Special article


J. Patnick1†, D. Ransohoff2†, W. Atkin3‡, J. Ma Borras4, M. Elwood5, G. Hoff6, M. Nadel7, A. Russo8, J. Simon9, E. Weiderpass-Vaino10, M. Zappa11 & R. Smith12*

1The Manor House, Sheffield, UK; 2University of North Carolina at Chapel Hill, Chapel Hill, NC, USA; 3Cancer Research UK, London, UK; 4Institut Català d’Oncologia, Barcelona, Spain; 5National Cancer Control Initiative, Melbourne, Australia; 6Institute of Population-based Cancer Research, Oslo, Norway; 7Centers for Disease Control and Prevention, Atlanta, GA, USA; 8Local Health Authority of Milan, Milan, Italy; 9Queen’s University, Kingston, Canada; 10International Agency for Research on Cancer, Lyon, France; 11Center for Study and Prevention of Cancer, Florence, Italy; 12American Cancer Society, Atlanta, GA, USA

Introduction

All screening programs involve a trade-off between benefits, limitations and risks [1–3]. Quality assurance efforts and program evaluation are intended to ensure that these competing elements are kept in balance, by helping to maximize benefit and minimize risk. In the case of screening for colorectal cancer, this means maximizing the potential mortality reduction while minimizing the undesirable side effects of screening, such as the potential morbidity associated with colonoscopy. In order to achieve this potential, attention to quality assurance is among the chief prerequisites for successful screening programs. The elements of a quality assurance program must be understood and appreciated, and be monitored over both the short- and long-term and linked with program outcomes. Quality assurance requirements will vary with the mode of screening for colorectal cancer that is under consideration.

The Workshop mainly considered population-based screening of asymptomatic individuals, and recognized that a population could be defined as anything from an individual clinician’s practice to millions of residents in a nation state. The defining characteristics are a target asymptomatic population, and the systematic invitation to be screened for colorectal cancer. The discussion attempted to concentrate on the elements common to all modalities of screening rather than to identify separate indicators for each modality.

Key issues, barriers and challenges, and recommendations

A. Assessing safety and thoroughness of the screening process

Issues. The first domain concerns the safety and thoroughness of the screening process itself, involving such issues as:

(i) Is there a mechanism in place to ensure that all eligible members of the population have access to the screening test?

(ii) Is the patient appropriately prepared to understand the procedure and its risks and benefits?

(iii) Is proper follow-up arranged regarding such things as pathology reports and plans for possible subsequent examination?

(iv) Is the examination itself as thorough and accurate as it can be?

(v) Are persons performing procedures appropriately trained?

(vi) Is the procedure done in a safe manner?

These features of quality involve, but go well beyond, the simple performance of a test itself. Furthermore, screening often demands higher quality in some areas of performance than does a evaluation of the patient with symptoms, since, by definition, there are no symptoms to guide the practitioner.

Barriers. The main barrier to assessing and assuring safety and thoroughness is that consensus strategies and protocols for assessing these features have not been fully developed. However, experience from other fields, such as mammography screening for breast cancer, demonstrates that baseline standards can be established. Ongoing processes can then be devised to develop both knowledge and guidelines and then to keep them under regular review [4].

*Correspondence to: Dr R. Smith, American Cancer Society, 1599 Clifton Road NE, Atlanta, GA 30329, USA. Tel: +1-404-329-7610; E-mail: Robert.Smith@cancer.org

†Co-chairs
‡Rapporteur

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Recommendations. Establish an on-going process that can review evidence to develop baseline quality guidelines and standards, and then keep them under review as knowledge and experience widens. This might, perhaps, be analogous to the efforts for mammography screening by the American College of Radiology or the European Network for Breast Cancer Screening. Ideally, an international effort to develop consensus strategies and protocols for measuring and monitoring quality assurance can become a priority for several international professional organizations already committed to advancing screening for colorectal cancer.

Just as the mammography quality assurance process has taken decades to evolve into a mature evidence-based effort, expectations and timetables must be realistic for colorectal cancer screening.

