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## Should medical students be routinely offered BCG vaccination?

Sanjaya N Senanayake and Peter J Collignon

**TO THE EDITOR:** We disagree with the recent recommendation of Graham and colleagues that all medical students should be offered BCG vaccination.<sup>1</sup> In countries with a low prevalence of tuberculosis (TB), the side effects from the vaccine and losing the use of a Mantoux test to readily diagnose recent TB infection outweigh any benefits of a vaccine with relatively poor efficacy.

The incidence of pulmonary TB in Australia is low (3.3 per 100 000 per year) and only 1.5% of isolates are multidrug-resistant.<sup>2,3</sup> Thus, the likely exposure of medical students and doctors in Australia to pulmonary TB (let alone multidrug-resistant TB) will be low. In addition, most hospitalised patients with pulmonary TB would have been suspected of having TB before being sent to hospital, so adequate respiratory precautions should have been in place for most. This makes the risk of transmission to health care workers very small.

Information from the *Australian immunisation handbook* is also very relevant to this debate.<sup>4</sup> BCG can be effective, but mainly in preventing disseminated TB in children (>80% efficacy). In adults, the overall protective efficacy is only about 50%,<sup>4</sup> and the sole Australian study showed, at best, a protective efficacy of only 30%.<sup>5</sup> The effect of BCG may not persist for more than 10 years but repeat vaccination is not recommended.<sup>4</sup>

Adverse events occur in about 5% of those vaccinated, with 2.5% being injection site abscesses and 1% lymphadenitis. About 1% of vaccinees may need medical attention as a result of the adverse event. Anaphylactoid reactions can occur, and keloid scarring can also occur (although rarely) at the injection site. The vaccine is "live", and therefore contraindicated in anyone who might have HIV, other forms of immunosuppression, or generalised skin diseases.<sup>4</sup>

Graham and colleagues believe the problem of BCG vaccination interfering with the interpretation of Mantoux results can be overcome by using whole blood-based interferon assays, such as QuantiFERON-TB Gold, purportedly unaffected by BCG vaccination.<sup>1</sup> However, the data for QuantiFERON-TB Gold need to be treated with some caution because it is a new test and there is no gold standard against which to compare it for diagnosing latent TB. The specificity of interferon assays in diagnosing latent TB has been estimated at 95% or more,<sup>6</sup> but this will still result in a poor positive predictive value if the pretest probability of latent TB infection is low — and this is the case for health care workers in Australia.

In summary, Australia is far more likely to protect its health care workers from TB through effective hospital infection control measures and migrant screening than through a vaccination program with a mediocre vaccine.

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David N Durrheim and Michael J Hensley

**TO THE EDITOR:** Graham and colleagues correctly assert that medical students are at increased risk of infection with *Mycobacterium tuberculosis* in settings where they are treating patient groups with a high prevalence of active pulmonary tuberculosis (TB).<sup>1</sup> This is well illustrated by the increasing prevalence of latent TB infection among medical students in their later clinical years in countries where community TB incidence markedly exceeds that of Australia.<sup>2</sup>

Their case for a standard approach to screening of medical students at course entry has great merit, and their arguments in favour of using an interferon gamma release assay to screen for latent TB infection would

bring Australia into line with current international best practice.<sup>3</sup>

However, the data presented do not substantiate a policy of offering BCG vaccination to all Australian medical students whose screening test result for latent TB infection, whether by interferon gamma or tuberculin skin testing (TST), is negative. Although BCG offers definite benefits in reducing the risk of life-threatening disseminated disease in children under 2 years of age, it does not offer dependable protection against pulmonary TB in adults.<sup>4</sup> Medical students who are vaccinated with BCG may be lulled into a false sense of security, and neglect other more effective infection control measures that would reduce their risk of TB exposure and infection.<sup>3</sup> Although BCG is a relatively safe vaccine, there is a small but well defined risk of local and systemic adverse events.<sup>5</sup>

We therefore support a standardised approach to screening medical students with TST or, preferably, interferon gamma at course entry and exit. Screening for latent TB infection should be offered whenever merited during the course of study, after exposure to active TB disease in Australia or abroad. The benefits of chemoprophylaxis on conversion outweigh the risks associated with isoniazid use, and the risks associated with BCG may not be acceptable where the risk of TB exposure for many Australian medical students is currently negligible.

