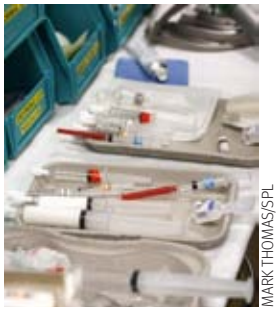
Drug administration errors in anaesthesia and beyond

Innovative systems can work, but only if they are fully adopted by clinicians



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RESEARCH, p 730

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No anaesthetist will complete a career without encountering a drug error. For each anaesthetic procedure performed, the risk of such an error occurring is 0.01-0.75%.[1] Drug errors in anaesthesia are mainly errors of drug administration because, except for preoperative or postoperative care, anaesthetists do not prescribe drugs. In operating theatres, they select, prepare, label, and administer all the drugs needed for the procedure. As a result, commonly known strategies to minimise errors in the prescription of drugs in hospitals, such as computerised physician order entry and decision support systems, are of little use in anaesthesia.[2]

In the linked study, Merry and colleagues test a new system designed to tackle this problem.[3] Their randomised trial on more than 1075 anaesthetised patients compared a new multimodal system they developed with conventional drug administration. The new system was based on the best evidence based practices designed to minimise administration errors,[4] and it combined customised drug trays and prefilled bar coded syringes with colour coded drug labels and standardised concentrations. To mimic double check procedures they also used a bar code reader that was connected to a laptop computer. When the system was consistently used the overall drug error rate—including drug administration errors—was reduced from 11.6 (95% confidence interval 9.3 to 13.9) to 9.1 (6.9 to 11.4; P=0.045).

These findings are consistent with previous studies showing that bar code scanning technology greatly reduces drug administration errors,[5 6] which account for 38% of all drug errors occurring in hospitals.[7] However, the main innovation of Merry and colleagues' system is that it offers a fully integrated solution that combines not only bar code technology but also prefilled syringes, clearly labelled and customised into a drug tray. Syringes are all prepared in the pharmacy or by the manufacturer, rather than in the operating theatre as is conventional practice. This minimises errors in syringe labelling and drug preparation—because of high quality control standards in the drug manufacturing industry, about one error occurs per one million drug preparations, which compares favourably with the error rate of 3-23 per 100 drug preparations when drugs are prepared by medical or nursing staff in hospitals.[8 9] This is particularly relevant to areas such as paediatrics or cancer care, where errors in drug type or dosage can lead to serious adverse events. It could also be considered in hospitals to minimise errors in ABO blood transfusion, which currently occur at a rate of one per 12 000 units administered.[10]

The study is also innovative with its use of a randomised design to demonstrate the effectiveness of a new multimodal system. Too often, new technologies are implemented in hospitals without preliminary evaluation, in the common belief that innovation is inherently better for patients. However, this is not always true. By testing their new procedure under the rigorous conditions of a clinical trial, Merry and colleagues not only showed its effectiveness but also its weaknesses. One of these is poor compliance. Their new multimodal system was used fully only 18% of the time. Why?

It may be that the new system is cumbersome. It is well known that safety rules that increase the workload and decrease efficiency tend to be progressively ignored by front line operators, often with the silent complicity of management.[11] However, this is apparently not the case here, because the multimodal system did not add extra work compared with usual practice.[3]Therefore, the alternative explanation may lie elsewhere, in the intrinsic tension between the imposition of strict procedures and professional autonomy. Because medical knowledge is complex and takes a long time to acquire, control of the content and process of work practice is in the hands of the profession.[12] The use of standardised procedures to organise, dispense, check, and administer drugs, such as those used in this multimodal system,[3] inherently challenges professional autonomy. Such procedures may be perceived by anaesthetists as unnecessary "bureaucratic" steps for drug administration, particularly in straightforward cases. This is a problem that deserves particular attention because even the best innovations, if not fully adopted by clinicians, will remain ineffective.

