Where is the theory? Evaluating the theoretical frameworks described in decision support technologies

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Abstract

Objective: To identify and describe the extent to which theory or theoretical frameworks informed the development and evaluation of decision support technologies (DSTs).

Methods: The analysis was based on the decision technologies used in studies included in the Cochrane systematic review of patient decision aids for people facing health screening or treatment decisions. The assumption was made that DSTs evaluated by randomized controlled trials, and therefore included in the updated Cochrane review have been the most rigorously developed.

Results: Of the 50 DSTs evaluated only 17 (34%) were based on a theoretical framework. Amongst these, 11 decision-making theories were described but the extent to which theory informed the development, field-testing and evaluation of these interventions was highly variable between DSTs. The majority of the 17 DSTs that relied on a theory was not explicit about how theory had guided their design and evaluation. Many had superficial descriptions of the theory or theories involved. Furthermore, based on the analysis of those 17 DSTs, none had reported field-testing prior to evaluation.

Conclusion: The use of decision-making theory in DST development is rare and poorly described. The lack of theoretical underpinning to the design and development of DSTs most likely reflects the early development stage of the DST field.

Practice implications: The findings clearly indicate the need to give more attention to how the most important decision-making theories could be better used to guide the design of key decision support components and their modes of action.

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Keywords: Decision-making; Decision support technique; Decision support system; Decision aid; Theory; Decision theory; Model; Theoretical framework

1. Introduction

Although there is increasing interest in supporting the participation of patients in decision-making by the use of decision support technologies (DSTs), there is also a poor understanding of how DSTs achieve their impact on outcomes [1]. While the number of published DSTs has tripled since 1999 [2], there is a growing concern that development has been independent of relevant theoretical frameworks. Over the past decade, little attention has been given to the theoretical foundation underlying the development of heterogeneously developed DSTs [2]. Although there are guidelines and criteria being produced for the design and evaluations of DSTs [3], their development process, content and evaluation does not seem to recognise the need to adhere to any conceptual or theoretical framework relevant to decision-making.

The terms “theory” and “model”, often confounded, are associated with an overwhelming variety of definitions [4]. However, these are independent concepts that need to be carefully defined and distinguished. In the present study, we chose to define theory as a set of inter-related propositions (theoretical constructs) that constitute a framework for describing, explaining and predicting the decision-making process. Theories propose to explicate the rules and mechanisms by which the outcomes are achieved. Compared to a model, a theory tends to address global behaviours in general context and to be discipline specific. According to Hawking [5], a good theory “satisfies two requirements: it must accurately describe a large class of observations on the basis of a model that contains only a few arbitrary elements, and it must make
definite predictions about the results of future observations”. Models are informed by one or more theories and have a very limited capacity to predict behaviours. A model may also include processes or constructs that are not based on theory. Finally, models make an extensive use of representations in describing a phenomenon or the interactions between a set of constructs. While theories describe and explain behaviour in an attempt to predict it, models are essentially descriptive.

Most interventions in this field appear to have been developed in a practical manner, using a wide range of medias, timeframes and purposes. DSTs have also been noted to achieve different levels of effectiveness [6]. More importantly, the design of the majority of DSTs seems to be primarily informed by researchers who create products that combine information and graphical elements to portray risk but generally lack a theoretical hypothesis about how patients will achieve decisions, with or without health professionals [7]. The potential impact of a theoretical foundation on the quality and efficacy of DSTs has never been formally assessed.

Health conditions are often associated with several treatment or screening options, each involving significant levels of harms and benefits. Decisions to undertake a treatment or a screening test depend on the differences between the harms and benefits of each option and how these are valued and evaluated by patients and their clinicians. As a consequence, the patient’s perspective needs to be taken into account. Contexts such as these give rise to the need to involve patients in deciding on their care in order to make optimal decisions that are ideally consistent with their knowledge, values and long-term goals. To achieve these goals, there is increasing interest in developing technologies that support patients when they face tough decisions, for themselves or others in their families. Those interventions, referred to here as DSTs (also known as patient decision aids) provide information about the treatments or screening options made available to patients. They are designed to help patients choose between two or more courses of action by providing information about the probabilities associated with the risks and benefits of each option.

A literature review of health technologies intended to influence patient informed decision-making assessed the theoretical basis of 547 studies of interventions ranging from the comparison of information mediums or simple provision of additional information to the use of DSTs [8]. The research was not exclusively focussed on DSTs and did not address the question as to what extent theory had guided the development and evaluation of the DSTs. The findings showed that theory was not frequently used in health technologies. Indeed, 82% of the studies did not refer to, or make use of any theory. Amongst those which did explicitly refer to decision-making theories, there was little account of the way in which the theory had been used. For instance, there was no clear specification of how the theoretical concepts or framework described were subsequently applied to the practical design of the DST.

