Screening programs

Dear Editor

I applaud the article by Barratt (*AFP* January/February 2006) and letters to the editor (Manaszewic and Barratt *AFP* July 2006) that give exposure to the often overlooked complexity of screening programs. Many public health interventions create ethical tensions between fully informed consent and incentive payments that regard more as better.

One of the main sources of information on breast screening for GPs is the National Breast Screening program itself. Correctly, their goal (and presumably their performance measure) is to ensure high coverage of the target group with breast screening. Understandably, they promote screening in a positive way, and we tend to follow suit. However, there are many ways to present the same information that each lead to different impressions on the public.

What constitutes the fairest, most useful way to present risk information is a fascinating area for more development and training for clinicians. For example, the likelihood of an asymptomatic woman not having breast cancer changes very little after a negative screen test, but this does not get a lot of mention, if any. An ethical problem can arise when incentives (at individual or organisational level) to promote certain treatments, achieve vaccination coverage, or recruit people to screening programs may bias the way information is presented. More thorough discussion of risks versus benefits is often uncomfortable ground for clinicians, and can take a lot of time. Decision support tools like that being trialled by the University of Sydney may prove to be part of the solution.

The truism that 'all screening programs cause harm and some cause more good than harm' is poorly understood by many clinicians. I encourage *AFP* to continue to address these issues accurately.

Dan Ewald
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Item 291

Dear Editor

I agree with the authors of the article 'Item 291: Progress in cooperation between GPs and psychiatrists (*AFP* March 2006) when they say that 'item number (291) is not simply for the usual communication from a psychiatrist'. In my experience, the 'usual communication' from our psychiatric colleagues about patients is very little communication or no communication at all.

I asked the Royal Australian and New Zealand College of Psychiatrists, the Medical Board of South Australia and Medicare Australia about their policies or requirements for doctors seeing referred patients to reply to referrals and to provide progress reports at reasonable intervals to the referring doctor. All three organisations replied that they have no expectation or requirement for doctors seeing referred patients to reply to the referrals or to provide progress reports.

Item 291 improves on this by specifying and requiring that the psychiatrist communicates with the referring doctor.

Medical Insurance Group Australia has informed me that a specialist's failure to provide an opinion and progress report about a referred patient would expose that specialist to legal liability if harm came to the patient from such lack of communication.

Oliver Frank
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Whitespot

Dear Editor

Whitespot (also called 'blebs') is a relatively common breastfeeding problem, but not many people have heard of it – including doctors. As a result, breastfeeding women are being treated with unnecessary and often ineffective procedures such as needle extractions, ultrasound and antibiotics.

Whitespot consists of tiny white spots at the end of the milk duct on the nipple. Milk is prevented from flowing out during breastfeeding or expressing. As a result there is a build up of milk in the duct, causing pressure and a painful red lump in the breast at the site of the milk gland.

If a patient presents with blocked ducts, lumps or mastitis it is important to look closely at the nipple to see if whitespot is present. Instant relief can is by removing the correct whitespot (not all whitespots cause blockages and some women may have more than one at a time). This is best done straight after a breastfeed or by applying a warm, wet compress over the nipple and breast. The patient can first try massaging the nipple behind the site of the whitespot. If this does not work, the whitespot can be removed by gently scraping with a sterile needle. When done correctly there is no pain and women with regular occurrences of whitespot often learn to do this themselves.

I recommend patients and doctors contact either The Australian Breastfeeding Association or the Australian Lactation Consultant Association for further advice.

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Vertebroplasty

Dear Editor

We read with concern Guduguntla and Subramaniam's (*AFP* May 2006) claim that vertebroplasty is a safe, effective and cost effective treatment for osteoporotic spinal fractures. To be able to make such a claim, there should be either Level I (summaries of well conducted RCTs), or at least Level II (at least one properly conducted RCT) evidence.[1] There are no completed RCTs of vertebroplasty and so its effectiveness including the ability to relieve pain, as well as both short and long term safety remains unproven. The promotion of vertebroplasty in routine care is therefore both premature and potentially dangerous.

There are many examples of seemingly beneficial therapies found to be ineffective or harmful when tested in rigorous studies.[2,3]

Nonrandomised studies may produce biased results for a range of reasons.[4] The natural history of painful osteoporotic spinal fractures is to improve over time, often rapidly; the concept of 'regression to the mean' indicates that on average pain is likely to have improved or regressed to an average, regardless of treatment; and placebo responses may vary 30–70% and the placebo response of an invasive procedure is likely to be accentuated.[5] Furthermore, volunteers who agree to have the new therapy are likely to be different to those either who either refuse or are not offered it.

Several recent studies have suggested that vertebroplasty may increase the risk of further spinal fractures, particularly in vertebrae adjacent to treated spinal fractures or if cement leakage into the adjacent disc has occurred. Trout et al[6] reported that the relative risk of having a new spinal fracture adjacent to a treated spinal fracture was 4.62 (95% CI: 4.35–4.89). Time to fracture was also significantly faster. In another study, 58% of vertebrae adjacent to discs containing cement subsequently fractures compared with 12% vertebrae not adjacent.[7] In a multivariate study of predictors of new vertebral body fracture, cement leakage into the disc was the only significant predictor of vertebral fracture.[8] Unfortunately none of these studies were controlled or provided information about osteoporosis treatment.

