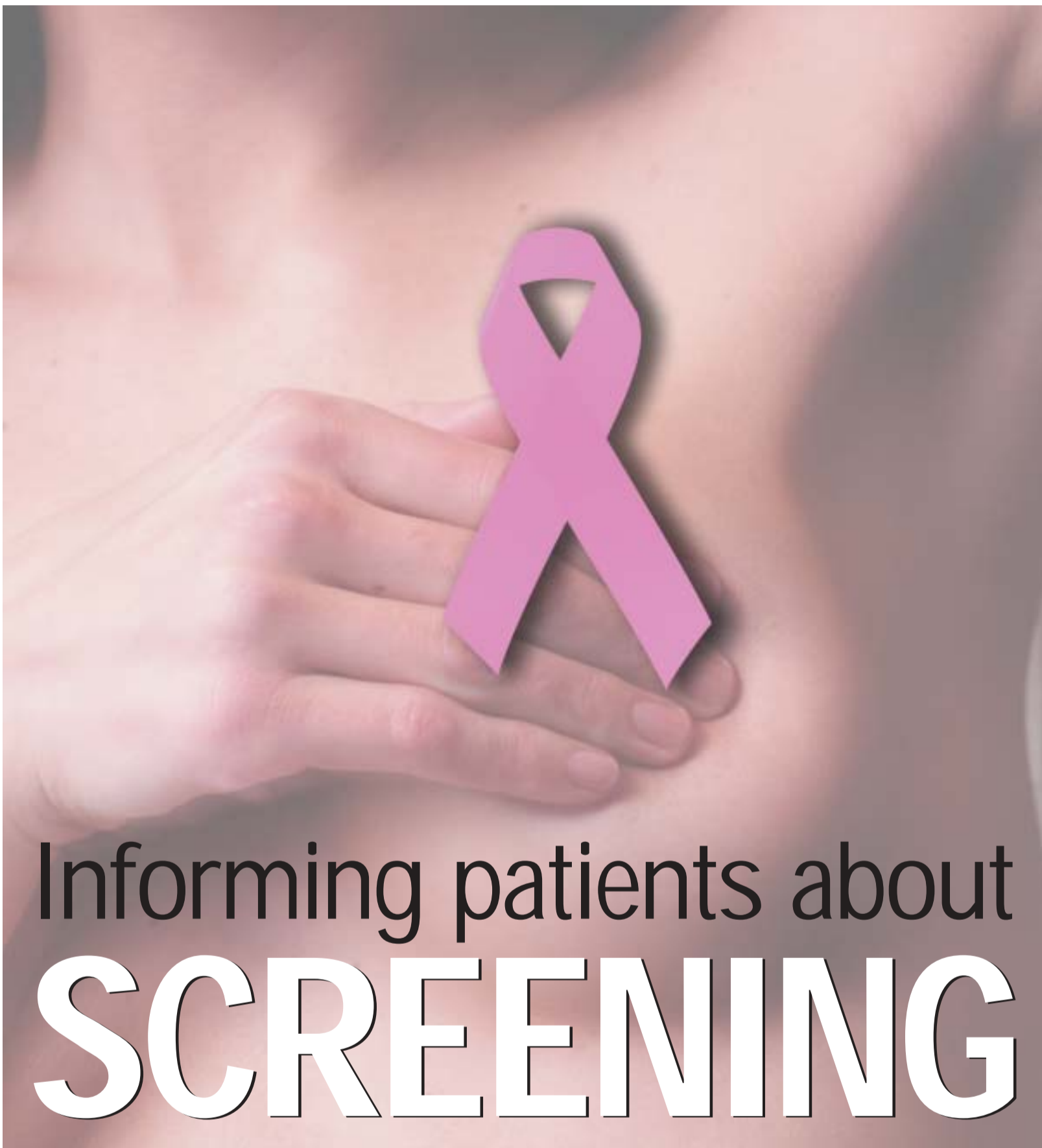


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Informing patients about **SCREENING**

Background

DISCUSSING and conducting screening is a common activity in general practice. A request for a checkup is one of the most common 'reasons for encounter', according to a report on general practice activity in Australia 2004-2005.¹

The RACGP *Guidelines for Preventive Activities in General Practice* recommend up to 23 preventive activities for Australian adults, many involving some form of 'screening'.²

A recent article in the *BMJ* was highly critical of many Australian and other breast-screening programs for not providing balanced information to women.³ The same article

also suggested that GPs should play a key role in discussing these issues with their patients and expressed concern about screening program invitations and reminders bypassing GPs.

What is screening?

The Medical Screening Society (MSS) is an international group of experts in the field of screening, established in 2002. Their published definition of screening reflects current thinking that we should try to balance the evidence for potential benefits of screening against the potential harm that may be done to healthy 'screenees'. The MSS definition states that:

*Screening is the systematic application of a test or enquiry to identify individuals at sufficient risk of a specific disorder to warrant further investigation or direct preventive action, amongst persons who have not sought medical attention on account of symptoms of that disorder.*⁴

To further highlight this point, the RACGP guidelines have adopted parts of the UK National Screening Committee definition, which states that screening will: "... identify those individuals who are more likely to be helped than harmed by further tests or treatment to reduce the risk

of a disease or its complications".

There are several key points to note in these definitions:

- Screening is performed on people without symptoms.
- The screening test does not necessarily provide a diagnosis but rather identifies people at increased risk. The follow-up tests aim to make a diagnosis.
- Screening should identify those at sufficient risk to warrant further investigation of preventive action (in other words, there should be enough potential benefit to justify the potential cost, intrusion and intervention to the patient).

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Types of screening

WITHIN this definition there are several different mechanisms by which screening can be introduced and some terms worth clarifying.

Screening mechanisms

Population screening

These are large-scale, organised and systematically implemented programs. Examples in Australia include mammography for breast cancer screening, Pap smears for cervical cancer screening and, in the near future, faecal occult blood testing (FOBT) for colorectal cancer screening.