Another study investigated the theoretical basis of interventions designed to promote patients’ informed decision-making in the clinical context of cancer screening [9]. The findings showed that 5 of a total of 14 interventions referred to a theoretical framework. However, among those interventions that were described as “theory-based”, it was not clear how the specified theory had shaped the design of the specific intervention. None of the articles reporting the development and evaluation of the DSTs commented on the utility of the chosen theoretical foundation.

To conclude, there is no clear description of a deliberate avoidance of theory nor is there detailed attention to how some, albeit a minority, used a specific theory for design, development and evaluation. Similarly, the effect of a theoretical foundation on the impact and efficacy of a DST has not been formally assessed. DSTs that are not based on theory may be as efficient and reliable as interventions guided by a relevant theoretical basis, however, for the time being we are unable to assess this area. The aim of the present study is to describe and analyse rigorously developed DSTs in order to determine the contribution of decision-making theory to their conception, design, development and evaluation. As a sample frame, we reviewed the 55 published randomized controlled trials of DSTs included in the Cochrane systematic review [2].

2. Methods

2.1. Inclusion criteria

Our sample frame was the 55 trials of “patient decision aids for people facing health treatment or screening decisions”, included in the Cochrane systematic review. The assumption was made that DSTs evaluated by randomized controlled trials included in a Cochrane review would have been among those most rigorously developed. In the Cochrane review 22,778 citations were identified and 55 randomized controlled trials of DSTs were extracted and included in the review. The interventions focussed on 23 different screening and treatment decisions related to various clinical contexts. The DSTs were evaluated in randomized trials and typically compared to usual care (usual verbal information or provision of routine information leaflet) or to simpler decision tools.

2.2. Methodology for the theoretical review of articles

All DSTs to be considered were independently rated by two of the authors (M-AD & MS). They reviewed all full text articles reporting the development and evaluation of the DSTs in a randomized controlled trial. Any mention of a theoretical framework in the text or in the reference list was noted. The nature and category of the identified theoretical framework were then discussed between authors. The agreement between raters regarding the theoretical review of article was examined. After a theoretical framework was identified and named, the authors of the article were contacted and asked how they used theory to inform the design and evaluation of their DSTs. They were informed that the theoretical review of their decision tools would be based on their published work if they did not provide a reply within two months. All relevant articles were analysed carefully to assess the degree to which a pre-specified and named decision-making theory or model had informed the development and
evaluation of the DST. We specifically looked at the extent to which decision-making theories guided the conception of the DST, the prototype development, field-testing (if applicable) and evaluation. In the present study, field-testing was defined as the process whereby the DST's prototype is shown to patients faced with the chosen treatment or screening options and asked to comment on its content, usability and usefulness [10].

3. Results

In the present study, 78 full text articles reporting the development and evaluation of the DSTs in a randomized controlled trial were reviewed. In total, 55 trials of “patient decision aids for people facing health treatment or screening decisions” were included in the Cochrane systematic review. However, the authors note that three DSTs [11–13] have been evaluated in two or more trials [14–18]. There may have been small changes between versions but we made the assumption that the theoretical framework would remain the same. We therefore chose to base our analysis on 50 DSTs and their associated publications. Furthermore, when reviewing the 78 citations, the consistency between raters was high. Only one citation out of 78 generated disagreement and was resolved after a second analysis had been performed.

