

turing proposals should be accompanied by clearly stated, measurable objectives against which the new system's performance can be monitored and scrutinised. Proposals for change should also be accompanied by estimates of the transitional and ongoing costs to be incurred in pursuit of its benefits.

Commitment to the routine measurement and publication of key indicators of the performance of the health system would also greatly improve the ability of politicians to justify and be held accountable for structural change and of the public to engage in informed debate. A template for such assessments could include, for example: indicators of the technical efficiency of providers, transactions costs as a proportion of total spending, horizontal equity (the extent to which those with similar levels of need receive similar services), reductions in levels of ill health and of health inequality attributable to health services, and users' experiences of services.

New Zealand's health sector is headed back to the future. Whether that future holds the solutions to New Zealanders' health aspirations is unclear. A commitment to rigorous evaluation of the current social experiment is required to determine whether the future is better than the past.

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## Appraising organised screening programmes for testing for genetic susceptibility to cancer

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Public health officials rely on criteria developed by Wilson and Jungner for assessing whether or not to implement population screening programmes. These criteria were developed over 30 years ago, when screening primarily focused on detecting early stages or precursors of chronic disease. With the introduction of testing for genetic susceptibility, particularly for cancer, it is important to assess whether these criteria can continue to be applied in the decision making process. We report on a workshop that assessed criteria for population screening in the context of testing for genetic susceptibility to cancer.

Many criteria for the evaluation of screening programmes have been proposed,<sup>1,2</sup> and most are similar to those proposed by Wilson and Jungner in a 1968 World Health Organization report.<sup>3</sup> The criteria are based on a simple linear model of disease progression (figure) in which screening tests primarily detect a preclinical asymptomatic phase.

The continuum of screening has expanded to include a range of other states. The figure illustrates another model for screening—screening for risk factors or susceptibility, the detection of risk factors or disease<sup>4</sup> (such as blood pressure or cholesterol concen-

### Summary points

Screening has expanded from early detection of disease or its precursors to include testing for susceptibility, such as genetic testing for cancer

The Wilson and Jungner framework for evaluating screening tests, produced for the World Health Organization in 1968, is commonly used for population screening

The relevance of this framework for testing for genetic susceptibility to cancer has not previously been assessed

A modified Wilson and Jungner framework can continue to provide a robust approach to evaluating testing for genetic susceptibility

tration), or the identification, through the detection of genetic markers, of individuals who have increased susceptibility to disease.<sup>5</sup> Separate consideration of

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Details of the workshop participants can be found on the BMJ's website

**Table 1** Criteria for assessment of screening

Wilson and Jungner	Crossroads 99*
<b>Knowledge of disease</b>	<b>Knowledge of population and disease</b>
Condition must be important problem	Burden of target disease should be important
Recognisable latent or early symptomatic stage	Target population or population at risk identifiable
Natural course of condition, including development from latent to declared disease, should be adequately understood	Considerable level of risk or latent or preclinical phase
<b>Knowledge of test</b>	<b>Feasibility of screening procedures</b>
Suitable test or examination	Suitable test or examination
Test acceptable to population	Entire screening procedure acceptable to population
Case finding should be continuing process and not "once and for all" project	Screening should be continuing process and encompass all elements of screening procedures
<b>Treatment for disease</b>	<b>Interventions and follow up</b>
Accepted treatment for patients with recognised disease	Interventions that have physical, psychological, and social net benefit available
Facilities for diagnosis and treatment available	Facilities for adequate surveillance, prevention, treatment, education, counselling, and social support available
Agreed on policy concerning whom to treat as patients	Consensus on accepted management for those with positive test results
<b>Cost considerations</b>	<b>Societal and health system issues</b>
Costs of case finding (including diagnosis and treatment of patients diagnosed) economically balanced in relation to possible expenditures on medical care as whole	Costs should be balanced in economic, psychological, social, and medical terms and with healthcare expenditures as whole
	Appropriate screening services accessible to entire population without adverse consequences for non-participants
	Appropriate confidentiality procedures and antidiscrimination provisions for participants and non-participants

\*Ethical, legal, and sociobehavioural issues are considered across all domains. Screening should be considered within framework that recognises fundamental human rights.

these forms of screening is important as the type of interventions that can be offered to individuals who have positive test results can differ: treatment in the case of traditional screening, interventions to modify the risk factor, or counselling if susceptibility is identified. Thus, the criteria for evaluating programmes at the population level for such tests could differ.