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**Maryza Graham, Tanya M Howley, Robert J Pierce and Paul DR Johnson**

**IN REPLY:** The intention of our article was to highlight inconsistent approaches to tuberculosis (TB) prevention in Australian medical schools and stimulate a new informed debate. We therefore welcome the responses from Senanayake and Collignon, and Durrheim and Hensley.

Interference with interpretation of tuberculin skin testing (TST) is one argument cited against the use of BCG vaccination for health care workers. While we agree that the new blood-based tests need further evaluation, unlike TST, they are not affected by BCG because they employ TB-specific antigens. The lack of a gold standard for diagnosis of latent TB affects *both* TST and the blood-based tests. Recent reviews of these new tests have been favourable — including one that states that, compared with TST, these new assays seem to have “better correlation with surrogate measures of exposure to *M. tuberculosis*” and that “because of their higher specificity they may be helpful in low-prevalence, resource-rich settings where cross-reactivity due to BCG may pose difficulty in BCG interpretation”.<sup>1</sup> In fact, this article summarised the specificity of these new tests as *between* 95% and 100%. Other authors found a specificity of 98.1%.<sup>2</sup>

We agree that infection control is crucial in preventing nosocomial TB transmission, but every infection control practitioner has seen patients with unrecognised TB admitted to an open ward. One missed patient can mean contact-tracing and testing of dozens of staff. The Melbourne Mantoux study (involving 14 Melbourne hospitals) found that health care work and years of hospital employment were significantly associated with a positive Mantoux result — indicating the risk to Australian health care workers is not “negligible” as Durrheim and Hensley state. Nosocomial outbreaks of TB are well documented in low-prevalence countries.<sup>1,3</sup>

BCG is by no means a perfect vaccine. However, while BCG efficacy was once thought to only last 10 years, a recent large study suggested that it persists for 50–60 years,<sup>4</sup> and there is new evidence that BCG vaccination may prevent some primary infections.<sup>5</sup> While the risk of health care-associated tuberculosis in Australia is currently low, it would be unwise to assume this will remain the case, or that doctors will only work in safe environments. What will be the effects of HIV, further immigration from high-risk countries, drug resistance

and the increasing use of immunosuppressant medications on the incidence of TB? We stand by the recommendations in our article, although we acknowledge they are controversial. There should, however, be no controversy about the need for a consistent policy concerning TB prevention in our medical schools.

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## Does the presence of heart failure alter prescribing of drug therapy after myocardial infarction?

Lauren J Bailey and Vasi Naganathan

**TO THE EDITOR:** In a recent observational study, Krum et al concluded that the treatment of heart failure after myocardial infarction in Australian teaching hospitals is suboptimal because angiotensin-converting enzyme (ACE) inhibitors,  $\beta$ -blockers and aldosterone antagonists are underutilised.<sup>1</sup> We believe that another explanation, mentioned by the study's authors, is worth exploring further — for valid clinical reasons, it was not appropriate for certain patients to start or continue taking some of these medications. An understanding of the enrolment criteria of relevant clinical trials is informative.

The large, long-term ACE inhibitor trials quoted by Krum et al — SAVE,<sup>2</sup> TRACE<sup>3</sup> and AIRE<sup>4</sup> — between them screened 34 037 patients with myocardial infarction and left ventricular dysfunction. Only 5986 patients (18%) met the inclusion/exclusion criteria to be enrolled in one of the trials. Unfortunately, the CAPRICORN<sup>5</sup> ( $\beta$ -blocker) and EPHEsus (aldosterone antagonist) trials did not publish the number of patients screened versus the number randomised, but a glance at their exclusion criteria explains why, for some patients, it may not have been appropriate to start these medications during their hospital stay. Some of the exclusion criteria for CAPRICORN were: unstable angina, ongoing therapy with antiarrhythmics (except amiodarone), secondary or tertiary heart block or sick sinus syndrome unless paced, uncontrolled hypertension (>160/95 mmHg), bradycardia (heart rate, <60 beats/min), hypotension (systolic blood pressure, <80 mmHg), requirement for intravenous diuretics or inotropes, chronic obstructive pulmonary disease with ongoing inhaled  $\beta_2$ -agonist or steroid therapy, and unstable insulin-dependent diabetes.