<table>
<thead>
<tr>
<th>Theoretical foundation</th>
<th>DST components informed by theory</th>
<th>First author, year</th>
<th>Health decision addressed in the DST</th>
<th>Format</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decision analytic method based on the expected utility theory</td>
<td>Conception; prototype development; evaluation</td>
<td>Bekker [19,33], 2004</td>
<td>Prenatal diagnostic screening for down syndrome</td>
<td>Decision analysis plus consultation</td>
</tr>
<tr>
<td>Decision analytic method based on the expected utility theory</td>
<td>Conception; prototype development; evaluation</td>
<td>Clancy [20], 1988</td>
<td>Hepatitis B vaccine</td>
<td>Leaflet + decision analysis</td>
</tr>
<tr>
<td>Decision analytic method based on the expected utility theory</td>
<td>Conception; prototype development; evaluation</td>
<td>Montgomery [22,70], 2003</td>
<td>Hypertension treatment</td>
<td>Decision analysis</td>
</tr>
<tr>
<td>Decision analytic method based on the expected utility theory</td>
<td>Conception; prototype development; evaluation</td>
<td>Rothert [23], 1997; Holmes-Rovner [21], 1999</td>
<td>Hormone replacement therapy</td>
<td>Discussion or personalized decision exercise</td>
</tr>
<tr>
<td>Decision analytic method based on the expected utility theory</td>
<td>Conception; prototype development; evaluation</td>
<td>Van Roosmalen [24,71], 2004</td>
<td>Treatment options for BRCA1/2 mutations carriers</td>
<td>Video + leaflet with decision analytic method</td>
</tr>
<tr>
<td>Multiple attribute and multiple criteria decision-making theories</td>
<td>Conception; prototype development; evaluation</td>
<td>Dolan [36], 2002</td>
<td>Colon cancer screening</td>
<td>Standardized interview (using the analytic hierarchy process) + leaflet</td>
</tr>
<tr>
<td>Ottawa decision support framework</td>
<td>Conception; evaluation (partial use of the theories)</td>
<td>Hunter [41,72], 2005</td>
<td>Prenatal diagnostic testing</td>
<td>Audiotape and booklet</td>
</tr>
<tr>
<td>Ottawa decision support framework</td>
<td>Conception; prototype development; evaluation (partial use)</td>
<td>Lalonde [42,47], 2006</td>
<td>Cardiovascular health treatment</td>
<td>Video + booklet</td>
</tr>
<tr>
<td>Ottawa decision support framework</td>
<td>Conception; prototype development; evaluation (partial use)</td>
<td>O’Connor [13,14,17, 48,49,73,74], 1998</td>
<td>Hormone replacement therapy</td>
<td>Audiotape + booklet</td>
</tr>
<tr>
<td>Ottawa decision support framework</td>
<td>Conception; prototype development; evaluation (partial use)</td>
<td>Shorten [43], 2005</td>
<td>Birthing options after previous caesarean</td>
<td>Booklet</td>
</tr>
<tr>
<td>Combination of behavioural models of decision-making</td>
<td>Poor use of theory</td>
<td>Lerman [50], 1997</td>
<td>Breast cancer genetic testing</td>
<td>Discussion and counselling</td>
</tr>
<tr>
<td>Cognitive-social health information processing model (C-SHIP)</td>
<td>Conception; prototype development</td>
<td>Miller [53,54], 2005</td>
<td>Breast cancer genetic testing</td>
<td>Discussion + leaflet</td>
</tr>
<tr>
<td>The preventive health model</td>
<td>Conception; prototype development</td>
<td>Myers [55,56,75], 2005</td>
<td>PSA testing</td>
<td>Discussion + leaflet</td>
</tr>
<tr>
<td>Social cognitive theory</td>
<td>Conception (partial use); prototype development (partial use); evaluation</td>
<td>Partin [57,76], 2004</td>
<td>PSA testing</td>
<td>Video</td>
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<tr>
<td>Health belief model</td>
<td>Early conception; evaluation</td>
<td>Schapira [59], 2000</td>
<td>Prostate cancer screening</td>
<td>Booklet</td>
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<tr>
<td>The transtheoretical model</td>
<td>Poor use of theory</td>
<td>Pignone [77], 2000</td>
<td>Colon cancer screening</td>
<td>Video</td>
</tr>
<tr>
<td>Empowerment model</td>
<td>Early conception</td>
<td>Davison [62], 1997</td>
<td>Prostate cancer treatment</td>
<td>Written information package + audiotape of medical consultation + discussion</td>
</tr>
</tbody>
</table>
3.1. Prevalence of “atheoretical” DSTs

Of the 50 DSTs, 17 refer to a decision-making theory, the majority of which could be categorised as ‘normative’ theories (see Table 1). Thirty-three out of 50 DSTs did not refer to a theoretical foundation (see Table 2). Based on the rigorous analysis of all citations reporting the development and evaluations of the DSTs, we concluded that, as far as we could determine, the conception, the prototype development and the evaluation of 33 DSTs was not based on any theoretical foundation. All 17 authors of theory-based DSTs were contacted and asked to provide additional information regarding the use of theory in conceiving, developing and evaluating the intervention. Seven authors answered, providing additional literature or describing and elaborating on the use of a specific theoretical framework.

