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**Low participation to organised colorectal cancer screening in France:
underlying ethical issues**

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Abstract

International studies have shown a significant reduction in colorectal cancer (CRC) mortality following the implementation of organised screening programs, given a sufficient participation rate and adequate follow-up. The French national CRC screening program has been generalised since 2008 and targets 18 million men and women aged 50–74. Despite broad recommendations, the participation rate remains low (29.8%), questioning the efficiency of the program. A panel of experts was appointed by the French National Cancer Institute to critically examine the place of autonomy and efficiency in CRC screening, and propose recommendations.

In this paper, we explore the ethical significance of a public health intervention that falls short of its objectives owing to low take-up by the population targeted. First, we analyse the reasons for the low CRC screening participation. Second, we examine the models that can be proposed for public health actions, reconciling respect for the individual and the collective good. Our expert panel explored possible ways to enhance take-up for CRC screening within the bounds of individual autonomy, adapting awareness campaigns and new educational approaches that take into account knowledge and analysis of socio-cultural hurdles. Whereas public health actions must be universal, target actions should nonetheless be developed for non-participating population sub-groups.

Keywords:

Colorectal cancer screening, Participation, Organised program, Ethics, Proportionate universalism

Electronic word count: 3144

Introduction

Colorectal cancer (CRC) is the third most common cancer in Europe and the second most frequent cause of death from cancer in both women and men (Ferlay et al., 2015). Its incidence in France is 38.4 per 100,000 population in men and 23.7 per 100,000 in women (world standardized) (INCa, 2014a). CRC mortality reduction is thus a public health objective in Europe (European Union Council Recommendation, 2003) and other industrialised countries. The rationale for CRC screening is that it helps identify cancers at an early stage, which can allow timely treatment and offer greater chances of recovery (Faivre, 2001). Several trials have shown a significant reduction in mortality following the implementation of organised screening programs: i) guaiac faecal occult blood test (gFOBT) (Binder-Foucard et al., 2013) (Faivre et al., 2004) (Hardcastle et al., 1996) (Kronborg et al., 1996) (Mandel et al., 1999) and ii) with the more recent faecal immunological test (Ventura et al., 2014) (Giorgi Rossi et al., 2015).with

In 2008, an organised screening program targeting 18 million people was generalized in France. It is managed by local structures and coordinated by the French National Cancer Institute (INCa) commissioned by the Ministry of Health along national guidelines (Azimafoussé Assogba et al., 2015). Since, every two years, asymptomatic individuals without any family or personal history of adenoma or CRC nor inflammatory bowel disease are sent an individual invitation to undergo guaiac faecal occult blood testing or, since 2015, immunochemical test. This letter tells them about the CRC screening program and encourages them to consult their general practitioner (GP) to get the test. If the person meets the requirements for inclusion in the program, the GP delivers the test, which is performed by individuals themselves at home and sent without charge to a laboratory taking part in the program. The GP then informs the local management structure that the test has been carried out. If there is no response

to the invitation letter from individuals after three months, a reminder is sent. If there is still no response from them after twelve months, a further reminder is sent (Leuraud et al., 2013).

Although CRC screening has proved to be effective, participation in the French program remains low: 32.1% for the period 2010-2012 (Azimafoussé Assogba et al., 2015) and 29.8% for the period 2013-2014 (INVS, 2014). It remains to evaluate the effect on participation due to the introduction of the immunochemical test in 2015. This participation rate is below the 45% rate recommended by the European guidelines (European Commission, 2010) (INCa, 2014b).

The effectiveness of organised screening at a nationwide level is directly related to the rate of participation: an insufficient participation may thwart the public health objective. The low participation rate and under-use of CRC screening by the target population question the efficiency of the program. Organised screening mobilises significant human and financial resources. Screening 100 000 individuals aged 50–74 years using immunochemical test, every two years for 20 years, is estimated to cost around 75 million euros. The cost of the test distribution makes up 6% of the total cost (Lejeune et al., 2014). If the participation is low, the impact on mortality decrease is low and so the cost of saving one life increases.

In this context, a panel of experts was commissioned by INCa to analyse the reasons for the low participation and to explore the underlying ethical issues in order to propose possible modifications in the CRC screening program in France (INCa, 2016).

This article is a synthesis of the report produced by the experts.