The authors also state that the Medical Services Advisory Committee's (MSAC) has recommended Medicare funding for vertebroplasty. We understand that this is an interim rebate, for limited indications. When further evidence becomes available, the MSAC recommendation will be reviewed and the rebate may be continued, expanded, restricted or withdrawn depending on the results of current trials. Several technology appraisals undertaken by international health policy makers have reported inadequate high quality evidence on which to base such a reimbursement decision.[9]

A multicentre NHMRC funded RCT is currently underway in Melbourne (ACTRN012605000079640) to provide much needed evidence of the efficacy and safety of vertebroplasty for painful osteoporotic fractures. All trial participants are being followed for 2 years so that the question of long term safety and, in particular, risk of future fractures can be assessed. Unrestricted Medicare funding has the potential to seriously undermine the success of this and other trials by not only providing easy access to an unproven treatment but also by lending implicit support to its use. This may result in a situation where the true effects of this treatment may never be established. At present, the trial has recruited almost a quarter of the required sample and is expected to be complete within 4 years. It will provide pivotal evidence regarding the value of vertebroplasty.

Vertebroplasty may be a highly efficacious and safe treatment for painful osteoporotic spinal fractures but at the present time, in the absence of RCTs, promotion, dissemination and routine use of this procedure outside of the research setting remains unjustified.

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References

1. National Health and Medical Research Council. NHMRC additional levels of evidence and grades for recommendations for developers of guidelines. Available at www.nhmrc.gov.au/publications/_files/levels_grades05.pdf.
2. Echt D, Liebson PR, Mitchell LB, et al. Mortality and morbidity in patients receiving encainide, flecanide, or placebo. The Cardiac Arrhythmia Suppression Trial. N Engl J Med 1991;324:781–8.
3. Moseley J, O'Malley K, Petersen NJ, et al. A controlled trial of arthroscopic surgery for osteoarthritis of the knee. N Engl J Med 2002;347:81–8.
4. Jarvik JG, Kallmes DF, Deyo RA. Point of view: kyphoplasty: more answers or more questions? Spine 2006;31:65–6.
5. Moerman DE, Jonas WB. Deconstructing the placebo effect and finding the meaning response. Ann Intern Med 2002;136:471–6.
6. Trout AT, Kallmes DF, Kaufmann TJ. New fractures after vertebroplasty: adjacent fractures occur significantly sooner. AJNR Am J Neuroradiol 2006;27:217–23.
7. Lin EP, Ekholm S, Hiwatashi A, Westesson PL. Vertebroplasty: cement leakage into the disc increases the risk of new fracture of adjacent vertebral body. AJNR Am J Neuroradiol 2004;25:175–80.
8. Komemushi A, Tanigawa N, Kariya S, et al. Percutaneous vertebroplasty for osteoporotic compression fracture: multivariate study of predictors of new vertebral body fracture. Cardiovasc Intervent Radiol 2006;24:24.
9. Hollingworth W, Jarvik JG. Evidence on the effectiveness and cost effectiveness of vertebroplasty. A review of policy makers' responses. Acad Radiol 2006;13:550–5.

Reply

Dear Editor

It is 19 years since the first seven vertebroplasties were reported in 1987. There are only a few RCTs currently underway trying to provide much needed information on the efficacy and safety of vertebroplasty for painful osteoporotic fractures. An estimated 38 000 vertebroplasties and 16 000 kyphoplasties have been performed in the USA,[1] which speaks for its effect in relieving pain.

There are more than 70 published studies on percutaneous vertebroplasty. Although the scoring of individual studies quality is variable, the uniformity of findings does provide some evidence of efficacy. It is very unusual to find completely concordant conclusions from such studies in interventional radiology, but this is uniquely the case in percutaneous vertebroplasty.

There are no completed prospective randomised studies of vertebroplasty versus conservative management. The main reason for this is that at the clinical level vertebroplasty is so obviously effective in pain palliation that operators and referring physicians are usually quickly convinced of its efficiency and are then loath to randomise patients. There is also difficulty in randomising elderly patients who have severe pain to a control arm that often includes a sham procedure.

The large number of case series has shown that in experienced hands, the chance of a complication of percutaneous vertebroplasty that causes major illness or requires surgery is extremely low. The risk is higher with malignant

disease and lowest in the osteoporotic patient group. Analysis of the Maude database in the USA shows that from an estimated 130 000–160 000 transpedicular vertebroplasties there were three reported deaths.[1]

The natural history of painful osteoporotic spinal fractures is to improve over time. The MSAC's interim rebate for limited indications for vertebroplasty respects the concept of natural history, and has included the wording 'not controlled by medical therapy'. Patients risk significant morbidity related to deep vein thrombosis and bedsores if denied vertebroplasty after conservative therapy.

A Medicare item number for vertebroplasty has been in effect since November 2005. The lack of RCTs was noted but the concordance of all other studies suggested to the MSAC committee that funding was appropriate. This has been limited to patients who do not respond to conventional therapy or cannot tolerate the pain or side effects of the therapy. This is quite appropriate and was the stated indication in my article. The funding will be reviewed in 3 years, which is standard practice. It is unfortunate that when funding is reviewed, the data from the Melbourne study will be still be unavailable.

Finally, regarding the comment that Medicare funding could undermine the Melbourne study into vertebroplasty in terms of recruitment; this should never be a basis for a decision regarding public medical funding. While most osteoporotic spinal fractures are well managed with conservative therapy, there is a subset with intolerable pain or complications from narcotics. We know from Australian experience and published studies that vertebroplasty will get the majority of these patients out of their agonising pain. This was the principle applied by MSAC.

The RCTs currently underway will not answer all the questions about vertebroplasty, but will give additional and valuable information in what has emerged as an excellent technique in the palliation of severely painful spinal fractures.

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Reference

1. Nussbaum DA, Gailloud P, Murphy K. A review of complications associated with vertebroplasty and kyphoplasty as reported to the Food and Drug Administration medical device related website. J Vasc Intervent Radiol 2004;15:1185–92.

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