Such programs define a target group deemed to be at sufficient risk of disease (often defined by age and/or family history). They also have systems for recalls and reminders, and registers. There are quality assurance systems that require regular reporting and evaluation against population level health outcomes.

Case finding

Tests or enquiries are performed at the time a patient may present for other reasons. They are often proactively instigated by the clinician. Usually there is no recall and reminder system or large scale evaluation in place. Examples might include chlamydia screening in sexually active women under 25 or measuring blood pressure in healthy adults.

Common epidemiological terms

Lead-time bias

This refers to an overestimation of the survival time for a disease. It is caused by a backward shift of the starting point of disease because earlier diagnosis makes it appear as though there is a greater survival benefit from screening.

The amount of lead time necessary to favourably alter the natural history of a disease varies according to the disease itself and the availability of effective treatment after early detection.

If early detection does not enable use of treatment that has greater benefit than if it were applied when the disease was clinically detectable, the age at which advanced illness or death occurs will be unchanged despite the added lead time.

Ideally the effect of early detection from screening should be measured by randomising people to be screened or not screened, with mortality as the endpoint. If survival rates are used in the randomised trial, the follow-up should be appropriate for the natural history of the disease. Figure 1 may help explain this.

Inconsequential disease

This is 'disease' detected by screening but not likely to

Figure 1: Lead-time bias. The arrows signify the intervals for screen-detectable disease and lead time, respectively; t_0 is the time at which disease becomes screen-detectable, t_1 is the time at which screening occurs, and t_2 is the time at which disease becomes clinically detectable or symptomatic.

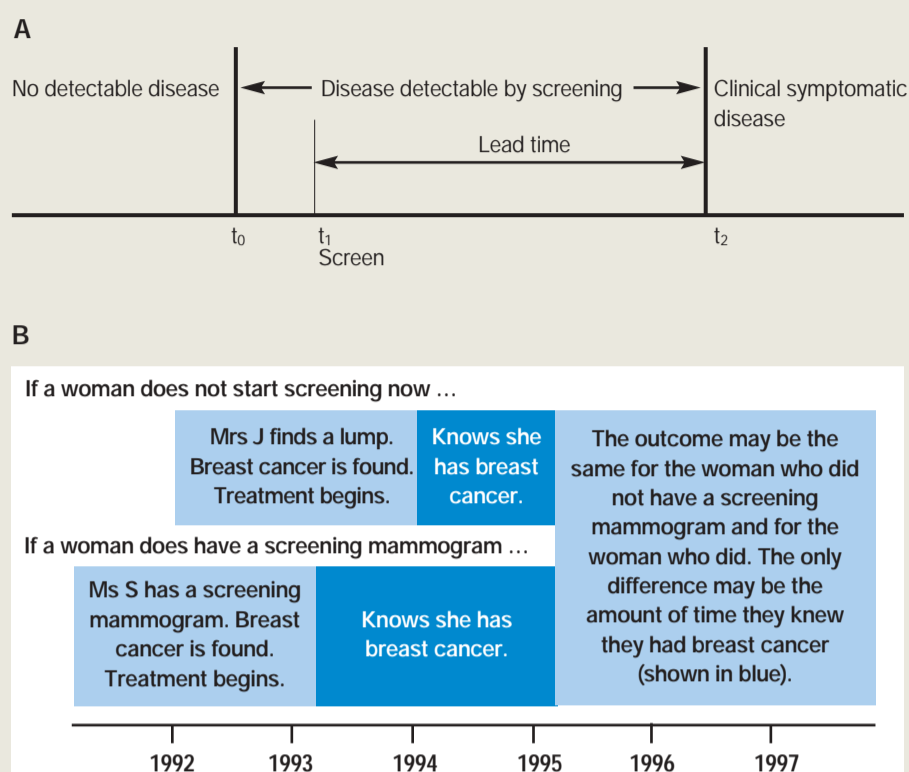
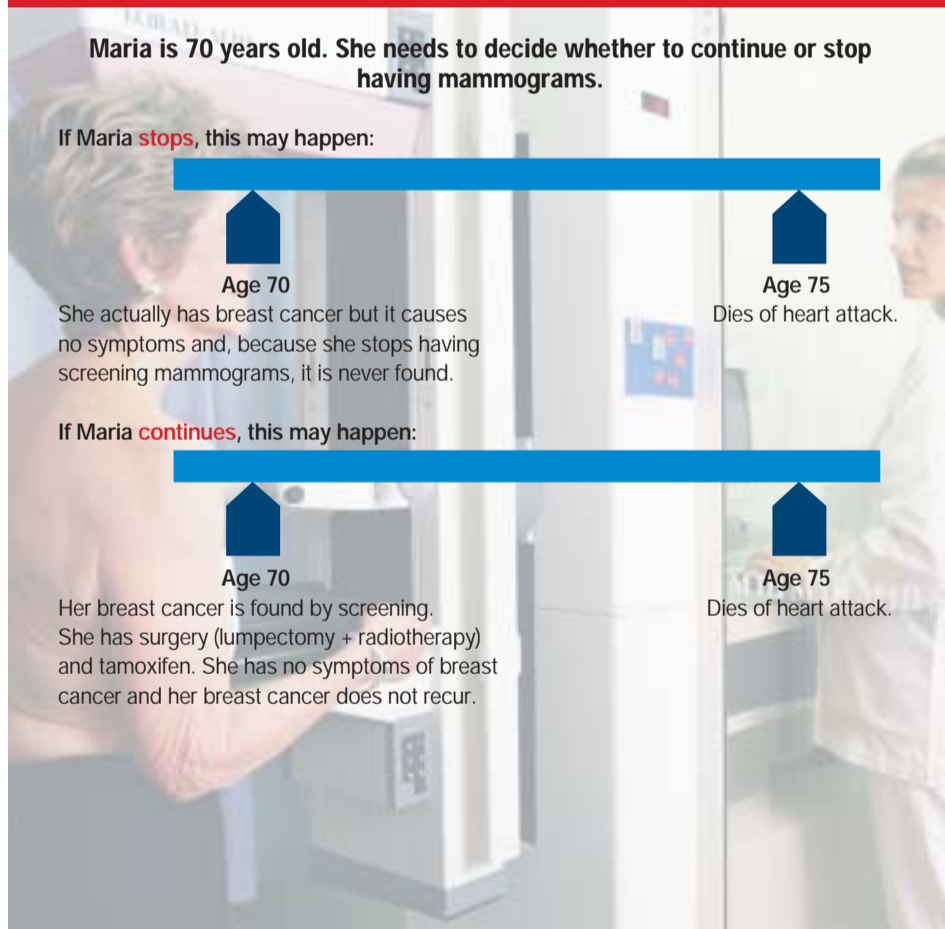