Finally, efforts to minimise errors in drug administration should not focus exclusively on hospital care. Many drugs such as anticoagulants, insulin, and vaccines are given to patients in family practices or in nursing homes. This should not be ignored by researchers, and improvement initiatives to tackle the risk of drug administration errors in these settings should be thoroughly considered.

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Eye markers of cardiovascular disease

Xanthelasmata are predictive, but arcus corneae is not

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Most clinicians are aware that arcus corneae and xanthelasmata are related to hyperlipidaemia, but results have been conflicting on whether they provide extra information compared with traditional risk factors when predicting the risk of cardiovascular disease.[1-3] In the linked prospective cohort study, Christoffersen and colleagues assess whether xanthelasmata and arcus corneae, individually and combined, predict risk of ischaemic vascular disease and death in the general population.[4]

Arcus corneae and xanthelasmata are recognised signs of hyperlipidaemia when seen in younger patients.[5 6] The arcus corneae associated with hyperlipidaemia, "arcus lipoides," is a white discoloration of the peripheral cornea near the corneoscleral limbus, which is generally separated from the limbic edge by a zone of normal cornea.[1] Arcus lipoides ranges from a barely visible arc in one of the poles of the cornea to a complete dense ring. In contrast, other age related peripheral corneal opacities commonly blur into the limbus.[7] Arcus is more common in black people than in white people,[8] and in men than in women.[1]

Xanthelasma palpebrarum is the most common cutaneous xanthoma. It consists of soft, yellow plaques that appear on the medial aspects of the eyelids bilaterally. It most often occurs in middle aged and older adults. Raised low density lipoprotein-cholesterol is the most common dyslipidaemia associated with xanthelasmata. Both xanthelasmata and arcus corneae are composed of cholesterylesters similar to those found in serum low density lipoprotein-cholesterol and very low density lipoprotein-cholesterol. They share similar risk factors and have pathophysiological similarities with atherosclerosis,[1 9] but normolipidaemic patients can also develop arcus and xanthelasmata.[6 9]

Christoffersen and colleagues' study looked at 12 745 people aged 20-93 years who were free of ischaemic vascular disease at baseline and were followed for between 31 and 33 years. After controlling for established cardiovascular disease risk factors, xanthelasmata predicted the risk of myocardial infarction (hazard ratio 1.48, 95% confidence interval 1.23 to 1.79), ischaemic heart disease (1.39, 1.20 to 1.60), severe atherosclerosis as determined by ankle brachial index (1.69, 1.03 to 2.79), and death (1.14, 1.04 to 1.26). The risk of ischaemic heart disease became stronger (1.56, 1.25 to 1.94) when xanthelasmata and arcus were both present but did not change significantly for other outcomes.

These results indicate that xanthelasmata are an important predictor of cardiovascular disease events and death beyond its known association with hyperlipidaemia. These findings are consistent with a previous case-control study that showed a higher prevalence of cardiovascular disease in patients with xanthelasmata (11%) compared with matched controls without xanthelasmata (1%).[10] Likewise, a larger population cohort study found that xanthelasmata predicted all cause mortality, although mortality from cardiovascular disease was not reported.[3]

Christoffersen and colleagues' results differ from those of a recent smaller study,[2] however, which found similar rates of clinical cardiovascular disease events in patients with and without xanthelasmata (8% *v* 7%). In Christoffersen and colleagues' study, arcus corneae did not predict outcomes in multivariate models—some,[11] but not all,[12] previous studies agree with these data.

As with any study, the current study has some limitations. The data are derived from a relatively homogeneous, predominantly white, population. The study did not include black people, in whom corneal arcus has historically been more prevalent. Data were collected by "trained nurses or medical laboratory technicians," but it is not clear whether any distinction was made between arcus lipoides and other age related peripheral corneal opacities. This is a potential problem in other studies,[11] and it might explain why arcus corneae was not an independent risk factor after adjustment for age in the Framingham cohort. However, these criticisms are minor and may simply reflect our personal reluctance to abandon using arcus as a possible marker of atherosclerotic risk, especially in people with low lipid values.

