

Informed Decision-Making and Capabilities in Population-based Cancer Screening

Ineke L. L. E. Bolt^{ID*†}, Department of Medical Ethics, Philosophy & History of Medicine, Erasmus MC, Rotterdam, The Netherlands

Maartje H. N. Schermer^{ID†}, Department of Medical Ethics, Philosophy & History of Medicine, Erasmus MC, Rotterdam, The Netherlands

Hanna Bomhof-Roordink, Department of Public and Occupational Health, Amsterdam UMC, Vrije Universiteit, Amsterdam, The Netherlands

Danielle R. M. Timmermans, Department of Public and Occupational Health, Amsterdam UMC, Vrije Universiteit, Amsterdam, The Netherlands

*Corresponding author: Ineke Bolt, Department of Medical Ethics, Philosophy & History of Medicine, Erasmus MC, Wytemaweg 80, 3015 CN, Rotterdam, The Netherlands. Email: i.bolt@erasmusmc.nl

†Bolt and Schermer contributed equally to this paper and share first authorship.

Informed decision-making (IDM) is considered an important ethical and legal requirement for population-based screening. Governments offering such screening have a duty to enable invitees to make informed decisions regarding participation. Various views exist on how to define and measure IDM in different screening programmes. In this paper we first address the question which components should be part of IDM in the context of cancer screening. Departing from two diverging interpretations of the value of autonomy—as a right and as an ideal—we describe how this value is operationalized in the practice of informed consent in medicine and translate this to IDM in population-based cancer screening. Next, we specify components of IDM, which is voluntariness and the requirements of disclosure and understanding. We argue that whereas disclosure should contain all information considered relevant in order to enable *authentic* IDM, understanding of basic information is sufficient for a *valid* IDM. In the second part of the paper we apply the capability approach in order to argue for the responsibility of the government to warrant equal and real opportunities for invitees for IDM. We argue that additional conditions beyond mere provision of information are needed in order to do so.

Introduction: Cancer Screening Programmes and IDM

Population-based cancer screening takes place in several—especially rich income—countries (Sivaram *et al.*, 2018). There are important differences in the organization of such programmes. Some countries (e.g. Denmark, The Netherlands) offer an organized screening programme characterized by a systematic invitation of the target population. These programmes are centrally

organized and monitored by a governmental screening organization to provide high-quality population-based screening. A formal permission from the government is required in order to run such screening programmes. In contrast, other countries, such as the USA, allow opportunistic screening: screening offered to an individual or to those who request a screening test without a definition of the target population and systematic invitation of citizens (Sivaram *et al.*, 2018). Another important difference amongst countries offering screening programmes

<https://doi.org/10.1093/phe/phac023>

Online publication date: 3 October 2022

© The Author(s) 2022. Published by Oxford University Press.

This is an Open Access article distributed under the terms of the Creative Commons Attribution-NonCommercial License (<https://creativecommons.org/licenses/by-nc/4.0/>), which permits non-commercial re-use, distribution, and reproduction in any medium, provided the original work is properly cited. For commercial re-use, please contact journals.permissions@oup.com

is the presence of a system of health care insurance; screening programmes are publicly funded and free of charge in some countries (e.g. in the Netherlands), while in other countries participants have to pay for screening and subsequent diagnostics and treatment.

Countries also differ considerably with respect to the legal requirements of national screening programmes. The Netherlands is among the few countries where conditions are legally regulated in the Population Screening Act (WBO) installed in 1992. A WBO permit is required for specific screening programmes, including cancer screening. The Centre for Population Screening at the National Institute for Public Health and the Environment (CvB-RIVM) coordinates the national population-based screening programmes offered on behalf of the Dutch government. It has to set the standards governing the quality and implementation of (new) screening programmes and to evaluate the quality of the programmes. Currently, the CvB-RIVM coordinates three population-based cancer screening programmes: breast cancer, cervical cancer and colorectal cancer. Since informed decision-making (IDM) is a quality indicator as stated in the Dutch Policy Framework for Population Screening for Cancer, it has to be evaluated whether and to what degree IDM is achieved (Klein and van Velzen, 2016).¹

Currently, different definitions of IDM and different measurement instruments are available (Marteau *et al.*, 2001; van de Berg *et al.*, 2006). In this paper we will address the following questions: what ought to be the components of IDM in the context of organized cancer screening which should also be included in a measurement instrument, and what exactly is the responsibility of the government in facilitating IDM?

In the first part of our paper we will distinguish two interpretations of the underlying value of IDM: autonomy as an ideal and as a right to self-determination. Next, we will describe how the value of autonomy is operationalized as informed consent in the context of medical practice and translate this to IDM in the context of cancer screening. We will discuss what voluntariness as a component of IDM entails in the context of cancer screening, and we will specify the requirements of disclosure and understanding.

In the second part we will address an important issue that has received little attention in the discussion about IDM to date, namely the extent to which invitees have an equal and real opportunity to make an informed decision (ID). We will apply the capability approach to argue that governments have a duty to ensure real and equal opportunities to make an ID regarding participation in cancer screening. We will use the capability approach to

formulate the abilities and resources that are important for the capability to make an ID, and argue that since these are important conditions for IDM they should also be part of a measurement instrument. Finally, we will draw conclusions regarding the responsibility of the government in warranting IDM in organized cancer screening.

The Value of Autonomy

Autonomy is considered to be a fundamental value in population-based cancer screening (Klein and van Velzen, 2016; WHO, 2020). The World Health Organization (WHO) for instance, values the capacity to make an informed and uncoerced decision (WHO, 2020).² And even though definitions of IDM differ, authors value autonomy as the underlying principle of IDM: ‘The fundamental goal in enhancing patient choice is to enable patients to come to an autonomous decision which reflects their personal preferences’ (Jepson *et al.*, 2005).

