Development of a web-based decision aid for initiating biological or targeted synthetic disease-modifying antirheumatic drugs (b/tsDMARDs) in axial spondyloarthritis

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ABSTRACT

Objectives To develop a web-based evidence-based decision aid to support shared decision-making in patients with axial spondyloarthritis (axSpA) who face a treatment decision to initiate or switch a biological or targeted synthetic disease modifying antirheumatic drug (b/tsDMARD).

Methods Through an iterative process, we systematically developed a decision aid based on evidence from the literature, explorative needs assessment interviews among patients and care providers, and input from experts of the SpA working group of the Dutch Society for Rheumatology and professionals on patient information employed at the Dutch Arthritis Society. The usability, ease of use and feasibility of the pilot version were tested among stakeholders and feedback was used to adapt the decision aid. Finally, a multifaceted strategy was used to introduce the decision aid in clinical practice.

Results The decision aid consists of (1) consultation support instructions in the context of disease control and treatment needs, (2) an overview of available treatment options for axSpA, (3) detailed information on b/tsDMARDs and an interactive option grid that facilitates comparison of characteristics and (4) a final check supporting patients to deliberate on the decision to initiate or switch a b/tsDMARD. Rheumatologists introduced the decision aid in several Dutch rheumatology settings and the Dutch Arthritis Society posted it on their website, social media and in their monthly newsletter.

Conclusion We developed an evidence-based decision aid to support axSpA patients who face a treatment decision to initiate or switch a b/tsDMARD and introduced this in clinical practice.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Important elements of shared decision-making are that patients are fully informed on their medical situation and that they receive evidence-based information on the expected effect of treatment options on disease outcomes and their personal life.

WHAT THIS STUDY ADDS

⇒ A web-based decision aid for patients with axial spondyloarthritis who face a treatment decision to initiate or switch a biological or targeted-synthetic disease-modifying antirheumatic drug was systematically developed.

⇒ Patients and care providers confirmed the decision aid's usability, ease of use and feasibility for making informed treatment decisions in clinical practice.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This decision aid supports patients and care providers with making shared treatment decisions that are responsive to patients’ needs, preferences and values.

⇒ Future studies should evaluate the overall impact of the decision aid on health outcomes and patient's experiences.

INTRODUCTION

The principle of shared decision-making (SDM) is a key element for providing high quality of care. SDM has been defined as the process of care providers and patients jointly participating in making health decisions. This is grounded in the paradigm that care should be based on the best evidence and should be respectful of, and responsive to, individual patient preferences, needs and values. Applying SDM requires that patients are fully informed on their medical situation and that they receive evidence-based information on the expected effect of treatment options on disease outcomes and their personal life. Patients can be informed on these aspects by paper-based or electronic tools, such as patient information leaflets, health education materials and decision aids. The latter are evidence-based tools designed to support patients in making specific and
deliberated choices among healthcare options and to support patients in communicating their considerations with care providers. According to the International Patient Decision Aids Standards (IPDAS) collaboration, decision aids should specifically state the decision, inform patients about their treatment options and associated benefits and harms, enable comparing treatment options and support patients in identifying personal values. Decision aids can help empower patients to make well-informed personal treatment decisions, thereby potentially increasing long-term satisfaction with the provided care.

A systematic Cochrane review concluded that patients who faced a treatment or screening decision and who used a decision aid, had more knowledge on their options, had increased accuracy of risk perceptions and experienced more agreement between informed values and care choices compared with usual care. In addition, the proportion of patients who were passive in decision-making or who experienced a decisional conflict, related to feeling uninformed, decreased. Moreover, this Cochrane review suggested that the use of decision aids might have a positive effect on the communication between patients and care providers.

For patients with axial spondyloarthritis (axSpA), the overarching principles of the 2022 update of the Assessment of SpondyloArthritis International Society/European Alliance of Associations for Rheumatology recommendations for disease management state that treatment of patients should aim at the best care and must be based on a shared decision between patient and rheumatologists.