Is there any harm in prescribing outside the inclusion/exclusion criteria for clinical trials? A population-based, time-series analysis linking prescription-claims data and

hospital admission records of 1.3 million adults in Canada<sup>6</sup> showed that hyperkalaemia-related deaths in hospital doubled after the RALES trial (spironolactone) was published in 1999. There was no reduction in re-hospitalisation for heart failure or all-cause mortality. The authors speculated that part of the reason for this was prescription of spironolactone to patients who would have been excluded from the RALES trial.

While we would not advocate prescribing strictly within the boundaries of the inclusion/exclusion criteria of clinical trials, it is important to understand these criteria, so that prescribing in “real world” patients is done with care.

We are reassured that Krum et al's study suggests there is discretion in the prescribing of drug therapy. Presumably, during ongoing medical assessment, it will be appropriate for some patients to commence some of these medications (potential benefit outweighs potential harm), while others may need to have their medications reviewed because of adverse events.

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### Henry Krum

**IN REPLY:** We thank Bailey and Naganathan for their thoughtful viewpoint regarding prescribing according to clinical trial criteria. We agree that prescribing in the real world often involves complex decision making, taking into account age, comorbidities, concomitant medications and other factors, whereby guidance regarding individual patients cannot readily be extracted from

clinical trial literature. This may certainly contribute to underutilisation of evidence-based drug treatment.<sup>1</sup> Nevertheless, several analyses support the contention that physicians who more closely adhere to evidence-based guidelines (which in turn are derived from randomised clinical trials) produce better outcomes for their patients.<sup>2,3</sup> Therefore, we would still advocate prescribing as closely as possible to guideline recommendations, while acknowledging that these recommendations may not always be readily applicable to every patient.

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## Guidelines for the management of acute coronary syndromes 2006

John W Eikelboom, Graeme J Hankey and Paul E Langton

**TO THE EDITOR:** The guidelines for managing acute coronary syndromes, published in a supplement to the *Journal* in 2006, provide a readily accessible tool for clinicians to enhance patient care.<sup>1</sup> However, unfortunately the recommendations concerning adjunctive anticoagulation in patients with acute coronary syndromes (ACS) are suboptimal.

The 2006 guidelines recommend that high-risk patients with non-ST-segment-elevation ACS should be treated with aggressive medical management, including unfractionated heparin or the low molecular weight heparin (LMWH) enoxaparin, based on evidence from randomised trials showing that these agents reduce the risk of non-fatal myocardial infarction (MI).<sup>1</sup> However, neither unfractionated heparin nor enoxaparin

have been shown to reduce mortality in patients with non-ST-segment-elevation ACS, even when compared against placebo, and enoxaparin increases the risk of bleeding when compared with unfractionated heparin.<sup>2-4</sup> By contrast, the OASIS-5 study, presented at the European Society of Cardiology Meeting in September 2005 and published in early 2006, showed that fondaparinux (a pentasaccharide inhibitor of factor Xa) compared with enoxaparin reduced death and stroke rates, and reduced the risk of bleeding by one half.<sup>5</sup> Updating the recommendation so that enoxaparin was replaced with fondaparinux for patients with non-ST-segment-elevation ACS would save six Australian lives at 30 days for every 1000 patients treated, and would cause 19 fewer bleeds.