In the field of medical ethics autonomy is generally interpreted in two different ways (Schermer, 2001).³ First, autonomy is considered to be an aspirational ideal. We strive to lead an authentic and autonomous life, and to make voluntary, well-considered decisions that are consistent with our personal values and beliefs. Authenticity here can be understood as ‘self-reflective acceptance of one’s own values’ (Faden and Beauchamp, 1986: 264). Authentic decisions are characterized by awareness, identification or acceptance of one’s preferences, motivations, attitudes, values and as such require critical reflection and identification (Faden and Beauchamp, 1986; Dworkin, 1988). Applied to cancer screening, autonomy in this sense would amount to an invitee having complete freedom to read and understand all relevant information, to reflect critically on the choice situation, to identify and scrutinize relevant personal preferences, motivations, values and the like, to make a decision consistent with his or her preferences and values, and to make a good decision, that is a decision that promotes what is conceived by the agent to be in his or her interests. Autonomy in this sense is an ideal that may be beyond the reach of many or most individuals but may nevertheless be considered a value worthy to strive for.

The second interpretation holds that autonomy is the right to self-determination, that is, the right to govern oneself, to make one’s own choices and to act upon them without being interfered with by others. Applied

to cancer screening, this right should be respected even if decisions of invitees are in conflict with their own interest, foolish, risky or mistaken. People should not be coerced, deceived or manipulated and be able to live their life without being controlled by others.

Authors do not always clearly distinguish the different interpretations of the value of autonomy, nor elaborate on the role of authenticity or the role of personal values.⁴ Some authors, however, explicitly argue that authenticity in terms of critical identification and reflection is too demanding because it would narrow the range of autonomous actions that are protected by the principle of respect for autonomy (Faden and Beauchamp, 1986).⁵ Even deliberate decisions might be excluded as autonomous if a person has not critically reflected on, for instance, their cultural assumptions or the origin of personal values. In order to avoid these problems, according to some authenticity could be reformulated as consistency in or stability of values underlying the decision. Such a condition, however, may also wrongly render some decisions non-autonomous; values can be in transition, revised or newly formed (Faden and Beauchamp, 1986; Beauchamp and Childress, 2019).⁶ Faden *et al.* note that a more promising approach may be to reformulate authenticity as 'non-repudiation of values': non-reflected motives and values may be perfectly authentic unless the person consciously repudiates them as inauthentic.

However this may be, the important point is that, rather than one, there appear to be diverging interpretations of autonomy: the right to self-determination and the ideal of authenticity. This distinction is not always made explicit and the precise role of values is not always clearly stated in accounts of autonomous decision-making. Authenticity in a substantial interpretation is prominent in the aspirational ideal of autonomy and plays a much more modest part in the right to self-determination. One could argue that the more preference-sensitive a decision is and the more serious its consequences for the person are, the more importance should be attached to authenticity and reflection on values (Kater-Kuipers *et al.*, 2020).

Operationalization of Autonomy: Informed Consent and IDM

In health care and medical ethics, the right to self-determination is operationalized as informed consent; in the context of screening one most often speaks of IDM.⁷ Both involve the (moral and legal) right to decide for

oneself whether or not to undergo treatments or to participate in screening programmes. Patients have the right to consent or refuse medical interventions, and invitees to cancer screening have the right to consent to or abstain from participation. By giving an informed consent, an invitee waives her right not to be interfered with (e.g. to undergo breast examination in the context of breast cancer screening or to have samples taken for cervical cancer screening) and as a consequence transforms the intervention from a morally (and legally) forbidden act into a permissible act (DeGrazia and Millum, 2021: 118). A valid informed consent, or valid informed decision-making (VIDM), however, does not necessarily have to be an authentic and beneficial decision, for an invitee has the right to make a rather unconsidered choice, or a choice they may later regret. The right to self-determination implies that rights should be respected even in cases where refusal or consent may not be beneficial for the person, not truly in line with their values, or even risky or foolish. The government should respect this right to self-determination and therefore has the moral duty to offer relevant information in a balanced and transparent way. Moreover, not only the content of the information but also the manner in which information is provided has to enable IDM; providing information in an understandable way and avoiding deception, manipulation and coercion.

The aspirational ideal of autonomy holds that authentic informed decision-making (AIDM) is the case if an invitee has fully understood all the relevant information and, comes to a well-considered decision after careful and critical reflection and deliberation on their personal preferences, motivations and values. Although this may be an aspirational ideal, the government is not obliged to *warrant* that an authentic decision is actually made conform the ideal of autonomy. This would be too demanding and leave too little room for people who may not be willing or able to make decisions in this way. The government does have an obligation, however, to make sure invitees are able to make VIDM. In the following section we discuss the key components of VIDM regarding cancer screening: voluntariness, disclosure and understanding of information.⁸ We will start with voluntariness as a key component of IDM.⁹

Voluntariness

A decision to partake in screening, or consent to a medical procedure should be voluntary. Voluntariness is threatened when individuals are the subject of coercion,

deception, undue inducements, manipulation and the like. There are no indications of coercion and coercive offers—the direct use of physical force or credible threats of harm—in organized cancer screening programmes; invitees are neither forced nor obliged to participate. Some may argue that the simple fact that an authoritative body such as the government offers screening induces invitees to participate. However, an offer in itself is not problematic as long as invitees are fully aware that participation is optional and not subjected to informational manipulation.¹⁰ It becomes more problematic when the offer is accompanied by a mass media campaign with the goal to increase screening participation, as is, for example, the case for breast cancer screening in Australia (Cancer Institute NSW). Such a campaign urging women to screen threatens the voluntariness of their decision, especially if the information provided is not well-balanced.