Is it premature to discuss criteria for organised screening programmes for testing for genetic susceptibility to cancer? We consider that it is better to have a discussion about such criteria now, before such tests become widely adopted.<sup>6,7</sup> We report on the Crossroads 99 conference, held in Toronto, Canada, in October 1999, in conjunction with an international symposium examining the ethical, legal, and sociobehavioural implications of notification of risk of breast, ovarian, and colorectal cancer. The workshop participants included consumers, healthcare providers (clinical geneticists, genetics counsellors, medical,

surgical, and radiation oncologists, public health specialists, psychologists, psychiatrists, nurses, social workers, and primary care physicians), researchers (basic scientists, epidemiologists, social scientists), lawyers, and ethicists.

The objective was to develop a consensus on a framework to be used for introducing population based screening programmes based on notification of risk for cancer. An explicit purpose was to ensure that the framework examined ethical, legal, social, and economic implications and could be applied to current and future tests for susceptibility.

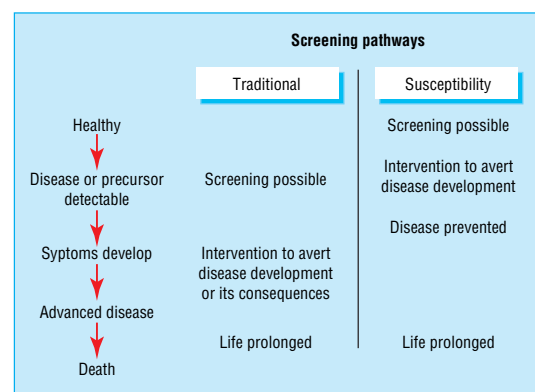
## Method

The Wilson and Jungner 1968 framework (table 1) for evaluating screening tests was presented as an example of a type of framework, but workshop participants were not bound to follow its structure or content. The workshop proceeded in three steps: identification of the domains or the major category headings for the framework; identification of criteria or the specific items within each domain; and prioritisation and selection of the criteria.

The workshop participants worked in multidisciplinary groups that identified key domains and criteria. Common themes from the groups were identified and the resulting model reviewed in a plenary session.

## Results

The overall thrust of the Wilson and Jungner framework was strongly agreed with, although there was some broadening of the domains and criteria. The consensus was that ethical, legal, and social issues should be dealt with across all the domains, rather than treating them separately. These issues were viewed as essential for all considerations involving a screening programme. Creation of a separate category for them could lead to their being marginalised.



Screening pathways compared over simplified natural course of disease. Traditional screening identifies early stage disease or precursors to disease. Susceptibility screening moves the process earlier and identifies risk of disease in individuals who are healthy. Thus resulting interventions aim to reduce risk of disease developing rather than trying to reduce severity or consequences of disease

The participants also recommended that all screening programmes should observe the basic universal principles of human rights, such as those in the convention on human rights and biomedicine.<sup>8</sup> This statement covers the primacy of the human being, equitable access to health care, privacy, right to information, non-discrimination, and use of predictive genetic tests. Considerations about new screening technologies and programmes that seek to apply them should pay attention to such fundamental principles.

### Knowledge of population and disease

Table 1 lists the original and revised framework. The first domain has been broadened to include characteristics of the population. This acknowledges that in testing for susceptibility it is important not only to understand the disease but also the population that is to be tested. The first criterion is essentially unchanged except the more commonly used term "burden of disease" is used. The burden ultimately being considered should be that of the disease to be prevented, not the condition or marker status that is being screened for. For example, in genetic screening for ovarian cancer it is the incidence and prevalence of ovarian cancer that is important in determining burden, not the prevalence of the marker status for the condition. An analogy may be drawn with cholesterol screening, in which "hypercholesterolaemia" is often labelled as disease. The prevalence of this state is far greater than that of the target conditions such as heart disease.