The recommendations of the 2006 ACS guidelines concerning the management of patients with ST-segment-elevation MI are similarly suboptimal. There are now convincing data from randomised trials that enoxaparin is more effective than unfractionated heparin for preventing recurrent MI in patients with ST-segment-elevation MI who have been treated with fibrinolytic therapy.<sup>4,6</sup> However, as in the case with non-ST-segment-elevation ACS, enoxaparin has never been shown to reduce mortality in ST-segment-elevation MI. By contrast, both the LMWH reviparin, and fondaparinux, reduce mortality,<sup>7,8</sup> and fondaparinux does so without increasing the risk of bleeding.<sup>8</sup>

We appreciate that rapid advances in the management of ACS make it increasingly difficult for evidence-based guidelines to reflect the best evidence from clinical trials. However, when new evidence becomes available that is clinically relevant at the individual and population level, we believe the guidelines working group and the *Journal* have a responsibility to update the readers.

**Competing interests:** John Eikelboom has received honoraria and is currently the recipient of research funding from GlaxoSmithKline and Sanofi-Aventis; Graeme Hankey has received honoraria for consulting on advisory boards and speaking at sponsored scientific symposia by Sanofi-Aventis, Bristol-Myers Squibb, Bayer, Boehringer Ingelheim, AstraZeneca, and Pfizer pharmaceuticals; Paul Langton has received honoraria for consulting on advisory boards and speaking at sponsored scientific symposia by AstraZeneca, Bayer, Boehringer Ingelheim, Merck Sharp & Dohme, Pfizer, Sanofi-Aventis, Servier, and Solvay pharmaceuticals.

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**IN REPLY:** We thank Eikelboom et al for presenting new data on acute coronary syndrome (ACS) management. In this field of rapid advances, another recent study, ACUITY, has also been published, which examined bivalirudin in ACS.<sup>1</sup> The Australian guidelines<sup>2</sup> are based on peer reviewed published reports, and neither OASIS-5<sup>3</sup> nor ACUITY<sup>1</sup> were released at the conclusion of the formulation of the guidelines. Also, fondaparinux is only available on the Pharmaceutical Benefits Scheme (PBS) in Australia for thromboembolic prophylaxis, and bivalirudin is currently only approved by the PBS for therapy during percutaneous coronary interventions.

The Australian guidelines are consistent with international guidelines for both unfractionated heparin and low molecular weight heparin considered as Grade A rec-

ommendations for treating non-ST-segment-elevation ACS, based on Level 1 evidence (American College of Cardiology/American Heart Association guidelines). For example, the FRISC trial showed a significant reduction in mortality and myocardial infarction with dalteparin (compared with placebo; 1.8% v 4.8%;  $P=0.001$ ) at 6 days, which persisted at 40 days.<sup>4</sup>

The Australian ACS guidelines are a living document, and new evidence, such as the OASIS-5 (fondaparinux)<sup>3</sup> and ACUITY (bivalirudin)<sup>1</sup> findings, will be considered on their relative merits in future updates of the guidelines (available on the National Heart Foundation Australia website at <http://www.heartfoundation.com.au>).

**Competing interests:** The authors are consultants, advisory committee members, or receive honoraria, fees for service, or travel assistance (independent of research related meetings) from, or have research or other associations with, the organisations listed: Constantine Aroney — CSL, Merck Sharpe & Dohme, Sanofi-aventis; Phil Aylward — Sanofi-aventis, Pfizer, Merck, Bristol-Myers Squibb, Boehringer Ingelheim, AstraZeneca, Procter & Gamble, Eli Lilly, The Medicines Co, Servier, CSL, Schering Plough.