Informational influence is a valid and recognized concern regarding voluntariness in the context of organized cancer screening (Ploug *et al.*, 2012). A potential influence is, for instance, when information is intentionally framed in such a way that invitees are more likely to participate [e.g. presenting reduced mortality figures in relative terms and overdiagnosis and overtreatment in absolute terms (Juth and Munthe, 2012)]. Making the option for non-participation more difficult by means of a pre-booked appointment or by asking non-participants to unsubscribe so ‘someone else can go in their place’ is another example (Ploug *et al.*, 2012). Informational influence can be qualified as morally problematic if it misleads and deceives invitees.¹¹

However, proponents of nudging argue that not all intentional (informational) influences threaten voluntariness, and that some influences can be perfectly in line with the value of autonomy. Nudges are defined as ‘interventions that steer people in particular directions but that also allow them to go their own way’ (Sunstein, 2015: 417). It is argued that nudging is justifiable from a libertarian-paternalistic view: as long as options are not blocked or burdened, and nudges steer individuals in such a way that they are, in their own judgement, better off (Thaler and Sunstein, 2008). However, as Ploug *et al.* convincingly argue, the use of nudges in organized cancer screening can not be justified by libertarian paternalism as nudges do not necessarily promote the welfare of individual invitees. Screening may be beneficial but participation can also be harmful to the well-being of individuals (Ploug *et al.*, 2012).¹² It cannot be assumed that invitees would be better off by being nudged.

Finally, a potential threat to voluntariness concerns (informational) influence exerted through the general public (e.g. by means of social media), family and friends. Empirical studies show that non-participants of colorectal cancer screening (CRC) experienced decision-making as not being completely free because they perceived the social norm to be to participate in CRC screening (Douma *et al.*, 2020). Although non-participants mentioned that it could be difficult to go against the social norm, it did not necessarily strongly influence their personal opinion. This finding seems to indicate that understanding and deliberation were not impeded, and that they were not unduly pressured into participation.¹³ Moreover, the nature of the relationship between invitee and informal parties is quite different from that between the government and invitees. In the latter, the government invites its citizens to participate in screening, and hence the government is responsible for the provision of objective, balanced and clear information, and should refrain from steering decision-making in any direction. The government cannot be blamed for invitees who are influenced by friends, family or other social parties, however. Social pressure to take part in screening programmes is not different from any other form of social pressure—such as following the latest fashion—and does not necessarily undermine autonomy (Wijsbek, 2000). Moreover, even if voluntariness were undermined by social pressure, it is not clear how the government could be held responsible for this.

In short, voluntariness is an important component of IDM. Measurement instruments should contain items to test whether invitees are fully aware that participation is optional. Whether or not invitees are the subject of informational manipulation, however, cannot be measured by asking invitees whether they have been manipulated, deceived and the like. Whether or not leaflets or other informational resources are misleading, deceptive or steering towards participation has to be explored by a critical analysis of these resources.¹⁴

Disclosure and Understanding

So far we argued that the government should abstain from coercion, deception and undue (informational) influences and provide relevant, balanced and objective information in an accessible manner to facilitate the IDM process. This follows from the right to self-determination: people should be able to make their own choices without coercion, pressure, misleading information and based on relevant information. Starting

from the ideal of authentic autonomy, the standard of information disclosure is, the more demanding, subjective standard (Faden and Beauchamp, 1986): disclosure of information should be tailored to the informational needs of invitees given their age, gender, health and (dis)ability, preferences, values and beliefs etc. In order to determine the content of the disclosure requirement, it is necessary to investigate what experts and, in particular, invitees deem relevant information in order to make an ID. Some may value information on the different success rates of screening (e.g. breast/cervical/colorectal cancer mortality, cancer mortality, all-cause mortality), whereas other invitees (in particular those who suffer from one or multiple diseases) may need information about life-expectancy. The content of the information for the disclosure requirement in the case of population-based cancer screening should thus be rather comprehensive, in order to enable invitees to make AIDM. The input of invitees is essential in order to further determine the content of the information to a diversity of citizen's informational needs.

Disclosure of information is of course not sufficient for IDM. Invitees should also understand the relevant information in order to make an ID. So far, studies on the extent to which information is understood by patients, research participants and invitees are not encouraging, to say the least (Mandava *et al.*, 2012; Sherlock and Brownie, 2014; Tomlinson *et al.*, 2016; Pietrzykowski and Smilowska, 2021). This fact raises the issue of sufficient understanding. Do invitees have to understand all the information provided or is it sufficient if they understand the core components? If so, what do those core components entail? Is it the government's duty to ensure that invitees have understood all the relevant information provided or only the core components?

In our view it is necessary to make a distinction between the two requirements of disclosure and understanding. The government should disclose all information that invitees and experts consider relevant in order to make an authentic decision and live up to the ideal of autonomy if they want. However, the government is not obliged to warrant that invitees understand each and every part of the disclosed information. Such a requirement would not only be unfeasible, but also beyond the right to self-determination. As stated earlier, invitees have the right to self-determination and thus to make their own choices; it is up to them to decide whether or not to make AIDM. Sufficient understanding as a prerequisite for VIDM is met as long as they understand the core components of information. What should the core components of VIDM include? Based

on existing literature, individuals should be aware that they are giving consent and 'not doing something else' and know how to exercise their right to give or refuse consent (DeGrazia and Millum, 2021) or as Faden and Beauchamp put it: a person must firstly (sufficiently) understand *that* an authorization is involved (Faden and Beauchamp, 1986). Invitees should thus understand that participation implies giving consent and should understand their right *not* to participate. Invitees of cancer screening are generally not explicitly being asked to give their consent or to sign a consent form. An invitee's consent is assumed when he or she actually participates in screening.¹⁵ It is thus essential that invitees are aware that they are giving consent for screening when they actually participate in screening and that certain actions (e.g. entering the location for mammography or sending the test kit with stool collection to the screening organization) imply giving consent for participation.

