

More light, less heat, in the breast screening debate?

Debate about the benefits and harms of breast screening programmes, which has rumbled on for decades, has entered a new phase of scrutiny on both sides of the Atlantic.

In the UK, an independent review of the National Health Service (NHS)'s breast screening programme is due to report in the next few months. The review was announced by National Cancer Director, Mike Richards, at the end of October 2011, and is being conducted in partnership with Harpal Kumar, chief executive of Cancer Research UK. In an attempt to have a truly fresh look at the debate – and in recognition of potentially entrenched views on the subject – the review panel is comprised of internationally renowned experts in epidemiology, medical statistics, breast cancer diagnosis and treatment, none of whom have previously published on breast screening.

In the US, the schism remains between the American Cancer Society (ACS) recommendations on one side and on the other, those released in 2009 by the US Preventive Services Task Force (USPSTF), which scaled back the role of mammography, clinical breast examination and breast self-examination. The USPSTF statement sparked controversy on publication but late last year, new Canadian guidelines were released which are broadly in line with the USPSTF's – and in fact recommend further reduction in the role of routine screening.

‘At the heart of the debate lie two deceptively simple-sounding questions – how many lives does breast screening save? And how much harm does it cause? We need to reach a consensus’

Harpal Kumar, Cancer Research UK

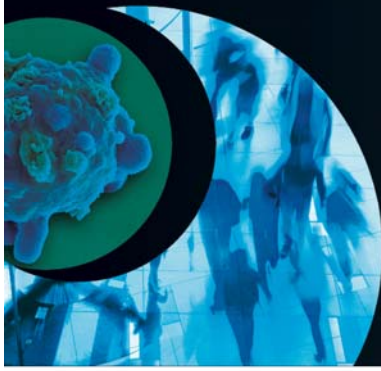
The subject is invariably debated at major cancer conferences, and last year's European Multidisciplinary Cancer Congress (Stockholm, Sweden; 23-27 September 2011) was no exception with a session devoted to the value – or otherwise – of screening for different types of cancer. Views on breast screening differed markedly, but afterwards, one delegate remarked that the measured and scientific tone of the discussion among those who disagreed vehemently was in itself a major step forward. It seems that the breast screening debate may finally have reached the stage where evidence can be reviewed dispassionately by experts, and unbiased information given to women.

These at least are two of the aims of the UK review. This review is particularly interesting because the UK screening programme has always been more limited in scope than those in the US, Canada, and some other parts of Europe. So while the USPSTF recommends two-yearly mammography for women aged 50-74 (as opposed to annual scans from age 40 still

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recommended by ACS), and the Canadian Task Force goes for screening every 2-3 years for those in the same age group, in the UK, mammography was originally offered to women aged 50-64 every 3 years. The age range covered by the programme was later extended to 50-70 years, and a further extension to include women aged 47-73 is currently being introduced through randomisation.

The UK review panel will consider evidence from randomised controlled trials and observational studies in the UK and elsewhere which have been published or accepted for publication. Articles providing opinions that do not contain original data or meta-analyses are not expected to have a bearing on the conclusions of what is intended to be a rigorous review of the evidence, rather than a formal systematic review.

‘There have been substantial benefits in screening trials. But there is debate on additional treatment effects and on the amount of overdiagnosis’

Harry de Koning, Erasmus MC

The key aim is to estimate both the likely benefits of breast screening, and the likely harms, including the risk of over-diagnosis. The range of uncertainty in the estimates will be given along with, if the evidence permits, assessments of benefits and harms for different age groups and subgroups (including DCIS diagnoses, socioeconomic and ethnic groups).

Harpal Kumar said: “At the heart of the debate lie two deceptively simple-sounding and more fundamental questions – how many lives does breast screening save? And how much harm does it cause? We need to reach a consensus on the answers to these questions in order to guide the further of breast screening.

“Many of the large trials into the benefits of breast screening took place over 20 years ago – a different era in terms of breast cancer treatment and outlook. Some experts question how well some of these trials were carried out. Nevertheless, most experts around the world agree that breast screening saves lives. Most experts also concede that some women suffer harm as a result.

