

# Dual equipoise shared decision making: definitions for decision and behaviour support interventions

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Keywords: shared , equipoise, decision aids, decision support, complex interventions

## Abstract

**Background:** There is increasing interest in interventions that can support for patients who face difficult decisions and for those who have chronic disease or who need to modify their behaviour to achieve better outcomes. Evidence for effectiveness is used to categorise patients care. Effective care is where evidence of benefit outweighs harm: patients should always receive this type of care, where indicated. Preference-sensitive care describes a situation where the evidence for the superiority of one treatment over another is either not available or does not allow differentiation: in this situation therefore, there are two, or more, valid approaches and the best choice depends on how individuals value the risks and benefits of treatments. Interventions to support patients cannot be designed on the same theoretical assumptions for these two areas.

**Discussion:** Preference sensitive decisions are defined by equipoise: situations where legitimate options need to be deliberated. Moreover, where both health care professionals and patients agree that equipoise exists, situations may be regarded as having 'dual equipoise': These are ideal conditions for shared decision making. There are however many situations in medicine where dual equipoise does *not exist*, where health professionals hold the view that scientific evidence for benefit strongly outweighs harm. This is often the case for behaviour change recommended for chronic disease management. Some patients however are either ambivalent or find it difficult to sustain optimal behaviours, i.e., patients will be in varying degrees of equipoise. Therefore situations where dual equipoise exists (or not) help clarify the definitions of two classes of support, namely, decision and behaviour change support interventions. Therefore: *'decision support interventions describe and justify the conditions where dual equipoise exist, provide information about options and about the short, intermediate and long-term outcomes which have relevant and important consequences for decision-makers'*. Whereas: *'behavioural support interventions describe, justify, and recommend actions which, over time, lead to predictable outcomes over short, intermediate and long-term timeframes, and which have relevant and important consequences for those who are considering behaviour' change'*.

**Summary:** Decision and behaviour support interventions have divergent aims, different relationships to equipoise and form two classes of interventions.

## Background

The interest in creating interventions which help patients to make decisions about treatments or tests or to help people considering immunisations, screening tests and other choices in health care has led to substantial debate in how these tools should be developed, designed and implemented [1]. These interventions have been in existence over the last two decades and are known by a number of different names (shared decision making programs, decision aids, decision support tools or technologies), a nomenclature indicative of an emerging field. The increasing number of such interventions underlines the fact that medicine is undergoing a significant shift in how the roles of physician and patient are defined. At the heart of this shift is the recognition that decisions in medicine need to accommodate two key issues. First, that significant *uncertainty* exists about the benefit versus harm ratio of many medical tests and treatments. Second, and largely because such uncertainty is increasingly being acknowledged, there is widening agreement that the unilateral imposition of professional opinion about how to manage clinical problems – an approach often labelled as paternalism – is no longer a valid mode of interaction in healthcare settings. As a consequence, interactions in healthcare now need to acknowledge that often a balance exists between harm and benefit of different options – a concept we call ‘equipoise’ and which we will describe in greater detail [2]. In short, patients are increasingly expecting to be informed and involved in the process of care. This shift towards collaboration is not only relevant when people face difficult decisions where there are high stakes, ‘narrow-window of opportunities’ and where outcomes are uncertain but also in situations where people need to manage long-term conditions or might want to consider making changes to their lifestyles in order to reduce future risks – in other words, conditions where there are long time-frames and, although the stakes are still high, the urgency is less pressing.

Health professionals are finding this role-shift challenging and although pre- and postgraduate training curricula have adopted patient-centred models over the last two decades, there is evidence that practitioners struggle to incorporate patient agendas [3], seldom ask about their fears and expectations and are unable to put shared and behaviour change counselling into practice into their day to day routines. Although we could conjecture about the underpinning reasons for this, we focus this article on the interest that has emerged over the last decade in *interventions* to more actively involve patients in their care, be they in paper-based formats such as leaflets or booklets, or videotapes, compact video disks or web-based tools. We wish to place these tools in the context of the wider literature concerned with the development and implementation of complex interventions to implement ‘best practice’ [4]. In addition, we wish to define the core components of these interventions in order to clarify the minimal requirements for classification and to examine whether or not there is a need to have more than *one class* of intervention support.

