Public awareness campaigns can help overcome some of these issues, while also promoting active and healthy lifestyles. Outreach programmes also are a valuable supplement to clinic based services for older women. Community based activities, including support groups and volunteer health promoters, hold special promise since they can maximise the interest and resources of the elderly themselves as well as the wider community.

No matter which interventions are selected, expanding services for older women will place new demands on healthcare providers. Providers should receive pre-service and refresher training to learn how to counsel women and treat common health problems. Equally important, educational programmes should aim to change providers' attitudes so that they value older clients. Following the lead of international agencies and local programmes, the global health community must work to address the health needs of older women, especially in the world's poorest countries.

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Competing interests: None declared.

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Balancing benefits and harms in health care

We need to get better evidence about harms

Should kids be plastered with sunscreen this summer? Is this likely to be more beneficial than harmful? How would we know? For example, sunscreen use has been associated with overexposure to the sun, perhaps because of overconfidence in its abilities.[1 2] Might there also be a potential risk of developing contact allergies, skin irritation, and rare but severe adverse effects? People making a decision about whether or not to use sunscreen need reliable evidence on the balance of benefits and harms. The same is true of all healthcare interventions, and unfortunately reliable evidence on harms is often lacking.

Great progress has been made in obtaining reliable evidence on the beneficial effects of interventions, but developments in the identification, interpretation, and reporting of harmful effects is more challenging. Randomised controlled trials are the best way to evaluate small to moderate effects of healthcare interventions, and much of the evidence for benefits from treatment comes from such studies. However, they are not always suitable to evaluate harms, and this was made clear during a recent meeting jointly organised by the Cochrane Collaboration and BMJ Knowledge in London.

There are various problems with randomised controlled trials in relation to harms and some of these problems affect systematic reviews too. Firstly, trialists may know which benefits to assess but may be unaware of potential harms of the interventions they are testing. Identifying unexpected harms is difficult when the delay between the intervention and the onset of side effects is long or when a cumulative exposure is necessary to trigger the harms. Harms may be measured or grouped differently among trials, making it almost impossible to summarise, aggregate, or interpret the evidence in meaningful ways. The debate about the potentially serious cardiovascular effects of cyclooxygenase-2 (COX 2) inhibitors illustrates some of these problems. Serious cardiovascular effects associated with the use of COX 2 inhibitors have been identified recently[3 4] because they were not systematically searched for in previous trials.[5] All this can lead to harmful drugs continuing to be used for many years before a warning is raised.

Problems exist with detection also. Rare harms may turn out to be more common than anticipated once flagged, but providing effective and balanced information to doctors and the public may be a complex and lengthy process. Even if the information is collected it might not be reported or indexed consistently well.[6]

Adverse effects can also be confused with the symptoms of the condition being treated. People taking analgesics for headache may develop analgesic induced headaches.[7] Until this was discovered people with migraine might have thought their condition was getting worse, increased the amount of analgesics they took to compensate, and found themselves being exposed to even more of a harmful treatment.

Raising the alarm about a potential harm can also do more bad than good if the quality of the evidence or

BMJ 2003;327:65–6

Proposals that came out of the workshop on harms and rare events

The QUOROM and CONSORT working groups will be sent the ideas and proposals produced during the meeting.

The *BMJ* will systematically ask authors of randomised controlled trials and systematic reviews to address harms. Guidance will be made available on bmj.com

The *BMJ* will dedicate a theme issue to harms in 2004.

A broader international conference aimed at improving the standards for assessing and reporting data on harms in randomised trials and systematic reviews will be organised by BMJ Knowledge and the Cochrane Collaboration.

The Cochrane Collaboration's Steering Group will discuss how to improve the reporting of harms in Cochrane reviews.

BMJ Knowledge and the Cochrane Collaboration will support their joint initiatives to improve the reporting of harms in their publications, which lead to the organisation of the recent meeting.

its reporting are poor. When insufficient data are available to ascertain the size of the problem for an intervention and for any alternatives, people may end up worse off. They might be deprived of an intervention that is on balance more beneficial than harmful and left with an alternative that might be worse. For example, misoprostol has been found to be an effective, cheap, and accessible way of inducing labour in the third trimester. However, controversy over its use has arisen because of potential harms of this prostaglandin analogue, including uterine rupture. Dinoprostone, the alternative prostaglandin, is more expensive, and what is more worrying is that the evidence proving that it is safer than misoprostol seems to be unavailable.[8]

Delegates at the recent meeting named a range of other sources of evidence of harms such as databases, observational studies, and specialised publications, but these have problems of their own. Databases are difficult to maintain and are not broadly accessible. Moreover, it is difficult to know how many people have been exposed. Reports from patients and case reports are susceptible to bias. Specialised publications are a very useful source of information,[9] but share some of the limitations of databases.

Emotional and psychological barriers are also involved in the reporting of harms. People and organisations may have competing or vested interests, or come under pressure to take a lenient approach. Reporting harms may cause more trouble and discredit than the fame and glory associated with successful reporting of benefits. Our blame culture offers few incentives for reporting harms, and little gratitude is to be expected by a healthcare provider or an institution reporting that the interventions they offered were harmful. Such a declaration could lead to criticism, legal liability, withdrawal of funding, and stigmatisation.

Some of the problems with using randomised trials to assess harms can be solved, but many cannot be. The recent meeting showed that pursuing collaborative multidisciplinary initiatives involving clinical epidemiologists, pharmaco-epidemiologists, biostatisticians, and medical writers among others, are promising. The meeting delivered proposals to improve the detection and reporting of harms in randomised trials, systematic reviews, and observational studies. Other proposals aimed at improving the recording of harms in databases and tackling methodological problems during the analysis and interpretation, especially of rare harms. For example, the reporting of adverse effects might be improved through initiatives such as CONSORT for randomised trials and QUOROM for reviews.[10 11]

The challenge of providing reliable information on the harms associated with health care is one for everyone. Those who do trials, reviews, and other types of research need to ensure that they investigate and report possible harms fairly and comprehensively. Those who publish and report research need to do so in a responsible balanced way. Those who use research to make decisions about health care need to look through the fog and beyond the hype, good or bad, to try to find the truth about the relative benefits and harms of interventions.

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Competing interest: None declared.

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What is a good death? Join in our online discussions

On 26 July the *BMJ* will publish a special issue on a good death, chock full of science, art, and debate. Even if you did not submit material to our theme issue, you can still contribute via bmj.com. Let us know your ideas on what's important for a good death by taking part in our online poll. In addition, after the issue is published on 26 July we will have a web chat with experts who will take your questions and lead a discussion. More details coming soon on bmj.com.