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## Conundrums in community-acquired pneumonia

Michael Montalto

**TO THE EDITOR:** A seminal 1997 article by Fine et al described the pneumonia severity score from the Pneumonia Patient Outcomes Research Team study and raised the role for Hospital in the Home (HIH):

For the remaining patients in [risk] classes II and III for whom treatment at

home with oral antimicrobial therapy is judged to be unsuitable, there are alternatives to traditional inpatient care. These include parenteral antimicrobial therapy at home or a short stay ... in a hospital observation unit.<sup>1</sup>

A recent article in the Journal by Charles et al<sup>2</sup> omitted a role for HIH in managing community-acquired pneumonia (CAP). Where their protocol mentions outpatient care, readers are led to interpret this as oral therapy only, managed by a general practitioner. Similarly, it is implied that inpatient therapy relates to traditional treatment in a hospital ward. No further clarification is given. This is a surprising omission, given that one of the authors has written extensively in support of HIH in the past.<sup>3</sup>

HIH administers hospital-level therapy (intravenous antibiotics, oximetry, rehydration, medical and nursing attendance, with 24-hour cover) to a clinical subgroup of CAP patients who can be defined and included within any protocol.

Evidence suggests that HIH can offer effective and safe treatment of patients with acute CAP referred directly from hospital emergency departments after diagnosis.<sup>4-6</sup> Many patients with pneumonia appreciate the option of well organised, acute, home-based care. An important and growing subgroup of patients living in residential nursing care facilities can also receive acute CAP treatment in facilities with HIH involvement.<sup>7</sup> A significant proportion of patients receiving HIH care have failed oral therapy.<sup>4-7</sup>

Why the omission of HIH? Protocols are tools of influence to be tussled over. This sometimes conflicts with their general aim of organising science into process and progress. Fine and colleagues' intent in investigating the use of pneumonia severity scores was to help address the question of where and how to treat acute pneumonia. One of the aims of developing scores was to broaden the treatment options, not to narrow them.

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Patrick J Bradley

**TO THE EDITOR:** The recent editorial on community-acquired pneumonia (CAP) stated that "even in an era in which penicillin resistance appears to be increasing among some *Streptococcus pneumoniae* isolates, there have been no documented failures of high-dose penicillin in treating pneumococcal pneumonia or bacteraemia".<sup>1</sup>

The medical literature suggests otherwise.

Firstly, North American guidelines do not mention penicillin at all, and, in one analysis of 25 996 hospitalised patients who received monotherapy, mortality was about 50% higher with penicillin monotherapy than with monotherapy with ceftriaxone, another cephalosporin, a macrolide or a quinolone.<sup>2</sup>

More importantly, however, the same study found that the mortality rate in patients (even low-risk patients) treated with two antibiotics, one of which was a macrolide, was half the mortality rate of patients treated with one antibiotic. Dual therapies used were a macrolide agent in combination with ceftriaxone, another cephalosporin, a penicillin or a quinolone. Best outcomes were achieved with a ceftriaxone-macrolide combination.

In a review of seven studies, Waterer<sup>3</sup> found that patients with severe pneumococcal pneumonia or bacteraemic pneumococcal disease who were treated with two antibiotics had a significantly lower mortality rate than patients treated with a single antibiotic. This was despite the fact that the patients treated with a single antibiotic were not as ill initially as those treated with two antibiotics.

Research by Waterer and colleagues<sup>4</sup> showed that the benefit of taking two antibiotics was most apparent in the highest risk hospitalised patients, in whom mortality was five times higher in those receiving one antibiotic than in those receiving two.

Thus, it is imperative that all patients with severe pneumococcal CAP be treated with two antibiotics, one of which should be a macrolide.

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**Patrick G P Charles, Paul D R Johnson and M Lindsay Grayson**

**IN REPLY:** Whether Hospital in the Home (HIH) care is suitable for managing patients with community-acquired pneumonia (CAP) depends on what is considered an appropriate use of resources. Overall, we see relatively few indications for treating CAP patients with parenteral antibiotics via HIH, as, in our experience, most patients who do not need supplemental oxygen and are well enough to be treated at home are usually also well enough to be treated with oral antibiotics. If they are not well enough to take oral antibiotics, then admission to hospital as an inpatient is generally appropriate. The occasional exceptions to this are selected patients in nursing homes (where around-the-clock supervision is available if required) and some patients with CAP caused by pathogens like *Pseudomonas* or *Acinetobacter* who benefit from longer treatment courses and may not have the option of oral antibiotics.