Figure 2: Inconsequential disease.



have any clinical significance to the patient if it had remained undetected. Examples of this include detection, through screening, of a cancer in an elderly person, which does not become clinically significant in their lifetime, and the person dies of unrelated causes.

Another example is some types of ductal carcinoma in situ detected at screening mammography. It may be that such 'disease' would not be of clinical significance but, because it is detected through screening asymptomatic women, they are faced with the dilemma of whether to have treatment or not (see figure 2).

Interval cancers

Cancers and other diseases can arise between screening rounds. Patients may not be aware of this and assume that an 'all clear' on a mammogram means that they will not develop cancer for at least another two years. Generally speaking, cancers are more aggressive in younger people and the proportion of interval cancers compared with screen-detected cancers falls with age.

For example, according to a recent paper based on Breast-Screen data⁵ the chance of a 40-year-old woman having breast cancer detected by screening over 10 years is 8.5 per 1000 and the chance of her developing interval can-

Table 1: Journal of the American Medical Association criteria for evaluating screening recommendations

How to use guidelines and recommendations about screening

- Is there evidence of benefit from randomised trials? If so, how large is the benefit?
- What are the harms, how large are they and how frequently do they occur?
- What is the net result of balancing the benefits and harms?
- Can the net result be improved by:
 - Screening people of different baseline risk for the target condition?
 - Using a different screening interval?
 - Using different screening tests?
- Is it cost effective and what are the resource implications?
- How will individuals' values and preferences be accommodated in individual decision-making about whether to be screened?

Table 2: Recommendation scheme for the US Preventive Services Task Force (USPSTF), 1998-present⁷

Quality of evidence	Net benefit			
	Substantial	Moderate	Small	Zero/negative
Good	A	B	C	D
Fair	B	B	C	D
Poor	I	I	I	I

- A: The USPSTF strongly recommends that clinicians provide [the service] to eligible patients. The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.
- B: The USPSTF recommends that clinicians provide [this service] to eligible patients. The USPSTF found at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.
- C: The USPSTF makes no recommendation for or against routine provision of [the service]. The USPSTF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation.
- D: The USPSTF recommends against routinely providing [the service] to asymptomatic patients. The USPSTF found at least fair evidence that [the service] is ineffective or that harms outweigh benefits.
- I: The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. Evidence that the [service] is effective is lacking, of poor quality or conflicting, and the balance of benefits and harms cannot be determined.

cers between and despite screening is about the same at 9.1 per 1000.

Compare this with 60-year-old women who have biennial mammograms and the chance of screening-detected cancer is 23.3 per 1000, with 9.2 per 1000 developing interval cancers.

Sensitivity and specificity

Sensitivity is the proportion of people with the disease who have a positive test — in other words the true positive rate. Specificity is the proportion of people without the disease who have a negative test — in other words the true negative rate.

How do we know a screening recommendation is valid?

Screening is a popular concept in the community because people generally agree with the old saying that 'prevention is better than cure'. However, as we have already discussed, the benefits of screening should outweigh the harms. Ideally this benefit should be assessed via a randomised controlled trial. The appraisal checklist in table 1, from the *Journal of the American Medical Association's Users'*

Guide series, is useful for this task.⁶

There are two main types of randomised controlled trial design for screening interventions. One type randomises people to receive screening or no screening and follows their outcomes (including follow-up after treatment).

The other type allows everyone to have the screening test and then randomises people with positive results to receive either treatment or no treatment. The second type of design is more commonly used when screening aims to detect a risk factor (eg, high blood pressure) rather than disease itself.

The choice of design depends on the type of screening test along with feasibility and ethical issues.

The US Preventive Services Task Force has developed a grid that makes recommendations based on the quality of evidence and the magnitude of net benefit for a preventive activity (table 2). It more explicitly reflects the trade-off between benefits and harms by reporting the 'net' benefit of screening as well as the quality and strength of the evidence.

Australian population screening programs and the evidence for them

AUSTRALIA has three main population screening programs and will have a fourth in 2006. These tests are available to all Australians in the relevant target group.

Eligibility for screening is usually based on population-level modelling and (if available) evidence from randomised controlled trials, which identifies those for whom the benefits of screening will outweigh the potential harms (eg, women aged 50-69 for mammography).

Asymptomatic eligible people are systematically recalled and reminded to participate at the recommended interval. Systems for follow-up and evaluation are in place.

Newborn screening

In Australia (and in all developed countries), newborns are tested for about 30 congenital metabolic disorders that are treatable if diagnosed early, before symptoms occur (table 3). The management of these programs is state based.

Only one of these conditions (cystic fibrosis) has randomised controlled trial evidence about the effectiveness of screening in newborns. Cystic fibrosis has a high enough birth prevalence (25-40 per 100,000 in Caucasians) to make a randomised trial of screening feasible.

Although congenital hypothyroidism has a similar prevalence, it is unlikely to be subjected to a trial for ethical reasons. The other disorders are so rare that trials would require extremely large sample sizes to detect any effect.

Two trials of cystic fibrosis screening (involving 1,124,483 infants) were included in a Cochrane review that showed no significant difference in lung function (FEV₁) by age seven years between the screened and unscreened groups, although chest X-ray scores (a surrogate for disease extent) at diagnosis were better in the screened group.