1. Causes of low participation

Causes of low participation in the CRC screening program have been analysed first, by a review of the literature data in this field, second by the testimonies of professionals

in charge of the screening coordination in regional monitoring centres and third by analysing data from the French Institute for Public Health Surveillance (InVS). First the absence of symptom and the feeling of being healthy are recognised as causes of low screening uptake (Chapple et al., 2008). In addition, one hypothesis is that people entering the program aged 50–60 years are not aware of this cancer, which is still infrequent in this age group (INVS, 2014). In France, CRC incidence increases sharply after age 60 (Binder-Foucard et al., 2013) (Faivre, 2001). Hence in the general population, there is a lack of knowledge about the risk of mortality due to this cancer because mortality is assumed to be high only in older people (INCa, 2013) (Gimeno-Garcia, 2012). Thus the risk of developing the disease is underestimated. Common thinking is also that testing concerns people already at high risk, in particular people with a family history of CRC (Aubin-Auger et al., 2001) (Bridou et al., 2011) (Chapple et al., 2008) (Wardle et al., 2000).

Finally, compared with breast cancer screening, CRC is less often publicly discussed in the media or among relatives, and it is less widely relayed by movements in favour of screening initiated by patient associations (Pucheu, 2008). All these findings echo the Health Belief Model theory (Champion et al., 2008) whereby screening participation depends on (i) feeling concerned by the risk of developing the cancer in question (perceived susceptibility) and (ii) being conscious of the severity of the disease (perceived severity).

Low socio-economic status has been correlated with lower participation. Non-participants and those with lower socioeconomic status tend to have less knowledge about the disease and the program (Molina-Barceló et al., 2011) (Whynes et al., 2003). Another factor is that CRC affects an intimate part of the body. It has been shown that participation is affected by disgust, causing behavioural avoidance. There is an anticipated disgust of the screening test because it involves collecting and handling

faeces, and then of rectal examinations entailing “penetration” if the test is positive (Reynolds et al., 2013) (Smith et al., 2005). Today, defecation is probably more a taboo than centuries ago, when people talked more readily with others about their faeces without anyone being offended. Gradually, certain natural needs such as defecating came to be restricted to private places reserved for this purpose. This modesty developed strongly in the 19th century with the progress of body hygiene (Le Breton, 1997) (Vigarelli, 2014). Disgust associated with the handling of the stool and keeping samples thus increases reluctance to use the test (Palmer et al., 2014). Screening was initially based on the guaiac faecal occult blood test, which required two samples from three successive stools, which is difficult to achieve in everyday life (Neilson and Whynes, 1995). The transition to the immunochemical test should reduce this averseness, as only one stool sample is necessary. It has been shown that this test is better perceived and has significantly raised participation rate (Deutekom et al., 2010) (Moss et al., 2016) (Toes-Zoutendijk, 2017).

2. Question of autonomy within an organised screening

There is a potential conflict between benefit for the community and respect for individual liberties (Gravel et al., 2010) (Massé, 2003) (Potter, 1975). This question is linked to issues of rights and obligations: how can we balance what every individual can expect from the health and social protection system with the aim to maintain collective benefit?

Historically, in France, many public health policies since the late 19th century have been based on a model where health intervention is imposed for the community's benefit or safety. This was part of a "welfare state", in which the state played a key role in the protection and promotion of the social well-being of its citizens and of the protection of the population's health. Vaccinations were compulsory, along with

tuberculosis screening and syphilis testing for young males during military service or when they married. These measures were imposed, and were justified by the axiom that in a democracy an individual has rights but also duties. This model is still widespread: obligatory schooling for children, compulsory voting in political elections in some countries, or in medicine and public health, obligation to track young children for vaccinations, etc. This choice is part of a philosophy described by Gadamer (1998), who points out that ethics of responsibility can thwart individual convictions, for the common good.

Starting in the 1970s, the policy of compulsory health measures was criticized as “paternalism”, defined as “an attitude or policy, taken by a person, an organization or a state, that limits some person’s or group’s liberty or autonomy for what is presumed to be that person’s or group’s own good” (Nys, 2008) (Buchanan, 2008).

From the 1980s, a movement emerged and expanded to involve people in the choices concerning their health, and introduced the concept of informed consent, according to which no action could be undertaken on a person’s body without their consent. Consideration of respect for autonomy in health choices gained importance in fundamental bioethics (Beauchamp and Childress, 1994), signalling the rejection of paternalistic attitudes. This trend culminated in France in the advent of the 2002 law on patients’ rights and the quality of the health system (French law, 2002), which introduced the principles of health democracy and gave every citizen an absolute right to information enabling them to make free decisions about their health.

