

## Evaluation of aid to diagnosis of pigmented skin lesions in general practice: controlled trial randomised by practice

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### Abstract

**Objectives** To determine whether an aid to the diagnosis of pigmented skin lesions reduces the ratio of benign lesions to melanomas excised in general practice.

**Design** Controlled trial randomised by practice.

**Setting** General practices in Perth, Western Australia.

**Participants** 468 general practitioners in 223 practices.

**Interventions** Intervention practices were given an algorithm and instant camera to assist with the diagnosis of pigmented skin lesions. All practices were given national guidelines on managing melanoma.

**Main outcome measures** Ratio of benign pigmented lesions to melanomas excised. Analyses conducted with and without inclusion of seborrhoeic keratoses.

**Results** At baseline the ratios of benign to malignant lesions were lower in the intervention group than in the control group. During the trial period the ratios were higher in the intervention group (19:1 *v* 17:1 without seborrhoeic keratoses and 29:1 *v* 26:1 with seborrhoeic keratoses). After adjustment for patients' age, sex, and socioeconomic status, the ratio was 1.02 times higher (95% confidence interval 0.68 to 1.51,  $P=0.94$ ) in the intervention group when seborrhoeic keratoses were not included and 1.03 times higher (0.71 to 1.50,  $P=0.88$ ) when seborrhoeic keratoses were included. General practitioners in the intervention group were less likely than those in the control group to excise the most recent pigmented skin lesion they managed (22% *v* 48%,  $P<0.001$ ) and to refer the patient to a specialist (16% *v* 27%,  $P=0.06$ ).

**Conclusions** Provision of the algorithm and camera did not decrease the ratio of benign pigmented skin lesions to melanomas excised by general practitioners.

### Introduction

A melanoma screening trial with Australian general practitioners showed high sensitivity (0.95, 95% confidence interval 0.90 to 1.0) for the diagnosis of melanoma but low specificity (0.49, 95% confidence interval 0.41 to 0.57).<sup>1</sup> This means that for every melanoma excised between 10 and 28 benign naevi are excised. Similar ratios have been found elsewhere.<sup>2</sup> Reducing the number of benign pigmented skin

lesions removed without decreasing sensitivity would reduce unnecessary surgery.

A trial of an algorithm and instant camera to improve general practitioners' skills in diagnosing pigmented skin lesions was conducted in two provincial cities in Queensland, Australia.<sup>3</sup> The ratios of benign lesions to melanomas excised in the two cities was significantly lower in the intervention city after the intervention. We replicated this intervention in urban general practice in Australia, using a controlled trial that randomised by general practice rather than by city.

### Methods

General practitioners on the mailing lists of the divisions of general practice in Perth were eligible. None were already using equipment to monitor pigmented skin lesions. General practitioners who joined a practice after randomisation or with whom we had had no contact before randomisation were also eligible. Those general practitioners who worked at multiple practices could participate at each practice, though they were asked to follow the protocol allocated to that practice.

All practices were given national guidelines on managing melanoma.<sup>4</sup> Doctors randomised to the intervention group were trained to use an algorithm (fig)<sup>3</sup> and an instant camera.

Randomisation was carried out with a computer generated randomisation code stratified by practice size. After randomisation, participants and research assistants who visited practices were not blinded to assignment. All coding of outcome data was done blind to assignment.

Evaluation was based on the ratio of benign to malignant pigmented skin lesions excised. We defined a malignant lesion as an in situ or invasive melanoma and a benign lesion as a naevus (including dysplastic naevus) or (in some analyses) a seborrhoeic keratosis. We included seborrhoeic keratoses because they are commonly mistaken for melanomas.<sup>5</sup> All pathology reports on excisions of pigmented skin lesions from 1 November 1998 to 31 August 2000 were obtained.

At the end of the study we sent the general practitioners a questionnaire on how they had managed their last three patients with pigmented skin lesions.

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**Statistical analysis**

The primary analysis was based on comparisons between groups. For consistency with the earlier trial<sup>3</sup> we did not include seborrhoeic keratoses in this analysis. Lesions were counted only if they were excised by a participating doctor at a study practice.

We used logistic regression to analyse data on individual lesions, allowing for the clustering by practice. Odds ratios, their 95% confidence intervals, and P values were obtained from these models (see [bmj.com](http://bmj.com) for details).