Screened children found to be positive had a longer duration of infection and were colonised earlier by *Pseudomonas aeruginosa*. Thus the early diagnosis of cystic fibrosis by screening has the potential to benefit pulmonary outcomes but these may be confounded by iatrogenic and other factors.

However, there is clear evidence of benefit for growth and nutrition outcomes arising from newborn screening for cystic fibrosis. Unscreened newborns later found to have the condition(s) were much more likely to have height and weight below the 5th centile (height: odds ratio [OR] 5.03, 95% confidence interval [CI] 1.63 to 15.63;

Table 3: Metabolic disorders screened for in newborns (NSW)

- Phenylketonuria (PKU)
- Congenital hypothyroidism
- Cystic fibrosis
- Galactosaemia
- Rare 'amino-acidopathies' (other than PKU):
 - Homocystinuria
 - Maple syrup urine disease
 - Tyrosinaemia types I and II
- Organic acidopathies
- Fatty acid oxidation defects
 - Medium-chain acyl-coenzyme A dehydrogenase deficiency
 - Other fatty acid oxidation disorders

Table 4: Outcomes in hypothetical cohorts of women undergoing, or not undergoing screening mammography⁶

1000 women aged 50 who have biennial mammograms for 10 years	1000 women aged 50 who do not have biennial mammograms for 10 years
242.0 recalled for extra tests	0
17.6 invasive breast cancer detected by screening	0
10.4 develop interval breast cancer*	0
28.0 diagnosed with invasive breast cancer	19.8 diagnosed with invasive breast cancer
4.9 have DCIS diagnosed**	0.4 have DCIS diagnosed
32.9 breast cancer diagnosis of any kind	20.2 breast cancer diagnosis of any kind
4.0 die from breast cancer	5.9 die from breast cancer
1000 women aged 40 who have biennial mammograms for 10 years	1000 women aged 40 who do not have biennial mammograms for 10 years
250.9 recalled for extra tests	0
8.5 invasive breast cancer detected by screening	0
9.1 develop interval breast cancer*	0
17.6 diagnosed with invasive breast cancer	13.2 diagnosed with invasive breast cancer
3.4 have DCIS diagnosed**	0.3 have DCIS diagnosed
21.0 breast cancer diagnosis of any kind	13.5 breast cancer diagnosis of any kind
2.0 die from breast cancer	2.5 die from breast cancer

*Interval breast cancers develop between screens

**DCIS = ductal carcinoma in situ — of unknown clinical significance



Take home messages — mammography screening

The take home messages from this model of mammography screening outcomes are:

- Breast cancer appears to be more 'aggressive' in younger women and the chance of interval cancer is roughly the same as for screening-detected cancer in younger women
- The chance of having breast cancer detected by screening increases with age, as does the reduction in mortality from breast cancer
- The chance of being recalled because of an abnormal test is about the same in both age groups (40-49 and 50-59) even though the cancer rate is lower in younger women. In other words the chance of a false positive is higher in younger women.

weight: OR 6.16, 95%CI 2.44 to 15.57].⁸

As it becomes increasingly feasible to screen for a whole range of metabolic and other genetic disorders, one of the major challenges for newborn screening is the evaluation of new technologies, and there are important associated ethical issues to debate.

The benefits of early diagnosis clearly need to outweigh the harms in any screening program, and monitoring the effect of false-positive results will be particularly important to establish the effects of more invasive follow-up investigations and unnecessary anxiety and expense.

In addition to the traditional tests for hypothyroidism, galactosaemia, cystic fibrosis and phenylketonuria, the introduction of electrospray tandem mass spectrometry in 1998 has resulted in rapid screening for 31 disorders from the heel-prick test in newborns in Australia.

An evaluation of this program⁹ showed that of 360,000 newborns tested

over four years, 560 (0.15%) required a second test or urgent follow-up because of an abnormal result. Fifty-seven of these 560 newborns were given a diagnosis of one of the 31 inborn errors of metabolism. Of these 57 cases, 48 were diagnosed by screening alone, two were diagnosed because of affected siblings and six were diagnosed clinically before, or at the same time as, screening.

In other words, a child with an abnormal result on mass spectrometry has about a 10% chance of disease. The cost per relevant disorder detected (excluding PKU) was US\$3,939.

It will be important to document the impact of outcomes such as false positives as well as the clinical and economic benefit of early diagnosis of an increasing number of conditions amenable to screening. The difference in cost of medical care between a child diagnosed earlier through screening and one diagnosed later is also not known.

DNA micro-array technology (used to measure gene expression) is likely to be the next frontier for this ethical debate in the very near future.

Mammography

Breast cancer is the most common registerable cancer (ie, not including non-melanoma skin cancer) in Australian women: there were 117.2 new cases per 100,000 population in 2001.

The incidence of breast cancer increased by 1.4% annually between 1991 and 2001, but breast cancer mortality declined annually by 2.2%. It is difficult to know how much of the increased incidence is due to potentially inconsequential disease such as some forms of ductal carcinoma in situ, which was not often diagnosed before screening.

There have been eight randomised controlled trials assessing the effect of screening mammography on breast cancer mortality and, controversially, only seven were included in a Cochrane review that concluded there is not enough evidence to show a survival benefit for mass-screening for breast cancer.¹⁰

Investigators subsequently defended the trial results and a revised analysis of the eight trials conceded there was a mortality benefit for mammography in women aged 50-69.¹¹ Researchers have adjusted this for attendance

at screening and estimated the mortality reduction to be about 37%.⁵

As breast cancer risk increases with age, mortality reduction will become greater in absolute terms because more women in the older age group will get breast cancer and have their cancers detected by screening.

Also, the number of false positives declines with age so that the net benefit is greater in women aged 50-69 compared with 40-49-year-olds, for whom the incidence is relatively low and the benefits do not outweigh the risk of false positives as clearly.