3.2. Normative theories of decision-making

Table 1 shows the theory-driven DSTs. Five DSTs referred to decision analysis [19–24], derived from the expected utility hypothesis, originally formulated in 1738 by Bernoulli [25] and later developed by many others [26–28]. The subjective expected utility theory, a normative theory of decision-making (based on the expected utility hypothesis) was introduced in 1954 by Savage [29]. Normative theories of decision-making specify how an individual should process information and make a decision under what are presumed ideal conditions. Decision analysis is the direct application of this theory, and was introduced in 1964 by Howard and Matheson [30]. The decision analytic method, and its direct application, the decision tree [31], have been widely used in designing DSTs for the last 10 years and was first applied to patient counselling in 1979 [32]. This method consists of assigning a cost and a probability of

### Table 1

<table>
<thead>
<tr>
<th>First author, year</th>
<th>First author, year</th>
<th>Health decision addressed in the DST</th>
<th>Format</th>
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</thead>
<tbody>
<tr>
<td>Auvinen [78,79], 2004</td>
<td>Barry [80], 1997</td>
<td>Prostate cancer treatment</td>
<td>Leaflet</td>
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<tr>
<td>Bernstein [81], 1998</td>
<td>Deschamps [82], 2004</td>
<td>Benign prostate hypertrophy treatment</td>
<td>Interactive videodisc</td>
</tr>
<tr>
<td>Dunn [85], 1998</td>
<td>Dunn [85], 2000; Phelan [84], 2001</td>
<td>Ischemic heart disease treatment</td>
<td>Video-cassette</td>
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<tr>
<td>Dunn [85], 1998</td>
<td>Dunn [85], 2000; Phelan [84], 2001</td>
<td>Hormone replacement therapy</td>
<td>Audiotape + booklet</td>
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<tr>
<td>Dunn [85], 1998</td>
<td>Dunn [85], 2000; Phelan [84], 2001</td>
<td>Back surgery</td>
<td>Interactive videodisc</td>
</tr>
<tr>
<td>Dunn [85], 1998</td>
<td>Dunn [85], 2000; Phelan [84], 2001</td>
<td>Poliomyelitis vaccines and choices of polio vaccination schedules</td>
<td>Video and leaflet</td>
</tr>
<tr>
<td>Dunn [85], 1998</td>
<td>Dunn [85], 2000; Phelan [84], 2001</td>
<td>PSA testing</td>
<td>Video</td>
</tr>
<tr>
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<td>PSA testing</td>
<td>Evidence-based booklet</td>
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<tr>
<td>Dunn [85], 1998</td>
<td>Dunn [85], 2000; Phelan [84], 2001</td>
<td>Breast cancer surgery</td>
<td>Audiotape + booklet</td>
</tr>
<tr>
<td>Dunn [85], 1998</td>
<td>Dunn [85], 2000; Phelan [84], 2001</td>
<td>Breast cancer genetic testing</td>
<td>CD-Rom + counselling</td>
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<tr>
<td>Dunn [85], 1998</td>
<td>Dunn [85], 2000; Phelan [84], 2001</td>
<td>Circumcision male newborns</td>
<td>Leaflet + verbal information</td>
</tr>
<tr>
<td>Dunn [85], 1998</td>
<td>Dunn [85], 2000; Phelan [84], 2001</td>
<td>Dental surgery</td>
<td>Endodontic decision board</td>
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<td>Dunn [85], 2000; Phelan [84], 2001</td>
<td>Menorrhagia treatment</td>
<td>Video + booklet</td>
</tr>
<tr>
<td>Dunn [85], 1998</td>
<td>Dunn [85], 2000; Phelan [84], 2001</td>
<td>Autologous pre-donation in cardiac surgery</td>
<td>Video + booklet</td>
</tr>
<tr>
<td>Dunn [85], 1998</td>
<td>Dunn [85], 2000; Phelan [84], 2001</td>
<td>Prenatal diagnostic testing</td>
<td>Interactive multimedia</td>
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<td>Dunn [85], 1998</td>
<td>Dunn [85], 2000; Phelan [84], 2001</td>
<td>Antithrombotic therapy for stroke prevention in atrial fibrillation</td>
<td>Decision aid</td>
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<td>Dunn [85], 2000; Phelan [84], 2001</td>
<td>Antithrombotic therapy</td>
<td>Audiotape + booklet</td>
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<td>Hormone replacement therapy</td>
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<td>Interactive videodisc</td>
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<td>Dunn [85], 2000; Phelan [84], 2001</td>
<td>Hormone replacement therapy</td>
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<td>Breast cancer genetic testing</td>
<td>Booklet</td>
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<td>Dunn [85], 1998</td>
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<td>Breast cancer surgery</td>
<td>Interactive multimedia</td>
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<td>Dunn [85], 2000; Phelan [84], 2001</td>
<td>Breast cancer surgery</td>
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<td>Breast cancer screening</td>
<td>Video + accompanying brochure</td>
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<td>Menorrhagia treatment</td>
<td>Booklet</td>
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<td>Breast cancer chemotherapy</td>
<td>Decision board + booklet</td>
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<td>Breast cancer surgery</td>
<td>Decision board</td>
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<tr>
<td>Dunn [85], 1998</td>
<td>Dunn [85], 2000; Phelan [84], 2001</td>
<td>Breast cancer surgery</td>
<td>Script</td>
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<td>Dunn [85], 1998</td>
<td>Dunn [85], 2000; Phelan [84], 2001</td>
<td>PSA screening</td>
<td>Script</td>
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<tr>
<td>Dunn [85], 1998</td>
<td>Dunn [85], 2000; Phelan [84], 2001</td>
<td>Colon cancer screening</td>
<td>Leaflet</td>
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<tr>
<td>Dunn [85], 1998</td>
<td>Dunn [85], 2000; Phelan [84], 2001</td>
<td>Pregnancy termination</td>
<td>Leaflet</td>
</tr>
</tbody>
</table>
occurrence to each outcome and to combine them in order to
generate the expected cost of each course of action. In the
context of DST development, patients are asked to specify the
utility of each available health option on a numerical scale. The
subjective utilities are then multiplied by the outcome
probabilities in order to identify the option with the highest
subjective utility. The decision analytic method seems to have
guided the conception of many pioneer DSTs in this field
[20,33–35] using the techniques of decision analysis to elicit patients’ values. In contrast to other theoretical frameworks, the
theory, and in particular the mechanisms of decision analysis
(decision trees and subjective expected utility calculations)
provide a recognisable architecture for the DST development.