B. Comparing results from different screening settings to learn about effectiveness and cost

Issues. While effectiveness is always best studied in randomized clinical trials (and has been studied in several trials for colorectal cancer screening), useful supplemental information about efficacy and quality can be obtained by examining non-randomized observational studies, such as those that will be established in different settings by different countries and health systems. Furthermore, randomized trial design is not necessary to provide useful information about such things as safety, yield (e.g. numbers of lesions found, positive and negative predictive accuracy of tests performed in different ways), cost and acceptability. Just as has been the case for mammography screening programs established in different settings, we can anticipate that, in the next decade, different programs of colorectal cancer screening will begin to compare experiences regarding such features. Pilot programs might be particularly useful in developing indicators and measures that are appropriate for a particular set of circumstances.

Barriers. To accomplish the kind of comparison described above does not require that each program be implemented in the same way, but it is does require that each program uses common data indicators, for example using similar nomenclature, about: (i) features of a group (e.g. terms such as ‘population’, ‘coverage’ and ‘completion’); (ii) features of the subjects (e.g. demographic data including age, gender; whether it is an initial or subsequent screening examination, and features that may confer increased risk); (iii) features of the examination and work-up (e.g. how the examination is performed or interpreted; criteria for an abnormal examination) [5, 6]; (iv) criteria for surveillance (e.g. what type of polyp prompts a recommendation for subsequent surveillance); and (v) what are criteria for pathological interpretation. This list is not exhaustive, but is intended to illustrate some of the features that may be measured. Again, a parallel experience in mammography screening may provide very useful lessons to anticipate both key issues as well as problems that might arise.

At present there is no uniform nomenclature to describe the features just identified. Some terms have been defined in the 7th IARC Handbook on Cancer Prevention, which covers breast cancer screening [7]. Specific terminology will need to be devised for colorectal cancer screening, for instance, regarding adenomatous lesions or the risks associated with undergoing screening and diagnostic tests. Development of common nomenclature should aim at facilitating direct comparison of different screening programs and allow comparison of activity across different states and countries, perhaps with gains in knowledge that can supplement randomized clinical trial data related to efficacy.

Recommendations. Experts from the field of breast cancer should advise leaders in colorectal cancer screening about the opportunities and challenges in comparing experiences among different screening programs. Preferably, in the very near future, several of the international groups focused on colorectal cancer screening should collaborate with organizations experienced with evaluating screening programs in order to develop appropriate terminology to be used in this effort. The Workshop suggested an initial list of common indicators for which precise definitions would allow comparisons of different types of screening programs.

The short-term indicators we suggest are shown in Table 1. The medium- and long-term outcomes that we suggest should be monitored are shown in Tables 2 and 3, respectively. These items should be the focus of further deliberations, and should have a range of values where possible. A number of quality control indicators (shown in Table 4) have also been identified, and there was consensus within our group that these should be in place before an individual physician or program begins screening. Nevertheless, minimum standards could be established, for example, for cleaning of endoscopes, for the facilities required and for staff training, perhaps combined with development of tools to monitor adherence to standards.

Table 1. Short-term indicators

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<tr>
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<tr>
<td>% population invited</td>
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<tr>
<td>% population accepting</td>
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<tr>
<td>% population completing screening process</td>
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<tr>
<td>within a given time period found to be screen</td>
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<tr>
<td>positive</td>
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<tr>
<td>Cancer and high risk adenoma rate (e.g. &gt; 1 cm</td>
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<tr>
<td>or high grade dysplasia)</td>
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<td>Stage of cancers diagnosed</td>
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<td>Negative outcomes within 30 days</td>
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Table 2. Medium-term outcomes

<table>
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<th>All colorectal cancers in a population stratified by invitation/attendance status to compare</th>
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<tr>
<td>% screened in the program</td>
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<tr>
<td>Cancer incidence rates</td>
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<td>Incidence rates of advanced cancer (Dukes’ C and D)</td>
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<tr>
<td>Interval cancers stratified by attendance status and screening center</td>
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<tr>
<td>Stage at diagnosis of interval cancers</td>
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<td>Date of diagnosis</td>
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<td>Costs, both actual and opportunity costs</td>
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Table 3. Long-term outcomes
- Disease-specific incidence
- Disease-specific mortality

Each should be stratified by invitation and attendance status

Table 4. Quality control
- Consumer information (including benefits and limitations of screening)
- Equipment standards and maintenance (including disinfection, etc.)
- Staff training and monitoring of performance
- Reporting (including pathology reports with inter-observer variation)
- Integration with symptomatic care

(for example, microbiological monitoring of disinfection procedures, endoscopist-dependent pick-up rates) [5]. Working with the relevant professional associations, evidence could be gathered to set professional standards and possibly to monitor those standards. Accreditation could then be considered when sufficient consensus is achieved on the minimum standards. With time and experience, appropriate regulatory frameworks could be devised.