The second criterion in this domain is new. There is need for acceptable and valid methods for identifying those individuals in the target population who are most likely to benefit from susceptibility testing. For example, the Amsterdam criteria identify those at risk for hereditary non-polyposis colorectal cancer.<sup>9</sup> The target population may be individuals or families. The need to identify the target population is not necessarily a new concept when it comes to screening as all accepted screening tests to date have had some component of identification of a target population, usually on the basis of age. However, the Wilson and Jungner criteria did not explicitly specify that the mechanism for selecting those eligible for screening should be reliable and valid.

In addition to being able to identify a latent or pre-clinical phase, knowledge of a measurable level of risk should be a criterion. For example, tests for BRCA1 or 2 mutations may identify an increase in risk of disease. To make decisions about screening programmes, knowledge of the level of risk (that is, penetrance) and its relevance is important. Relevance will depend on context and will certainly have to be an issue of on going research.

Natural course is also included from the original framework but is extended to include knowledge of the natural course from the state of susceptibility to the state of precursor or early disease. The risk of developing a disease, the stages it goes through, and the time periods over which this occurs should be well understood.

**Table 2** Example of application of new criteria to screening for genetic susceptibility to colorectal cancer

Crossroads 99 criteria	Testing for susceptibility to colorectal cancer	Met by new criteria
<b>Knowledge of population and disease</b>		
Burden of target disease should be important	Colorectal cancer is third commonest malignancy in United Kingdom, incidence is increasing	Yes
Ability to identify target population or population at risk	Amsterdam criteria are generally accepted; further research on accuracy of criteria is required; no large series of patients fulfilling Amsterdam criteria has mutation detection rate >70%	Partially
Considerable level of risk or latent or preclinical phase	Lifetime risk of colorectal cancer in those with two first degree relatives is 1 in 6; in those with autosomal dominant pedigree it is 1 in 2 (population risk is 1 in 50)	Yes
Natural course (from susceptibility to precursor, early disease, and advanced disease) should be adequately understood	Natural course from premalignant adenomatous polyps to malignant polyps is understood; whether progression is different in those with different mutations needs to be more clearly established	Partially
<b>Feasibility of screening procedures</b>		
Suitable test or examination	Known mutations can be screened for, familial testing protocols are required; acceptability in population is being assessed	Partially
Entire screening procedure acceptable to population	Acceptability of familial assessment and mutation testing in general population is not yet established	No
Screening should be continuing process and encompass all elements of screening procedures	Complete range of services required for screening (education, counselling, support) not in place	No
<b>Interventions and follow up</b>		
Interventions that have physical, psychological, and social net benefit available	Surveillance and treatment available but balance of physical, psychological, and social benefits not established; interventions such as chemoprevention are being evaluated	No
Facilities for adequate surveillance, prevention, treatment, education, counselling, and social support available	Level of services required and infrastructure not in place	No
Consensus on accepted management for those with positive test results	Emerging consensus on management of mutation carriers	Partially
<b>System issues</b>		
Costs should be balanced in economic, psychological, social, and medical terms and with healthcare expenditure as whole	Cost effectiveness in economic, psychological, social, and medical terms not established	No
Appropriate screening services accessible to entire population without adverse consequences for non-participants	Familial assessment and testing available only in specialised centres	No
Appropriate confidentiality procedures and antidiscrimination provisions for participants and non-participants	Appropriate procedures and provisions not yet completely studied or established	No

### Feasibility of screening procedures

This domain's title has been expanded, although the basic concepts are unchanged. Screening procedures involve more than the test alone. They include a range of activities from identification of the target population to recruitment, counselling, informed consent, administration of the actual test, and communication of the results.

In terms of the suitability of a test or examination, in addition to elements such as accuracy (sensitivity and specificity) and predictive value there needs to be an understanding of the value of the test results, standards for analysis, and a clear understanding of the limitations.

The test needs to be acceptable to the target or at risk population. This has conventionally been approached in terms of the discomfort of the test and its side effects. With testing for genetic susceptibility this approach needs to be broadened to include consideration of acceptability to the individual, family, and society in terms of psychological, ethical, legal, and social implications. An example of an issue that may need to be considered would be potential discrimination and denial of insurance. Potential side effects need to be considered in the context of the family. Even those individuals who do not participate in screening can suffer potential effects. For instance, individuals who decline to undergo a test may have relatives who have positive test results, and this information may not remain confidential. These individuals may then be identified as coming from the "positive family," even though they did not want to be tested. For example, three sisters out of four may decide to undergo testing for susceptibility for breast cancer. If two out of the three who are tested are identified as having a mutation, then that family will be labelled as "positive." The third sister, who has negative results, may disclose that she is not affected but that there is a mutation in the family. The fourth sister, who chose not to be tested, is then identifiable as being from an affected family and could suffer, even though she did not want to take part in testing at all.