Based on the analysis of all related publications and contact
with authors, we concluded that decision analysis informed the
early conception of all DSTs citing this theory: a decision
analytic consultation for prenatal diagnostic screening for
Down’s syndrome [33], a leaflet coupled with individualized
decision analysis for hepatitis B vaccine [20], a computerised
self-completed interview for hypertension treatment [22], a
discussion or individualized decision exercise for hormone
replacement therapy [23] and a video and leaflet addressing
treatment options for BRCA1/2 mutation carriers [24]. In all
publications, decision analysis (“subjective expected utility”
theory) was described as the theoretical framework supporting
the design of the DST. Furthermore, we concluded that decision
analysis guided the prototype development of the DSTs since
all interventions used a decision tree and were relying on the
utility analysis of all available health options. There is a lack of
data as to whether the DSTs were rigorously field tested and
found acceptable by patients and clinicians. The evaluation of
all “decision-analytic DSTs” seemed to be guided by theory
since the outcome measurements were assessing the match
between the treatment or screening plans and the patient’s final
decision.

One DST for colon cancer screening, combining an
interview with a leaflet [36] explicitly referred to the “multiple
criteria decision-making” (MCDM) [37] and “multiple
attribute utility theory” (MAUT) [38]. Both are normative
theories of decision-making, derived from mathematical
theories of multiple criteria or multiple attributes problem
solving [39]. Contrary to the subjective expected utility theory,
MCDM and MAUT do not elicit patients’ values using decision
analytic trees but frequently resort to an analytic hierarchy
process [40]. The analytic hierarchy process places options in a
comparison matrix of paired attributes, thus allowing the
decision maker to compare the consistency of preferences. The
“multiple criteria” and “multiple attribute” theories did
provide the conceptual framework for the DST and the
prototype development. The analytic hierarchy process was
used with patients to analyse the decision and compare all
available alternatives while integrating patients’ preferences
and values. However, there was no evidence of field-testing of
the DST with patients or physicians before evaluating the
intervention in a randomized controlled trial. The evaluation of
the DST seemed to be informed by theory since the outcome
measures (decision process and decision outcomes assessing
the match between the screening plans and patients’ final
screening choice) were consistent with the key postulates of the
MCDM and MAUT.

3.3. The Ottawa decision support framework

Four DSTs were based on “the Ottawa decision support
framework”: an audiotape and booklet DST for prenatal
diagnostic testing [41], a video and booklet DST for
cardiovascular health treatment [42], an audiotape and booklet
DST for hormone replacement therapy [13] and a booklet
providing information about birthing options after previous
cesarean [43]. The Ottawa decision support framework is a
combination of several decision-making theories including the
“expectancy value model”, “decision analysis” (described
earlier), “prospect theory”, the “conflict theory model of
decision-making” and the “theory of reasoned action”. First,
the “expectancy value model” [44] postulates that individuals
who are asked to choose between two or more options with
significant harms and benefits are more likely to opt for the
option with the highest expected values and success. This
model has similar characteristics to the subjective expected
utility theory with the difference that it does not require any
formal utility calculations. The “prospect theory” or “framing
bias theory” [28] was developed as a critique to the expected
utility theory accounting for the fact that most decision makers
do not normally behave in accordance with the axioms of utility
theory. Offering an alternative description of decision-making
under uncertainty, prospect theory distinguishes two phases in
the choice process: editing and evaluating. The editing phase
consists of analysing the offered prospects before evaluating
them and choosing the prospect of highest value (evaluating
phase). This theory also postulates that the choice between two
courses of actions is biased by the way in which the choices are
described or framed. For instance, prospect theory demon-
strated that losses loom larger than gains [45]. This has led to
significant attention being given to risk communication
formats. The “conflict theory model of decision-making”
[46] is based on the assumption that the decision-making
process generates stress, uncertainty and conflict within the
choice situation. The decision maker would therefore cope with
stress and uncertainty through the search for, and evaluation of
information and alternatives.