Moreover, individuals should sufficiently understand *what* they are authorizing the government to do (Faden and Beauchamp, 1986). A person must understand 'what he or she is agreeing to, that is, what the person obtaining consent will be permitted to do that he or she was not permitted to do before' (DeGrazia and Millum, 2021: 122–123). This condition holds that invitees should understand what the government or governmental bodies are permitted to do provided a valid consent is given. Invitees, in our view, should understand, at a minimum, the purpose of screening, the interventions during screening and the existence of potential drawbacks. Invitees might believe screening is for their own personal well-being. In principle, this is not the case: the balance of benefits and harms may be favourable at a population level but not necessarily at an individual level. Participation in screening can have adverse consequences for an individual participant, for example, if they receive a false positive outcome and have to undergo invasive follow-up tests. It should be clear to invitees that the setting of screening is public health and not clinical care for individual patients. Invitees should also understand the goal of the interventions and the potential disadvantages of participation, including the clinical pathway after receiving a positive test result. In short, information on the purpose of population-based cancer screening, the possibility of false positive/negative results, overdiagnosis and overtreatment is therefore required in order to achieve basic understanding. The details of the core components of information that should be understood for VIDM should be further determined with the input of invitees and experts.

IDM and the Capability Approach

The components we discussed so far—voluntariness, information disclosure and understanding—are generally considered as essential for IDM. What has received less attention in IDM definitions and measurement instruments are the conditions that need to be in place for people to actually *be able* to make IDs. Empirical studies show a great variety amongst invitees in their abilities to read and understand leaflets about screening programmes, for example, that may impede IDM (Fransen *et al.*, 2017; Okan *et al.*, 2019). Furthermore, personal or social circumstances of particular invitees may affect whether invitees have a real opportunity to make an ID. The idea that having equal and real opportunities to be and do is important when considering the duties of governments to ensure equality and well-being, is at the core of the capability approach (Sen, 1980; Robeyns, 2017). In our view, the capability approach offers a suitable approach to outline the responsibility of the government in warranting that different (groups of) citizens have equal opportunities to actually engage in IDM. In line with the capability approach, we will argue that it is a matter of health justice that governments offering cancer screening should warrant equal and real opportunities for citizens to make IDs about participation, as well as equal and real opportunities to participate if they decide to do so.

Amartya Sen introduced the capability approach in 1979 as a normative framework to assess quality of life in countries, to evaluate policies, and to determine the duties of the government to warrant equality and well-being (Sen, 1980). Sen used the capability approach to argue that gross domestic product is an inadequate indicator of social progress and prosperity of a country and that we need to look at the real opportunities available to people in order to evaluate well-being. Giving people equal resources is not sufficient to attain real equality, since people are differently placed to convert resources into actual well-being. Since then, the capability approach has been applied in many other contexts and for different purposes, such as to evaluate new biomedical technologies (Jacobs, 2020), to analyse gender equality (Robeyns, 2003), or to ground a human right to the capability to be healthy (Venkatapuram, 2011). Robeyns qualifies the capability approach as ‘an open-ended and underspecified framework, which can be used for multiple purposes’ (Robeyns, 2017: 29). Here, we provide a concise application of the capability approach to further outline the responsibility of the government in warranting an equal and real opportunity for IDM.

Inequalities in the capability for IDM imply inequalities in the opportunity to exercise one’s autonomy regarding screening decisions and may also exacerbate inequalities in health. Warranting equality of opportunity can be considered an important task of the government for the following reasons. First, the government has the means and is in the best position to protect and improve equal and real opportunities for IDM through financial funding of organizational bodies responsible for providing the public with balanced and transparent information and support in decision-making. However, ‘can’ does not imply ‘ought’: the fact that the government *can* play an important role as an agent of change is not a sufficient reason for arguing that it ought to warrant the capability for IDM. Second, the moral duty of the government in public health issues goes beyond promoting public health and respect for autonomy as a side-constraint. The government should also be committed to considerations of social justice and warrant that public health policies protect and improve the position of those most disadvantaged (Powers and Faden, 2006; Nuffield Council, 2007; Verweij and Dawson, 2013).¹⁶ In the context of population-based cancer screening this moral duty entails warranting equitable access to screening and, with respect to IDM, the duty to warrant the conditions for equal and real opportunities for IDM.

In order to further specify this duty, we will explain and apply those key concepts of the capability approach that are most relevant to the issue of IDM in the context of organized cancer screening.¹⁷

Applying the Capability Approach

Every application of the capability approach should contain the core concepts of *capabilities* and *functionings* (Robeyns, 2017). Capabilities are defined as the real opportunity to do and be, for instance, to possess real opportunities to travel, to vote or to read. Functionings are defined as the acquired or achieved capabilities, often phrased as ‘beings and doings’. Examples of ‘beings’ are being healthy, being literate, being educated, whereas travelling, voting or taking part in a debate are examples of ‘doings’ (Robeyns, 2017). For reading (a functioning), one needs reading skills, physical abilities and the like, all of which are needed for having the capability to read. It is important to note that one can have a capability without realizing it; a person who does not read books may be perfectly free to read books. Not having a certain functioning does not necessarily imply absence of the corresponding capability. The capability approach therefore stimulates us to focus on the actual ability of

persons: 'what people are able to do and what lives they are able to lead' and helps us to look at different dimensions when we have to gather data in order to evaluate policies or practices (Robeyns, 2017: 7). Applied to the context of cancer screening and IDM, we consider making an actual ID as a functioning whereas the real opportunity to make an ID is the corresponding capability. The government should ensure that the capability to make a VIDM is existent.

Another core idea of the capability approach is that people differ in the degree to which they can convert a resource into a functioning. This idea is captured by the concept of 'the conversion factors': 'the factors which determine the degree to which a person can transform a resource into a functioning' (Robeyns, 2017: 45).¹⁸ Resources are of particular interest to us when they enable functionings. A commonly given example of a valuable resource is the bicycle, which gives us the ability to move around in a pace faster than walking. However, abled individuals or those who learned to ride a bike generally can turn this resource into the functioning of mobility better than individuals with a physical handicap or those who did not learn to cycle. As noted above, cancer screening invitees differ significantly in their skills, abilities and circumstances. These differences may impede or promote the degree to which an invitee can convert a resource (e.g. information leaflet) into a functioning, as we will illustrate by using Robeyns' distinction between personal, social and environmental conversion factors.