‘Mammography screening by itself has little detectable impact on mortality due to breast cancer’

Philippe Autier, IPRI

“But estimating the numbers of lives saved and numbers of women harmed through anxiety, exposure to radiation, ‘overdiagnosis’ and ‘overtreatment’ is not simple,” Kumar said. When he announced the review in the *BMJ* – in response to an open letter from UK obstetrician Susan Bewley – Richards said, “I will do my best to achieve consensus on the evidence, though I realise this may not ultimately be possible. Should the independent review conclude that the balance of harms outweighs the benefits of breast screening, I will have no hesitation in referring the findings to the UK National Screening Committee and then ministers.”

Richards quoted the IARC (World Health Organisation’s International Agency for Research on Cancer) monograph which concluded that screening women aged 50-69 years reduced mortality by 35%. However, he acknowledged that a Cochrane Collaboration review did not support this finding.

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A similar dichotomy of views was expressed at the session on screening at the European Multidisciplinary Cancer Congress last year. Philippe Autier (International Prevention Research Institute, Lyons, France) said that reductions in breast cancer mortality in general populations might not be due to screening at all but rather to the introduction and increasing use of effective treatments, more efficient health systems, and increased awareness of breast cancer in the population. "Evaluation of the respective role of these factors is not straightforward, as they all occurred at about the same time from end of the 1980s, to 2000," he said.

In an attempt to untangle the contributing factors, Autier and colleagues considered neighbouring European countries with different levels of screening but similar access to treatment. They compared trends in breast cancer mortality in Northern Ireland (UK) versus Republic of Ireland; the Netherlands versus Belgium, and Sweden versus Norway. Countries of each pair had similar healthcare services and prevalence of risk factors for breast cancer mortality but differing implementation of mammography screening, with a gap of 10-15 years.

Using data from the WHO mortality database, they found that trends in breast cancer mortality rates varied little between countries where women had been screened by mammography for a considerable time, compared with those where women were largely unscreened during the same period. Autier said, "Our study adds further population data to the evidence of studies that have used various designs and found that mammography screening by itself has little detectable impact on mortality due to breast cancer." (*BMJ* 2011; 343:d4411)

"In most areas, breast cancer mortality rates started to decrease before, or around the time of implementation of screening," he said, adding, "Breast cancer mortality reductions have been more pronounced in women less than 50 years, even in countries where screening before age 50 is rare."

Epidemiological data, based on general population data, suggests that the direct impact of screening on breast cancer mortality "is most probably low or nil", he said. Screening has led to a reorganisation of breast cancer services that has benefited all breast cancer patients, including those who have not been screened.

However, randomised trials of screening (as opposed to epidemiological studies) *have* found mortality benefits from breast cancer screening; indeed, screening programmes were established on the back of results from these trials. Subsequent debate has focused on the methodologies used in the randomised trials, but in the UK, for example, Richards says that the Advisory Committee on Breast Cancer Screening advises "that breast screening saves lives and that the benefits considerably outweigh the harms."

In a similar vein at the European Multidisciplinary Cancer Congress, the screening session was chaired by Harry de Koning (Erasmus University Medical Center, Rotterdam, the Netherlands). Summing up, he quoted the randomised trials which have shown a benefit of screening. "There have been substantial benefits in screening trials," he said. "The benefit part has been shown, but indeed there is a lot of debate on additional treatment effects – what is the interaction

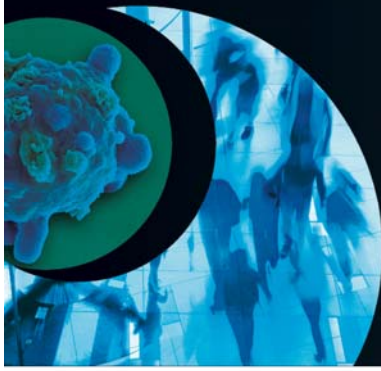
'I will do my best to achieve consensus on the evidence, though I realise this may not ultimately be possible'

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between screening and treatment? There's also a certain debate on the amount of overdiagnosis."

To de Koning, then, the benefits of screening are established; what needs continual reassessment is the potential harms. To Autier, not even the benefits are established. Any review of the subject will have to consider such widely differing viewpoints to make progress in finding the consensus that Richards would like to see.

But whatever the state of the evidence on the core value of screening, a key immediate question concerns the information given to women invited for screening. Susan Bewley said in her open letter to Richards, "In the past few years British women have not been told about the genuine doubts. Those millions of women passing through the breast screening treadmill have been unaware of the problems, criticism, and real numerical risks they face."