Based on the analysis of all related publications and contact
with authors, we concluded that the Ottawa decision support
framework did inform the early conception of the DSTs
mentioning this theoretical framework. The prototype devel-
opment of three out of four DSTs [43,47,48] was guided by
some of the theories included in the Ottawa decision support
framework and appeared primarily informed by the “conflict
theory model of decision-making” and the “expectancy value
model”. However, none of the DSTs appeared to be based
on a combination of all decision-making theories building up
the Ottawa decision support framework. The transfer of the
theoretical constructs (“expectancy value model” and the
“conflict theory model of decision-making”) into the concrete
design of the DST is mainly identifiable as a value clarification
exercise. One DST [41] (and related citations) did not show any evidence that its prototype development was concretely informed by theory. As far as we could tell, the theoretical constructs embedded in the social support theories do not appear to have guided the concrete design of the DSTs. However, prospect theory will have informed the framing of information and risk probability presentations. In brief, the interventions did not seem theoretically derived from all decision-making theories constituting the Ottawa decision support framework. This could be the result of the developers’ choice not to transfer all theoretical constructs into the concrete development of the DSTs. None of the related publications specified whether field-testing of the DSTs had been carried out prior to evaluation in a RCT. Similarly to the prototype development of the DSTs, their evaluations seem to be guided by some but not all of the theories included in the Ottawa decision support framework, namely the “expectancy value model” and the “conflict theory model of decision-making”. The outcome measurements were related to one of the theories in particular, the “conflict theory model of decision-making”. Decisional conflict, measured using the decisional conflict scale [49], is the main outcome measurement that appears to be informed by a theory embedded in the Ottawa decision support framework.

3.4. Combination of decision-making theories

One DST for breast cancer genetic testing, consisting of an education intervention and counselling session [50] used a combination of behavioural models of decision-making: the “theory of reasoned action” [51], the “consumer behaviour model” [52] and the “conflict theory model of decision-making” [46]. The “theory of reasoned action” postulates that the intention to engage in a behaviour is determined by the decision maker’s attitudes as well as the subjective norms of significant others regarding this behaviour. The “consumer behaviour model” is a model of consumer decision-making process that identifies a set of variables that shape decision-making such as individual differences, environmental influences or psychological processes. The analysis of all articles related to the DST’s development and evaluation did not provide any evidence that behavioural models of decision-making guided the design and prototype development of the DST. The publications do not mention whether the DST was rigorously field tested and found acceptable by patients and clinicians. Furthermore, the evaluation of the DST was not clearly informed by behavioural models of decision-making. Apart from knowledge, a very common if not systematic outcome measure in this field, the outcome variables did not relate to the theoretical framework.

One DST combining a leaflet with a discussion about the pros and cons of breast cancer genetic testing mentioned the “cognitive-social health information processing model” (C-SHIP) [53], developed by the DST’s developers [54]. It postulates that decision makers generally favour a systematic processing of information where both cognitive and emotional components (individual perception of risk, knowledge, beliefs, and expectancies) are integrated in the decision-making process. In their publications [53,54], authors of the DST thoroughly describe the C-SHIP model as the theoretical framework supporting the design of the DST. The educational intervention they developed is strongly anchored in the C-SHIP models since the most theoretical constructs are addressed and integrated into the concrete development of the DST. There is a lack of information as to whether the DST was rigorously field tested and found acceptable by patients and clinicians. Regarding the evaluation of the DST, the outcome measurements were related to the major components of the C-SHIP model and therefore matched theory.

One DST combining a consultation with a professional and a leaflet for PSA testing [55] referred to the “preventive health model” [56], created by the DST’s developers themselves and taking constructs from the “health belief model”, the “theory of reasoned actions” and the “social cognitive theory”. This model identifies a series of internal and external factors (e.g.: socio-cultural background, cognitive and affective representations associated with the disease or condition) that strongly influence people’s intention to act on their health. The preventive health model is comprehensively described in the publications reporting the development and evaluation of the DST and seems to have informed its early conception. The prototype development of the DST was also informed by theory since the “decision education session” used with patients in eliciting their values and reaching a decision is based on the key constructs of the preventive health model (preference clarification, cognitive evaluation, effective evaluation and social evaluation). There was no evidence whether field-testing of the DST had been conducted prior to its evaluation. The evaluation of the tool did not seem fully informed by the “preventive health model”. Only one key principle of the model (personal preference) was related to the primary outcome measure, “a screening decision preference score”.