Personal conversion factors are factors that 'are internal to a person, such as metabolism, physical condition, sex or intelligence' (Robeyns, 2017: 46). A few examples can show how personal conversion factors may hinder IDM. Some invitees lack the ability to read the leaflet (e.g. invitees with a visual handicap who do not have access to braille translations or audio versions) and thus are not able to transform leaflets as a resource into the functioning of making an ID. In a similar vein, invitees with low (health) literacy or whose (first) language is not included in the leaflet face difficulties in having access to and understanding information in the leaflet. Besides, standard leaflet designs may be more suitable for invitees with an analytic decision strategy and less helpful for invitees with an intuitive, spontaneous style (Robb *et al.*, 2020). Different styles of decision-making (e.g. analytical vs more intuitive) need to be taken into account in how information is provided and designed in order to facilitate decision-making (Timmermans, 2013). In order to provide invitees the capability to VIDM, the responsibility of the government goes beyond providing

a leaflet: information about cancer screening should be accessible for invitees with different capacities and skills (such as people with low (health) literacy, invitees with limited language proficiency, invitees with physical and/or developmental disability, invitees with limited or non-analytical decision-making skills).

Social conversion factors arise from the society in which invitees live, such as cultural and social norms, public policies, discriminatory practices, or forms of power related to class, gender, race or caste (Robeyns, 2017). Factors as prolonged stress and lack of time caused by unemployment, debts or informal caregiving to a relative or loved-one may stand in the way of IDM. Cultural beliefs and social norms also may complicate IDM. In the case of cervical cancer screening some Turkish- or Moroccan-Dutch invitees are afraid that participation of screening would make others think they are sexually active before marriage, have multiple partners, or are infertile (Hamdiui *et al.*, 2021). Do these beliefs threaten the capability to make an ID? Clearly, the capability to IDM is complicated if the decision of invitees is based on false or inaccurate information. The government should enable the real opportunity to IDM through providing information that is tailored to groups who hold cultural beliefs and norms that are based on false or incorrect information. Moreover, the government could support and facilitate the decision-making process (e.g. offering specific value-clarification aids and making invitees aware of false beliefs).

The capability to *participate* in screening is of course also important. The government should enable participation by removing obstacles that certain groups in particular face. The real opportunity to participate in screening may, for instance, be hampered when female invitees do not want to be examined by a male health care professional (Kerrison *et al.*, 2021) or when personal factors such as physical disabilities inhibit participation (e.g. entering the location for mammography or sending the test kit with stool collection to the screening organization). Although, as we already indicated, our focus is on the capability for IDM, and not on the capability to participate in screening, these obstacles to participate may also indirectly hinder the capacity to make IDs. This may be the case when invitees are factoring these obstacles into their decision. For instance, in the case of cervical cancer screening, Turkish- and Moroccan-Dutch women seem to have low self-efficacy expectations regarding the self-sampling test in contrast to the general Dutch population (Hamdiui *et al.*, 2021). New communication strategies, such as experience narratives, might increase low self-efficacy expectations

through improved confidence and as such support the decision-making process (Woudstra and Suurmond, 2019). Resources are thus adjusted in order to enable specific invitees to make IDs.

The third source of conversion factors arises from the physical (geographical location) or built environment that a person lives in, labelled as environmental conversion factors (Robeyns, 2017). Examples of these factors are unavailability of (public) transport or irregular public transport and distance to the screening facility. Currently, the corona pandemic may hinder participation because of the fear to be infected at the screening location or invitees may abstain from consulting their general practitioner due to a rush on the general practitioner's consulting hours. Further, even though cancer screening is free of charge, for some invitees follow-up medical research can be costly, in particular if health insurance coverage is insufficient. The key question here is again whether these obstacles hinder the capacity for IDM. In case these factors hamper the correct understanding of relevant information or the reasoning process, which may be the case if an invitee refrains from consulting their general practitioner, it certainly is. However, it seems that not all obstacles pertain to the capability for IDM, but rather to the capacity to actual participation in screening, such as the availability of public transport (which is also a capability that the government should warrant).

Measuring Capability or Functioning, Opportunities or Achievements?

The final question to be discussed is whether in evaluating IDM processes in cancer screening programmes, we should focus on capabilities, functionings or a mixture of both. Should one evaluate the *capability* of invitees to make an ID and therefore measure whether invitees score sufficiently on the items related to the capability for IDM? Or should one focus on the outcome and thus measure whether invitees actually achieved the 'functioning', that is, made an ID?

An important reason to focus on capabilities is to establish whether a government has fulfilled its duties of ensuring equality of real opportunity, as we have argued above. A second reason to focus on the capability for IDM instead of functioning is to avoid paternalistic concerns (Robeyns, 2017). In warranting capabilities one does not force persons into exercising a specific capability but leaves it up to them to decide which capability to choose and fulfil. Not everyone may find it very important to make IDs regarding cancer screening, and even if

they have the capability, they may not want to convert it into a functioning.

So, there are good reasons for evaluating the capability for IDM instead of the functioning (IDM). However, focussing on the capability for IDM may not be feasible. It may be quite difficult to establish whether the capability for IDM is present and much easier to establish a functioning (did the invitee at least make a VIDM). As Robeyns notes, this practical concern may be solved by using an analysis of functionings as a proxy for an analysis of capabilities. 'In the case of comparison of inequalities between groups it has been argued that group inequalities in functionings should be taken to reflect group-inequalities in capabilities, except if a plausible reason can be offered for why the members of those groups would systematically choose differently' (Robeyns, 2017: 112). If we measure inequalities in achieving IDM for certain groups of invitees, this may reflect inequality in the capability for IDM of this group (if another plausible explanation of this inequality is absent).