In patients with axSpA and persistently high disease activity (despite conventional treatment), the decision-making process for initiating a biological disease-modifying antirheumatic drug (bDMARD) or targeted synthetic DMARD (tsDMARD) has become more complex due to the availability of different drug classes that differ in mode of action, currently including five TNF-inhibitors, two IL-17 inhibitors and two JAK-inhibitors for patients with radiographic axSpA. These b/tsDMARDs have comparable effectiveness for axial manifestations, but differ in individual characteristics, such as the route of administration (subcutaneous, intravenous or oral), frequency of administration (daily, weekly, monthly or every few months), expected effect on extra musculoskeletal manifestations (uveitis, psoriasis, inflammatory bowel disease) and potential adverse effects.

In patients who face a treatment decision on whether and which b/tsDMARD to initiate, the drug characteristics should be balanced to find the best fit with patients’ personal values and preferences as they might require some changes in patients’ lives. For example, patients may need to take time off during working hours to visit a clinic for intravenous drug administration instead of taking tablets daily at home. This balance should be made on starting as well as on switching a drug. Previous studies have shown that patients with RA want to be informed about the characteristics of individual bDMARDs when deciding to initiate a drug. A decision aid could, therefore, be useful to support these patients in the decision-making process.

In 2017, one high-quality web-based decision aid has been developed in the Dutch language to support SDM in patients with inflammatory arthritis who are about to initiate or switch a b/tsDMARD. However, the decision aid was not specifically developed for the axSpA patient population. Consequently, important information on the effectivity of the b/tsDMARDs on extra musculoskeletal manifestations is missing. Furthermore, this decision aid has never been updated and recently approved treatment options are also lacking. The objective of this study is, therefore, to develop a new evidence-based and web-based decision aid, feasible for supporting SDM in patients with axSpA who face a treatment decision to initiate or switch a b/tsDMARD and introduce this in clinical practice.

**METHODS**

A steering group was assembled to refine the scope and setting, to guide the development process and to be responsible for the final decisions. The steering group consisted of a researcher (EB) and two rheumatologists with expertise in SpA. The development process was based on a Dutch guidance document of the Dutch Health Care Institute for the development of patient information and decision aids in accordance with quality standards, and on the internationally accepted process development model of the IPDAS collaboration. The development process comprised five iterative phases: (1) establishing the scope and setting, (2) designing the content by assessment of needs and search of evidence to support these needs, (3) development of a pilot version, (4) pilot testing and (5) introduction in clinical practice and evaluation (figure 1). Throughout the development process, we consulted patients with SpA, professionals on patient information employed at the Dutch Arthritis Society, and 18 expert rheumatologists from the working group SpA of the Dutch Society for Rheumatology. This paper was written in compliance with the Standards for Universal reporting of patient Decision Aid Evaluations (SUNDEA) checklist for decision aid evaluation studies.

**Phase 1: scope and setting**

The scope of the decision aid was to develop a decision aid that supports SDM in patients with axSpA who face a treatment decision to initiate or switch a b/tsDMARD. The intended setting was that the decision aid would be used by patients at home after their outpatient visit in which they discussed to initiate or switch a b/tsDMARD, as this would give patients sufficient time to reflect on their options. Patients would be informed by their rheumatologist on available drugs for their personal current medical situation and would receive a paper-based...
Phase 1 Establishing the scope and setting
By the steering group composed of a researcher, two rheumatologists with expertise on SpA and professionals on patient information employed at the Dutch Arthritis Society

Phase 2 Designing the content
Explorative needs assessment interviews
- Individual interviews with 14 patients with SpA regardless of bDMARD or tsDMARD use
- Group interviews with 12 care-providers
- Recruited at the rheumatology department of the MUMC+

Non-systematic literatures search on evidence to inform content of attributes

Phase 3 Developing the prototype
Technical development, design, testing against readability and hosting performed by the Dutch Arthritis Society

Prototype checked and approved by the working group SpA of the Dutch Society for Rheumatology

Phase 4 Pilot testing
First round pilot testing (alpha testing; usability in test environment)
- Individual interviews with 17 patients with SpA regardless of bDMARD or tsDMARD use
- Individual interviews with 13 care-providers
- Recruited at the rheumatology department of the MUMC+

Second round pilot testing (beta testing; feasibility in clinical practice)
- In 14 patients with axSpA in whom initiating a bDMARD or tsDMARD was considered
- Recruited by the working group SpA in 7 Dutch rheumatology centres