## Discussion

In the late 1980s, a group of clinician-researchers in Boston [5] built on Wennberg’s research showing that medical practice variation cannot be explained by varying disease prevalence [6]. Wennberg proposed dividing medical care into different types of care, which include ‘effective’ and ‘preference-sensitive’ care. Effective care is founded on strong evidence of effectiveness, which patients should always receive, where indicated. Preference-sensitive care on the other hand describes a situation where the evidence for the superiority of one treatment over another is not available: there are therefore two or more valid approaches to care and the best choice depends on how a patient values the risks and benefits of the treatments available. This work led to the definitions of unwarranted variation in preference-sensitive care as being due to a combination of different professional practice typically seen in different geographical areas and a failure to adequately incorporate patient preferences into decision making processes [7].

The need, therefore, for clinicians to work collaboratively with patients in preference-sensitive decisions, led to the creation of 'shared programs' and the establishment, over time, of the Foundation for Informed [8]. Around the same time, Annette O'Connor published work on the elicitation of patient preferences [9]. In 1998, an article appeared in which the term 'decision aids' was used to describe an intervention designed to help women consider whether or not to use hormone replacement therapy [10]. This was to be the first of many descriptions and evaluations of 'decision aids' at the Ottawa Health Research Institute, and a basis for many developments in this field. It was from these beginnings that the work began of collating an evidence base for the effectiveness of 'decision aids', resulting in a Cochrane Review [11]. In summary, these interventions are reported to have positive outcomes, such as user knowledge, accuracy of risk perceptions, satisfaction with decision making, to patients taking more conservative approaches to healthcare and to greater clarity about their personal preferences [11].

The most recent development has been the creation of a set of quality standards based on reviews of evidence pertaining to a number of relevant quality dimensions for these interventions. The work has been co-ordinated by the International Patient Decision Aids Collaboration (IPDAS). A two-round modified Delphi consensus process resulted in the publication of a checklist [1] and, more recently, the establishment of an instrument which is capable of generating a 'quality score' which will facilitate a quality assessment service and benchmarking exercise [12]. There will, no doubt, be debate about the applicability of these standards and concerns about the tendency for standards to restrict innovation and experimentation. Nevertheless, they signal a need for developers and researchers to pay attention to the 'active ingredients' of decision support interventions. In parallel, there are also indications that researchers who have been concerned with the development and quality of clinical guidelines are also working on the need to involve patients, not only making them accessible and relevant to patients' needs but also involving them in their production and evaluation [13]. It is a short step, therefore, before clinical guidelines, by being transparent about the availability of treatment options, will also qualify to be considered as decision support interventions [14].

Significant investments are being made in the development of decision support interventions, including more recently tools to help patients deal with long-term conditions (chronic diseases). Considerable efforts are being undertaken to implement these tools in real world settings, with many developers viewing these interventions as products in a marketplace, encouraged by policies which encourage the convergence of commoditised healthcare, informed choice and client-centred service design [15, 16]. However, many questions remain unresolved. The role of patients' stories (narratives or testimonials) in these interventions is debated [17] : narrative elements have undoubted impact, so how to achieve 'balance' remains problematic. In addition, how to best support a deliberation process is unresolved. Should people be encouraged to undertake exercises to 'clarify' their preferences, weigh-up competing attributes of options or should these processes be left implicit, leaving individuals to rely on inherent heuristic approaches [18] and intuition [19]. These uncertainties will remain until further research emerges but these tools will nevertheless continue to be produced and promoted [15].

Preference sensitive decisions: situations of dual equipoise

O'Connor's defines 'decision aids' as: ' interventions designed to help people make specific and deliberative choices among options by providing information about the options and outcomes that are relevant to a person's health status' [11]. This definition rests on the assumption that healthcare contexts exist where it is reasonable and legitimate to offer choice [20]. We contend that this in turn rests on the concept of 'equipoise' – the existence of options which are in balance in terms of their attractiveness or that the outcomes are to, a degree at least, equally desirable (or possibly,

undesirable) [2]. This balance between options need not be perfect, indeed it is doubtful whether for any one individual that perfect *equipoise* between choices ever exists, but insofar as is reasonable, equipoise can be deemed to exist when a majority of people would agree that it is reasonable and legitimate to consider making a choice between competing options.