Possible advantages of detecting disease by screening, such as having the option of conservation surgery, are not easy to measure.

Probably the best way to consider the possible outcomes of mammography is to consider several hypothetical cohorts of women who have, or do not have, biennial mammograms over 10 years (table 4).

Pap smears

In 1991, the Organised Approach to Preventing Cancer of the Cervix was established as a joint initiative of the Commonwealth, state and territory governments. In 1995 it was renamed the National Cervical Screening Program. The incidence of cervical cancer in women aged 20-69 was 17.1 per 100,000 in 1991 and was 9.5 per 100,000 in 2001. Mortality declined from 3.8 per 100,000 in 1993 to 2.2 in 2003.

However, despite this apparent 'success' some have questioned whether Pap testing results in an unacceptable level of 'inconsequential disease' or over-detection and over-treatment. There have been no good quality randomised trials of Pap testing for cervical cancer and for ethical reasons it is unlikely that there will be.

An analysis of cervical screening outcomes in Bristol (UK) from 1976 to 1996 showed that for every 10,000 women screened 1564 had abnormal cytology, 818 were investigated, 563 had abnormal histology and 176 had persistent abnormalities after two years.¹² In the absence of screening, 80 women would be expected to develop cancer by 2011, 25 of whom would die. With screening, 10 of those deaths would be avoided.

The analysis also reported that at least 80% of high-grade dysplasia would not progress to cancer. The lifetime risk of having abnormal cytology at some time



Newborn screening — take-home messages

- Newborn screening is available for an ever-increasing number of congenital problems without evidence of benefit or assessment of the impact of false-positive results
- Ethical issues need to be considered as a priority

Take home messages — Pap smears

- A substantial amount of inconsequential disease is detected through cervical screening.
- Even before the introduction of screening, cervical cancer was a relatively uncommon cancer.
- A very large number of women need to be screened to prevent one death from cervical cancer.

in their lives could be as high as 40% for women born since 1960.

There is also no evidence to support the use of liquid-based cytology in women of low-normal risk. A recent meta-analysis by Australian researchers showed that liquid-based cytology did not reduce the percentage of unsatisfactory slides, nor did it detect more high-grade lesions.¹³

Faecal occult blood testing for colorectal cancer

Colorectal cancer is the most common non-skin cancer in Australia, with a one in 21 lifetime risk. There have been three large, well-conducted, randomised controlled trials about the effect of FOBT on colorectal cancer.

Table 5: Eligibility for colorectal cancer screening by age and family history (NHMRC guidelines)¹⁵

<p>Category 1. FOBT recommended every two years from age 50 (98% of population)</p> <p>i. No personal history of colorectal cancer or ulcerative colitis and no confirmed family history of colorectal cancer; or</p> <p>ii. One first-degree (parent, sibling, child) or second-degree (aunt, uncle, niece, nephew, grandparent, grandchild) relative with colorectal cancer diagnosed at age 55 or older</p>
<p>Category 2. Colonoscopy every five years from age 50 (1-2% of population)</p> <p>i. One first-degree relative with colorectal cancer diagnosed before the age of 55; or</p> <p>ii. Two first- or second-degree relatives on the same side of the family with colorectal cancer diagnosed at any age</p>
<p>Category 3. Cancer genetic service referral (<1% of population)</p> <p>i. Three or more first- or second-degree relatives on the same side of the family diagnosed with colorectal cancer (suspected hereditary non-polyposis colon cancer); or</p> <p>ii. Two or more first- or second-degree relatives on the same side of the family diagnosed with colorectal cancer, including any of the high-risk features:</p> <p>a. Multiple colorectal cancers in one person</p> <p>b. Colorectal cancer before the age of 50</p> <p>c. At least one relative with endometrial or ovarian cancer (suspected hereditary non-polyposis colon cancer); or</p> <p>iii. At least one first- or second-degree relative with colorectal cancer, with a large number of adenomas throughout the bowel (suspected familial polyposis coli)</p> <p>iv. Somebody in the family in whom the presence of a high-risk mutation in the adenomatous polyposis coli (APC) gene or one of the mismatch repair (MMR) genes has been identified</p>

Biennial FOBT reduces colorectal cancer mortality by 23% and also reduces the incidence of further cancer through removal of precancerous polyps at follow-up colonoscopy.¹⁴ Despite the

Table 6: Outcomes of faecal occult blood test screening over 10 years in hypothetical cohorts*

1000 men aged 50 who have biennial FOBT for 10 years (no family history)	1000 men aged 50 who do not have biennial FOBT for 10 years (no family history)
7 may get colorectal cancer	8 may get colorectal cancer
2 may die from colorectal cancer	2 may die from colorectal cancer
3 cancers detected by screening	0
3 interval cancers	0
7 large polyps found	0
263 false positives	0
1 false negative	0
1000 men aged 60 who have biennial FOBT for 10 years (no family history)	1000 men aged 60 who do not have biennial FOBT for 10 years (no family history)
17 may get colorectal cancer	20 may get colorectal cancer
5 may die from colorectal cancer	7 may die from colorectal cancer
7 cancers detected by screening	0
6 interval cancers	0
18 large polyps found	0
252 false positives	0
2 false negative	0

*Unpublished

high prevalence of the disease and evidence for effective screening strategy, Australia is only now beginning an organised screening program.

Although the percentage mortality reduction is lower than for breast screening, the effect is greater because the 23% applies to a much greater number of men, and women.

However, as for other forms of screening, the net benefit versus harms must be considered. Similarly to patients with breast cancer, the relative benefit translates

Take home messages — colorectal cancer screening

- There is good evidence that biennial faecal occult blood testing reduces the mortality and incidence of colorectal cancer.
- 2006 will see the implementation of an organised colorectal cancer screening program.
- The reduction in mortality and incidence needs to be weighed up against the risks of false-positive results and 'unnecessary' colonoscopies.

into larger absolute gains in groups that have a higher baseline risk, eg, older age and male gender or positive family history.