Identified issues were resolved when needed

Phase 5 Introduction in practice and evaluation
Introduction of the final decision aid in practice
- By the researchers to all members of the working group SpA
- By the researchers to rheumatologists in several Dutch rheumatology settings
- By the Dutch Arthritis Society on their webpage, social media and monthly newsletter to patients
- By the Dutch Society for Rheumatology in their monthly newsletter to all members

Evaluation
- Entire development process using the IPDAS instrument

Figure 1 Phases of the development process for the decision aid for patients with axSpA facing a treatment decision to initiate or switch b/tsDMARDs. axSpA, axial spondyloarthritis; bDMARD, biological disease-modifying antirheumatic drug; tsDMARD, targeted synthetic disease-modifying antirheumatic drug.

information card with personalised b/tsDMARDs options and with a link to the website of the decision aid. Subsequently, patients would discuss the results whether or not to initiate a b/tsDMARD and which drug is preferred (if applicable) during their next outpatient visit or telephone consultation. Alternatively, if preferred, this
process could also take place during the outpatient visit together with the care provider.

**Phase 2: designing the content**

**Explorative needs assessment interviews**

The needs and wishes regarding the content and layout of a decision aid were identified in explorative interviews among patients and care providers, including rheumatologists, rheumatology fellows and specialised rheumatology nurses employed at the local rheumatology department. Individual interviews were planned with 15 patients with a clinical diagnosis of SpA who recently (≤2 weeks) discussed with their care provider to initiate a b/tsDMARD, followed by group interviews among ≥10 care providers (see online supplemental file 1 for more details on the methodology).17

In preparation of the interview, a non-systematic literature search was performed in PubMed to identify relevant needs for SDM on initiating b/tsDMARDs in patients with SpA, RA or PsA. Keywords for this search included ‘decision aid’, ‘treatment’ and ‘shared decision-making’. All interviews were performed by one trained and experienced interviewer. The interviews with patients started with a short explanation of patient-centred care and the principles of SDM. Next, the available Dutch web-based decision aid on starting or switching DMARDs in persons with inflammatory arthritis was shown as an example of how such tools can support clinical decision-making (available at http://www.reumanederland.nld/home).13 Further, obtained knowledge from the literature review was used to guide the semistructured interviews (see online supplemental file 2 for the interview guide). Interviews with care providers were organised as a group interview. First, results from the previously performed patient interviews were presented and care providers were asked to reflect on the relevance and feasibility of the discussed wishes. All interviews were analysed using the thematic structure of the interview guide. Finally, all needs and wishes were used for the development of the decision aid.

**Literature search**

Next, a non-systematic literature search was performed to retrieve data necessary to accommodate the needs and wishes identified from the explorative needs assessments. For individual characteristics of b/tsDMARDs, we checked the axSpA treatment guidelines of the Dutch Society for Rheumatology which includes elaborated evidence on the effectiveness and safety of drugs, the European public assessment reports on individual drugs of the European Medicines Agency and the Dutch pharmacotherapeutic database that encompasses independent information on drugs available in the Netherlands.18–21

**Phase 3: development of a pilot version**

Parallel to the development of our decision aid, a web-based information tool was launched by the Dutch Arthritis Society in collaboration with the Dutch Society for Rheumatology, which aimed to prepare patients with RA for making treatment decisions (available at https://reumanederland.nl/formulieren/keuzehulp/).22 This tool comprises: (1) consultation support instructions in the context of disease control and treatment needs and (2) an overview of available treatment options for RA. The steering group assumed that the type of information within these parts were also relevant to support SDM in patients with axSpA facing treatment decisions. For the development of the pilot version, we, therefore, adapted these two parts to align with the axSpA situation (forming parts 1 and 2 of our decision aid).

Next, two new parts (the actual decision aid, forming parts 3 and 4) were developed, based on the results of the literature searches and the explorative needs assessments interviews: (1) detailed information on b/tsDMARDs followed by an interactive option grid that facilitates comparison of characteristics and (2) a final check supporting patients to deliberate on the decision to initiate or switch a b/tsDMARD (box 1).