To assess the effect of the intervention on the numbers of lesions excised (including seborrhoeic keratoses), we calculated the annual number of excisions for each practice and grouped them into categories (melanomas: 0, >0 and <1, 1, 2, ≥3; benign lesions: 0, >0 and <5, 5-12, 13-27, 28-49, 50-99, ≥100). We used correlation coefficients to estimate changes within each intervention group between the baseline and trial periods.

**Calculations of sample size**

We estimated that we could recruit a maximum of 450 general practitioners, or about 225 practices with two doctors per practice (see [bmj.com](http://bmj.com)). From the results of the Queensland trial, we calculated that we needed nine months of follow up to achieve 80% power.

**Results**

**Participation and randomisation**

We identified 488 practices, of which 223 participated. Practices were randomised between 14 September 1999 and 8 February 2000. The intervention and control groups had similar durations of baseline and trial periods and were similar in terms of total general practitioners per practice and the number that participated within each practice, but differed slightly in their areas of socioeconomic status.

We identified 1221 GPs, of whom 468 participated in the trial. Fourteen GPs participated at multiple prac-

tices and of these, five worked at multiple practices allocated to both groups. More GPs working at intervention practices participated in the study, partly due to more GPs in intervention practices joining the trial after the practice was randomised.

Similar numbers of GPs in the two groups left their practices during the trial. No other GPs withdrew from the trial. Only 302 (65%) GPs completed the questionnaire at the end of the study.

**Excision of pigmented skin lesions**

During the two periods, the participants excised 8563 pigmented skin lesions: 295 (3%) melanomas (180 invasive and 115 in situ), 529 (6%) dysplastic naevi, 5065 (59%) other naevi, and 2674 (31%) seborrhoeic keratoses. The ratio of benign lesions to melanomas was 19 without and 28 with seborrhoeic keratoses. The number of excisions per practice ranged from none (42 practices) to more than 1000, with a median of 15. The number of melanomas varied from none (130 practices) to 31 with a median of 0.

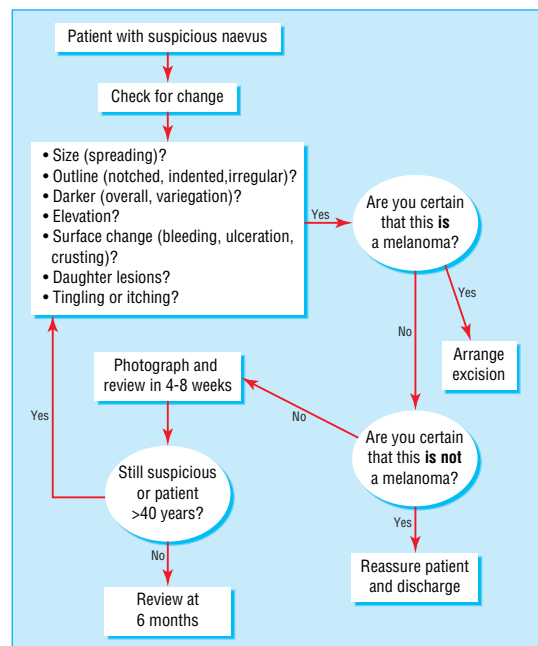
During the baseline period, the annual numbers of excisions of benign lesions and melanomas within practices were similar in the two groups. Overall, the intervention group excised more melanomas and more benign lesions and had more favourable ratios of benign lesions to melanomas (table). The apparent inconsistency between the figures within practices and the overall totals was due to the imbalance in specialist general practitioners—general practitioners to whom other doctors refer patients with pigmented skin lesions and who perform a substantial proportion of all excisions. Four of the total (five) were in the intervention group. When we excluded these GPs, the number of excisions of benign lesions was similar in the two groups, although the intervention group excised more melanomas and therefore had a lower ratio of benign to malignant lesions (table).

Neither group showed substantial changes in the excision rates within practices between the baseline and trial periods, and the correlation coefficients for the categorised rates in each group before and after randomisation were small and not significant (intervention group: benign lesions  $r = -0.01$  ( $P = 0.9$ ), melanomas  $r = -0.01$  ( $P = 0.9$ ); control group: benign lesions  $r = -0.01$  ( $P = 0.9$ ), melanomas  $r = 0.07$  ( $P = 0.3$ )). The overall rates showed little change in the control group, but decreased in the intervention group between periods (table), largely because of substantial reductions in a few practices with large numbers of baseline excisions.