The trend in public health policies is now no longer to impose, but rather to propose, especially in the domain of prevention. This is the case for the French organised screening for breast and colorectal cancer, based on voluntary participation. This model aims to balance public health requirements -inform and organise- with respect for freedom to participate or not. Information tools and campaigns have been

developed to invite the target population and raise awareness. A minimum level of collective participation is, however, necessary for the collective benefit to be achieved and for the action to be efficient. The challenge lies therefore in the information and education process, which should empower responsible individuals and raise awareness to prompt their participation. The nature of the information should motivate participation while also being complete; stating both benefits and risks in order respecting free decision.

In this model, health authorities expect a virtuous circle in which the individual, cognizant of the issues, will feel responsibility towards the community and so support the proposed action by participating. However, today it seems that respect of individual liberty is running counter to the collective objectives set by the public health system concerning screening efficiency and good use of public resources. The low participation in CRC screening shows the limit of this model, and questions the ethical justifications underpinning the program, particularly the distributive justice of resource allocation.

At a time when it is unlikely that a public health intervention such as screening could ever be imposed, one alternative would be the disengagement of health authorities, which would merely inform the population about the disease and the availability of a screening test; the screening would not be organised at the national level, but would be carried out as an individual initiative. In France, this choice is not currently possible, essentially for political reasons owing to a longstanding culture of healthcare solidarity. Relying on a strictly individual approach might widen health inequalities and also mean having to deal with cancer in more early stages, at better human and economic cost. A debate is ongoing concerning the legitimacy of any right to limit personal freedom (Selgelid, 2009) (Wilson, 2009) and under what circumstances it is legitimate for governments to curtail liberty in order to promote the health of the population. It is

difficult for people to regard health as a public good, rather than an individual concern. To address this issue, one model proposed for public health ethics is *personalism*, which considers health as a common good, and encourages values such as sociality, solidarity and responsibility to prevent and protect against avoidable diseases (Petrini, 2010). This approach encourages the exercise of a responsible autonomy where the notion of collective benefit has to be integrated.

Carter et al. (2006) addressed the issue in the following terms: Instead of asking “is this health promotion strategy instituting a paternalistic ‘nanny state’?” we are encouraged to ask “is this health promotion strategy providing individuals and communities with real opportunities they are likely to value?” The authors discuss health promotion ethics in the light of the capability approach developed by Amartya Sen in the 1980s (Sen, 1985). There is a growing interest in applying Sen’s capability approach to the evaluation of health care programs, including public health interventions. The approach suggests that well-being should be measured in terms of capabilities, i.e. what individuals can do to optimise collective health (Bussière et al., 2016) (Robeyns, 2005). Accordingly, a public health action should aim to understand and evaluate persons’ ability to act, and to propose actions to strengthen this ability.

3. Exploring possible ways to influence participation

Our expert panel stressed the importance of jointly exploring possible ways to influence participation.

Focus on education

The purpose of health education is to inform and educate people on both individual and collective issues, taking care not to judge, punish, stigmatize or exclude anyone.

The educational approach is a long-term enterprise that combines individual freedom and responsibility with a double objective: make better use of our health system, and enable persons to gain more control over their own health by developing individual skills and knowledge. Concerning cancer screening, the group stressed the importance of a national strategy that promotes the development of educational programs for health at school and at all ages. The emphasis is laid on the principles of responsibility, collective benefit and health expenditure priorities. This will help persons acquire behaviours such as taking up screening programs, with a positive impact on the population's health.

Diversifying approaches

It is essential to ensure that screening policy is well-understood by all the partners and that there is no further widening of existing social inequalities in the field of cancer prevention. With this objective, the Cancer Plan 2014–2019 will foster the development of institutional and association partnerships to: (i) pursue national information campaigns, (ii) maintain the mobilization of all stakeholders, and (iii) lend support to target population groups remote from the health care system or presenting socio-economic, linguistic or cultural particularities (INCa, 2013).

Diversification of awareness campaigns and of means for test delivery could be usefully promoted, backed by sociological and anthropological studies and grassroots actors such as associations or socio-educational workers with a good knowledge of population features. Such actions would also be particularly relevant for persons who do not habitually consult physicians (30–35% of the population). In parallel, the persons in charge of these actions would be given training, in conjunction with GPs and with an evaluation of these approaches.