The Dutch Arthritis Society was responsible for the technical development, layout and hosting of the web-based decision aid. In addition, the functional health literacy levels were ensured by testing readability across literacy levels using the Common European Framework of Reference for Languages language level B1, for which there is broad consensus that the majority of the population is able to read and understand the written information.23–25 Furthermore, we developed a paper-based information card with personalised b/tsDMARDs options and with a link to the website of the decision aid, which could be handed out to patients during a clinical visit (online supplemental file 3). The content and look and feel of the decision aid, and the paper-based card were approved by experts from the working group SpA of the Dutch Society for Rheumatology.

**Phase 4: pilot testing**

The pilot version of the decision aid was tested in two rounds. In the first round (alpha testing), we performed individual semistructured interviews with patients and care providers to evaluate its usability and ease of use and to check whether all agreed on information and layout wishes were adequately incorporated in the pilot version (see online supplemental file 4 for more details on the methodology).

During the interviews, participants were asked to read the different parts of the decision aid and to reflect on the content, usability, comprehensibility, layout, readability and expected future use according to the concurrent thinking aloud-method. In-depth questions and clarification of comments were asked when needed following a short semistructured interview guide (online supplemental file 5). After each individual interview with a patient, the research team evaluated whether data saturation was reached and if not, additional interviews were planned. Again, interviews were analysed using the thematic structure of the interview guide. Based on
Box 1  Summary of all parts of the decision aid

Part 1: consultation support instructions in the context of disease control and treatment needs
1. Discuss how your disease affects your life.
2. Formulate personal goals.
3. Discuss whether your treatment matches with your personal goals.
4. Discuss the disadvantages and advantages of your treatment options.
5. Schedule a new appointment and discuss how you are going to monitor your disease.

Part 2: overview of available treatment options for axSpA
1. NSAIDs.
2. Glucocorticoids.
3. DMARDs for patients with peripheral joint involvement.
4. b/tsDMARDs.

Part 3: detailed information on b/tsDMARDs in axSpA
1. Physical checks required prior to starting.
2. Necessary regular checks required during use.
3. Risk on infections.
4. Storage of drugs at home.
5. Requirement for and response to vaccination.
6. Instructions to inform rheumatologist on (wished-for) pregnancy and breast feeding.

Information shown in an interactive option grid that facilitates comparison of characteristics:
1. Route of administration.
2. Frequency of administration.
3. Need for a step-up approach.
4. Year of approval drug for axSpA.
5. Drug class (TNFi, IL17 or JAKi).
6. Expected time before effect can be experienced.
7. Expected effect on axial joints.
8. Expected effect on peripheral joints.
9. Expected effect on enthesitis.
10. Expected effect on psoriasis.
11. Expected effect on ulcerative colitis and Crohn's disease.
12. Expected effect on anterior uveitis.
13. Most frequent adverse events.
15. Web link to lay information on medication.

Part 4: a final check supporting patients to deliberate on the decision to initiate or switch a b/tsDMARD
1. Print or save the information in the option grid.
2. Discuss your preferences on initiating or switching a b/tsDMARD with your rheumatologist.
3. Be aware that you do not have to start a (new) drug at this moment.
4. Consider whether you have sufficient information of make an informed decision.
5. Discuss any remaining any questions or worries with your rheumatologist.

Spondyloarthritis

Part 3: detailed information on b/tsDMARDs in axSpA

Part 4: a final check supporting patients to deliberate on the decision to initiate or switch a b/tsDMARD

Part 5: introduction in clinical practice and evaluation

Phase 5: introduction in clinical practice and evaluation

A multifaceted strategy was devised to introduce the decision aid to care providers and patients in Dutch rheumatology settings. The researchers assessed the quality of the final version of the decision aid using the IPDAS instrument.28

RESULTS
Phase 1: scope and setting

The steering group decided that a web-based decision aid was preferred over a paper-based aid, as this is more easily accessible for care providers and patients. However, the decision aid can be printed and used on paper for patients who prefer paper-based tools or have limited health literacy or digital skills. Furthermore, the decision aid should be published on the open to use website of the Dutch Arthritis Society, which is considered a comprehensive and credible source of information on rheumatic and musculoskeletal diseases and available treatment options (in Dutch: https://reumanederland.nl/).

Phase 2: explorative needs assessments

Semistructured explorative interviews were performed with 17 patients and 12 care providers using an interview guide to identify needs and wishes regarding the content and layout of the decision aid (table 1).

