



**Health
Information
and Quality
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An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Health technology assessment (HTA) of a population-based colorectal cancer screening programme in Ireland

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Ethical Commentary

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Ethical issues

In the context of public health policy, considerations such as screening for disease, or the provision of a vaccine to the population at large, ethical discussion must take into account not only the application of the principles to individuals, but also the benefit, costs and risks to the public. Ethical criteria play an important role in developing any new healthcare technology or intervention.

There are four principles of medical ethics that are commonly used to assess issues in health care. These are:

- Autonomy
- Beneficence
- Non-maleficence
- Justice.

The first three criteria are more commonly applied to individual relationships between doctors and patients, whereas the final criterion is applied in discussions relating to the fair allocation of health care resources. Considerations of fairness in the context of a screening programme would include access to screening irrespective of ability to pay, fair distribution across all socio-economic groups, fairness as between genders unless the disease is gender specific, and fairness in relation to the prioritisation of expenditure on a screening programme for one particular disease at the expense of others.

Screening for colorectal cancer presents an opportunity to develop preventative tools to maximise benefit to the population. From an ethical perspective therefore, it may be seen as having a positive effect due to the prevention of disease. This would be in keeping with the utilitarian model of resource allocation which recommends the provision of services which will have the greatest effect on the largest number of people.

However, there is no progress without cost and investment, and all healthcare expenditure has both positive and negative implications. The conditions and context of each new development needs assessment on a case-by-case basis to ensure maximum benefit and minimum risk. For a screening test such as one for colorectal cancer to have an impact in terms of population health, it is necessary to ensure a high uptake of the screening programme, the minimisation of any risks associated with the screening and diagnostic tests by the implementation of quality assurance processes, and a comprehensive and adequately resourced follow-up treatment programme for those who need it.

The European Commission recommends that in all screening programmes measures must be in place to ensure that the tests are meaningful, the condition is serious, the test is highly predictive and follow-up actions must be available in terms of healthcare interventions. It also states that the relevance of the condition being screened for must be validated and regularly evaluated within the public health context; that the appropriate environment for providing information prior to testing and relevant post-test counselling be in place prior to offering such screening; that pilot programmes be undertaken prior to general introduction; and that the economic dimension of screening programmes be considered carefully. The following issues therefore arise for consideration:

- reliability and quality assurance
- transparency
- autonomy and respect for personal choice
- the provision of information and consent
- the protection of vulnerable groups
- confidentiality - the right to know and not to know, the duty to disclose and warn others
- equity in access
- control over samples and data
- the management and communication of uncertainty.

As well as the importance of the clinical aspects involved in ensuring reliable and high quality testing, the provision of information and counselling is considered an essential requirement in screening for serious disorders. Screening for colorectal cancer involves the testing of individuals, both men and women, who have no symptoms of the disease and are apparently well. It is important therefore to ensure that all relevant information is discussed with those individuals being tested to ensure that their consent to the test is voluntary and truly an informed choice. This requires the expertise of professionals who have specific training in the field. Simple printed information should be made available to anyone who has undergone testing, as well as the opportunity for further explanation and discussion offered.

In the context of disclosure of information prior to screening there are a number of ethical issues that need to be carefully considered and discussed in relation to the analysis of risks and benefits. Although the early detection of symptoms of colorectal cancer may be of life-saving benefit, there is also the potential for negative effects such as:

- false positive test results which may give rise to unnecessary distress for the individual and his/her family, as well as the possibility of further investigations being carried out on healthy individuals
- false negative results, which may give false security and ultimately delay the accurate diagnosis, with potentially fatal consequences

- physical side-effects or risks of testing, investigation and treatment, such as perforation of the colon or bleeding, including possible death
- psychological difficulties in informing an apparently healthy individual that they have signs of early cancer.

Increased public awareness of the disease through media and other information campaigns may serve to familiarise the public with general information regarding the benefits of early detection through testing, but in order to achieve the objectives of informed consent, further and more comprehensive information must be provided to ensure that the individual who chooses to be tested understands the purpose, potential risks and benefits, the possibility of misdiagnosis, and the alternatives to being tested. Communication of test results must respect the dignity, privacy and confidentiality of the individual, and counselling should be offered to enable the individual to understand the consequences of the test result for him/her and other family members. Guidelines should be developed to assist in the communication of the risks and benefits of screening.

The recommendation in this report favours the FIT based programme in 55 -74 year olds as the optimal strategy due to its greater overall effectiveness in reducing colorectal cancer mortality rates. However, it is also acknowledged that there may be a small risk of death, one per year, arising from the increased number of colonoscopies. The question may be posed as to whether this small risk is acceptable from an ethical perspective given that the majority of those who are screened will not have cancer. This raises two issues – the potential benefit of screening to those who test positive and who may therefore receive early and effective intervention, and the possibility that someone may be inadvertently harmed by the screening procedure. Public health measures generally rely upon the importance of maximising the benefit to the community as well as minimising, to the greatest extent possible, any possible risks or side-effects inherent in the measure to be taken.

In relation to the screening methods adopted in this report, it is ethically justifiable to recommend FIT on the basis of its expected benefit to society while at the same time ensuring that the colonoscopy procedures are carried out to the highest standards in order to minimise to the greatest degree possible any inadvertent risk of harm.

In relation to the proposed expenditure which the screening programme will necessarily entail, it is important to also recognise the long-term resource savings in terms of colorectal cancer treatment, and more importantly, the health gains for those whose length and quality of life will be enhanced by a screening programme. Allocation of healthcare resources is inevitably a question of balancing different priorities. Given the potential ultimate cost-saving and overall expected health gain it is therefore considered ethically justifiable to recommend expenditure on the FIT programme.

All other options evaluated in this HTA as alternatives to the recommended strategy (biennial FIT implemented within two years in ages 55 to 74 years) do not raise any additional ethical issues other than those already discussed in this commentary.