Most decision support interventions have been developed to tackle 'preference-sensitive' decisions where equipoise exists. A good example is the situation where a woman has been diagnosed as having early stage breast cancer and needs to decide whether to have surgery that removes or conserves the breast (mastectomy or breast conservation) [21]. In this situation, the decision is relatively urgent, cannot be deferred indefinitely, and, moreover, is a difficult one to make because there is more than one legitimate option that can be considered. Research indicates that the outcomes of mastectomy and breast conservation surgery are more or less comparable: there is no significant difference in long-term mortality [22, 23]. Health professionals *recognise* this decision as one where there the outcomes are to larger or greater extent equivalent, or are for sufficiently equivalent for many individual circumstances to allow patient preferences to have a vote, probably a determining vote, in deciding the surgical procedure chosen. Patients, once knowing this equivalence, understand that it is a 'preference-sensitive' decision because they place differential emphases on issues such as breast conservation, body image, sexuality and recurrence rates of local cancer. This decision can therefore be considered to have 'dual equipoise': both health professionals and patients agree conceptually that individual preferences are legitimate arbitrators of choice. We propose that professionally-situated equipoise is a pre-condition to the existence of 'dual equipoise' interactions, and that these in turn facilitate shared and, as a result, are a pre-condition for the implementation of decision support interventions. Examining this proposal, we suggest that *dual equipoise* helps both the professional and the patient accept the validity of discussing options, patients to understand why their preferences are relevant and that the option attributes deserve deliberative work. Given these characteristics the consideration of surgical options in early breast cancer unequivocally meets 'dual equipoise' criteria: it has reasonable, available and legitimate options, which need to be carefully deliberated.

This argument brings us to a definition:

*'decision support interventions describe and justify the conditions where dual equipoise exist, provide information about options and about the short, intermediate and long-term outcomes which have relevant and important consequences for decision-makers'.*

This is a broad definition, but it does require clarity about the nature of equipoise and whether the equipoise is located in one or more actor in any given interaction, an issue to which we return. Secondly, it requires information provision, and thirdly, the presence of two or more options, accepting that taking no action is a legitimate option. It remains quiet about how individuals should undertake the task or process of deliberation. We take the view that we do not yet have sufficient evidence on which to stipulate such an addition. When we examine 'decision support interventions' from this vantage point, we notice that the majority of interventions have tackled decisions which we regard as having 'dual equipoise', where professionals (or at least professionals who are willing to acknowledge uncertainty, in its many guises, and help patients become involved in decisions) are willing to spend time introducing the concept of choice and undertake the inevitable additional work of addressing the questions and anxieties that arise [24]. We need here to address the issue of terminology. We have chosen to use the term 'decision support intervention' in preference to the more widely used term 'decision aid'. We do this in order to draw attention to the issue that the term 'aid' may not sufficiently encompass the range of potential interventions that are being developed and tested, for instance the arrival of multi-media web-based interactive and collaborative media. Secondly, we will inevitably need to re-focus our evaluation beyond the artefact itself and to recognise

that these tools are examples of complex interventions [4], where the issues of how they are used, when and by who, is as important to the contribution to impact as will be the content of the artefact itself.

### Situations without dual equipoise

It follows therefore that here are also situations which lack dual equipoise. These are situations where strong evidence exists in favour of specific treatments or tests, or where there is a clear consensus that one approach is superior over another or that a change in lifestyle leads to greater benefit than harm. Perhaps some will argue that we are skating over patients' rights of self-determination, and that the principles of patient autonomy should apply even when professionals hold views about effective care. This is not the case. Indeed, we argue that excellent clinicians will explore patient agendas to the full, no matter how much those agendas run counter to prevailing scientific views. However, we also wish to see patient involvement flourish in real clinical settings. In situations where benefits clearly outweigh harms, professionals will not regard them as having dual equipoise and the deliberations will not be considered worth the investment required to achieve shared decision making. In other words, we are pragmatists more than we are ethicists who support mandatory autonomy [25].