The NHMRC guidelines for colorectal cancer screening recommend FOBT only

for people of average risk. Higher-risk Australians should consider colonoscopy or be referred to genetic counselling. Eligibility for, and possible outcomes of, FOBT screening are summarised in tables 5 and 6.

Helping patients make informed choices about screening

Informed consent and agreement on preventive activities

THE RACGP guidelines state that "agreement should be reached between clinician and patient about what preventive actions are to be taken" and "consumers should be informed of the evidence so that they can make an informed choice about participation". These principles are also part of the US Preventive Services Task Force recommendations.

As we have become increasingly aware of the need to consider net benefits and harms, there has been a shift toward ensuring that patients are informed about these benefits and harms and that they make an informed choice to participate in screening.

The US Preventive Services Task Force recommendations maintain there are four characteristics of an informed and joint decision about screening. The patient must:

- Understand the risk or seriousness of the disease or condition.
- Understand the screening procedure, including the risks, benefits, alternatives and uncertainties.
- Have weighed his or her values regarding the potential harms and benefits associated with the service.
- Have engaged in decision-making at a level he or she desires and feels comfortable with.⁷

These principles from the USPSTF and the RACGP need a



Table 7: Special considerations when discussing screening with patients*

- Screening can lead to the over-detection of inconsequential disease (see earlier). We should discuss the chance of having inconsequential disease as well as the chance of clinically important disease detected by screening.
- Patients need to have information not only about the screening test, but the potential follow-up investigations that may ensue.
- For some screening activities (eg, cancer) the benefits of reduced mortality or incidence are delayed and occur only after a number of screening rounds. The risks of false positives and other downsides of screening, however, accumulate with each testing round.
- A large number of healthy people will usually have to undergo screening for a few to benefit. These very small numbers should be presented by using large and consistent denominators (eg, outcomes per 10,000 people screened).
- Individual patients will vary in what is important to them. It is important to allow patients to respond to the given information by indicating their preferences.
- The evidence for some screening activities is unclear. If possible, uncertainty should be conveyed by a range of numerical estimates.
- There is a high level of support for screening in the community. The limitations of screening may challenge the underlying beliefs of some consumers.
- Financial incentives and gains for the promotion of screening should be declared.

*Adapted from Barratt, et al, 2004¹⁶

more detailed discussion, as there are other considerations when discussing screening with patients. The following points are particularly worth bearing in mind, although they create several challenges because of the complexity of the issues (table 7).

Effective communication tools for informing patients about screening

Achieving all or even some of this in

a busy general practice setting is challenging. Communication tools may be able to help. A recently published systematic review¹⁷ summarised the evidence for:

- Effective tools for communicating to increase patients' understanding of evidence.
- Effective formats for communicating probabilities of screening outcomes.
- Effective strategies for eliciting patient preferences.

Key points to take away from this review are that:

- Communication tools in most formats (verbal, written, video, provider-delivered, computer-based) increase patients' understanding of the evidence.
- Communication tools are more likely to be effective if they are structured and particularly if they are personalised or interactive.
- Probabilities of screening out-

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comes should be presented in graphical frequency distribution format, with a common denominator and time duration (eg, three out of 1000 people over five years) rather than using words.

■ Illustrations such as cartoons and graphs (particularly vertical bar graphs) seem to aid understanding.

■ Decision aids have the potential to achieve all these objectives and also have the capacity to elicit patient preferences through their value clarification exercises.

Decision aids

Probably the most widely used definition of decision aids is from the Cochrane Library's systematic review, which states that:

Decision aids are interventions designed to help people make specific and deliberative choices among options by providing information about the options and outcomes that is relevant to a person's health status. The specific aims of decision aids and the type of decision support they provide may vary slightly, but in general they are designed to enable people to:

a) understand the probable outcomes of options by providing information relevant to the decision;

b) consider the personal value they place on benefits versus harms by helping clarify preferences;

c) feel supported in decision making;

d) move through the steps in making a decision; and

e) participate in deciding about their health care.¹⁸

There is strong evidence that these tools (which can be delivered by booklets, web sites, videos, touch-screen computers, etc) increase patient involvement in decisions, improve knowledge about options and reduce decisional conflict.

Several decision aids for screening have been developed and evaluated. Several trials of prostate cancer screening decision aids have shown they:

- Improve understanding of the pros and cons of PSA testing.
- Increase patient involvement.
- Lower decisional conflict.
- Reduce the proportion of men having the test.¹⁹

An excellent example of a deci-

sion aid for PSA testing can be found at the PROSDEx web site (see Online resources, page 32).

There are also trials underway in Australia to evaluate decision aids for women aged 40-49 and 70+ considering mammography, and a recently completed trial for an FOBT screening decision aid.

As such tools become more readily available it is hoped they will be a useful resource for practitioners and consumers, facilitating informed consent. Snapshots from two online resources are included in figure 3 and it is anticipated that others will be freely available later in 2006.

If you would be willing to promote the trial to eligible 40-49-year-old women in your practice, please contact Erin Mathieu (erinm@health.usyd.edu.au) for further information, a copy of the decision aid and details of how the women can access the decision aid and participate in the trial via the Internet.

These communication tools will increasingly become available, particularly as online resources. Some useful web sites are listed under Online resources on page 32.

Figure 3: Examples of online screening decision aids.*



* See Online resources (page 32) for web site addresses.

Author's case studies

Should everyone have a mammogram?

A FIT and healthy 39-year-old woman sees you for her Pap smear and asks whether she can have a mammogram. A close friend of hers has just been diagnosed with breast cancer and she is now very worried that she might meet the same fate.

She has been taking the oral contraceptive pill intermittently for the past 15 years, has no other health problems and breast examination is normal. She is single, a lawyer and you only see her about once each year, usually for an URTI, travel advice or her Pap smear.

There is no family history of breast cancer. She believes that everyone should have a mammogram to avoid ending up like her friend.

Comment

It is important to point out several factors to this patient.

