Editor's note: this letter (and Dr Dixon's reply) are presented to allow readers to consider this important topic in some depth. Both groups of authors substantially reduced their original manuscripts by editorial request.

Melanoma management in 2007

Dear Editor

We read with interest a recent article in which the case history of a patient with cutaneous melanoma was discussed (*AFP* November 2006).[1] While we agree that melanoma management need not be 'fancy', nor undertaken necessarily in a tertiary institution, we strongly disagree with the statement that 'effective management of melanoma is simply about early detection and wide excision'. Several other management options need to be considered. For example, there is now persuasive evidence from a large, randomised, multicentre clinical trial that sentinel node (SN) biopsy, with immediate complete lymph node dissection (CLND) if nodal metastatic disease is found, improves survival outcome in patients with melanomas 1.2–3.5 mm in thickness.[2] In this trial, the 5 year survival rate was 72.3% +/– 4.6% following early CLND for a positive SN, but only 52.4% +/– 5.9% when initial SN biopsy was not performed and CLND was undertaken only when disease in regional nodes became clinically detectable (hazard ratio for death 0.51, p=0.004). Other benefits of SN biopsy are that accurate staging is achieved, disease free survival is prolonged, improved control of disease in the regional node field is achieved, and the best possible prognostic estimate can be given to the patient.[3] All these things are important, as well as the great but unquantifiable psychological benefit to the patient of avoiding a second surgical procedure months or years after initial melanoma treatment. Other recently published studies indicate that SN assessment is also of value in patients with melanomas <1.2 mm in thickness. Indeed, recent data suggest a SN positivity rate of 5–10% for melanomas 0.75–1.0 mm in Breslow thickness, with the highest positivity rates in younger patients.[4,5] Internationally acknowledged leaders in melanoma management have concluded recently that SN biopsy should now be regarded as 'standard of care' for patients with intermediate thickness melanomas.[6]

We also disagree with Dr Dixon's statement that SN biopsy can be performed if desired after wide excision, because there is 'no demonstrated difference in the accuracy of the test' under these circumstances. This statement was based on the results of a single, small study in which the methodology was questionable,[7] and it should be noted that the authors of that study concluded that SN biopsy should ideally be performed at the same time as wide excision of the primary melanoma. Although SN biopsy can certainly be performed after wide excision, it is likely to be unreliable and represents suboptimal management.[8] In support of this contention is the evidence that lymphatic mapping by lymphoscintigraphy is less reproducible after wide excision than it is after excision biopsy only.[9] This means that the lymph nodes marked as SNs after wide excision may not be the SNs that originally drained the primary melanoma site.

Dr Dixon goes on to suggest that it is important to avoid any delay in performing wide excision resulting from the need to make arrangements for simultaneous SN biopsy, but there is no evidence to support this suggestion and simple logic suggests that it is not correct. To perform a wide excision as a matter of great urgency is clearly unnecessary, as a melanoma of intermediate thickness has in all probability been present for several months at least. Careful planning of management is required, and even if performing a SN biopsy involves a delay of a few days, it is still the appropriate way to proceed. This brief delay may have the additional advantage of allowing time for pathology review by pathologists with special expertise in the assessment of melanomas, often an important aspect of determining the nature and extent of optimal surgical management.

Nor can we agree with Dr Dixon's therapeutic nihilism in relation to the management of metastatic melanoma. There is good evidence that surgery can be effective if metastatic disease is localised, and procedures such as isolated limb infusion or perfusion with cytotoxic drugs for patients with recurrent disease confined to a limb produce tumour remission in over 50% of patients.[10,11] For those with nonlocalised metastatic disease, although response rates are admittedly low, standard chemotherapy achieves long term remission in some cases and recently available new drugs targeting specific metabolic pathways, currently being tested in clinical trials, hold great promise.[12]

The role of specialist multidisciplinary care for patients with melanoma is well established, and is recommended in NHMRC guidelines.[13] As with other cancers, there is no doubt that patients with potentially life threatening melanomas are generally best served by assessment in high volume, specialised centres. Every patient has the right to choose whether or not to accept the medical advice that he or she is given, but it is important to provide correct advice, based on sound, up-to-date evidence, so that a truly informed decision can be made.