Regarding information needs and wishes, both patients and care providers suggested information they deemed necessary to know for making treatment decisions on initiating or switching b/tsDMARDs. Care providers categorised their information needs and wishes between general information on b/tsDMARDs and information on specific characteristics of each b/tsDMARD (box 1).

Regarding layout needs and wishes, it was suggested by both patients and care providers that the decision aid should be concise and clear and that its readability could be increased by using icons, dropdown menus and pop-up windows. Furthermore, the decision aid should be useable on a mobile device, should include support functions for patients with limited literacy and/or digital skills (eg, reading-aloud and text magnification functions) and should be available in a print-format for patients who prefer paper-based tools.

Finally, regarding emotional and support needs and wishes, care providers and patients suggested to stimulate comments retrieved from the interviews, revisions were made. In the second round (beta testing), we evaluated the feasibility of the final version in clinical practice in±15
patients to reflect whether they felt sufficiently prepared to make an informed decision.

Patients also wished that the decision aid includes a textual reminder on the possibility to discuss treatment options with friends and family and that they could ask any remaining questions on emotional and support needs with their care providers.

**Phase 3: development of a pilot version**

The decision aid was developed as a one-page tool on the website of the Dutch Arthritis Society and is also readable and functional on mobile devices. On top of the page, the overall aim of the decision aid was stated and the parts and support functionalities on this page were briefly introduced (box 1).

The first part, ‘consultation support instructions in the context of disease control and treatment needs’, informed patients on how to prepare for making treatment decision in the context of outpatient visits, such as gaining insight into what personal aspects matter most and advice to bring notes to outpatient visits.

The second part, ‘an overview of available treatment options for axSpA’, informed patients on all available drugs for the treatment of axSpA (ie, non-steroidal anti-inflammatory drug, glucocorticosteroids, conventional synthetic DMARDs and b/tsDMARDs) and information on when these drugs are indicated.

The third part, ‘detailed information on b/tsDMARDs and an interactive option grid that facilitates comparison of characteristics’, informed patients on what they need to know prior to initiating a b/tsDMARD and includes an interactive option grid that facilitates comparing characteristics of these drugs. A maximum of five drugs can simultaneously be compared in the option grid.

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**Table 1** Characteristics of participants in needs assessment interviews and pilot testing

<table>
<thead>
<tr>
<th></th>
<th>Explorative needs assessment</th>
<th>Pilot testing</th>
<th>Alpha testing</th>
<th>Beta testing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Care providers</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rheumatologists</td>
<td>6</td>
<td>7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rheumatology fellows</td>
<td>4</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specialised rheumatology nurse</td>
<td>2</td>
<td>3</td>
<td></td>
<td></td>
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<tr>
<td><strong>Patients</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, years (range)</td>
<td>53.5 (23–80)</td>
<td>53.3 (21–78)</td>
<td>47.8 (9.0)</td>
<td></td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>9 (52.9)</td>
<td>5 (35.7)</td>
<td>9 (64.3)</td>
<td></td>
</tr>
<tr>
<td>Disease duration, years†</td>
<td>13.8 (10.5)</td>
<td>16.2 (10.4)</td>
<td>‡</td>
<td>‡</td>
</tr>
<tr>
<td>Past and current use of b/tsDMARDs†, n (%)</td>
<td>14 (82.3)</td>
<td>12 (85.6)</td>
<td>‡</td>
<td>‡</td>
</tr>
<tr>
<td><strong>Educational attainment, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>5 (29.4)</td>
<td>10 (71.4)</td>
<td>9 (64.3)</td>
<td></td>
</tr>
<tr>
<td>Middle</td>
<td>7 (41.2)</td>
<td>4 (28.6)</td>
<td>2 (14.3)</td>
<td></td>
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<tr>
<td>Low</td>
<td>4 (23.5)</td>
<td>0 (0.0)</td>
<td>2 (14.3)</td>
<td></td>
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<tr>
<td>Unknown</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>1 (7.1)</td>
<td></td>
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<tr>
<td><strong>Living status, n (%)</strong></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Living alone</td>
<td>3 (17.6)</td>
<td>4 (28.6)</td>
<td>1 (7.1)</td>
<td></td>
</tr>
<tr>
<td>Living with partner without children</td>
<td>9 (52.9)</td>
<td>7 (50.0)</td>
<td>5 (35.7)</td>
<td></td>
</tr>
<tr>
<td>Living with partner with children</td>
<td>2 (11.8)</td>
<td>3 (21.4)</td>
<td>7 (50.0)</td>
<td></td>
</tr>
<tr>
<td>Living without partner with children</td>
<td>1 (5.9)</td>
<td>0 (0.0)</td>
<td>1 (7.1)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>2 (11.8)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td></td>
</tr>
<tr>
<td><strong>Occupational status, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed</td>
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<td>10 (71.4)</td>
<td>12 (85.7)</td>
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<tr>
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<td>2 (14.3)</td>
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<td>Disabled for work</td>
<td>6 (35.3)</td>
<td>2 (14.3)</td>
<td>2 (14.3)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>3 (17.6)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td></td>
</tr>
</tbody>
</table>