Conclusion

We discussed IDM as an important moral and legal prerequisite for organized cancer screening and the government's duty to evaluate whether and to what extent IDM is achieved, as it is stated as a quality indicator in the Dutch Policy Framework for Population Screening for Cancer. Based on a distinction between autonomy as a right and an ideal we have argued for the central components of IDM and translated them to the context of organized cancer screening. We discerned potential threats to voluntariness as a condition for IDM and stressed that the government should ensure that invitees are fully aware that participation is optional. Further, we argued that understanding of core components of information is needed for a VIDM. In addition, we argued that the government should strive to disclose all information considered relevant by invitees and experts in an accessible manner, taking into account the informational needs of a variety of invitees in order to enable AIDM.

Finally, we underlined the importance of additional conditions needed in order to warrant equal and real opportunities to IDM and for the responsibility of the government to warrant these conditions. An analysis from the capability approach contributes to an understanding on what people need to have a real and equal opportunity for IDM. Certain (groups of) invitees may

need additional support or specific resources to be truly able to make an ID.

We are aware that our analysis of IDM is a rough sketch that is in need of further elaboration in order to be operationalized. In this respect it is important to point out that different views on human information processing and decision-making used in applications of the capability approach may lead to different ideas on the resources that are considered to be important. It is thus important to be explicit about views on human decision-making underlying IDM and measurement instruments.

Funding

This research was funded by [ZonMw - the Netherlands Organization for Health Research and Development](#) (Grant No. 531002032).

Conflict of interest

The authors declare no conflict of interest.

Notes

- 1 · In the field of population-based (cancer) screening the terms ‘informed choice’ (Marteau *et al.*, 2001; Jepson *et al.*, 2005), ‘ID’, or ‘IDM’ (e.g. Van den Berg *et al.*, 2006) are the preferred terms whereas in medical ethics and clinical practice the term ‘informed consent’ is commonly used. See for an overview of the rationales offered for the preference of each term (Kater-Kuipers *et al.*, 2020). Kater-Kuipers *et al.* argue that the reasons to prefer informed choice or IDM are all captured by the *ethical* notion of informed consent. We agree with Kater-Kuipers *et al.* but prefer the term IDM in the context of population-based cancer screening, because it expresses the decisional process and aligns with the terminology in the context of cancer screening.
- 2 · Autonomy is also explicitly mentioned in the criteria drawn up by the WHO in 2008 as an addition to Wilson and Junger’s ten criteria: ‘The programme should ensure informed consent, confidentiality and respect for autonomy’ (Andermann *et al.*, 2008).
- 3 · See also for instance, Faden and Beauchamp (1986: 236), Beauchamp and Childress (2019: 102), DeGrazia *et al.* (2021). In philosophy, for instance Joel Feinberg differentiates between autonomy as ideal and right (Feinberg, 1986).
- 4 · For instance, DeGrazia *et al.* include values as part of their definition of autonomous actions but it is not clear how this should be interpreted: ‘In bioethics, autonomous actions are generally defined as’: ‘an agent A performs action X autonomously if and only if (i) A performs X (a) intentionally, (b) with sufficient understanding, (c) sufficiently free of controlling influences; and (ii) A decided, or could have decided, whether to X in light of A’s values’ (DeGrazia and Millum, 2021: 99–100). In contrast, Beauchamp and Childress’ definition of autonomous actions does not include ‘values’ (Beauchamp and Childress, 2019: 102).
- 5 · Beauchamp and Childress specifically criticize authenticity as interpreted in split level theories of autonomy, which is the capacity to reflectively identify with or oppose one’s basic desires or preferences through higher level desires or preferences (Beauchamp and Childress, 2019: 100–104).
- 6 · Value-consistency (as consistency between intention and behaviour) is for instance used in the IDM measurement tools of Marteau *et al.* (2001). If the decision made (do/do not intend to participate in screening) is consistent with the attitude (the ‘choice actually made’ (do/do not participate in screening) the choice is considered consistent with personal underlying norms and values.
- 7 · In line with note 1, we believe that informed consent is equivalent of IDM with regard to its underlying goal and components.
- 8 · See Beauchamp and Childress (2019: 122). In the same line, Faden and Beauchamp: an informed consent includes intentionality, understanding and the absence of controlling influences (Faden and Beauchamp, 1986). See also DeGrazia *et al.*’s definition in note 3. For different definitions of IDM see van de Berg *et al.*, 2006.
- 9 · Capacity or competence of individual patients is also considered to be a condition of informed consent in medical practice. Competence is assessed when physicians presume that the patient is incapable of determining his or her will regarding a specific choice situation. Individual assessment of competence, however, is not feasible in the context of public health.
- 10 · See Elton (2021) for a discussion on the framing effect of an invitation to screening and her suggestion to provide metainformation as a strategy to tackle this issue.

- 11 · See for a clear analysis of instances of control (DeGrazia and Millum, 2021). Deception is defined as: ‘one person deliberately inducing another to believe something that the first party believes to be untrue’ (DeGrazia and Millum, 2021: 108).
- 12 · Moreover, nudging may reduce trust of invitees in the government since invitees may rightfully expect transparent communication of the government. See for instance Blumenthal-Barby: ‘The point here is the reasonable expectations of invitees in the government and the moral obligations associated with the relationship, and whether the informational influence damages the relationship due to a lack of respect, equality, trust etc.’ (Blumenthal-Barby, 2012: 359).
- 13 · ‘They did feel a pressure because of it, and a need to explain or defend their decision more (Quote 8, Table 2). This often resulted in them having slight doubts and taking the time to think through their decision once more’ (Douma et al., 2020: 11).
- 14 · See for instance Ploug et al. for a critical analysis of the informational resources of the Danish breast cancer screening programmes (Ploug et al., 2012) and van Dijk et al.’s critical assessment of the Dutch colorectal screening programme (van Dijk et al., 2016).
- 15 · ‘This is why some authors prefer the term ‘informed choice’ instead of ‘informed consent’ (Jepson et al., 2005).
- 16 · Within the space of this article we can not provide the argument for social justice as a normative ground of public health. See Powers and Faden’s theory on social justice as the basic moral foundation for public health (Powers and Faden, 2006). See also Verweij and Dawson and the Nuffield report on public health arguing that the government has a particular responsibility to protect and promote the health of vulnerable groups (Nuffield Council on Bioethics, 2007; Verweij and Dawson, 2013).
- 17 · Robeyns describes all the core concepts needed for an application of the capability approach (Robeyns, 2017). In this brief account we cannot discuss all the core concepts. The elements we do not discuss are not at odds with our application.
- 18 · Robeyns gives a broader interpretation of the conversion factors than Sen did who focuses on material and/or measurable resources while Robeyns’ interpretation also includes intangible resources such as educational degrees (Robeyns, 2017: 45).