In 2007, the first step in melanoma management is still to perform an excision biopsy of the suspect lesion with 2 mm margins, both to establish a definite melanoma diagnosis and to determine the Breslow tumour thickness

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and other histological features that will determine management and prognosis. If the diagnosis is confirmed, however, and the Breslow thickness is >1.0 mm, it is not appropriate to perform an urgent wide excision, which may deny the patient the opportunity of having a successful SN biopsy procedure (and to do so may even have medicolegal consequences). Even for patients in whom loco-regional or systemic metastasis does occur, the situation is by no means hopeless, and treatment options that are sometimes effective are available.

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Reply

Dear Editor

Recently a large randomised controlled trial (RCT) of sentinel lymph node biopsy (MSLT-I) was published.[1] Our judgment differs with the stated interpretation of the data in MSLT-I. This was a well designed RCT, although there has been criticism of the Sydney arm of the trial.[2] Patients were randomised on a 3:2 basis to be managed with or without a SLNB after their malignant melanoma was diagnosed. Those that had a sentinel node showing melanoma went on to completion lymphadenectomy (CL) in that nodal region. Controls had metastatic disease including nodal disease managed if and when it occurred.

On an intention to treat basis, those randomised to SLNB had a 5 year survival of 87.1% vs. 86.6% for those who did not have the intervention done, (p=0.4).[1] There was no difference; no survival advantage.

An RCT is about comparing an intervention group to a control. As soon as one breaks from this and starts comparing some of the intervention group with some of the controls, the RCT validity is gone. There is such a sub-analysis in the manuscript stating that those in whom nodal disease was discovered by SLNB faired better (72%, 5 year survival) than those who were observed and then later found to have nodal disease (52%, 5 year survival).

Because we know each randomised group did as well as the other, we know the remaining intervention patients (SLNB negative patients) faired worse then the remaining controls. Over 5 years, the mortality rate in those that had a negative SLNB (10%) was over 40% higher than the mortality of the corresponding remaining controls (7%). This confirms that some false positives (3+%) and false negatives (3+%) exist. Around one-quarter of SLNB positive patients were never going to progress to clinical metastatic disease.

Other authors have described how patients can have a positive SLNB that does not progress to clinical nodal disease.[3,4] Some micrometastases of melanoma in a lymph node may not be clinically significant.[5,6]

It is claimed that SLNB may improve 5 year disease free survival. Patients who have had a positive SLNB and then CL are unlikely to later develop nodes in that region. Patients with observation may well develop nodes in that region. The disease free survival figures that would be comparable would be disease free, other than regional nodal disease. The manuscript does not publish this data, which must be available. We don't know whether the SLNB positive patient should go on to CL. Early data suggests no significant outcome difference whether proceeding to CL or not.[7]

The MSLT-I trial demonstrated that 10.1% of patients who undergo SLNB develop complications.[8] Indeed the complication rate rose to 37.2% in those patients who were SLNB positive and went on to CL. SLNB complications include facial nerve damage,[9] brachial plexus trauma, lymphoedema, chronic seroma, chronic infection, and scar contraction issues.[10]

The SLNB procedure provides the patient with further information on their survival prospects. Patients with a melanoma over Breslow 1.2 will know (based on MSLT-I) that they have a 72% 5 year survival if they are SLNB positive vs. 90% who are SLNB negative. It remains in 2007 that the single feature of a melanoma that is most predictive of long term survival is the Breslow thickness of the tumour.[11,12]

Is this surgery justified to provide added prognostic information for the patient? There are difficulties in choosing the optimum management and this call is for the patient to make once he/she is informed that the SLNB will not improve their long term survival. Subsequent serious complications from the procedure may produce difficulties when defending a negligence case if a survival benefit had been claimed during counselling before surgery.