A good example of this kind of situation and one which faces clinicians daily is supporting a patient manage a long term condition. For the majority of these conditions, there is good evidence that links specific processes to good outcomes – either adhering to medication or modifying lifestyle. Achieving the goals of good control for high blood pressure, diabetes, managing kidney or heart failure requires continued engagement in a set of behaviours. Managing a chronic disease is therefore all about changing and sustaining behaviours. Professionals are not in equipoise. Clinical practice guidelines clearly delineate how professionals should operate. Patients however, either don't know or don't realise the discrepancy between their short term behaviour and long term goals [26]. The professionals' task is to support the patient in understanding the situation, to set agendas, to address ambivalences and, ultimately to see the discrepancy between what they are doing and ultimately want for themselves. The role of approaches such as behaviour support interventions such as motivational interviewing and behaviour change counselling is clear in these situations. Some of the tools developed to help patients in this area have also been called 'decision aids', but might need re-conceptualisation as a different class of intervention.

Examining one example in depth, we consider a common situation. An overweight 50 year old lorry driver recently diagnosed with diabetes is struggling to control his blood pressure and weight. The patient also faces the challenge of trying to give up smoking whilst also learning about diabetes and balancing his own preferences and other demands on his time. The clinician is an excellent communicator and, where he feels able, shares decisions with patients. However, despite his respect for the patient's right to autonomy and self-determination, the clinician feels professional responsibility to explain risks and consequences. Whereas there are opportunities to pose valid choices (such as a range of quit smoking methods or whether to prioritise weight loss versus blood pressure control), the professional feel there is a larger overriding goal and is *not* in equipoise. His agenda is to modify the individuals' risk profile and, although he aims to do that with sensitivity and tact, he nevertheless has a clear agenda to motivate him to adopt a healthier lifestyle and to better manage his long term condition.

The patient however is ambivalent about the problem. He is among other drivers who have come to little harm from smoking and, besides, a beer with his friends is a valued escape from a tedious routine. He appreciates his clinician's concern and does his best to adhere to an agreed new medication regime – but he is, at best, ambivalent about whether to make all the suggested changes.

This is a stark example perhaps, but *dual* equipoise is clearly *not* present. For the professional, the evidence points in a clear direction and the patient has other, competing, priorities. We contend that interventions designed to deal with these kinds of problems are probably best regarded as ‘behavioural support interventions’ rather than decision support interventions. Motivational interviewing and behaviour change counselling are good examples of such interventions, aimed at supporting individuals to recognise actions which are important to them and to gain confidence in being able to sustain the behaviours over time [26]. This argument, in turn, brings us to a definition:

*‘behavioural support interventions describe, justify, and recommend actions which, over time, lead to predictable outcomes over short, intermediate and long-term timeframes, and which have relevant and important consequences for those who are considering behaviour’ change’.*

### Definitions of decision and behaviour support interventions

From these two descriptive accounts, we wish to move to compare the two definitions and to discuss their implications. The table provides a summary of their key characteristics. These descriptions are deliberately brief: they provide only an outline of what such an intervention could eventually contain. The point is to draw attention to the issue dual equipoise as a design determinant. Dual equipoise assumes that all parties in the decision space agree that preferences are paramount – that there is sufficient equivalence among options to allow personal preference to hold sway. In addition, such decisions are discrete in that they occurs at a single time points, are often irreversible, and commonly, relatively urgent. A decision to undergo a surgical procedure, to have a test, to enter a screening programme – all these are decisions where dual equipoise exists, albeit to greater degrees, depending on ambient professional or policy perspectives. There are many ways in which interventions can be designed to address this episode, ranging from a brief description or comparison of options to elaborate interactive multimedia website. It remains to be seen whether or not such interventions will conform to standards such as those set by IPDAS, or indeed whether the IPDAS Collaboration is nimble enough to adapt to innovations over time. At the core of the definition however, which is the rationale for putting it forward, is the assumption of *dual equipoise*, and unless an intervention is clear about the nature of the dual equipoise and the provenance of the evidence on which it makes such a claim, we contend that it cannot be classed as a decision support intervention.