C. Selected major issues relating to quality assurance

Issue 1: use of colonoscopy surveillance after polypectomy. What is an appropriate surveillance regimen for persons with screen-detected adenomas? As screening with any modality is increasingly done, large numbers of persons with polyps will be identified and become candidates for follow-up surveillance colonoscopy. In the past, recommendations have been very aggressive, based on the now-abandoned belief that all persons who have had polyps have a substantially increased subsequent risk of colorectal cancer. Because people can be risk-stratified and because some persons with the presence of small polyps and the absence of large polyps have a normal or even lower than normal risk, the use of aggressive surveillance in such persons may be wasteful and even harmful. At present, recommendations from health-care organizations are in conflict with respect to follow-up strategies [8]. From the standpoint of a health-care system, depending on thresholds for abnormality and risk, the costs of post-screening surveillance of individuals with abnormal test results could place a huge strain on resources [8].

Barriers. Conflicting professional recommendations may constitute a barrier to restraint in using intensive colonoscopy surveillance in low-risk persons. Economic incentives and fear of legal liability may also be a factor associated with overly aggressive surveillance, as may concerns about the quality of the preparation, and missed lesions. Concern about poor preparation or about missed lesions may also contribute to overly aggressive surveillance.

Recommendations. For countries beginning to implement screening programs, we recommend that clear and evidence based guidelines for post-polypectomy surveillance be established, and that they should be supported with appropriate economic incentives to support adherence. Further research is needed to determine optimum follow-up regimens appropriate to different economic and health-care delivery circumstances. Issue 2: use of family history as a marker of colorectal cancer risk. One important issue is how to identify and manage surveillance for individuals with a family history of colorectal cancer. Requirements for surveillance and management of particular syndromes, such as hereditary non-polyposis colorectal cancer and familial adenomatous polyposis, is better understood than is surveillance for the individual with a single first-degree relative who developed colorectal cancer after the age of 50 years. The first question is to what degree this kind of family history (as well as other kinds of family histories, such as those with more than one first-degree relative, first- and second-degree relatives, a first-degree relative diagnosed before age 50 years, etc.) confers an increased risk of colorectal cancer. The second question relates to surveillance and management, i.e. with ordinary screening tests beginning at a younger age, more intensive screening tests like colonoscopy, as well as other possible options.

Barriers. Barriers include a lack of basic knowledge about the degree of risk conferred by different kinds of family history, as well as conflicting interpretations and recommendations by different professional recommending organizations.

Recommendations. More research is needed to understand the nature and degree of risk conferred by family history, and this issue is among those that could benefit from international collaboration. Professional organizations’ recommendations should not be overly aggressive until there is sufficiently strong evidence about the degree of risk.

Issue 3: use of personal data. A general issue affecting all screening programs and, indeed, most public health research and interventions, is the use of personal data. The quality assurance and evaluation data required are derived from bringing together results from individual screening and follow-up events. Without evaluation of quality assurance data, the performance and safety of a screening program or an individual practitioner cannot be assessed.

Barriers. Protection of personal data and patient privacy is now an issue worldwide.

Recommendations. Individuals undergoing screening should be advised of the integral nature of quality assurance evaluation to screening and encouraged to allow their data to be used in aggregated form. Regulatory authorities should consider the importance of availability of information, while maintaining the protection of privacy, in framing legislation.

Summary
In the last decade the effectiveness of screening for colorectal cancer has been demonstrated. In the coming decade the challenge is to implement safe and effective screening for the at-risk population. Quality assurance measures and monitoring processes need to be developed by appropriate professional organizations. When screening programs are introduced,
health authorities and provider institutions offering screening are responsible for ensuring the implementation and utilization of quality assurance programs.

References