3.5. Cognitive and social theories of decision-making

A video-based DST for PSA testing [57] referred to the “social cognitive theory” [58]. This model describes the developmental changes that individuals undergo over the course of their existence and is structured around the concept of agency. Agency is defined as the process whereby individuals get intentionally involved in their self-development and adaptation and therefore in the decisions that concern them directly. The early conception and the prototype development of the DST were partly informed by the social cognitive theory. The pamphlet they designed addressed two key constructs of the social cognitive theory (knowledge and attitudes, provision of information). However, the DST did not seem to integrate environmental factors and behaviours which the authors described as key dimensions of the social cognitive theory. The publications do not mention whether the DST was rigorously field tested and found acceptable by patients and clinicians. The evaluation was driven by the social cognitive theory since all dimensions embedded in the theory were integrated in the outcome measurements.
One DST offering a booklet for prostate cancer screening [59] mentioned the “health belief model” [60]. It identifies the factors that influence and determine preventive health care behaviours. The model postulates that the way an individual perceives the susceptibility, seriousness, benefits, and barriers associated with each health option influences the final decision. The “health belief model” did inform the early conception of the illustrated pamphlet decision aid they developed. The content of the DST was based on focus groups in which the health belief model was used to probe focus group members about their knowledge and feelings related to prostate cancer screening. However, analysis of the associated publications did not provide any evidence of the transfer of the health belief model’s key constructs (susceptibility, seriousness, benefits, and barriers associated with each health option) into the development of the DST. None of the related publications specified whether field-testing of the DST had been undertaken prior to its evaluation by RCT. The evaluation of the DST seemed to be informed by the health belief model. The outcome measurements (knowledge, natural history of prostate cancer, subjects’ perceptions of available screening tests and intended screening behaviour) were related to the major theoretical constructs of the health belief model.

3.6. Behavioural theories of decision-making

A DST combining a video- and colour-coded brochures for colon cancer screening [59] referred to the “transtheoretical model of behaviour change” [61]. It is a model of intentional change that has taken constructs from 18 major theories of psychotherapy and behavioural change. The transtheoretical model of behaviour change describes how people acquire or modify a behaviour using emotional, cognitive and behavioural components. It is organised in stages (the five stages of change): precontemplation, contemplation, preparation, action and maintenance. The early conception of the DST was partially informed by this model. The colour-coded brochures on colon cancer were explicitly based on the transtheoretical model of behaviour change. However, the 11-min educational video that patients were asked to watch before being given the brochure did not seem to rely on any theoretical foundation. There is a lack of data as to whether the DST was field tested and found acceptable by patients and clinicians. Finally, there is no evidence that the evaluation of the DST was explicitly informed by the transtheoretical model of behaviour change.

One DST for prostate cancer treatment [62] using a card-sort technique referred to the “empowerment model” [63], which drew on management and psychology theories. Empowerment is defined as the process whereby individuals’ belief in their self-efficacy is enhanced and includes five stages [64]. When given sufficient decisional power, individuals are more likely to assume an active role in decision-making and to achieve their desired outcomes. The empowerment model, thoroughly described by the DST’s authors seemed to have informed the early conception of the intervention. However, the five stages of empowerment described in the model did not appear to be integrated in the prototype development of the tool. There was no evidence whether field-testing has been carried out. The evaluation of the DST was not explicitly informed by theory since none of the outcome measurements (sociodemographic variables, preferred roles, levels of anxiety, and levels of depression) seemed to directly relate to the process of empowerment.

To summarize, the early conception of all “theory-driven” DSTs seemed to be informed by theory. However, some interventions relied on their chosen theoretical framework in a more thorough way than others. The prototype development of 13 out of 17 DSTs appeared to be informed by theory to a variable degree. The data analysis suggested important variations in the degree to which theoretical constructs were applied to the concrete development of the DST. The evaluation of 14 out of 17 DSTs was partially informed by theory and could reflect the difficulty to use and apply key theoretical constructs in a substantive manner. The transfer of key theoretical constructs into the design of a DST is a subject that requires further attention. Finally, none of the 17 DSTs that relied on theory reported to have been field-tested prior to evaluation in atrial.

