# Letter from Glasgow

### PILOT SITES FOR COLORECTAL CANCER SCREENING GET THE GREEN LIGHT

Colorectal cancer is a major public health problem in the United Kingdom, ranking as the second commonest cause of cancer mortality. There are over 30 000 new cases each year with nearly 20 000 deaths. The vast majority (>90%) of these are in people over 55 years of age with, as expected, an increasing incidence with age giving a lifetime risk of colorectal cancer for British people of 1 in 25. Colorectal cancer is conventionally divided into four Duke's stages—A to D. The 5-year survival varies from 80% for stage A to <40% for stages C and D. It is estimated that the annual cost to the National Health Service (NHS) of colorectal cancer is over £ 250 million.<sup>2</sup> So what is the public health response to this immense challenge? The answer is to see whether a population-based colorectal cancer screening programme is possible. To this end, the Department of Health in Scotland and England<sup>3</sup> bid for two pilot sites for colorectal screening by faecal occult blood (FOB) testing and colonoscopy for those who are positive and require investigation. The pilot sites will be selected and supervised by the UK National Screening Committee.

The National Screening Committee was formed in 1997 to advise all four Departments of Health in the UK—England, Northern Ireland, Scotland and Wales—about screening programmes. The remit of the National Screening Committee is to advise on:<sup>4</sup> the case for implementing new population screening programmes not presently purchased by the NHS; implementing screening technologies of proven effectiveness but which require controlled and well-managed introduction; and the case for *continuing*, *modifying* or *withdrawing* (emphasis mine) existing screening programmes: in particular, programmes inadequately evaluated or of doubtful effectiveness, quality or value.

An initial review of screening programmes by the National Screening Committee revealed a large number of screening programmes in existence. However, only four were national programmes covering the whole target population and were cost-effective. Note that the reference is to screening programmes and not simply screening tests. The four screening programmes were:

- 1. The Cervical Screening Programme for women aged 20–65 years (20–60 in Scotland) using cervical smears every 3 years;
- The Breast Screening Programme for women aged 50-64 years using mammographic screening every 3 years;
- 3. The neonatal heel prick test for hypothyroidism; and
- 4. The neonatal heel prick test for phenylketonuria (PKU).

The Department of Health circular outlined the challenge of colorectal cancer to public health. It noted the need to take account of lead-time bias and hence the necessity of assessing new screening programmes not only by measuring the impact of the programme on the stage of presentation and survival time, but also its impact in a randomized controlled trial. The groups in a randomized controlled trial are followed up and the differences in a number of variables are measured including:

- colorectal cancer incidence (number of new cases each year);
- colorectal cancer mortality within each group; and
- all-cancer mortality within each group.

The National Screening Committee reviewed the evidence for colorectal cancer screening<sup>5-7</sup> and the Committee concluded that—

particularly on the basis of the two papers<sup>6,7</sup> on high quality randomized controlled trials of colorectal cancer screening—there was sufficient evidence to recommend to the government pilot screening programmes at two sites in Britain. It should be noted that although randomized controlled trials reduce chance differences and minimize bias, they are only a prerequisite to proceeding to the next stage—piloting the screening programme in the real world of health care and not in the (often) well-resourced academic setting where the randomized controlled trial is likely to have been conducted.

In 1968, Wilson and Jungner<sup>8</sup> published, on behalf of the World Health Organization, their ten criteria for assessing screening programmes. These criteria have stood the test of time. Holland and Stewart<sup>9</sup> grouped the criteria into four categories: the condition, diagnosis, treatment and cost. The Medical Research Council suggested updating and adding four additional principles<sup>10</sup> to the original ten (harm from screening should be small, guidelines should be developed on giving results, need for periodic review of screening arrangements, and cost–benefit analysis should be done on demographic or case-type basis because 'cases' are not homogeneous). Similarly, the National Screening Committee thought the ten criteria were useful but did not give enough weightage to:

- 1. the adverse effects of screening (particularly important given the small but real risk of gastrointestinal perforation whilst undergoing colonoscopy;
- the strength of evidence about the effectiveness of the screening programme; and
- 3. the opportunity costs of screening.

So, what is proposed in the pilot sites for colorectal cancer programmes? There will be population-based screening for all adults aged 50–69 years in the pilot areas and the programme will entail:

- 1. an invitation letter to all eligible adults in the pilot area with a reminder letter after four weeks to those who have not responded to the initial invitation to be screened;
- 2. biennial screening using FOB testing with no dehydration of samples to minimize the false-positive rate;
- 3. further investigation of those positive on FOB testing by colonoscopy (with double contrast barium enema and sigmoidoscopy, if colonoscopy cannot be completed); and
- 4. appropriate follow up and treatment for those found to have polyps as well as colorectal cancer.

