detail for decision making		
Describes the condition	9 (75%)	5 (83%)
List the treatment options	12 (100%)	6 (100%)
List the option of doing nothing	4 (33%)	4 (67%)
Describes the natural course	8 (67%)	5 (83%)
Describes positive features	11 (92%)	6 (100%)
Describes negative features	12 (100%)	6 (100%)
Include chances of positive and negative outcomes	7 (58%)	2 (33%)
Present probabilities of outcomes in an unbiased and understandable way		
Use event rates specifying the population & time period	4 (33%)	2 (33%)
Compare outcome probability using the same denominator & time period	4 (33%)	2 (33%)
Describe uncertainty around probabilities	4 (33%)	0 (0%)
Use visual diagrams	7 (58%)	2 (33%)
Use multiple methods to view probabilities	5 (42%)	2 (33%)
Allow a patient to select a way of viewing probabilities	3 (25%)	1 (17%)
Allow a patient to view probabilities based on their own situation	9 (75%)	0 (0%)
Place probabilities in context of other events	8 (67%)	3 (50%)
Use both positive and negative frames	5 (42%)	2 (33%)
Include methods for clarifying and expressing values		
Describe the procedures & outcomes to help patients	5 (42%)	4 (67%)
Ask patient to consider which positive or negative features matter most	8 (67%)	5 (83%)
Suggest ways for patients to share what matters most with others	8 (67%)	4 (67%)
Include structured guidance in deliberation and communication		
Provide steps to make a decision	2 (17%)	2 (33%)
Suggest ways to talk about the decision with a health professional	7 (58%)	6 (100%)
Include tools [worksheet, question list] to discuss options with others	10 (83%)	4 (67%)

Table 3B
DAT development evaluation based on IPDAS quality criteria.

Development Criterion	N(%) N = 12 (Peer-reviewed)	N(%) N = 6 (Grey-literature)
Present information in a balanced manner		
Able to compare positive or negative features of options	8 (67%)	6 (100%)
Shows negative/positive features with equal detail	1 (8%)	4 (67%)
Have a systematic development process		
Include developers' credentials or qualifications	12 (100%)	5 (83%)
Finds out what users need to discuss options	5 (42%)	0 (0%)
Peer reviewed by patients and experts in the field	9 (75%)	3 (50%)
Field tested with users (patients and/or practitioners)	12 (100%)	0 (0%)
Use up to date scientific evidence that is cited in a reference section or technical document		
Provides references to evidence used	6 (50%)	5 (83%)
Report steps to find, appraise, summarize evidence	0 (0%)	0 (0%)
Report date of last update	1 (8%)	4 (67%)
Report how often patient decision aid is updated	0 (0%)	2 (33%)
Describe the quality of scientific evidence	2 (17%)	1 (17%)
Uses evidence from studies of patients similar to those of target audience	5 (42%)	4 (67%)
Disclose conflicts of interest		
Report source of funding to develop and distribute the patient decision aid	10 (83%)	3 (50%)
Report whether authors of decision aid stand to gain or lose by choices made by patients using decision aid tool	4 (33%)	5 (83%)
Use plain language		
Written at a level that can be understood by majority of patients	7 (58%)	5 (83%)
Written at grade 8 equivalent or less	6 (50%)	0 (0%)
Provide ways to help patients understand information other than reading	7 (58%)	1 (17%)

review, as these were not published with the development or evaluation trials.

3.5. Effectiveness trials of DATs

The most common study design for assessing the effectiveness of DATs was an RCT (88%). Prevalent outcomes captured in these peer-reviewed evaluation studies include: decisional conflict (68%), knowledge (58%), decisional satisfaction (52%), accuracy of risk expectations (32%), DAT acceptability (16%) and decisional confidence (16%). The efficacy of DATs in terms of improving these decisional outcomes varied across studies. Many showed significant improvements from baseline with respect to several decisional outcomes. However, fewer showed significant improvements when compared to alternative procedures (e.g. standard care). Evaluating the effectiveness of DATs was beyond the scope of this review.

4. Discussion

We report that among the 18 DATs identified from the peer-reviewed and grey literature, only one DAT focused on surgical menopause and one targeted natural and surgical menopause. Both of these DATs were found in the grey literature [37]. Overall, the highest quality criteria for DATs was in content evaluation such as providing information about HT and menopause and including explicit methods for values clarification. Yet, several limitations were identified. Very few studies reported the full development of the DAT involved, and less than half of DATs were informed by a needs assessment to identify the decisional needs of their target population. Most DATs primarily focused on HT as a treatment option and did not provide a comprehensive account of all other options. None of the DATs reported the steps involved in finding, appraising and summarizing scientific content of the tool and only two reported how often the DAT is updated [36,37].

DATs for surgical menopause were only found in the grey literature with no published evidence of development and evaluation [37,39]. These DATs lacked several measures of quality related to the presentation of outcome probabilities and/or the quality of scientific evidence informing content. Also, there were no reports that the tools' development was informed by a needs assessment. In terms of qualification and certification, one tool did not qualify as a DAT, and both tools were not "certified" and may potentially pose a risk of harmful bias. While these standards are fairly new and have not been validated, they still suggest that available DATs for surgical menopause may not be adequate for use by patients.

More than half of published DATs were published before the WHI and have not been updated since. These DATs do not reflect recent evidence and recommendations on HT. Even the DATs published after the WHI are now at least 7 years old and may not align with current treatment guidelines. None of the identified DATs reported criteria of updating the DAT and only 1 published DAT reported the date of last update. Another factor to consider is the lack of information on the clinical uptake of these DATs. Despite established benefits of DATs in

Table 4
Results of qualification and certification screening of identified DATs from grey literature.