The intervention group had a slightly higher ratio of benign lesions to melanomas during the trial period (table). After adjustment for practice size and patients' age, sex, and socioeconomic status, the odds ratio from the primary analysis was close to unity. Its confidence interval was consistent with at most about 32% lower ratio of benign to malignant lesions in the intervention group.

**Compliance and reported management of pigmented skin lesions**

We provided intervention practices with 482 packets of film (4820 possible photographs), and 85 practices requested at least one additional packet of film during the trial.



Algorithm to assist with the management of patients with pigmented skin lesions

Odds ratios and confidence intervals for analysis of benign pigmented skin lesions and melanomas

	Control			Intervention			Odds ratio* (95% CI)	P value
	Benign	Melanoma	Ratio	Benign	Melanoma	Ratio		
<b>Excisions in baseline period</b>								
Excluding seborrhoeic keratoses	1345	61	22	1805	100	18	0.82 (0.60 to 1.13)	
Including seborrhoeic keratoses	1965	61	32	2615	100	26	0.79 (0.57 to 1.09)	
Excluding specialist GPs†	1788	51	35	1716	67	26	0.70 (0.45 to 1.09)	
<b>Excisions in trial period</b>								
Excluding seborrhoeic keratoses	1361‡	79	17	1559	81	19	1.02 (0.68 to 1.51)	0.94
Including seborrhoeic keratoses	2037	79	26	2369	81	29	1.03 (0.71 to 1.50)	0.88
Excluding specialist GPs†	1803	72	25	1562	57	27	1.06 (0.70 to 1.61)	0.78
Excluding GPs who joined trial after practice was randomised†	1737	63	28	2279	76	30	0.99 (0.67 to 1.47)	0.98

\*Adjusted for practice size and patients' age, sex, and socioeconomic status.

†Analysis includes seborrhoeic keratoses.

‡Numbers in trial period are numbers excised per year for comparison with baseline period.

One hundred and twenty (82%) control GPs and 131 (85%) intervention GPs who returned the questionnaire reported that they had dealt with at least one pigmented lesion during the trial. One hundred and thirty (84%) intervention GPs reported that they photographed at least one patient. The median number of patients photographed was eight.

When we asked about the last patient with a pigmented lesion that they managed, GPs in the intervention group reported that they referred fewer patients to specialists, photographed more lesions, and excised fewer lesions. When patients were referred, there was little difference between the groups in choice of specialist ( $P = 0.45$ ).

## Discussion

The provision of a camera and algorithm to general practitioners to help them manage patients with suspicious pigmented lesions did not decrease the ratio of benign lesions to melanomas they excised. During the trial period, the ratio was actually slightly higher in the intervention group. There was some evidence, albeit not significant, that the intervention group excised fewer melanomas during the trial period, raising the possibility that some melanomas were missed.

How valid are these results? Chance is unlikely to explain the apparent lack of effect on the ratio of benign to malignant lesions as the lower bound of the confidence interval for the primary analysis (0.68) excludes strong effects and is barely consistent with the 32% lower ratio of benign to malignant lesions in the intervention group of the previous trial.<sup>3</sup>

The ratio of benign to malignant lesions was lower in the intervention group before randomisation, which should have favoured finding a lower ratio during the trial period. Exclusion of the specialist general practitioners, most of whom were in the intervention group, had no impact on the results. Although more GPs in the intervention group joined the trial after their practice was randomised, their exclusion also had little effect. All analyses were adjusted for patient characteristics that might affect the ratio of benign lesions to melanoma—namely, age, sex, and socioeconomic status.

Compliance seemed high, as indicated by use of film and general practitioners' reports on the number of patients that they photographed. Our objective evidence on number of excisions by the intervention general practitioners suggests that most practices

showed little change, but that in practices where there were many excisions before baseline, there was a reduction. We do not know what proportion of this change was due to the intervention rather than to regression to the mean. Some contamination might have been present because five general practitioners were in both groups, but fewer doctors in the control group reported photographing skin lesions, and in the control group excision rates were similar before and after randomisation.