Our judgment is that not all melanoma patients need tertiary care, especially in Australia where many patients live 100s of kilometres from major centres. However, we agree that for selected melanoma patients tertiary care is essential, especially those with delayed diagnosis or metastatic disease. We are not aware of objective evidence demonstrating a survival benefit when Australians with melanoma are routinely managed in a tertiary multidisciplinary centre.

We recommend that patients are offered a prompt suitable wide excision once a melanoma is diagnosed but not yet completely excised. It would be concerning if patients waited weeks

or months to have their needed melanoma excision after an incomplete biopsy because they were awaiting an SLNB booking. SLNB is not a 'standard of care' in melanoma management.

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Cervical screening

Dear Editor

I wish to refute Dr Rogers' advocacy of the left lateral position for vaginal speculum examinations (*AFP* May 2007). I am a practising GP and Director of the Clinical Teaching Associate (CTA) program at the University of Melbourne. This program, partly funded by Papscreen Victoria, teaches a best practice method of gynaecological examination to medical students, registrars and practice nurses.

In the CTA program we believe that women prefer the dorsal position for Pap tests. We face people when we are talking to them. It is hard for a patient to hold a conversation with a blank wall; it is impossible for the doctor to pick up nonverbal communication such as facial expression when directed at a blank wall.

Also, the cervix is easy to find in the dorsal position. The pelvis can be tilted by having the patient slip a small firm pillow under her buttocks. When the bivalve speculum is inserted, it is angled at 45 degrees to the bed. The cervix usually slides into view. Using the dorsal position empowers the woman and is not technically difficult – in fact it leads to a best practice method of examination both in technique and communication.

Christine Fairbank
Parkville, Vic

Mental health

Dear Editor

Congratulations to the theme authors of April *AFP*. The article 'Adjusting to illness and other major life events' brilliantly summarised the thoughts and coping strategies necessary for GPs to derive an appropriate plan for their distressed patients.

The article 'Using problem solving therapy in general practice' beautifully detailed the use of PST in general practice. Actually, my father taught me this approach and I have been practising PST on myself, my family and my patients with great success; but this article has given me a better and more structured way of thinking and convincing my patients. In my opinion, the concept and use of PST relating to life events should be introduced early in life (eg. at school level) so that young adults can face life's challenges with greater confidence.

The article 'Depression and anxiety: pharmacological treatment in general practice' was easy to understand and relevant to the GP.

Ranjan Gupta
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Incorrect diagnosis

Dear Editor

The risk management article in the April 2007 issue of *AFP* discussed a claim in which the patient unsuccessfully alleged his GP had made an incorrect diagnosis of psychosis.[1] On 10 May 2007, the patient was successful in his appeal against the trial judge's decision.[2] The New South Wales Court of Appeal found that on the accepted evidence, the GP should not, in the exercise of reasonable care, have diagnosed the patient as suffering from a psychotic condition and the GP was negligent in so doing. The Court of Appeal set aside the judgment entered by the trial judge and instead awarded the patient damages of $255 561.95 plus his legal costs.

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Quality framework

Dear Editor

I read with interest your important articles on the quality framework for general practice (*AFP* January/February 2007). However, I was increasingly concerned that they all referred only to quality of the structure and process of general practice, and not to outcomes, until in the final article Britt, Miller and Bayram noted that: 'in Australia we do not have a good national measure of health outcomes'. I am not sure that we have many good local or even individual measures of outcomes of care either.

We need to be gathering more evidence that quality structures and processes in general practice result in quality patient outcomes, which means more emphasis on clinical audit, evaluation and research. It was reassuring to note that the research section in the same issue of *AFP* contained the results of two such projects, and the five ideas from the Registrar Research Workshop were all clinical outcome orientated. We need to increase our emphasis on quality patient outcomes and their measurement.

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