Table Definitions and key characteristics of decision and behaviour support interventions

Definitions	Decision support interventions	Behaviour support interventions
	<i>‘decision support interventions describe and justify the conditions where dual equipoise exist, provide information about options and about the short, intermediate and long-term outcomes which have relevant and important consequences for decision-makers’.</i>	<i>‘behavioural support interventions describe, justify, and recommend actions which, over time, lead to predictable outcomes over short, intermediate and long-term timeframes, and which have relevant and important consequences for those who are considering behaviour’ change’.</i>
Key characteristics	Describe a decision where there is legitimate dual equipoise.	Describe the consequences (risks) of different behaviours / actions.

	Options are equal and clearly delineated.	Options, if present, are ranked.
	Option attributes clearly delineated, compared.	Describe a range of safe (risk reducing) behaviours / range of consequences of unsafe (risk enhancing) behaviours.
	Intermediate and long-term outcomes described, using social, psychological and biological consequences and decision making processes and interventions are provided at cross-road points.	Intervention involves interaction, data collection and feedback over time, to support behaviour modification.
	A recommendation (decision or action) is avoided.	A recommendation is generated, albeit negotiated.

In situations where dual equipoise does not exist, the weight of evidence (or consensus) is such that a professional, to maintain integrity to profession and to society, is swayed to recommend an action or to motivate an action or a change of behaviour. Helping a patient to achieve good self-care in diabetes or in heart failure and so on, entail a series of behaviours where benefits far outweigh risks, and therefore, ultimately, the clinician is obliged to set out an agenda and which may be at odds with patient preferences. Similarly, there are many ways in which interventions can be designed to address the task of providing support for a recommended action or behaviour. A time-honoured method is the establishment of a continuing relationship with a supportive informed clinician, as is exemplified by a primary care model. More recently, programmes which support the development of self-care and self-management have been developed [27-30]. Future programmes will no doubt build on these interventions, by enhancing patient motivation, creating patients capable of co-producing health care, engaging patients more closely in monitoring their illness, capable of reacting to data feedback methods. At the core however, is the assumption that there are a set of actions and behaviours that will enhance their outcomes, which rather than be episodic recurrent decisions, will become automatically integrated into daily routines.

#### Decision and behaviour support interventions: implications

This article proposes new and separate definitions for interventions which propose to help people arrive at high quality decisions and for interventions to initiate and maintain behaviours which lead to improved outcomes in healthcare contexts. We are aware of previous definitions and hope the arguments put forward here help to clarify the debates surrounding the scope of these methods and the terminology being used. We further felt it necessary to clarify why these two classes of interventions are different to each other in terms of *dual* versus *single* equipoise, hoping that we will prevent researchers and developers lumping together approaches that need different theoretical foundations [31]. Developers need to design tools that are clear about the different goals, characteristics and motivations of users and place more emphasis on theories that align with the different tasks of either undertaking deliberative choices or initiating and sustaining behaviour change.

Although we agree that patient-centeredness is wide enough to apply to all health care interactions the concept of shared applies best to situations where *dual* equipoise exists; behaviour change methods on the other hand, such as motivational interviewing or behaviour change counselling, applies to situations where dual equipoise is unavailable. We avoid going into more depth about these kind of interventions: there is a vast literature, and given the interest in self-management approaches to chronic diseases, it is likely that behaviour support interventions and the potential to harness the

power of feedback from monitoring techniques and personalised interactive tools (web and telephony) will continue to be an area for further development. The design of decision support interventions, as they engage with web 2.0 and wiki technologies is also at a stage of evolution, and although standards are emerging, they will require modification as innovations and further research is published.

## Summary

We believe that, over time, both decision and behaviour support interventions will become important components of health care pathways. However, as we hope to have demonstrated, they have divergent aims, different relationships to equipoise and, by definition, form two intervention classes: decision and behaviour support interventions (DESI and BESI). By being clear about definitions and overall goals, we hope that our ability to use appropriate theories to design and evaluate their impact will also improve.

### List of abbreviations used:

DESI: decision support interventions

BESI: behavioural support interventions

IPDAS: International Patient Decision Aids Collaboration

**Competing interests:** The authors declare that they have no competing interests.

**Authors' contributions:** GE and DF initiated the discussion with SR; all authors contributed to the final manuscript.

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