How do we reconcile the results from this trial with those from the previous apparently successful one?<sup>3</sup> The design and settings of the two trials were different. Our design is stronger because we randomised multiple practices rather than two cities. It was conducted in a metropolitan rather than a remote provincial setting, where there was only one dermatologist. Perth has numerous specialists in skin diagnosis to whom general practitioners could refer patients. We had no objective data on referrals to specialists, although general practitioners in the intervention group reported that they were less likely to refer patients in the trial period. Perhaps it is more common for general practitioners to refer diagnostically worrying lesions to such services in Perth, in which case we might have been measuring the wrong sort of

### What is already known on this topic

A previous trial in Australia showed that the use of an instant camera and algorithm for the management of pigmented skin lesions in provincial general practice reduced the ratio of excisions of benign lesions to melanomas without reducing the number of melanomas diagnosed

### What this study adds

A similar trial in a capital city in Australia, with a stronger study design and randomisation by practice rather than town showed no reduction in the ratio of benign to malignant lesions excised

The reasons are not clear, but the contradictory results may be related to differences in large cities rather than small ones (where specialists are not so available)

lesion. Despite these differences, there is no obvious explanation for the discrepancy.

We had few eligibility criteria that would limit the external validity of the study. GPs particularly interested in skin lesions may have been more likely to participate, but the ratios that we observed were similar to that found in an analysis of all excisions sent to a pathology service in Victoria.<sup>5</sup> GPs in Australia practise on a fee for service basis, and excisions of malignant skin lesions attract a higher payment than excisions of benign skin lesions.

In conclusion, our results do not show that photography of pigmented skin lesions in general practice in Australia decreases the number of benign lesions excised without compromising sensitivity of the diagnosis of melanoma.

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Contributors: See [bmj.com](http://bmj.com)

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Competing interests: None declared.

Ethical approval: The Human Research Ethics Committees of the Royal Australian College of General Practitioners and the University of Western Australia approved the study protocol. No consent was sought from patients, whose names were not sought.

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### Corrections and clarifications

*England is in a sexual health crisis, MPs say*  
In this news article by Zosia Kmietowicz, we wrongly suggested that Dr Helen Lacey worked in Manchester (14 June, p 1281). In fact she is a consultant in the departments of genitourinary medicine in Rochdale and Bury.

*New South Wales cracks down on commercial scanning*  
In the full version (which appears on [bmj.com](http://bmj.com) only) of this news article by Christopher Zinn (21 June), we inadvertently misspelt the name of Dr Paul Condoleon.

## A paper that changed my practice

### Asking the right question

Ten years ago I was feeling overwhelmed by the plethora of scientific papers at the annual Australasian STD Congress when I noticed a paper to be presented in one of the smaller lecture theatres. It looked as if it might be relevant to my work in a city sexual health clinic: *Should the question "Have you been sexually abused?" be asked routinely when taking a sexual health history?*

Of 407 patients asked this question in September 1992 at the Auckland Sexual Health Centre, 90% had never been asked this before by a health professional, 31% disclosed past abuse, and for 26% this was their first disclosure. Given the context of the study, such high levels were not unexpected, but it was the final statistic that changed my life: only two patients were unhappy about being asked the question.

The authors acknowledged that patients from high risk behaviour groups—such as street kids, sex workers, substance misusers, and those with unsafe sexual practices—comprised a higher proportion of their case load than was so for an average family practice. Previous studies of non-clinical populations have shown that a history of child abuse significantly increases the risk of such behaviour, and many psychosomatic and psychosexual complaints may indicate previous abuse as well as the more familiar sexually related consequences of sexually transmitted disease, HIV infection, unwanted pregnancy, and genital neoplasia.

Some years later, while researching a talk on the effects of sexual abuse on pregnancy, I became aware of other issues I had previously failed to consider sufficiently. For example, a history of an eating disorder (typically bulimia), patients who refuse a smear

or pelvic examination, patients who will see only a woman doctor, women with chronic pelvic pain or symptoms that seem to be psychosomatic, and so called difficult patients. All these could be linked with a history of early sexual abuse or assault, and we can recognise these behaviours as being an attempt to regain control after a frightening or degrading experience.

Should we, I asked myself, be re-evaluating some of our more challenging patients, whether male or female? Since then I have followed the practice of asking about sexual abuse much more often, especially with patients such as these. All doctors are now expected to be able to ask important questions with tact and understanding, so it has also been useful to alert medical students in several countries to this valuable question while training them in communication skills.

Many patients remain reluctant to disclose a history of sexual assault unless given the opportunity by a safe and sensitive inquiry. The healing process begins with validation combined with appropriate counselling.

Incidentally, this relatively short and simple paper was awarded the prize for the best paper of the congress. I suspect many other delegates who heard it also took its message to heart and changed their practice.

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