The question of assistance to perform the test also needs to be discussed. There may be a gap in perception between health professionals, who find an act simple, and the

general population, for which it is a complicated task. This has been shown in the field of therapeutic education, where patients express the need to be trained and supported (e.g. insulin injection). To respect the principle of equity, this approach must also recognise that some citizens may have physical or psychological impairments that limit self-execution of the test. Such assistance would optimize the quality and performance of tests.

Other strategies for the distribution of the test kits could also be considered. Direct sending of the test could significantly enhance participation as was recently shown in a French pilot study (Piette et al., 2016). This approach deserves re-assessment, in terms of both participation and cost effectiveness, especially since the introduction of the chemical test (Lejeune et al., 2014). In Netherland the introduction of FIT test enclosed within the invitation mailed results in the participation rate above 65% (Toes-Zoutendijk et al., 2017). Implication of pharmacists have also been shown to be a successful alternative, with good results in terms of participation and sustainability of the whole process (Mancini et al., 2016) (Santolaya et al., 2017).

These diversified approaches help reaching those who do not regularly consult a physician and those who are not proposed the test during a consultation.

Enhance the role of general practitioner

The involvement of GPs can be effective in improving screening compliance. However, their motivation is essential but their implication stays variable and could be reinforced (Federici et al., 2006). In France GPs play a central role in the organisation of the CRC screening program. They estimate the CRC patient's risk level based on personal and/or family history. However, GPs often lack the time to address the issue of screening when a person consults for another reason. One recommendation might be that a medical consultation focused on prevention be supported by our health insurance system every two years.

Evolutivity of the program

One aspect of the programs is their ability to evolve based on the latest scientific evidence. For example, epidemiological data which showed that in France the proportion of diagnosed CRC cases and polyps is very low before age 55 years, and remains low in women before age 60 (Table 1)(INVS, 2014). However these data should be reassessed with the immunochemical test which has been shown more sensitive (Dancourt et al., 2008).

Finland, Sweden and England have chosen to offer their programs from age 60 years (Kobayashi et al., 2016) (Artama et al., 2017) (Blom et al., 2014). Considering that participation of in the 50-60 age group is lower than in other age groups, this raises the question of reviewing the age of entry in the program that the benefit of screening would be more efficient starting at age 60 (Hot et al., 2010) (Blom et al., 2014).

Conclusion

A better understanding of the reasons for non-participation to CRC screening might help develop appropriate actions targeting identified non-participating population sub-groups. According to the conclusions of our panel group, diversifying strategies would help to "reach" the target population in its cultural and social diversity and to flatten social inequalities recurrently observed face to screening. This approach would enable:

- To offer a response for all, but with a modality or intensity that varies; the actions are universal, but with a development adapted to specific situations,
- To reduce or eliminate barriers to access that impedes the use of existing resources.

In this "graduated approach", the differences between socio-demographic groups are lessened insofar as additional actions benefit populations that were the most

excluded. In the same way, evaluation of programs should thus not measure only participation rates, but also the impact on the abilities of individuals.

This is based on the concept of proportionate universalism, which proposes that action must be universal, but with scale and intensity proportionate to the level of disadvantage (Marmot et al., 2010) (Benach et al., 2013).

These propositions are in line with the principles and values for public health described by Massé (2003): no maleficence of the action proposed, respect of autonomy, but also respect of the common good, responsibility, and solidarity.

Conflict of interest

There are no conflicts of interest.

Author contribution

GM, ND, SD drafted the initial manuscript. All authors contributed to several rounds of revisions. All authors have read and approved the final version of the manuscript.

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Table 1. Rate of advanced adenomas* and cancers detected according to age and sex for the time period 2011-2012 in France. The rates were calculated from INVS data (InVS, 2014).

Rate of advanced adenomas detected per 1000 women or men screened						
Age	50-54	55-59	60-64	65-69	70-74	50-74
Female	1.6	1.9	2.3	2.9	3.4	2.3
Male	3.7	4.9	5.8	6.5	7.3	5.5
Rate of cancer detected per 1000 women or men screened						
Female	0.5	0.8	0.9	1.2	1.7	1
Male	0.8	1.6	2.1	2.8	3.6	2

* Most CRCs develop from adenomas, among which “advanced” adenomas (≥ 1 cm in size and/or high-grade dysplasia and/or villous component) are considered to be the clinically relevant precursors of CRC, associated with a high risk of colorectal cancer.