Breast cancer is more common with age and at age 39 her risk of invasive breast cancer is about 17.6 per 1000 over 10 years. Even if she has a mammogram every two



There are no guarantees that she will be free of breast cancer even if she has negative mammography.

years, there is almost an equal chance that a cancer will arise between mammograms (13.2 per 1000). So there are no guarantees that she will be free of breast cancer even if she has negative mammography.

Cancer tends to be more aggressive in younger people and is less likely to be detected by screening. Also, about 250 out of 1000 40-year-old women will be recalled for further testing even though only 17 of these will have invasive breast cancer. Sixty women in this age group will have a biopsy, although most will

not have cancer diagnosed.

After discussing this with her you may decide to give her a referral for screening mammography and let her consider her options. At least she will be aware of the limitations and potential risks associated with screening mammography at her age, even if her personal preferences sway her toward having the test.

With the benefit of hindsight, should PSA screening have been done?

A 75-year-old patient was recently admitted for transurethral resection of the prostate after several years of worsening urinary problems. Histopathology showed some minor foci of adenocarcinoma.

He attends with his wife who is asking why you had not performed a blood test for prostate cancer when he had been to see you some years ago to discuss this. He does not have a family history of prostate cancer and you had discussed the pros and cons of PSA testing with him at that time, advising him that the evidence was inconclusive

as to whether PSA testing reduced mortality or improved quality of life for patients with prostate cancer.

You had referred him to the PROSDEx decision aid on the Internet and he had discovered that seven in every 1000 men his age are diagnosed each year with prostate cancer. He realised that there were limitations to the PSA test and that one in five people who have normal PSA test may still have prostate cancer. In other words, it could be missed.

He also learnt that two in every three men with an elevated PSA level do not have prostate cancer. He is now faced with the uncertainty of deciding whether to continue watchful waiting or have other treatments, as the clinical significance of his cancer is uncertain. While he was fully informed and aware of the limitations of PSA as a screening test for prostate cancer, his wife was not. The discussion was helpful for her.

Screening has risks as well as benefits

A 52-year-old woman sees you for her Pap smear because

she has not had one for four years. She also reports difficulties in her marriage over the past few years.

She is found to have CIN1, which she decided with her gynaecologist to treat after it persisted for six months, even though you explain to her that only 10% of CIN1 will progress to invasive cervical cancer. After day surgery she develops a DVT and requires anticoagulation and frequent monitoring.

She comes to see you, expressing regret at having the treatment, and wishes that she had waited longer to see if the abnormality resolved spontaneously. You discuss with her the natural history of cervical cancer and she is reassured for the future and now has a new appreciation of the potential risks of screening.

The discussion leaves both of you feeling unsettled and wishing that a more evidence-based discussion about the natural history of cervical cancer had been undertaken when she first had her abnormal result. Unfortunately, family friends had put doubts in her mind despite your best efforts.

GP's contribution



DR LINDA MANN
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Case study

JIM, 53, was concerned about missing out on prostate cancer screening — "You screen my wife with 'Paps' all the time," was his way of putting it. He was informed that determining the PSA was only part of the screen for prostate cancer. He had no significant family history but did have mild prostatic hypertrophy on digital examination.

After using a decision tool and learning about transrectal ultrasound and the risks inherent in the sequelae of testing, he elected to have the test. His PSA result was 30µg/L with a free/total ratio of 12% (our local lab says: total PSA of 2.5-25µg/L and free PSA/total PSA <10% suggests prostatic carcinoma is highly likely. Free PSA/total PSA >25% suggests benign prostatic hypertrophy is

highly likely).

Jim was referred to a urologist and had a transurethral resection. He suffered postoperative prostatitis after this, was off work for two weeks and miserable for some months, but did not have cancer.

Questions for the author

Jim's brother, Tom, is also a patient and I expect will come to

see me, seeking advice about screening. How can I put Jim's experience into context to help Tom decide on screening?

The message to Tom is still that we do not have any good evidence that PSA testing in men without symptoms reduces prostate cancer mortality or provides treatment benefits that outweigh potential harms

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from false alarms and invasive follow-up tests.

Assuming that Tom is also in his 50s, his risk of developing prostate cancer remains low. You could refer him to the PROSDEX web site (see online resources) for more information about the PSA test.

The decision tools do not include personal experience as a confounder. How do GPs help patients balance this in their thinking?

Personal experience is indeed an important influence on the decision made by patients and their doctors. An online database of personal experiences (DIPEX: www.dipex.org) has been developed in the UK to include a range of patient experiences around particular health issues. There are PSA examples that might be helpful.

What is the best way to discuss results that are neither



'normal' nor in the 'risk associated' range.

It is important for patients to realise that medical tests can be inconclusive, and this is one

of the factors to consider in informed choice. This is one of the problems with PSA testing and one of the reasons that people may choose to defer testing until they are older.

General questions for the author

Are there cultural aspects or variations according to ethnicity in patients' decisions to screen? Are any of the decision aids available in languages other than English or are they being developed for other cultures?

There has been limited work on decision aids with people from a range of ethnic backgrounds, mainly in treatment decisions. Cultural attitudes to screening and the role of decision aids in non-English-speaking people is an area of need.

The Sydney Health Decision Group are currently evaluating a bowel cancer screening decision aid for people with low literacy (English language only at this stage).

In my experience, patients overestimate their likelihood of suffering inherited disease or cancer after the first round of screening. What aspects of GP counselling can put this risk into better perspective?

Providing risk information in what is termed 'natural frequency formats' (eg, seven out of 1000, five out of 1000, etc) has been shown to improve people's perception of risk. Generally speaking it is best not to use terms such as high or low because they have different meanings to different people.

Decision aids generally provide risk information in natural frequency formats. For example, if we considered 1000 women who are 60 years old and have no family history of bowel cancer, we can expect about 14 of these women to develop bowel cancer over the next 10 years.

These online tools can therefore provide useful information for GPs to use as well.