Not only is there a need for informed consent and counselling that is inclusive of families and, when appropriate, communities (for example, ethnic groups), screening programmes need to ensure that there are staff and facilities available for such services. Delivery of the screening programme should include provision of education for consumers and health professionals.

### Interventions and follow up

This domain underwent considerable expansion, although the criteria are conceptually the same. Rather than considering only treatments for disease we consider a range of interventions and follow up strategies. The evaluations of these interventions should examine social and psychological aspects as well as physical aspects. The interventions need to have demonstrable net benefit on these dimensions. For example, prophylactic mastectomy may be an effective intervention for reducing risk of cancer in carriers of the BRCA mutation, but evidence would also be required on its psychological impact. Physical benefits would need to be traded off against potential adverse psychological or social effects.

Facilities for all aspects of follow up need to be available. There are many services required in addition to diagnosis and treatment. Prevention includes

primary means through dietary modification, chemoprevention, and prophylactic surgery. Surveillance, such as colonoscopy in those at high risk for colorectal cancer or the CA 125 blood test or transvaginal ultrasound for women at high risk for ovarian cancer, can itself be a series of screening tests. A screening programme needs to ensure that such services are available, accessible, and of high quality. The population tested will require education, counselling, and social support. Resources to support the practitioners who deliver the services, particularly those at the primary care level, need to be available.

### Societal and health system issues

The last category of the original framework examined costs. We propose expansion to societal and health system issues. A full range of costs, including psychological and social, need to be considered.

The principle of equity needs to be observed to ensure that appropriate screening services are accessible. It is vital to ensure that non-participation in such programmes does not adversely affect individuals. Conversely, it will be important to ensure that there is not the potential for conflict between those who are affected with the disease or susceptibility to the disease and the population at large.

Such screening programmes must ensure that there are no injustices based on test results and that there is adequate provision to ensure privacy and confidentiality of the information collected.

### Discussion

The Crossroads 99 conference confirmed the overall usefulness of the original Wilson and Jungner framework. Given that it was developed well before modern testing for genetic susceptibility, its robustness is a testament to the foresight of the authors. Table 2 shows the hypothetical application of the Crossroads 99 framework to testing for susceptibility to colorectal cancer.<sup>10-12</sup> This illustrates which of the new criteria are not yet met and the usefulness of the new framework in identifying issues for further evaluation and research.

While the workshop primarily considered testing for genetic susceptibility to cancer, the new criteria should be valuable in the consideration of other genetic or susceptibility testing. For example, screening for hereditary haemochromatosis has emerged as a controversial issue.<sup>13</sup> Among the issues to be examined with this test are the criteria for selecting the target population; the natural course and burden of disease; the interventions that could be offered to those who are screened, particularly in young people; the psychological and social effects of being tested; and the balance of economic, psychological, and social effects. System issues are paramount: screening programmes should be efficient, accessible, of high quality, ensure consumer choice, and respect the fundamental principles of human rights.

We hope that this revised framework will facilitate debate and comment regarding the development of screening programmes based on testing for genetic susceptibility. Ultimately, criteria such as these will be the basis for evidence based policy decisions for genetic screening programmes. Such a framework can provide an organised approach to the institution of

screening programmes for susceptibility to ensure that fundamental issues, such as adequacy of resources for informed consent, capacity for follow up interventions, and systems issues are examined. While the potential benefits of such programmes are huge, the risks are considerable, and indiscriminate use could overwhelm our health systems.

The Crossroads 99 meeting was held in November, 1999, in Toronto, in memory of Kathryn Taylor, PhD, who conceived the idea, developed the proposals, and garnered the support for it.