Dimension	Item		1	2	3	4	5	6	Total number of DATs fulfilling the criterion (N = 6) N(%)
Qualifying Criteria									
Information	1	DAT describes health condition or problem for which index decision is required		x	x	x	x	x	5 (83%)
	2	DAT explicitly states the decision that needs to be considered (index decision)		x	x		x		3 (50%)
	3	DAT describes the options available for the index decision	x	x	x	x	x	x	6 (100%)
	4	DAT describes the positive features (benefits/advantages) of each option	x	x	x	x	x	x	6 (100%)
	5	DAT describes the negative features (harms, side effects, or disadvantages) of each option	x	x	x	x	x	x	6 (100%)
Number of items met			3	5	5	4	5	4	
Certifying criteria									
Information	1	DAT shows the negative and positive features of options in equal detail (using similar fonts, sequence, and representation of statistical information)		x	x		x	x	4 (67%)
Evidence	2	DAT (or associated documentation) provides citations to the evidence selected	x	x	x	x	x		5 (83%)
	3	DAT (or associated documentation) provides a production or a publication date	x					x	2 (33%)
	4	DAT (or associated documentation) provides information about the update policy		x	x				2 (33%)
	5	DAT provides information about the levels of uncertainty around event or outcome probabilities							0 (0%)
Disclosure	6	DAT (or associated documentation) provides information about the funding source used for development		x	x		x		3 (50%)
Number of items met			2	4	4	1	3	2	

1. MenoPro App (NAMS); 2. Menopause: Should I Use Hormone Therapy (HT)? (Healthwise); 3. Hysterectomy and Oophorectomy: Should I Use Estrogen Therapy (ET)? (Healthwise) 4. Interactive decision tree (menopause matters); 5. Hormone therapy: Is it right for you? (Mayo clinic); 6. Impact of a decision aid videotape on young women's attitudes and knowledge about hormone replacement therapy. (Kerner, David).

general including knowledge gains by patients and improvement in the quality of decision and decision-making, it has been shown that DATs are often poorly adopted in clinical settings [40]. In our review, none of the identified reports discussed dissemination and implementation plans to promote clinical utilization. Strategies to implement and evaluate DATs into routine clinical setting should be considered. For example, health providers' knowledge, attitudes and behaviors toward DATs have been identified as barriers to successful implementation in clinical settings [41–43]. One approach to overcome this barrier and improve clinical relevance is to involve health care providers during the DAT development. Additionally, health providers' views and interest in adopting tools into a clinical setting need to be considered.

Similar to the review by Carpenter et al., we found that none of the identified DATs discussed a full range of available menopausal treatment options or resources to allow for an informed value-based treatment decision [11]. Most tools focused only on HT decision making and very few included other available treatment options. Furthermore, many tools did not provide a clear presentation of HT outcome probabilities. To help women make informed preferences and therefore informed decisions, it is important to clearly present them with all valid options and their subsequent risks and benefits. The length, depth and form of information presented should be informed by a needs assessment on the population of choice and their respective health providers.

To our knowledge this is the first scoping review to evaluate the quality of content and development of DATs for managing menopause. Our search strategy was comprehensive and aimed to target both published and unpublished work in the field. We also followed a strict process to reduce the risk of inaccuracy and bias in articles screening, data extraction and evaluation. A few limitations should be noted. Very few studies reported the development of a DAT, therefore most of the data on development was based on what was reported in the evaluation trials which may have not included a detailed account of the tool's development. Since most were developed before the IPDAS the need to transparently disclose the systematic process of the tools' development may not have been recognized. Similarly, many of the DATs from the peer-reviewed literature were inaccessible and therefore certain features, such as disclosure of conflict of interests, developers' credentials or qualifications, and references to evidence used, may not have been accurately captured from supporting documents. However, we were able to evaluate most other features that were included in the published reports. We also limited our search to English language. Findings from our review may have also been affected by publication bias due to the tendency of publishing interventions with significant findings. To reduce the possible influence of publication bias in our study, we searched the grey literature for unpublished work.

5. Conclusion

Our scoping review has identified limitations in the quality of available DATs for menopause that may affect the decisional effectiveness as well as clinical utility of the DAT. This review especially highlighted the lack of DATs addressing the complex decision involved with managing surgical menopause and its long-term implications. Essentially, a tool to help women suffering from symptoms with surgical menopause should be considered.

Contributors

TS was responsible for study concept and design, acquisition of data, analysis and interpretation of data, drafting of the manuscript, critical revision of the manuscript for important intellectual content, statistical analysis, administrative, technical, material support, approval of the final version, and is accountable for accuracy and integrity of the work.

HS was responsible for study conduct, interpretation of data, drafting of the manuscript, critical revision of the manuscript for important intellectual content, approval of the final version, and is accountable for accuracy and integrity of the work.

SR was responsible for study concept and design, interpretation of data, critical revision of the manuscript for important intellectual content, study supervision, approval of the final version, and is accountable for accuracy and integrity of the work.

TC was responsible for study concept, design and conduct, critical revision of the manuscript for intellectual content and approval of the final version.

NY was responsible for study concept and design, acquisition of data, analysis and interpretation of data, drafting of the manuscript, critical revision of the manuscript for important intellectual content, and administrative, technical, material support, study supervision, approval of the final version, and is accountable for accuracy and integrity of the work.

Conflict of interest

All authors declare they have received no support from any organization for the submitted work; and no financial relationships in the previous three years with any organizations that might have an interest in the submitted work. NY has provided continuing education and/or participated in Advisory Boards for Pfizer Canada and Aspen Pharmaceuticals.

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Ethical approval

Ethical approval was not required for the research conducted for this review.

Provenance and peer review

This article has undergone peer review.

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