Manuscript received: May 2022

References

- Andermann, A., Blancquaert, I., Beauchamp, S., and Déry, V. (2008). ‘Revisiting Wilson and Jungner in the Genomic Age: A Review of Screening Criteria Over the Past 40 Years’. *Bulletin of the World Health Organisation*, **86**, 317–319. doi:10.2471/BLT.07.050112
- van den Berg, M., Timmermans, D. R., ten Kate, L. P., van Vugt, J. M. and van der Wal, G. (2006). ‘Informed Decision Making in the Context of Prenatal Screening’. *Patient Education and Counseling*, **63**, 110–117. doi: 10.1016/j.pec.2005.09.007
- Blumenthal-Barby, J. S. (2012). ‘Between Reason and Coercion: Ethically Permissible Influence in Health Care and Health Policy Contexts’. *Kennedy Institute of Ethics Journal*, **22**, 345–366.
- Cancer Institute NSW. *Not In My Family* [Online], available from: <https://www.breastscreen.nsw.gov.au/campaigns/not-in-my-family> [accessed 25 July 2022].
- DeGrazia, D., Millum, J. (2021). *A Theory of Bioethics*. Cambridge: Cambridge University Press. doi: 10.1017/9781009026710
- van Dijk, G., Blanker, M., Noordzij, A. and ter Borg, M. (2016). ‘Voorlichting over darmkankerscreening deugt niet’. *Medisch Contact*, **49**, 18–21.
- Douma, L. N., Uiters, E., Verweij, M. F. and Timmermans, D. (2020). ‘Autonomous and Informed Decision-making: The Case of Colorectal Cancer Screening’. *PLoS ONE*, **15**, e0233308. doi: 10.1371/journal.pone.0233308
- Dworkin, G. (1988). *The Theory and Practice of Autonomy*. Cambridge: Cambridge University Press.
- Elton, L. (2021). ‘Non-maleficence and the Ethics of Consent to Cancer Screening’. *Journal of Medical Ethics*, **47**, 510–512.
- Faden, R. R., and Beauchamp, T. L. (1986). *A History and Theory of Informed Consent*. New York/Oxford: Oxford University Press.
- Feinberg, J. (1986). ‘Harm to Self’. *The Moral Limits of the Criminal Law*. New York: Oxford University Press.
- Fransen, M. P., Dekker, E., Timmermans, D. R. M., Uiters, E. and Essink-Bot, M. L. (2017). ‘Accessibility of Standardized Information of a National Colorectal Cancer Screening Program for Low Health Literate Screening Invitees: A Mixed Method Study’. *Patient Education and Counseling*, **100**, 327–336. doi:10.1016/j.pec.2016.09.004
- Hamdiui, N., Marchena, E., Stein, M. L., van Steenberg, J. E., Crutzen, R., van Keulen, H. M., Reis, R., van