Furthermore, a report submitted to the Victorian Department of Human Services regarding HIH care of CAP patients at a number of Melbourne HIH units identified significantly worse outcomes at some centres, mainly related to inappropriate patient selection. Notable, but fortunately rare, cases included some patients with pulmonary embolism incorrectly diagnosed as CAP. Given that between 20% and 50% of patients given a diagnosis of CAP in the emergency department do not have pneumonia confirmed by a radiologist,<sup>1-3</sup> the ability of busy emergency department doctors to select patients appropriately is definitely a concern. Thus, HIH treatment of CAP patients may be appropriate occasionally, but very careful patient selection is vital.

In response to Bradley, the statement that there have not been any failures in treating pneumococcal CAP with penicillins refers to microbiological failures due to antibiotic resistance. Although several studies have suggested that combination therapy may reduce mortality from bacteraemic pneumococcal infections, all of these have been retrospective observational studies. Thus, they lack the ability to control accurately for potential confounding variables such as disease severity, patient or family wishes, pre-morbid quality of life, or “not for resuscitation” status. Data are also lacking on co-infection with “atypical” pathogens such as *Legionella*. The immunomodulatory effects of macrolides, quinolones and tetracyclines on treatment response are also still being elucidated.<sup>4</sup> We agree with the CAP treatment recommendations in the Australian antibiotic guidelines,<sup>5</sup> which recommend dual therapy with a  $\beta$ -lactam antibiotic plus either a macrolide or doxycycline for all patients who are not allergic to these drugs.

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## Chronic disease self-management education programs: challenges ahead

**Sarah M Dennis, Nicholas A Zwar, Iqbal Hasan and Mark F Harris**

**TO THE EDITOR:** The article by Jordan and Osborne<sup>1</sup> highlights some of the key issues to be addressed if chronic disease self-management programs are going to be effectively incorporated into the Australian health care system, particularly in primary care.

Although the National Chronic Disease Strategy<sup>2</sup> recommends that self-management programs be integrated and supported at all entry points into the health care system, many of the self-management strategies and programs have been developed with little engagement of general practitioners and have not been integral components of primary health care. Jordan and Osborne highlight that, without the support of GPs, programs such as the Expert Patients Programme<sup>3</sup> may have limited success.

We recently completed a systematic review for the Australian Primary Health Care Research Institute to explore the evidence for managing chronic disease in primary care, with specific reference to the Australian health care system.<sup>4</sup> The self-management programs found to be most effective were those that developed self-efficacy in relation to specific behaviours, such as diet and exercise for diabetes, rather than those that were more general. The combination of self-management support with delivery system design changes (such as multidisciplinary team care and follow-up) was effective in improving patient health

outcomes for a number of chronic diseases. This highlights an important and developing role for practice nurses in chronic disease management. Given the burden of chronic disease in Indigenous populations, it is important to conduct more research on the role of self-management education and support in Indigenous communities, as there were few relevant studies identified in our systematic review.

The funding available through the Australian Better Health Initiative<sup>5</sup> will enable primary health care professionals, such as GPs and practice nurses, to receive self-management education training. Furthermore, to ensure that self-management support is embedded in primary care, we suggest that self-management support be included in care plans or annual cycles of care for conditions such as diabetes. Self-management support could also be incorporated into allied health services that are provided as part of a care plan.

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*The Medical Journal of Australia (MJA)* is published on the 1st and 3rd Monday of each month by the Australasian Medical Publishing Company Proprietary Limited, Level 2, 26-32 Pyrmont Bridge Rd, Pyrmont, NSW 2009. ABN 20 000 005 854. Telephone: (02) 9562 6666. Fax: (02) 9562 6699.

E-mail: [medjaust@ampco.com.au](mailto:medjaust@ampco.com.au). The Journal is printed by Webstar Australia, 83 Derby Street, Silverwater, NSW 2128.

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27,887 circulation as at  
26 October, 2006



ISSN 0025-729X