This point appears to have been accepted by the UK review from the outset. Its terms of reference include an expectation that it will recommend "key messages regarding risks and uncertainty that need to be considered when drafting new communications materials regarding the breast screening programme. This will include considerations of effectiveness."

'We have focused on persuading rather than educating, implying that there is an a priori best choice for each individual'

**Michael Edward Stefanek,
Indiana University**

The importance of public education has strong advocates in the US. Michael Edward Stefanek (Indiana University, US) argued (*J Natl Cancer Inst* 2011; 103:1821-6) that professional medical groups and patient advocacy organisation have spent much time developing, debating and promoting cancer screening guidelines. "If we agree on the premise that individuals are supposed to be informed before making medical decisions, including decisions about cancer screening, then the time and talent of such groups could be much better spent educating the public on the harms and benefits of cancer screening."

"We have too often ignored the fact that people have different values related to false positives, false negatives, overdiagnosis, and perhaps most critically, overtreatment. We have focused on persuading rather than educating, implying that there is an a priori best choice for each individual."

Reasonable people may disagree over the benefit of any given screening strategy, he concluded. In a call for the open-mindedness and generosity of spirit which is going to be essential for progress to be made in what has been such a heated debate, he urged professionals and advocates to work together "to develop an approach to screening that embraces, encourages, and routinely provides both the harms and benefits of cancer screening tests to all patients in a transparent fashion. It involves a fundamental respect for individuals and a tolerance for truly informed decisions even if, as individuals ourselves, we would not make the same choice."

Helen Saul

For further information, see USPSTF guidelines (*Ann Intern Med* 2009; 151:716-726); www.canadiantaskforce.ca; *BMJ* 2011; 343:d6894 and *BMJ* 2011; 343:d6843. Details about the UK review at: http://info.cancerresearchuk.org/publicpolicy/ourpolicypositions/symptom_Awareness/cancer_screening/breast-screening-review/

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Cancer care suffers as Eurozone spending cuts bite

As Eurozone countries wrestle with continuing financial crisis, signs are emerging that care for cancer patients is being adversely affected.

In 2011, Greece, Portugal, Ireland and Italy were forced to take a series of austere measures in order to stave off bankruptcy and qualify for bailout loans from the European Union and International Monetary Fund. Under the loan terms, each country agreed to cut its spending on healthcare in 2012 and beyond.



Christos Markopoulos
Athens University

‘In some instances, cancer drugs are not available in public hospitals which have outstanding pharmaceuticals bills’

In Greece, austerity drives have seen the healthcare budget cut by around €1.9 billion since 2009 and under its current agreement with creditors, officials say as much as €700 million will have to be made in healthcare savings in 2012.

They have resulted in an increase in national healthcare fees and the introduction of co-payments at public hospitals. Cancer patients are paying for the national crisis with their health, according to Christos Markopoulos, breast cancer specialist at Athens University Medical Hospital. "Two of my patients stopped their treatment recently not because of the side effects but because of the increased cost on the national health system and the waiting time for approval. They just gave up," he says.

To save on the cost of drugs in public hospitals, the Greek government introduced an auction system in 2011, where pharmaceutical companies bid to provide the lowest price.

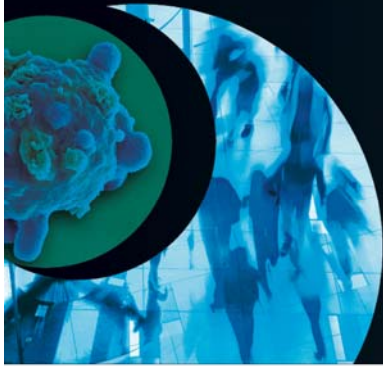
The system has been reported to be successful but it has delayed the use of the latest cancer therapies in public hospitals. "New cancer drugs are being approved in Greece but going through the bidding process for getting the lowest possible price takes months," says Markopoulos. "In some instances, cancer drugs are not available in public hospitals which have outstanding pharmaceuticals bills."