4. Discussion and conclusion

4.1. Discussion

The analysis of 50 DSTs that have been subjected to evaluation by randomized controlled trial showed that only a third had described the contribution of decision-making theories or models to their design, development and evaluation. When these 17 DSTs were considered in depth, there was little evidence that developers were basing the design, construction and evaluation of DSTs in line with theoretical principles and predictions. The analysis of all publications reporting the development and evaluation of the 17 DSTs that relied on a theoretical framework showed that those interventions were evaluated without prior field-testing. It raises the issue of the validity and usability of interventions that have not been tested with patients or professionals [10]. It was also uncommon for outcome measurements to be based on explicit theoretically derived hypotheses. The exceptions were DSTs based on “subjective expected utility theory” (SEU) since the theoretical framework provided an explicit architecture (decision tree) for the development of the DST and for its evaluation (match between screening or treatment plans and final decision). However, the validity and appropriateness of these decision analysis based interventions are questioned. The strengths, weaknesses and practical obstacles to the implementation of decision analysis into clinical practice are the subject of much debate [65]. Although decision analysis can prove beneficial when applied to treatment or screening decisions, substantial obstacles need overcoming for the decision analysis based interventions to be useful and adapted to clinical settings. With the exception of SEU theory, our results suggest that the initial effort to use theoretical frameworks in the early stages of the DST conception becomes impoverished when developing and evaluating prototypes. Most DST developers seem to fail in
applying theoretical constructs to the three core components of a DST: presentation of information, value clarification and decision deliberation. Furthermore, about 66% of the DSTs we analysed did not refer to any decision-making theory or model and could therefore be described as “atheoretical” interventions. Other conceptual frameworks might have informed the early conception of the tool but decision-making theories were not mentioned in any publications that we reviewed. The assumption was therefore made that 33 out of 50 interventions were lacking a theoretical basis. The findings are consistent with previous studies conducted in this field [8,9] and confirm the tendency to develop and implement DSTs without relying on theory.

Two limitations need to be considered in interpreting the results of this study. The sampling frame only includes DSTs evaluated in RCTs. Independent or commercial DST developers are not included in this sample since it was assumed that highest quality DSTs would have been submitted to evaluation. The bias generated by the specificity of the sampling frame, which could also be described as a methodological strength, could be addressed by including a wider range of DSTs, produced by smaller developers and not evaluated in randomized trials. A further limitation lies in the assumption that some DST developers might have used theory in conceptualizing the intervention but did not mention it in their published work. One might argue that if theory had played a crucial part in developing the DSTs, the related publications would reflect this strength and therefore specify how theory informed its conception.

Strengths of this study were the quality of the sampling frame and inclusion criteria. All DSTs were evaluated in a randomized controlled trial and included in a Cochrane review. We therefore expect these interventions to be of a high standard and to have been mainly developed by academic institutions. The Cochrane systematic review of patient decision aids for people facing health treatment or screening decisions published in 2003 has been amended and updated on a regular basis [2,66–68]. All 78 citations included in our analysis were rated by two independent reviewers. The authors of this article are experienced in developing DSTs and are members of the International Patient Decision Aid Standards (IPDAS) collaboration, which is developing a set of criteria to assess the quality of available DSTs [69].

4.2. Conclusion

The present study is the first to have looked in detail at the practical transfer of the theoretical constructs into the development, field-testing and evaluation of a large number of DSTs addressing 23 screening or treatment decisions. The results suggest a consistent difficulty to use a chosen theory or model in guiding the prototype development and evaluation of the DST. This might have significant implications on future guidelines for developing DSTs and on the efficacy and reliability of intervention that do not rely on any theoretical foundation.

4.3. Practice implications

We do not set out to be critical of existing DSTs but provide data to reflect on the proliferation of heterogeneous and frequently atheoretical DSTs in a range of health contexts and to assess their mechanisms and processes. Having shown that DSTs impact on a number of important patient outcomes (anxiety, decisional conflict, regret and satisfaction with the decision) when used in RCT settings, it is now time to consider their design and components in more depth. There are many decision-making theories that describe, explain and predict how individuals make complex decisions. Decision-making theories and models also describe the factors or situations likely to impair the decision-making process and lead to poor decision outcomes and decisional regret. As a consequence, integrating specific theoretical constructs into the development of interventions that are explicitly aimed at facilitating decision-making processes may have a significant impact on the decision quality and outcomes. The potential impact of theory combined with the current lack of strong theoretical foundation for DSTs’ design justifies the need to investigate how these interventions affect decision-making. Attempts at creating standards are taking place, such as the development of IPDAS criteria [3], but it is clear that the evidence base for the contribution of theory to the design of DST components and their effectiveness is missing. This article signals the distance left for us to travel and the necessity to quickly establish whether theory-based DSTs are more likely to lead to better decisions. It also emphasises the necessity to consider how different decision-making theories or models can be used in developing a DST and specifically applied to three core DST components: information presentation, value clarification and decision deliberation.

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