References

Available on request from julian.mcallan@reedbusiness.com.au

Online resources

- Sydney Health Decision Group: www.health.usyd.edu.au/shdg
- Ottawa Health Research Institute: <http://decisionaid.ohri.ca/AZinvent.php>
- Prostate Cancer Screening Decision Aid (PROSDEX): www.prosdex.com
- Database of Individual Patient Experiences (DIPEX): www.dipex.org
- Bowel Cancer Screening Decision Aid: www.cancerscreeningdecision.org
- Australian Screening Mammography Decision Aid Trial: www.mammogram.med.usyd.edu.au



How to Treat Quiz

Informing patients about screening
— 2 June 2006

INSTRUCTIONS

Complete this quiz to earn 2 CPD points and/or 1 PDP point by marking the correct answer(s) with an X on this form. Fill in your contact details and return to us by fax or free post.

FAX BACK

Photocopy form and fax to (02) 9422 2844

FREE POST

Australian Doctor Education Reply Paid 60416 Chatswood DC NSW 2067

ONLINE

www.australiandoctor.com.au/cpd/ for immediate feedback

1. Which TWO statements about screening for disease are correct?

- a) The benefits of screening should be supported by evidence from randomised controlled trials
- b) Screening is performed on people with symptoms
- c) Most screening tests do not provide a diagnosis
- d) The potential benefits of screening always outweigh the significance of any potential harms

2. Which terms used in screening are correctly defined below (choose TWO)?

- a) Lead-time bias refers to overestimation of the survival time for a disease
- b) Inconsequential disease refers to disease that patients are not concerned about
- c) Interval cancers are those that arise between screening rounds
- d) Sensitivity is a measure of the true negative rate

3. Polly, 40, presents for her Pap smear and asks about breast screening. A neighbour who attended the program was recently diagnosed with breast cancer at 60. Which information would you be most likely to give Polly to help her reach a decision about screening (choose TWO)?

- a) A negative mammogram would mean she would be highly unlikely to develop breast cancer in the next two years
- b) False positives are more likely in younger women

- c) Mortality reduction in her age group is about 37%
- d) DCIS is much more likely to be diagnosed in the screened than unscreened population

4. Polly is uncertain about whether to start screening. What considerations should be presented in a decision aid to help Polly (choose TWO)?

- a) Any benefit is delayed but any harm is relatively immediate
- b) Minimal information about the procedures required if a screening test is positive
- c) Information about any financial gain to the organisation offering screening
- d) Clear guidance that any benefit from screening is more important than any harm

5. Polly asks whether her mother, 73, should have breast screening. Which ONE factor related to screening in older women outside the target range should Polly's mother consider in her decision?

- a) Lead-time bias does not apply to older women
- b) The chance of diagnosing disease for which successful treatment does not increase life span is greater in women over 70 compared with women in the target age group
- c) Breast cancer is very rare in women over 70
- d) Screening becomes less effective in detecting breast cancer in women over 70

6. Melinda, 25, attends for her Pap smear. She is dismayed that a friend says she

'doesn't believe in having them' and asks you about the pros and cons of screening. Which TWO statements about cervical cancer and screening are correct?

- a) Cervical cancer is relatively common in young women, compared with other cancers
- b) The role of cervical screening is supported by many good-quality randomised controlled trials
- c) The lifetime risk of a woman having abnormal cytology at some time could be as high as 40% for women born since 1960
- d) Liquid-based cytology detects the same number of high-grade lesions as Pap smears

7. Melinda sees you a year later in early pregnancy. A friend's child has recently been found to have cystic fibrosis and Melinda asks about Australian screening practices for this condition. Which TWO actions are you most likely to take?

- a) Explain that there is randomised controlled trial evidence of the effectiveness of screening in newborns
- b) Advise Melinda against screening if there is no history of the condition in the family
- c) Explain that unscreened children with this condition may still be diagnosed because of poor weight and height centiles
- d) Emphasise that research clearly shows improved lung function through early diagnosis and intervention

8. Frank, 52, wants to know if bowel cancer screening is worthwhile for him. What information are you most likely to give him to help

his decision (choose THREE)?

- a) Biennial FOBT reduces colorectal cancer mortality by about 23%
- b) The largest absolute gains occur in groups with a higher baseline risk
- c) The NHMRC guidelines for colorectal cancer screening recommend FOBT for all people over 50
- d) The effect of mortality reduction is greater than for breast cancer because of the larger target population

9. Eileen, Frank's wife, has a family history of bowel cancer: her sister was diagnosed at 47 and her father at 72. Eileen is 51. What screening would you advise her to have (choose ONE)?

- a) Biennial FOBT
- b) Colonoscopy every five years
- c) Genetic screening
- d) No screening because of the relative harm compared with any benefit

10. What changes in risk occur when 1000 men aged 50 with no risk factors have biennial FOBT over 10 years, compared with 1000 similar men aged 60 undergoing the same screening (choose TWO)?

- a) The interval cancer rate is about double that in the younger men
- b) The death rate will be about twice as high in the younger men
- c) The false-positive rate is similar in both groups
- d) Less than half the number of polyps are found in the younger men

CONTACT DETAILS

Dr: Phone: E-mail:

RACGP QA & CPD No: and /or ACRRM membership No:

Address: Postcode:

The mark required to obtain points is 80%. Please note that some questions have more than one correct answer. Your CPD activity will be updated on your RACGP records every January, April, July and October.

NEXT WEEK The last 25 years has seen incredible advances in the understanding of the genetic basis of many single-gene disorders, with carrier testing available for an increasing number of autosomal recessive and X-linked recessive disorders. The next How to Treat looks at antenatal and prenatal screening for genetic conditions. The authors are **Associate Professor Martin B Delatycki**, consultant clinical geneticist, Genetic Health Services Victoria, Royal Children's Hospital, Parkville, Victoria, and **Dr John Massie**, consultant paediatric respiratory physician, department of respiratory medicine, Royal Children's Hospital, Parkville, Victoria.

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