New and extended roles and functions in health care are being created, such as physician assistant and nurse practitioner. These changes are expected to create new ways of sharing work and more flexible education and training, as advocated by Hutchinson.¹

Making the most of change

As medical educators, we would be wise to seize the opportunities offered by changes in health care to improve the quality of learning in the workplace. Commitment in the workplace is crucial for successful improvement. Clinical teachers have a pivotal role in education and training. Dornan showed that clinicians will dissociate from educational innovations, despite their essentially positive attitude, when educators fail to attend to their concerns and neglect to secure their support.³ Clinicians' support should not be taken for granted, given the pressure exerted on them by hospitals and universities to deliver more services and research. Evidently, a prerequisite for good medical education is a workable balance between the competing demands made on clinical teachers. Transparent funding for education and a climate that fosters

educational activities through material and immaterial rewards are important steps in this direction.

As educators we need to support the teachers in their environment. The workplace is a complex environment characterised by manifold interactions. We should enlist the support of other professionals and work with them as a team to ensure that our students are appropriately prepared to take on their professional responsibilities. We might look to clinical governance and learn how to make good use of the associations between quality of service to patients and quality of education and training. Last, but not least, we should focus more of our research efforts on change processes to seek evidence of effective mechanisms of change—to improve and convince.

Competing interests: None declared.

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Commentary: Australian perspective

J Jill Gordon

Hutchinson explores the likely educational impact of changes in health service design and delivery on the part of the NHS in England.¹ In Australia, we envy the way in which centralist arrangements in the UK help to disseminate improvements to services and training.² Here, funding is split between the Commonwealth and the states and between the public and private sectors. Despite the differences, however, many similar concerns and problems prevail.

Rather than a patient led environment, Australia is still working toward one that is more patient centred. Patient centred care is embedded in the national patient safety framework developed under the auspices of the Australian Council for Quality and Safety in Health Care.³ It is designed to address the educational needs of managers, clinicians, and support staff at all levels. Ensuring its dissemination remains the biggest challenge.

Patient participation

Many of the most interesting changes in patient led teaching have been in undergraduate education. At the University of Sydney, for example, students are taught by young people with diabetes, intravenous drug users, carers, transplant recipients, and many others. As part of their assessment in evidence based medicine, students are required to ask patients whether their information needs have been met in a way that is acceptable and helpful. There are many other examples. The new graduate entry programmes necessarily enrol older students, and 20-25% of students admitted during the first five years at the University of Sydney had a first degree in a health profession such as

nursing or physiotherapy. In practical terms, this has meant that one or two students in each problem based learning group could contribute from first hand experience of other careers.

Fewer changes have occurred at postgraduate level, and nothing to match the UK plans for lay input in the development and delivery of assessments.¹ New South Wales has established an Institute for Medical Education and Training,² a body similar to the Postgraduate Medical Education and Training Board, creating an opportunity to adopt this idea, if it proves to be more than a token.

Plurality

As in the UK, attempts to mix skills have met resistance in Australia.⁴ New South Wales has only 65 nurse practitioners, but some educational initiatives may increase this number, especially in rural areas.⁵ Role substitution undoubtedly needs serious attention, but the diagnosis and management of complex illnesses, as opposed to routine care, require a well grounded understanding of disease mechanisms. This point is easy to gloss over to avoid the charge of elitism.

Having experienced the headaches of negotiating student and trainee placements and ensuring quality of teaching in multiple sites, I predict a full blown migraine for those responsible for dealing with "a plurality of providers." Negotiations for placements consume precious time and create friction as medical schools try to accommodate increased student numbers. Particularly in the for-profit sector, careful monitoring (another time consuming activity) is

Medical Education,
Northern Clinical
School, University
of Sydney, NSW
2006 Australia

J Jill Gordon
associate professor

jill.gordon@arts.
usyd.edu.au

needed to ensure that promises to provide appropriate education, and not just training, are actually kept.

As Hutchinson notes, funding is always contentious and the goal of payment by results for service and education is elusive. Australia will watch with interest.

Competing interests: None declared.

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Research methods

Is restricted randomisation necessary?

Catherine E Hewitt, David J Torgerson

Restrictions during randomisation make it easier for investigators to guess the next allocation. Statistical correction of any imbalance in confounders at the end of the study is equally accurate for most trials and would be safer

York Trials Unit,
Department of
Health Sciences,
University of York,
York YO10 5DD
Catherine E Hewitt
PhD student
David J Torgerson
director

Correspondence to:
D Torgerson
djt6@york.ac.uk

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Randomised controlled trials commonly use some form of restriction when allocating participants—for example, blocking, stratification, or minimisation.^{1 2} The main reason is to achieve a better balance of known confounders. For an individual trial simple randomisation may lead to some chance imbalances on some variables. These imbalances are unimportant if the variables have a weak relation with the outcome. However, if by chance the groups differ at baseline on one or more confounding variables, the trial result may be misleading; this effect could be in either direction.

Stratification and minimisation are used to reduce these chance imbalances. Blocking needs to be used in combination with stratification to ensure that roughly equal numbers of participants are randomised to each of the treatments in the individual strata.¹ Otherwise, it is statistically equivalent to using simple randomisation. However, using restricted randomisation can generate its own problems.

Problems with restricted randomisation

Introducing any form of restricted randomisation increases the risk of subversion (conscious or unconscious) and technical error. Most examples of known subversion relate to situations where allocation

What will come next?

sequences are public knowledge or the concealment of the allocation is inadequate, such as using sealed envelopes that can be tampered with.^{3 4} However, this type of subversion is not specific to restricted randomisation.

With restricted randomisation subversion remains possible even when adequate precautions have been taken to conceal the randomisation sequence.⁵ In an open trial, if we know the block size and we keep a record of previous allocations then we will always be certain about the last allocation in the block. Furthermore, we will also often be able to guess the penultimate allocation correctly. If trialists make predictions only when they are certain of the next treatment, then for a block size of four they will be able to predict 33% of the treatments and for a block size of six they will be able to predict 25%. However, if the trialist simply guesses that the next treatment will be opposite to the previous treatment, then for a block size of four they will be correct 71% of the time and for a block size of six they will be correct 68% of the time.⁶

Predictability can be reduced by using larger block sizes or more than one block size. However, the best way to reduce predictability is to keep the block size hidden and to blind all people in the trial to the treat-

Table 1 Method of randomisation and sample size in trials published in four journals in 2002

Type of randomisation	Journal					Sample size		
	BMJ	JAMA	Lancet	NEJM	Total (%)	Minimum	Maximum	Median
Restricted:								
Minimisation	3	0	12	2	17 (7)	74	20 536	573
Block size small* and fixed	8	8	20	14	50 (22)	16	9 366	301
Block size large† and fixed	3	4	10	1	18 (8)	21	4 136	570
Block size mixed	1	8	5	1	15 (6)	40	42 418	894
Block size random	1	1	2	1	5 (2)	156	7 152	290
Block size unclear	4	4	13	6	27 (12)	40	16 608	920
Simple	6	4	4	7	21 (9)	60	2 475	190
Unclear	9	16	18	36	79 (34)	12	67 800	382
Total	35	45	84	68	232	12	67 800	376

NEJM=New England Journal of Medicine.

*<10.

†≥10.

References w1-w14 are on bmj.com