Contributors: VG was chair and principal author. He planned the meeting, prepared background materials, drafted the manuscript, prepared revisions, and is overall guarantor for this paper. A D DePetrillo, Cancer Care Ontario, Canada, and Zeev Rosberger, McGill University, Canada, co-chaired the conference and assisted with planning of meeting and preparation of materials. Timothy A Caulfield, University of Alberta, Canada; Mary Jane Esplen, Samuel Lunenfeld Research Institute, Canada; E Richard Gold, University of Western Ontario, Canada; Joan Murphy, University of Toronto, Canada; Donna Stewart, University of Toronto, Canada; Anne Summers, North York General Hospital, Canada, were conference facilitators and led discussion groups at workshop. Brian Doan, Toronto-Sunnybrook Regional Cancer Centre, Canada; Deborah Hellman, University of Maryland, United States; Claudine Giguere; Pamela James, York University, Canada; Raluca Nedelcu, Princess Margaret Hospital, Canada, were the recorders and reporters. A list of other participants who took part in the workshop can be found on the *BMJ's* website. All members of the working group reviewed the submission draft of the manuscript and had an opportunity to provide comments.

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### *A memorable doctor*

#### The life of an Egyptian doctor

A freezing day on 5 January 1882. "I was born in a state of white asphyxia, the worst form of foetal distress. I was breathless when I was born and did not meet life with screams as most babies do. The midwife and doctor who attended my mother took me for dead. I was placed, together with the placenta, in a copper tray near an open window. My family was told that I was stillborn. Half an hour later my aunt Hana whispered to the midwife that she noticed that the baby was breathing feebly every few minutes whereupon the midwife wrapped me up, cut the cord, and did what she could to resuscitate me."

From such a precarious start to life, Naguib Mahfouz went on to become the first Egyptian professor of obstetrics and gynaecology at Kasr-El-Aini Hospital, a post he occupied until he retired in 1947. Among his many achievements, his research into surgical techniques of fistula repair made him world famous. He was a prolific author on a wide variety of subjects including urinary and faecal fistulas, fibroids, ectopic pregnancy, ovarian tumours, pelvic infections, and endometriosis.

The Mahfouz museum at Kasr-El-Aini Hospital, which he founded at his own expense, contains a unique collection of obstetric and gynaecological specimens. His magnum opus, the *Atlas of Mahfouz's Obstetrics and Gynaecological Museum* (John Sherratt, 1949), was described by the then president of the Royal College of Obstetricians and Gynaecologists, Sir Eardley Holland, as "no doubt the best book that has appeared in obstetrics and gynaecology." Mahfouz became a fellow of the Royal College of Physicians and an honorary fellow of the Royal College of Obstetricians and Gynaecologists, the Royal College of Surgeons of England, and the Royal Society of Medicine.

In his autobiography (*The Life of an Egyptian Doctor*, Livingstone, 1966) Mahfouz tells why he specialised in obstetrics and gynaecology: "One day ... Dr Shoukry ... asked me to help him in a difficult case of labour. I went with him to his clinic and there found on the operating table a lady whom they had tried,

unsuccessfully, to deliver with forceps without anaesthesia. For two hours Dr Shoukry tried, unsuccessfully, to deliver the head with forceps but it would not come down. He then asked me to change places with him and try to do a podalic version and bring down a foot as my hand and arm were thinner than his. I declined saying that I had no experience whatsoever in deliveries. Dr Shoukry tried to pull down a foot and it took him a whole hour before he succeeded. He and his assistant were able to deliver the body of the foetus up to the shoulders only but the head would not come down. They went on pulling the shoulders until the body of the foetus was severed from the head. I suggested taking the patient to the Government hospital or else calling an obstetric surgeon into consultation. They replied that among all the Egyptian and foreign doctors in Alexandria there was not one who was an Obstetrician. In the morning ... I was told that she (the patient) had died during the night with the baby's head still in her uterus. ... It was then that I resolved to do everything in my power to study obstetrics and gynaecology and to dedicate my life to help women suffering from difficult labour."

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We welcome articles of up to 600 words on topics such as *A memorable patient*, *A paper that changed my practice*, *My most unfortunate mistake*, or any other piece conveying instruction, pathos, or humour. If possible the article should be supplied on a disk. Permission is needed from the patient or a relative if an identifiable patient is referred to. We also welcome contributions for "Endpieces," consisting of quotations of up to 80 words (but most are considerably shorter) from any source, ancient or modern, which have appealed to the reader.