The knock-on effects are being felt in clinical research. "Pharma profits in Greece have gone down and companies cannot afford to sponsor clinical trials. Restrictions have been placed on how much they can spend, and a couple of trials have left Greece," says Markopoulos. Sharing best practices and disseminating results has also been affected, according to

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Markopoulos. "Sponsors for cancer congresses were easy to find up until a couple of years ago. Of course we are going to continue, but it is getting harder day by day."

The end of 2010 saw a flurry of senior hospital staff retiring early in all disciplines in advance of changes in the law which would cut pensions and raise the age of retirement. "Many senior staff exercised their right to early retirement to avoid pension cuts. At the moment in the public sector, you can only hire 1 new person for every 5 or so retirements. There are some exclusions, but university hospitals are not among them," says Markopoulos.

'We expect significant changes this year with access to services becoming more difficult, delays in approving new therapies and in expanding screening programmes'

Liam Grogan
Ireland

Markopoulos has noticed a rise in the number of cancer patients admitted through the national health system which, combined with staff shortages, has created a huge problem: "If you have fewer doctors looking after more patients then naturally you don't expect the best quality of care from them," he says.

In Portugal, the government agreed to cut healthcare spending by 5% in 2012 – some €550 million under the terms of its 78-billion bailout. However, with one third of Portugal's hospitals insolvent, medical institutions are actually being asked to make a 10% reduction in healthcare costs according to Francisco Pimentel, medical oncologist at Aveiro University. Pimentel feels it inevitable that cuts already made are having an impact on cancer diagnosis. "Access to supplementary means of diagnosis such as MRI or PET-CT scans have been restricted if they are not available in-house. It is likely that the rapidity of diagnosis and staging is already compromised for cancer patients," he says.

'It is likely that the rapidity of diagnosis and staging is already compromised for cancer patients'

Francisco Pimentel
Portugal

There are no restrictions on the use of chemotherapy and biotherapies, explains Pimentel, but he and his colleagues are concerned that waiting times for cancer surgeries will be affected under the new cuts. "Waiting times for surgery have increased from month to month for patients in other disease areas and we expect this will also become a reality for cancer patients as the economic situation gets worse," he says.

worrying Portugal's cancer community. "The programme content has not been disclosed and there is uncertainty whether cancer networks already implemented will continue [to be funded]," says Pimentel.

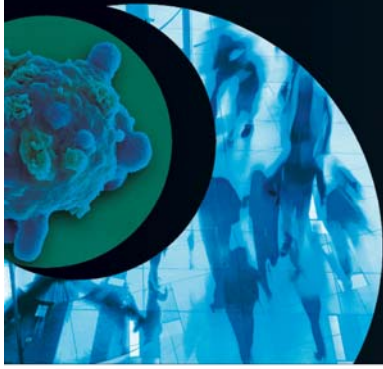
'Staffing for specialised cancer nursing and palliative care nursing has got worse'

Pierfranco Conte
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With €868 million due to be cut from Ireland's health spending in 2012, oncologists feel there will inevitably be changes in medical services. "[There has been] no major change yet in Ireland however we expect significant changes within this year with access to services becoming more difficult, delays in approving new therapies and delays in expanding screening programmes due to start in 2012 particularly colorectal screening," says Liam Grogan, consultant medical oncologist at Beaumont Hospital, Dublin.

Speaking on Radio 1 RTÉ's Morning Ireland programme on 18 January, 2012, Ireland's health minister James Reilly confirmed that colorectal cancer screening programmes are being delayed by months but would go ahead later this year.

At around €800 billion, Italy is facing a public debt more than that of Greece, Portugal and Ireland combined. New health spending cuts will amount to €5 billion from 2013.

Italy's 20 regions manage their own healthcare systems with a share of funds transferred from central government. Oncologists are watching and waiting to see whether efficiency drives will improve current difficulties in the regions. "There are problems with access to cancer drugs in some regions such as the South of Italy where the control of expenses is less efficient," says Pierfranco Conte, Director of the Division of Medical Oncology at the University Hospital of Modena. "Paradoxically it is harder to get reimbursement for innovative drugs in the south of Italy although per capita spending is higher there. Access to cancer screening also varies between regions."

Meanwhile effects have been seen in staffing. "There have not been cuts in the number of doctors in Italy for the moment but more temporary doctors have been brought in, particularly in speciality areas," says Conte. "However, staffing for specialised cancer nursing and palliative care nursing has got worse."

*Saffina Rana,
Brussels*

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