

# Separating Risk Assessment from Risk Management Poses Legal and Ethical Problems in Person-Centred Care

Mette Kjer KALTOFT<sup>a,b</sup>, Jesper Bo NIELSEN<sup>b</sup> and Jack DOWIE<sup>c,b,1</sup>

<sup>a</sup> Odense University Hospital Svendborg, Denmark

<sup>b</sup> University of Southern Denmark, Denmark

<sup>c</sup> London School of Hygiene and Tropical Medicine, UK

**Abstract.** Accelerating progress in screening technologies, e.g. genetic testing, means more individuals are facing the stressful decision of whether to request the test. Fully-informed and preference-based consent, as well as ethical practice, requires the full range of benefits and harms from any test or treatment to be identified and assessed from the individual's point of view. For both ethical and legal reasons, we see the decision on whether to undertake a genetic screening test being increasingly seen, in future, as calling for a personalised analysis of the full range of subsequent management options. The conventional dissociation of 'risk assessment' and 'risk management' phases is thereby ruled out. One way of addressing the resulting challenge is through personalised multi-criterial decision support tools. In this vision paper we provide conceptual proof of method of how such an interactive online tool could function. The polygenetic genetic screening decision is used, solely as illustration.

**Keywords.** risk assessment, risk management, person-centred decision support, breast cancer genetic screening

## 1. Introduction

While apparently innocent and attractive - "let's just do the test and see what it says and then decide what to do after we know the result" - this sequencing infringes the legal, ethical, and economic principle that no screening test (often called a 'risk assessment'), should be done unless the consequences of its possible results have been thought through. In many medical text books this is conveyed in statements such as 'A test should be done only if its results will affect patient management by causing the probability of disease to cross the treatment threshold'. As legally required, and as ethically expected in person-centred care, the decision on whether to undertake a screening test accordingly calls for an ex ante analysis of the full range of management (often called 'risk mitigation') options.

Failure to adhere to this best practice principle opens the person up to over diagnosis and overtreatment in a cascade of unnecessary tests and treatments -and their consequences. This is much less likely to occur if the decision had been addressed as one of multi-criterial risk management - or simply as making the best decision -from

---

<sup>1</sup> Corresponding Author, Jack Dowie, LSHTM, London WC1H 9SK, UK; E-mail: jack.dowie@lshtm.ac.uk.

the initial starting point. Separating an initial risk assessment phase from a subsequent risk management phase (on the basis of a now known assessment) also interferes with the autonomy of the person. It biases their information processing, through focusing the decision making on the criteria measured in the risk assessment, often a single outcome such as risk of developing breast cancer. Whether or not to undertake a risk assessment should therefore embrace all the benefits and harms that matter to the person in the management decision, not only those addressed in the restricted risk assessment. Whether to have a risk assessment can therefore only be satisfactorily answered in the light of a full multi-criterial management analysis. This will enable the individual to give an informed and preference-based consent testing. The aim of this vision paper is to suggest how a ‘perfected’ informed consent [1]—might be met when, as we envisage, the future demands it. The method is Multi-Criteria Decision Analysis (MCDA). The result is a decision support tool which provides the conceptual proof of method which is a necessary condition for empirical development. The polygenetic test for breast cancer is used as the illustrative case [2].

## 2. Method

Multi-Criteria Decision Analysis is widely used in many public and private-sector decisions, but the health care sector has been relatively slow to adopt it [3]. The type of MCDA most compatible with ethical person-centred decision making, and most able to ensure informed and preference-based consent, is the value-based, compensatory model. This takes the form of a ‘weighted-sum’ model, which multiplies the personalised numerical ratings for the performance of each option on each criterion by the relative weight assigned to the criterion by the person, and then sums these weighted ratings to get an overall preference-sensitive score for each option.

AnMCDA-based Personalised Decision Support Tool (PDST) therefore involves determining and inputting:

- the relevant *criteria*, including the possible benefits and harms; these may be offered in a menu from which the person selects a subset at the point of engagement with the tool (‘Pick Your Own’)
- the available *options*; this list should be without provider censoring or filtering and including ‘do nothing’ and ‘watchful waiting’, as baseline and/or options
- the evidence-based- or, where necessary - expertise-based performance *ratings* for all options on all criteria, except those where the person is the expert, such as treatment burden, which they rate at engagement
- the person’s characteristics (age, sex, etc.), which act as personalising modifiers of the performance ratings at the point of engagement

At engagement, the individual enters their weights for the included criteria and the full set of expected value scores for the options are displayed as the preference-sensitive opinion of the tool.

## 3. Results

A draft MCDA-based PDST for home use in the genetic screening decision for breast cancer is presented, as the conceptual proof of method necessary in advance of full

protocol and tool development. No empirical data are presented, since it is irrelevant for this purpose. The PDST is built within the Annalisa MCDA template [4], but the software choice is also irrelevant in this proof of method. The tool deals with two scenarios. In one, the person has already had a risk assessment, such as one based on family history, and their probability of breast cancer from this test is available. In the other, no such prior risk assessment has been done. The sequence, as the tool is engaged with, is as follows:

### 3.1. Management analysis for average risk

The person enters their criterion weightings and option burden ratings. Clicking next displays the full management MCDA which contains all possible options, without censoring or filtering apart from legal or biological restrictions. It is pre-populated with age- and sex- specific average population option ratings for all criteria, plus the newly-entered person's self-reported burden ratings for each option. The option scores generated are for a woman at average risk (e.g. 12.5%), but preference-sensitised. The illustration in Figure 1 has some possible options and criteria, and only default values.