This is a very brief summary of the programme. From a public health perspective, the issues about the pilot sites are quite clear. The research evidence from randomized controlled trials shows a benefit of colorectal cancer screening. But to put this into practice, the pilot sites need to be able to answer questions (in the real world of health care) about such things as the acceptability of the programme to the population, the role and training of professionals, setting up of robust structures (including information systems) to manage the programme, linking it with the developing cancer units, clarifying the quality standards for the programme, and the cost of the programme.

A key aspect for the pilot sites is to learn from the experience of other national population-based screening programmes, particularly the Breast and Cervical Screening Programmes. In many ways, the Breast Screening Programme has been a model with additional resources allocated to it at the start in 1988 and with quality assurance built into, rather than bolted onto, the programme. The Cervical Screening Programme has always been the poorer, if older, relation of Breast Screening. However, there is much to learn from there too about working effectively with primary care staff and dealing sensitively with women invited for screening.

The two pilot sites are currently being selected on the basis of initial bids, and then visits to, and presentations from the five sites which got through the initial scrutiny of bids. The pilot sites have to be up and running by the end of 1999. The millennium promises to be an interesting and busy time for primary care, health promoters, public health professionals, GI surgeons, gastroenterologists, pathologists, radiologists, nursing staff, and administrative staff in both sites. The rest of the NHS will await their verdicts with, if not bated breath, then certainly with anticipation. I will keep you posted.

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## Letter from North America

#### THE POLITICS OF MEDICAL PUBLISHING

The Clinton scandal has had far-reaching and damaging effects in all spheres of American lives. Indeed, far enough into the hallowed halls of medical publishing.

The Journal of the American Association (JAMA), the flagship publication of the American Medical Association (AMA), has entered 115 years of continuous publication. The JAMA has had 17 years of success under the leadership of George D. Lundberg. Yet suddenly, on 15 January 1999, E. Ratcliffe Anderson, Executive Vice President of AMA summarily fired Lundberg saying: 'Dr Lundberg through his recent actions has threatened the historic tradition and integrity of JAMA by inappropriately and inexcusably interjecting JAMA into a major political debate [Clinton's impeachment] that has nothing to do with science and medicine.'

'There is no question that over many of the past several years Dr Lundberg and his fine staff—always working with complete editorial independence—have advanced the stature of *JAMA*', said Anderson who took office in June 1998. 'Over time, however, I have lost confidence and trust in Dr Lundberg's ability to preserve that high level of credibility and integrity.'

The reason that precipitated Dr Lundberg's dismissal was the early publication<sup>1</sup> of an already accepted article, unsolicited by the *JAMA*, which had passed peer review and editorial scrutiny, that reported a spectrum of opinions as to what constitutes sexual relations. A survey of 599 students in 1991 sought to determine which interactions individuals would consider as having 'had sex'. The conclusions: 'The findings support the view that Americans hold widely divergent opinions about what behaviors do and do not constitute having sex.'

The quality of the article was judged widely as 'rather pedantic' and in the words of an editor of a prestigious journal, 'too

trivial for a major medical journal'. The widespread hue and cry that followed questioned the departure from the tradition of medical publishing remaining independent of political interests. Hundreds of e-mail and other messages poured into the AMA, most criticizing Anderson's actions. Several fellow editors praised Lundberg's accomplishments and wrote editorials highly critical of this action. 'I believe that medical editors have an obligation to publish not only articles that are well reasoned, informative, and carefully reviewed, but also ones that are sufficiently timely to contribute to the development of public policy. Expediting a review and advancing the date of publication of a study or opinion piece is often justified. Firing an editor for doing so is an irrational decision and an ominous precedent,' wrote Jerome P. Kassirer, in the New England Journal of Medicine.2 In addition to finding a new editor for JAMA, an independent search committee has been formed to ensure the publication's integrity.

In a joint statement released early in February, the AMA and Dr Lundberg give Dr Lundberg credit for building *JAMA* and the related archives journals into the 'finest and most well-respected scientific medical journals in the world'. The statement makes no mention of Dr Lundberg being fired, instead it uses terms such as departure, parting ways, separation and retirement. It does not speak of Dr Lundberg's previous contention that he was considering all options, 'including litigation', in response to his abrupt dismissal. Neither side would comment on whether severance had been paid. The world of organized medicine and medical publication is closely watching for further developments.

### REFERENCES

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