

## Medical ethics and screening: on what evidence should we support ourselves?

Ética médica e rastreamento: em quais evidências deveríamos nos apoiar?

*Ética médica y tamizaje: ¿sobre qué evidências deberíamos nos apoyar?*

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*If screening had been a drug, it would have been withdrawn from the market. Thus, which country will be first to stop mammography screening?*

(Peter C. Gøtzsche)<sup>1</sup>

This issue of RBMFC addresses the subject of medical ethics, the backbone that should guide both the demands in health services and health technologies provision, as well as the practice of family and community physicians. As a stimulus for reflection, the Debate section tackles the “Preventive mandatory mammography” policy in Uruguay, while in the Section Essays, Jamouille and Gomez discuss the concept of quaternary prevention: action that aims to offer ethically acceptable alternatives to patients in order to prevent the excess of medical interventions.<sup>2</sup> Despite considerable technological and social transformations that directly affect people’s health, ethics in medicine continues to morally shape health problems and health policy decisions with implications for patients, physicians and health institutions.

In a practical analytical and easy to understand guidance for health professionals, Gillon<sup>3</sup> discusses the four principles and scope of medical ethics: autonomy, beneficence, non-maleficence and justice. The latter encompasses the distributive justice, individual right justice and legal justice. These four principles provide a baseline for dialogue across different cultures, religious beliefs and political positions, as these principles are considered to be *prima facie*: a duty which is compulsory on all occasions unless it is in conflict with equal or stronger duties.<sup>4</sup> Thus, based on these four principles that underlie ethics in medicine and consequently the application of the quaternary prevention, cancer screening programme will be critically analysed as a preventative strategy.

Screening programmes entails the use of an initial selective tool or a sieve phase (i.e. mammography) to separate asymptomatic persons within the target population, that will need to undergo a classificatory or diagnostic phase - which involves a ‘gold standard’ for defining a disease (i.e. anatomopathology) – to finally offer patients a definitive preventive treatment for the condition screened.<sup>5</sup> Since this type of intervention is performed on healthy individuals, the ethical requirements in the cases of screening programmes are very high, because the risks of damage are not balanced against real suffering (a clinically manifested disease), but are anchored in a potential future of illness and death. In this case, the principle of non-maleficence (do not harm) prevails over the principle of beneficence (the desire to promote the patients’ wellbeing), since asymptomatic persons, who perceive themselves as healthy, may have their health perception shaken indefinitely due to a biomedical intervention. The most often cited damages in the literature are psychological (due to the uncertainties of false positives, false assurance of false negatives, and borderline conditions that require a closer monitoring such as Cervical Intraepithelial Neoplasia - CIN I, II, III), as well as the physical consequences resulting from treatment itself, such as impotence or urinary incontinence, in the case of screening and treatment of prostate cancer.

**Como citar:** Norman AH. Medical ethics and screening: on what evidence should we support ourselves? Rev Bras Med Fam Comunidade. 2014;9(31):108-110. Disponível em: [http://dx.doi.org/10.5712/rbmfc9\(31\)933](http://dx.doi.org/10.5712/rbmfc9(31)933)

Since in the screening and/or health check ups the intervention is usually a 'mirage-guided' or 'probability-guided', it can result in 'damage without the potential benefits',<sup>6</sup> as in the case of invasive procedures (to clarify 'images' or 'positive' exam results produced in the selective or sieving phase) which can result in complications, but the biopsy turnout to be normal. For instance, colonoscopy, laparoscopy, biopsies (liver, kidney, prostate), in which those procedures may end up producing complications (intestinal perforation, anaesthesia complications, major artery perforation, sepsis) with the potential to scale up into hospital readmission, with stress for patients and families and/or an even worse scenario: patients' death with a benign finding. Therefore, screening programmes intrinsically carry the potential to convert healthy people into sick individuals at the population level, and consequently are highly iatrogenic and could be summarized as follows: *"For many are called, but few are chosen..."*, but many will need to suffer for to very few be cured.

This is particularly true in the case of breast cancer screening with mammography, which renders physiopathologically insignificant cancers (overdiagnosis) exposing previously healthy women to significant damages due to radiotherapy. Gotzsche et al.<sup>7</sup> highlighted important risks of adverse effects as consequence of radiotherapy, such as heart failure (27%) from circulatory cardiac damage and/or induction of lung cancer (78%). Furthermore, a recently published systematic review in the British Medical Journal<sup>8</sup> on the adverse effects of cancer screening, found that only a third of randomized controlled clinical trials was concerned in measuring and controlling for potential harms of screening intervention. This article is very important because it has a direct effect upon the practice of health professionals, who cannot address security parameters on cancer screening interventions with their patients, since there is an information selection bias that emphasizes only the positive aspects of screening, for lack of controlling and monitoring of potential harms in most screening clinical trials.

From an ethical stance, this context of uncertainty undermines the patients' autonomy, creating false empowerment, since women do not have a more complete view on the potential harms and benefits of breast cancer screening programmes.<sup>9</sup> To truly empower women and strengthen their autonomy for deciding upon interventions that directly affect their health, there is a need for information to be more transparent and also to reveal potential harms of the interventions. Moreover, the language used for the dissemination of information should be neutral, of simple understanding, culturally accessible, so that the users of the health system can better decide about their own health.<sup>3</sup>

From the perspective of public health, distributive ethic justice, and limited healthcare budget - that any health system faces - screening programmes diverts financial resources - which should primarily be allocated to the treatment and care of sick individuals - towards healthy people, with the potential to produce new real patients, due to the damage of the interventions on healthy bodies, generating more costs to the health system and society in general.

Fortunately, screening programmes are increasingly losing their strength, especially in Europe. For instance, the Swiss Medical Board<sup>10</sup> found no scientific rationale for the maintenance of breast screening programmes in light of current available scientific evidence. In Denmark, the rate of mortality attributable to breast cancer have not reduced due to the implementation of systematic breast cancer screening programme with mammography over 17 years follow up,<sup>11</sup> however, it has produced an overdiagnosis rate of 33%.<sup>12</sup> Similar trends in mortality over the last 30 years were also observed in the United States,<sup>13</sup> as well as in Canada, the accumulated 25 years monitoring of the effects of breast cancer screening, did not render reduction in mortality from breast cancer, but resulted in 22% of overdiagnosis.<sup>14</sup> Thus, to Peter C. Gotzsche,<sup>1</sup> one of the world's leading authorities on the subject, the best method we have to reduce the occurrence of breast cancer is to stop screening with mammography.

From an ethical and scientific point of view,<sup>10</sup> screening programmes should be discontinued or restricted to high-risk groups or very specific situations, and the focus of prevention should be redirected towards interventions on early-symptomatic patients, since breast cancer treatment has improved considerably in recent decades, and this is likely to be the responsible for improving the quality of life of affected women.<sup>1</sup> The Canadian Task Force<sup>15</sup> on preventive health care in their last update (2011) regarded as weak recommendation the breast cancer screening with mammography every 2-3 years in age group 50-69 years-old, because they considered the evidence for screening only of moderate quality. The Brazilian Ministry of Health<sup>16</sup> also acted correctly in limiting the financial incentives for breast cancer screening for the age group 50-69 years.

Therefore, 'there is nothing wrong saying no to mammography',<sup>9</sup> because when acting upon asymptomatic healthy people, the principle of non-maleficence should override the principle of beneficence. Thus, the challenge left for family and community doctors is to individualize each case in this 'sea of uncertainty', sharing with their patients the often hidden potential harms attributed to cancer screening in order to operationalize in daily practice the concept of quaternary prevention.

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