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# Risk Thresholds and Risk Classifications Pose Problems for Person-Centred Care

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**Abstract.** Classification of a continuous risk score into risk levels is common. However, while the absolute risk score is essential, it is arguably unethical to label anyone at 'high, moderate or low risk' of a serious event, simply because management based on a single criterion (e.g. avoiding the target condition) has been determined to be effective or cost-effective at a population level. Legally, mono-criterial risk labeling can inhibit the obtaining of a fully-informed, preference-based consent, since multiple considerations (various benefits and harms) matter to most individuals, not only the single criterion that is the basis of the provided risk category. These ethical and legal challenges can be met by preference-sensitive multi-criteria decision support tools. In this future vision paper, we demonstrate, at a conceptual proof-of-method level, how such decision support can and should be developed without reference to risk-level classifications. The statin decision is used as illustration, without any empirical claims.

**Keywords.** risk thresholds, risk classifications, person-centred decision support, Multi-Criteria Decision Analysis

## 1. Introduction

In their recent investigation of General Practitioner (GP)s statin prescribing for the primary prevention of Cardiac Vascular Disease (CVD), Robinson et al. found no upward 'blip' at either of the guideline thresholds placed on the New Zealand-adjusted Framingham CVD risk score [1]. However, in person-centred care, the case for using an absolute risk score in decision making, rather than managing on the basis of a threshold-based segmentation of the risk scale (e.g. into high, moderate or low risk), cannot rest on whether or not clinicians actually practice this way. To give their informed and preference-based consent to any test or treatment, the person must be informed about the harms and benefits of all the relevant options, with the magnitudes of those harms and benefits being assessed on the basis of their personal importance weights at or near the point of decision. While this requirement is rarely fully met today (except in surgery) it will be a prominent feature of the future we envisage and address in this vision paper. A key implication is that it will not be acceptable to focus on the single outcome proposed as the main criterion, e.g. CVD in the above case, Fracture in the bone health case, Breast cancer in an oncology case. The decision

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process must address the other criteria -considerations and things that matter to the person - equally as seriously and equally as analytically. When combined with the requirement for the individual to be able to weight those criteria explicitly and transparently, one is driven towards some form of multi-criteria analysis personalised decision support tool [2]. The need for a single-criterion, threshold-based guideline, based on average patients, becomes moot.

We can find no analytical basis for particular thresholds (e.g. 10%, 15%, 20%) and resulting risk characterisations – for most conditions - other than population level effectiveness and cost-effectiveness analyses. While appropriate at the policy level, this makes them inappropriate in person-centred care. It is unethical to tell someone they are at ‘high, or moderate, or low risk’ of a serious event simply because the standard management for the relevant risk range has, or has not, been determined to be cost-effective – or simply effective by some single criterion - at a population level. The Frax®-based guidelines in relation to primary prevention of fractures [3,4] and screening guidelines for most cancers are guilty of the same offence. From a wider perspective, risk classifications are just another way of clustering individuals to simplify guidelines and service provision. As a result, average group preferences are often used, inappropriately, in preference-sensitive individual decisions.

The argument against segmentations of risk measures is even stronger when it extends to basing management decisions solely on the individual’s relative risk in a statistical distribution for a population. Hypertension provides a highly relevant example, where the typical risk classification includes defining the disease on the basis of systolic and diastolic blood pressure levels above 130/90 or 140/90. A disease called osteoporosis exists if (and only if) an individual’s bone mineral density is 2.5 standard deviations below a group norm (that for a young white US female). Diabetes is a further example. All these statistical definitions infringe the individual’s right to make a decision based on their individual absolute risk, as well as possibly being a major source of over diagnosis and overtreatment [5].

The aim of this paper is limited to providing proof of method, at a conceptual level, that decision support tools based on the technique of Multi-Criteria Decision Analysis (MCDA) can claim to meet both the ethical requirements for person-centred care and the legal requirements for consent. This is done - necessarily - without reference to any thresholds or classifications imposed on continuous risk measures. The example of a statin decision support tool is provided, but purely as illustration. It has no empirical claims to be a properly developed and validated tool.

## **2. Methods**

The type of decision support tool we envisage becoming a familiar feature of the e-health future - because of their ability to meet these twin requirements - are based on MCDA. As noted in the recent ISPOR Task Force reports, MCDA methods are widely used in public-sector and private-sector decisions on transport, immigration, education, investment, environment, energy, and defence, and but the health care sector has been relatively slow to apply them [6,7].

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 scores to get an overall preference-sensitive score for each option.

The performance ratings for all options on all criteria must be on the same continuous 0-1 (0 to 100%) scale and be personalised to the absolute risk of the individual concerned. Any segmented classification of an absolute risk for any criterion will undermine cross-criterial comparability and hence the coherence of the analysis.

### 3. Result

The illustration is of a multi-criterial personalised decision support tool for the statin decision: Should I go, or not go, to my general practitioner to discuss taking statins?

It shows how an overall opinion can be obtained from such a tool without any threshold-based risk classification and indeed that the tool requires the unclassified absolute risks to be input wherever these are relevant.

The statin decision support tool, built within the Annalisa implementation of MCDA [2], involves the person:

1. completing an online instrument to obtain an estimate of their personalised absolute risks of All-Cause and Cardiovascular Mortality in the next ten years
2. self-assessing their blood pressure and total cholesterol level, which are the two inputs required, along with age, sex and smoking status, to complete the online EuroSCORE-based instrument
3. self-rating the treatment burden of statins
4. assigning relative importance weights to four criteria (two 10 year mortalities, statin side effects and statin burden).

All these inputs are on continuous scales, albeit with different granularity, but without any threshold cut-offs. The tool is best understood by engaging with it. It is accessible at <https://goo.gl/H7P51r>.

The tool is derived directly from Støvring et al. [8] and purports only to translate the data in that study into multi-criteria decision support format as an illustrative proof of method. It adds two of the other criteria that would be needed in personalised tools - treatment side effects and treatment burden - and others maybe added in a fully-developed tool. We reiterate, its purpose here is purely illustrative, not empirical.

#### 4. Discussion

Publicly accessible, multi-criteria analysis-based personal decision support tools are widely available to consumers in many areas of life. Which (UK), Tænk (Denmark), and Choice (Australia) are familiar examples of comparison services that support the decision as to which fridge, which vacation package, or which insurance package to obtain. While health decisions are undoubtedly more important, it is fallacious to assume that a different decision support structure is necessarily required here [9]. Deeper thinking about what goes into that structure, especially the criterion weightings and performance ratings, may be the route to higher quality ‘tough’ decisions.

A decision support tool (DST) is distinguished from an ‘Information Support Tool’ by (i) the structuring of the information it presents in decision-relevant form, and (ii) the elicitation of the person’s preferences (criterion weights) at or near the point of decision, and (iii) the presentation of an algorithmic synthesis of the information and elicited preferences as scores for all the options included in the aided analysis. Some ‘patient decision aids’ (Option Grids, Mayo Cards) meet the first requirement, but do not satisfy the other two. They are also usually designed solely for use within clinical encounters and are available only through a health provider.

In conclusion, risk thresholds and classifications based on single criterion effectiveness and/or cost-effectiveness are inappropriate in person-centred care, even if possibly useful in policy-making and research. Personalised multi-criterial decision support tools avoid threshold-based risk classification and thereby facilitate the ethical and legal practice that will be demanded in the coming digital paradigm [10].

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