Results are reported as mean (SD), unless reported otherwise.

*Six patients who participated in the explorative need assessment interviews also participated in the alpha testing.
††This information was retrieved from patients’ medical records.
‡This information could not be retrieved as the online questionnaire was answered anonymously.

b/tsDMARD, biological or targeted synthetic disease modifying antirheumatic drug.
The final part, ‘a final check supporting patients to deliberate on the decision to initiate or switch a b/tsDMARD’, supported patients in determining whether they had sufficient information to make a treatment decision. It was pointed out that remaining questions on treatment options or their personal worries and beliefs could be discussed with their care provider and that patients can refrain from initiating or switching a b/tsDMARD on their request. Experts from the working group SpA suggested minor textual revisions on the content and layout of the pilot version.

**Phase 4: pilot testing**

**Alpha testing**

For the alpha testing, individual semistructured interviews were performed with 14 patients and 13 care providers (table 1). Eight out of 14 patients (57.1%) who participated in the explorative needs assessment interviews also participated in the alpha testing. Overall, participants confirmed that all parts of the decision aid were useful for making treatment decisions on initiating a b/tsDMARD, especially the option grid enabled them to compare treatment options in a structured manner. Based on results from the alpha testing, minor modifications were made in the content and layout of the decision aid, including rephrasing of sentences and use of icons (see online supplemental file 8) for the received comments during alpha testing phase and performed actions by the steering group and professionals from the Dutch Arthritis Society and online supplemental file 9 for the final version of the decision aid).

**Beta testing**

For the beta testing, we assessed the feasibility of the decision aid in 14 patients recruited from 7 rheumatology centres in the Netherlands (table 1). All patients agreed they felt motivated to use the decision aid. Also, there was broad agreement that the decision aid was feasible to use in clinical practice (figure 2). Notwithstanding, one-third of the patients were neutral on the additional value of the decision aid on making treatment decisions and on recommending the decision aid to other patients. Two patients found that the decision aid was not easy to use nor that the duration of the decision aid was acceptable. However, the steering group and the Dutch Arthritis Society jointly decided to refrain from any further adjustments.

**Phase 5: introduction in clinical practice and evaluation**

For the multifaceted strategy, the decision aid was introduced by the researchers to rheumatologists in several hospitals and to all members of the working group SpA. In addition, the Dutch Arthritis Society repeatedly promoted the decision aid to patients and care providers on their website, social media and in their monthly newsletter. The paper-based information card with personalised b/tsDMARDs options can be requested free of charge at the Dutch Arthritis Society to continuously facilitate the use of the decision aid in clinical practice. In the future, the decision aid will be further promoted whenever possible.

The final version of the decision aid met 32 out of 38 (84.2%) items of the IPDAS quality instrument (online supplemental file 10). The remaining items were not
explicitly stated in the decision aid because of lack of evidence or because of fear of abundant information, which might hinder the usability of the decision aid. The quality of the decision aid was officially approved by the board of the Dutch Society for Rheumatology.