- den Muijsenbergh, M. E. T. C. and Timen, A. (2021). 'Decision-making, Barriers, and Facilitators Regarding Cervical Cancer Screening Participation Among Turkish and Moroccan Women in the Netherlands: A Focus Group Study', *Ethnicity & Health*, **27**, 1147–1165. doi: [10.1080/13557858.2020.1863921](https://doi.org/10.1080/13557858.2020.1863921)
- Jepson, R. G., Hewison, J., Thompson, A. G. H. and Weller, D. (2005). 'How Should We Measure Informed Choice? The Case of Cancer Screening', *Journal of Medical Ethics*, **31**, 192–196.
- Juth, N., and Munthe C. (2012). *The Ethics of Screening in Health Care and Medicine. Serving Society or Serving the Patient?* Dordrecht, Heidelberg, London, New York: Springer Verlag.
- Kater-Kuipers, A., de Beaufort, I. D., Galjaard, R. J. H. and Bunnik, E. M. (2020). 'Rethinking Counselling in Prenatal Screening: An Ethical Analysis of Informed Consent in the Context of Non-invasive Prenatal Testing (NIPT)', *Bioethics*, **34**, 671–678.
- Kerrison, R. S., Travis, E., Dobson, C., Whitaker, K. L., Rees, C. J., Duffy, S. W. and von Wagner, C. (2021). 'Barriers and Facilitators to Colonoscopy Following Fecal Immunochemical Test Screening for Colorectal Cancer: A Key Informant Interview Study', *Patient Education and Counseling*, **105**, 1652–1662. doi: [10.1016/j.pec.2021.09.022](https://doi.org/10.1016/j.pec.2021.09.022)
- Klein, A. and van Velzen, R. (2016). *Beleidskader Bevolkingsonderzoeken naar Kanker. RIVM Rapport 2016-0168*.
- Jacobs, N. (2020). 'Capability Sensitive Design for Health and Wellbeing Technologies', *Science and Engineering Ethics*, **26**, 33631–33391. doi: [10.1007/s11948-020-00275-5](https://doi.org/10.1007/s11948-020-00275-5)
- Mandava, A., Pace, C., Campbell, B., Emanuel, E. and Grady, C. (2012). 'The Quality of Informed Consent: Mapping the Landscape. A Review of Empirical Data From Developing and Developed Countries', *Journal of Medical Ethics*, **38**, 356–365. doi: [10.1136/medethics-2011-100178](https://doi.org/10.1136/medethics-2011-100178)
- Marteau, T. M., Dormandy E, Michie, S. (2001). 'A Measure of Informed Choice', *Health Expectations*, **4**, 99–108.
- Nuffield Council on Bioethics, (2007). *Public Health: Ethical Issues*. London: Nuffield Council on Bioethics.
- Okan, Y., Petrova, D., Smith, S. G., Lesic, V. and Bruine de Bruin, W. (2019). 'How Do Women Interpret the NHS Information Leaflet About Cervical Cancer Screening?' *Medical Decision Making*, **39**, 738–754. doi: [10.1177/0272989X19873647](https://doi.org/10.1177/0272989X19873647)
- Pietrzykowski, T. and Smilowska, K. (2021). 'The Reality of Informed Consent: Empirical Studies on Patient Comprehension-Systematic Review', *Trials*, **22**, 57. doi: [10.1186/s13063-020-04969-w](https://doi.org/10.1186/s13063-020-04969-w)
- Ploug, T., Holm, S. and Brodersen, J. (2012). 'To Nudge or Not to Nudge: Cancer Screening Programmes and the Limits of Libertarian Paternalism', *Journal of Epidemiology and Community Health*, **66**, 1193–1196.
- Powers, M., and Faden, R. (2006). *Social Justice: The Moral Foundations of Public Health and Health Policy*. Oxford: Oxford University Press.
- Robb, K. A., Gating, L. P., von Wagner, C. and McGregor, L. M. (2020). 'Preference for Deliberation and Perceived Usefulness of Standard and Narrative-Style Leaflet Designs: Implications for Equitable Cancer-Screening Communication', *Annals of Behavioral Medicine*, **54**, 193–201. doi: [10.1093/abm/kaz039](https://doi.org/10.1093/abm/kaz039)
- Robeyns, I. (2003). 'Sen's Capability Approach and Gender Inequality: Selecting Relevant Capabilities', *Feminist Economics*, **9**, 261–392. doi: [10.1080/1354570022000078024](https://doi.org/10.1080/1354570022000078024)
- Robeyns, I. (2017). *Wellbeing, Freedom and Social Justice: The Capability Approach Re-Examined*. Cambridge, UK: Open Book Publishers, doi:[10.11647/OBP.0130](https://doi.org/10.11647/OBP.0130)
- Schermer, M. H. N. (2001). *The Different Faces of Autonomy. A Study on Patient Autonomy in Ethical Theory and Hospital Practices*. Ridderkerk: Ridderkerk BV.
- Sen, A. (1980) 'Equality of What?', in McMurrin, S. (ed.), *The Tanner Lectures on Human Values*. Salt Lake City: University of Utah Press, pp. 196–220.
- Sherlock, A., and Brownie, S. (2014). 'Patients' Recollection and Understanding of Informed Consent: A Literature Review', *ANZ Journal of Surgery*, **84**, 207–210, doi: [10.1111/ans.12555](https://doi.org/10.1111/ans.12555).
- Sivaram, S., Majumdar, G., Perin, D., Nessa, A., Broeders, M., Lyngge, E., Saraiya, M., Segnan, N., Sankaranarayanan, R., Rajaraman, P., Trimble, E., Taplin, S., Rath, G. K. and Mehrotra, R. (2018). 'Population-based Cancer Screening Programmes in Low-income and Middle-income Countries: Regional Consultation of the International Cancer Screening Network in India', *Lancet Oncology*, **19**, e113–e122. doi: [10.1016/S1470-2045\(18\)30003-2](https://doi.org/10.1016/S1470-2045(18)30003-2)
- Sunstein, C. (2015). 'The Ethics of Nudging', *Yale Journal on Regulation*, **32**, 413–450.
- Thaler, R. H., and Sunstein, C. R. (2008). *Nudge: Improving Decisions About Health, Wealth, and Happiness*. Yale University Press.
- Timmermans, D. R. M. (2013). *Wat beweegt de kiezer? Over de betekenis van weloverwogen en geïnformeerde keuzes voor gezondheid en preventie*. Den Haag/ Amsterdam: ZonMw/VU Medisch Centrum.

- Tomlinson, A. N., Skinner, D., Perry, D. L., Scollon, S. R., Roche, M. I. and Bernhardt, B. A. (2016). “Not Tied Up Neatly With a Bow”: Professionals’ Challenging Cases in Informed Consent for Genomic Sequencing’. *Journal of Genetic Counseling*, **25**, 62–72.
- Venkatapuram, S. (2011). *Health Justice: An Argument From the Capabilities Approach*. Cambridge: Polity Press.
- Verweij, M.F., and Dawson, A. (2013). ‘Public Health Ethics’, in LaFollette, H. (ed.). *The International Encyclopedia of Ethics*. Blackwell Publishing, pp. 4220–4230.
- World Health Organization. Regional Office for Europe, European Observatory on Health Systems and Policies, Sagan, Anna, McDaid, David, Rajan, Selina. *et al.*
- World Health Organization. (2020). *Screening Programmes: A Short Guide. Increase Effectiveness, Maximize Benefits and Minimize Harm*. Copenhagen: WHO Regional Office for Europe. Licence: CC BY-NC-SA 3.0 IGO.
- Woudstra, A. J. and Suurmond, J. (2019). ‘How Narratives Influence Colorectal Cancer Screening Decision Making and Uptake: A Realist Review’. *Health Expectations*, **22**, 327–337. doi:[10.1111/hex.12892](https://doi.org/10.1111/hex.12892)
- Wijsbek, H. (2000). ‘The Pursuit of Beauty: The Enforcement of Aesthetics or a Freely Adopted Lifestyle?’ *Journal of Medical Ethics*, **26**, 454–458.