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Participation rate or informed choice? Rethinking the European key performance indicators for mammography screening

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ABSTRACT

Despite the intensive controversies about the likelihood of benefits and harms of mammography screening almost all experts conclude that the choice to screen or not to screen needs to be made by the individual patient who is adequately informed. However, the "European guideline for quality assurance in breast cancer screening and diagnosis" specifies a participation rate of 70% as the key performance indicator for mammography screening. This paper argues that neither the existing evidence on benefits and harms, nor survey research with women, nor compliance rates in clinical trials, nor cost-effectiveness ratios justify participation rates as a reasonable performance indicator for preference-sensitive condition such as mammography screening. In contrast, an informed choice rate would be more reasonable. Further research needs to address the practical challenges in assessing informed choice rates.

1. Background

Breast cancer is a serious illness and an important cause of death among women. Mammography screening (MS) as a measure for early detection of breast cancer involves potential benefits (reduced mortality) and harms (through overdiagnosis and overtreatment) for the participating women [1–3]. For many years now two questions have been discussed controversially: (1) do MS-related benefits outweigh the MS related harms? [1,2,4–7] and (2) do the existing information materials and current physician counselling allow an adequately informed choice by individual women for or against participation in MS programmes? [8–10].

However, the necessity of informed decision making resulting in *informed choices* on whether to participate in MS programmes or not seems to be uncontroversial. According to Rimer et al. informed decision making in cancer screening occurs when an individual understands the disease or condition being addressed and comprehends what the clinical service involves, including its benefits, risks, limitations, alternatives, and uncertainties; has considered his or her preferences and makes a decision consistent with them; and believes he or she has participated in decision making at the level desired [11]. The most important outcome of informed decision making is whether patients make informed choices, and not which specific choices they make [11,12].

However, no performance indicator of the current "European guideline for quality assurance in breast cancer screening and diagnosis" (last updated in 2006) asks for the frequency (rates) of informed choices in national MS programmes [13]. According to the European guideline, a performance indicator reflects the provision and quality of the activities constituting the screening process without contributing directly to reduction in mortality [13]. Though the European guideline presents "Potential communication quality indicators" in a special chapter on "Guidance on

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breast screening communication" these indicators are not part of the key performance indicators that primarily guide the *normative* evaluation of national MS programmes in Europe. In contrast, the European guideline explicitly states that a 70% participation rate is *acceptable* and a 75% participation rate is *desirable* [13]. Participation rate is defined as the number of women who have a screening test as a proportion of all women who are invited to attend for screening.

How does this work out in practice? How can we know in advance that 70% of eligible women will make (or should make) the informed choices in favour of MS? Furthermore, how can we know that the 70% of women that finally participate include only those that made the informed choice in favour of MS?

2. Analysis

2.1. Can the evidence on potential benefits and harms of MS justify what participation rate is desirable?

Using the participation rate as a performance indicator makes sense when there is broad and uncontroversial consent among physicians, clinical epidemiologists and patients that the benefits of a given screening intervention clearly outweigh the risks. Newborn screening for phenylketonuria and congenital hypothyroidism might be such a case. Against this background, a reasonable performance indicator for newborn screening programmes is a participation rate of 100%.

The Cochrane review on MS as well as the evidence report for the US Preventive Services Task Force (USPSTF) both highlight the concern as to whether the magnitude of benefit is sufficient to clearly outweigh the harms [1,2]. The recent analysis of the Independent UK Panel concludes that a favourable benefit–harm ratio exists [5]. Despite the controversies about the likelihood of benefits and harms of MS, all three reviews state explicitly that whether this trade-off becomes acceptable cannot be made on scientific grounds alone. The UK Panel, for example, concludes that "information should be made available in a transparent and objective way to women invited to screening so that they can make informed decisions".

In conclusion, the existing evidence on potential benefits and harms speaks against a priori judgments as to whether 50%, 70%, or 90% of women should participate in MS. MS seems to be a *preference-sensitive condition*. In preference-sensitive conditions patients value outcomes differently or equipoise exists between closely matched strategies (here: to screen or not to screen) [14,15]. Such situations require well informed (shared) decision making that takes the patient's preferences into account [16]. Other preference-sensitive conditions are, for example, inhaled long-acting beta-agonists in asthma treatment [17] or surveillance of an indeterminate pulmonary nodule [18].

2.2. Can survey research on women's attitudes towards MS justify what participation rate is desirable?

The European guideline does not explicitly explain or justify how they determined the 70% participation rate as desirable. In the guideline's preface the authors mention that experiences in Europe demonstrate that MS can be "feasible" in terms of reducing mortality in countries with participation rates varying between 70% and 90%. However, the authors do neither reflect on the MS related harms at this point nor do they mention whether the information basis for this "feasible" implementation of a MS programme was adequate.

Other sources such as the evidence report for the USPSTF and the UK Panel partly argue for some sort of an a priori judgement on the willingness of women to participate in MS by referring to findings from survey research. For example, the evidence report for the USPSTF conclude "early evidence suggests that women will tolerate a high risk for false-positive results". This conclusion refers to survey findings showing that 63% of women would accept 500 instances of false-positive results to save one life [19]. Also the UK Panel refers to one focus group organized by Cancer Research UK and former survey research data (without references) to argue that many women feel that accepting the offer of breast screening is worthwhile [5].

It is right that these survey data demonstrate that a substantial proportion of women would participate in MS after being adequately informed about benefits and harms. However, when it comes to the determination of "desired" participation rates (as *key* performance indicator) could survey data on women attitudes play any reasonable role? Even if the internal validity of the relevant survey findings is appropriate, we need to critically evaluate whether these findings also have appropriate external validity. In other words, to evaluate the performance of MS programmes we should evaluate not just how women decided in academic surveys that according to their study protocol applied high standards for shared decision making and informed choices. We also need to evaluate whether in real-life physician counselling on MS allows women to make informed choices.

Measuring informed choice as primary endpoint in preventive medicine clearly is a new concept. However, this concept is more and more applied in practice. For example, a multi-dimensional measure of informed choice was developed and validated by Marteau et al. [20,21]. In a first randomized-controlled trial Steckelberg et al. employed this concept of informed choice for evaluating patient decisions about participation in colorectal cancer screening [12].

To put the above analysis on the role of survey data on the determination of participation rates into practice: Those responsible for national MS programmes should be satisfied with a participation rate of 70% only if they know (from valid evaluation activities) that the 70% of invited women who participated in MS and the 30% who did not participate all made informed choices. Otherwise, we do not know whether we face the (hypothetical) scenario that although 70% of invited women participated these women include 30% that would not have participated and exclude 30% of women that would have participated would they all have been informed adequately.