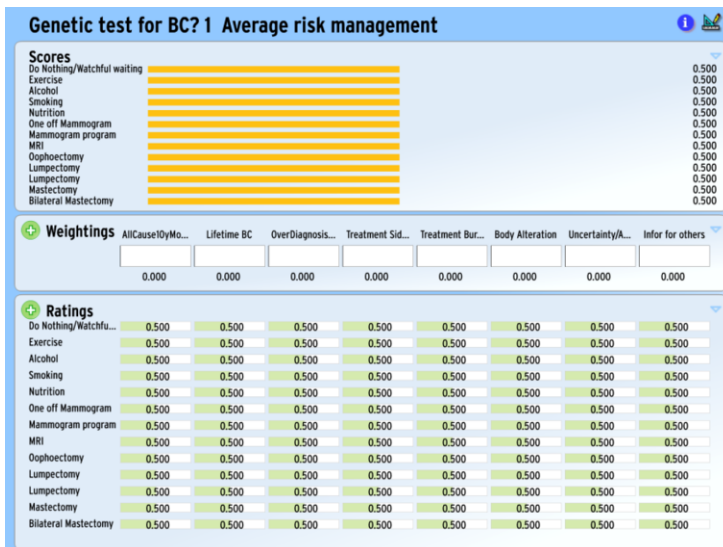


Figure 1. Screen from draft Breast Cancer genetic screening decision support tool (illustrative)

### 3.2. Management analysis for prior risk

A prior risk assessment, such as one based on familial risk, is available [5]. When the person enters this result into the tool, on clicking they can instantly see the full adjusted management MCDA, using the weights they entered previously. If there is not a superior test available, such as a polygenetic one, the tool's decision support ends here.

### 3.3. Management analysis given range of possible risks from a polygenetic test

On clicking, the person sees the full management MCDA adjusted for their lowest possible polygenetic risk result. This will reflect the characteristics of the prior test if

they have had one, otherwise it will be the lowest for an average woman. On clicking again, the full management MCDA for their highest possible polygenetic risk appears.

3.4. *The differences between all the option scores for the highest and lowest possible results are visually displayed.*

This hypothetical exploration has determined, and displayed visually, the comparative management implications of three possible test results. The person can now make a fully informed and preference-based decision whether to go for the polygenetic test.

3.5. *Management analysis after polygenetic test, if it has been undertaken*

Person enters their result on receipt and immediately sees their final full management MCDA with the personalised opinion emerging from the PDST.

#### 4. Discussion

An MCDA-based PDST can be used inter-mediatively, ‘delivered’ by a clinician in a shared decision making process to help the patient arrive at the best decision for the patient. In contrast, it can be used apomediatively (‘direct-to-consumer’) by the person in the community to help them decide for themselves, including whether to consult [6]. If they do so decide, the tool can be used inter-mediatively in the consultation. The purpose of an MCDA-based PDST is not to reduce decision conflict, anxiety, worry, or any of the many psychological effects of stressful decisions surrounding health. A proposed PDST, such as the current one, will make clear what is involved, and emphasise that consent to engage with it should only be given if the person feels able to cope with what they will meet. In this case it will be designed to support the person in seeking to make the best decision on whether to have a polygenetic test, doing so in the light of a full, preference-sensitive management analysis that meets the legal and ethical requirements we believe will characterise the future of healthcare.

#### References

- [1] W. Nelson, K. Clay, Transitioning to ‘perfected’ informed consent. Mutual understanding calls for shared decision making, *Healthc Exec.* **26** (2011), 54–5.
- [2] N. Mavaddat, P.D.P. Pharoah, K. Michailidou, et al., Prediction of breast cancer risk based on profiling with common genetic variants, *J. Natl. Cancer Inst.* **107** (2015), 1–15.
- [3] P. Thokala, N. Devlin, K. Marsh, et al., Multiple Criteria Decision Analysis for Health Care Decision Making — An Introduction : Report 1 of the ISPOR MCDA Emerging Good Practices Task Force, *Value Health* (2016), 1–13.
- [4] J. Dowie, M.K. Kaltoft, G. Salkeld and M. Cunich, Towards generic online multicriteria decision support in patient-centred health care, *Health Expect.* **18** (2013), 689–702.
- [5] A. Brédart, J. Kop, A.C. Antoniou, et al., Use of the BOADICEA web application in clinical practice: appraisals by clinicians from various countries, *Fam Cancer* **17** (2017), 31–41.
- [6] G. Eysenbach, Medicine 2.0: Social networking, collaboration, participation, apomediation, and openness, *J Med Internet Res.* **10** (2008), 1–11.