**DISCUSSION**

We described the development of an evidence-based decision aid that is feasible to support SDM in patients with axSpA who face a treatment decision to initiate or switch a b/tsDMARD and its introduction in clinical practice. Patients can use this tool at home for retrieving more information, which will enable them to discuss their preferences for the decision with their rheumatologist. The systematic development process consisted of state of the art consecutive phases, including explorative needs assessment interviews, development of a prototype and usability, ease-of-use and feasibility testing among patients and care providers. Experts on axSpA and professionals on patient information from the Dutch Arthritis Society were involved throughout all phases of the development process. The final version of the developed decision aid provides consultation support instructions in the context of disease control and treatment needs, informs on all available treatment options for axSpA, provides detailed information on b/tsDMARDs, facilitates comparison of characteristics and supports patients to deliberate on the decision to initiate or switch a b/tsDMARD. The pilot-testing phases revealed that the usability, ease of use and feasibility of the decision aid were acceptable. The final decision aid was introduced to patients and care providers in several Dutch rheumatology settings.

During several phases of the development process, both care providers and patients mentioned that the SDM process in absence of a decision aid is mainly focused on deciding whether or not to initiate a (new) b/tsDMARD, and to a lesser extent on which b/tsDMARD is preferred in the scenario in which two or more drugs are available. In daily practice, the decision on which b/tsDMARD is preferred depends not only on patient’s clinical situation, but also on care providers’ knowledge, experiences and habits related to prescribing b/tsDMARDs, as well as preferential prescription policies within a rheumatology setting. During the prototype development phase, we encountered challenges in realising some information needs from patients. For example, patients wished that the proposed effect of b/tsDMARDs on disease manifestations in the option grid could be tailored towards their personal medical situation, such as their b/tsDMARD history. However, this is challenging as failing a first b/tsDMARD might affect the proposed effectiveness of a second b/tsDMARD compared with b/tsDMARD naïve patients.

We also refrained from the IPDAS recommendation to present the effectiveness of b/tsDMARDs as natural frequencies as there is limited evidence for some drugs. Instead, we used simultaneously descriptive terminology and icons to report the effectiveness of these treatment options in the option grid (ie, positive effect but more evidence is needed (icon: +), positive effect (icon: ++) and strong positive effect (icon +++). Both care providers and patients found this way of presenting effectiveness of b/tsDMARDs in the option grid useful.

The overall impact of the decision aid on patient and disease outcomes does not only depend on patient’ knowledge retrieved from the decision aid, but also on their skills and power. For example, patients should have adequate health literacy and decision-making skills, such as applying health information and eliciting one’s own preferences. In addition, patients need power to believe in their capacity to influence the decision-making process, such as believing that they have permission to participate and having confidence in the value of their own abilities.

This study has some limitations. A first limitation is that, due to the COVID-19 pandemic, some patients who participated in the explorative needs assessment interviews refused participation in the pilot testing. This could explain the inclusion of more higher educated patients and patients with a job, which may not be representative for the total axSpA population. Also, we could not evaluate whether their envisioned information and design needs were adequately incorporated in the decision aid. Second, selection bias might also have occurred by inviting patients for the feasibility testing phase via posts on social media, the website of the Dutch Arthritis Society and the monthly newsletter, as this requires sufficient digital skills of patients. Therefore, our findings on the usability, ease of use and feasibility of the decision aid might not be generalisable to patients who attained lower education, who are not employed or who have lower health literacy or digital skills. However, we consulted professionals on patient information throughout the development process to ensure the ease of use of the decision aid by all patients.

This study also has notable strengths. First, we involved patients and care providers in nearly all phases of the development process to enhance broad acceptance and use of the developed tool in clinical practice. Second, the web-based design facilitates that the decision aid is accessible anytime and anywhere on a well-known website for patients with rheumatic diseases, which is also readable and functional on mobile devices. Besides, the decision aid can be printed and used on paper for patients who prefer paper-based tools or have limited health literacy or digital skills. As a result, the decision aid can be used by patients themselves at home, as well as together with care providers during outpatient visits. Third, the overall quality of the decision aid is endorsed by national recognised accreditation of the Dutch Society for Rheumatology, which confirms the correctness of the presented information. Fourth, we were able to evaluate the decision aids’ usability and ease of use as well as its feasibility, of which findings have optimised the tool for use in clinical practice.
In conclusion, we developed an evidence-based decision aid to support patients who face a treatment decision to initiate or switch a b/tsDMARD and introduced this in clinical practice. Future studies should evaluate the overall impact of the decision aid on health outcomes of patients as well as improving the patient’s experiences with the decision-making process.

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