What do these results mean in practice? Overall, the evidence highlights the importance of a comprehensive physical examination and suggests that xanthelasmata could be used by general clinicians to help identify people at higher risk of cardiovascular disease. These people may have an enhanced biological propensity to deposition of cholesterol in vascular and soft tissue, which is not fully represented by their fasting lipid profiles. Because xanthelasmata are composed of foam cells similar to those present in atherosclerotic plaque, they may be a better marker than arcus corneae of the intra-arterial atherosclerotic process. Patients with xanthelasmata may therefore require more aggressive management of risk factors.

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Leukotriene receptor antagonists as first line or add-on treatment for asthma

Have lower efficacy but similar effectiveness to inhaled corticosteroids

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Asthma is one of the most prevalent chronic diseases in children and adults. Despite effective drugs and evidence based guidelines, most people with asthma have suboptimal control, even in countries with free access to medical care and drugs.[1-3] Several reasons may be at play. To control asthma, a sequence of events must be successfully accomplished by patients and doctors, including patient awareness that symptoms are bad enough to seek medical care; adequate diagnosis and recognition of poor control by the doctor; accurate identification of the source of poor control (environmental triggers, adherence, inhalation technique, comorbidity, suboptimal treatment, or combinations thereof); appropriate adjustment of treatment if indicated; and sufficient patient adherence to both drug based and non-drug based recommendations. Any break in the sequence can lead to poor control.

Consequently, to assess the benefit of a drug, efficacy trials call for objective confirmation of the diagnosis, careful patient selection with regard to control and comorbidities, rigorous drug prescribing, and close monitoring of subjects, all of which result in higher drug use than typically seen in clinical practice. Meta-analyses of efficacy trials have clearly confirmed the superiority of low dose inhaled corticosteroids over leukotriene receptor antagonists (LTRAs) given as monotherapy and of long acting β2 agonists over LTRAs as adjuncts to inhaled corticosteroids.[4 5] Consequently, in most national and international guidelines, LTRAs are the second choice for use as monotherapy or as adjunctive treatment.[6-9]

Until recently, however, it was not known whether in real life practice the effectiveness of LTRAs as monotherapy or add-on treatment to inhaled corticosteroids reflected results derived from efficacy trials. Two recently published pragmatic trials tackled this question by recruiting adults from primary care practices[9]; the diagnosis of asthma was made by a doctor without the usual spirometric requirement to document obstruction, reversibility, or airway hyper-reactivity. In both trials, slight impairment in asthma related quality of life or asthma control was all that was required for eligibility. Patients were randomised to LTRAs or inhaled corticosteroids in the monotherapy trial or to LTRAs versus long acting β2 agonists as adjuncts in the adjunctive treatment trial. The drugs were prescribed in an open label fashion, with doctors being able to add, switch, or stop treatment as indicated and patients claiming them at pharmacies as needed. More patients in the LTRA groups were prescribed a change in drug class or step-up treatment over the two years of the trials than their counterparts (31% *v* 21% in the monotherapy group and 25% *v* 0% in the adjunctive treatment group), suggesting that the response to LTRAs was suboptimal. Patients were clearly more adherent to LTRAs than to long acting β2 agonists as adjunctive treatment. The high retention rate (>90%) of both trials surpassed those of traditional efficacy studies. Of note, contrary to efficacy trials, no significant difference between the groups was found in quality of life, symptom scores, or exacerbations that required oral corticosteroids.

How can there be such discordance between efficacy and effectiveness studies? Specific features of pragmatic trials reflect important real life practice issues; in this case ascertainment of diagnosis, level of control, physician prescribing, and patient adherence may have all played an important role in the findings.

In these effectiveness trials, simple widely applicable inclusion criteria and minimal exclusions meant that a wide spectrum of patients was enrolled. Although this approach reflects usual practice, it is also subject to substantial diagnostic error, as highlighted by a Canadian study, where a third of adults treated for asthma did not have asthma.[10] Enrolled patients had mild obstruction and relatively good asthma control, which may have decreased the advantage of inhaled cortico steroids over LTRAs and of long acting β2 agonists over LTRAs, because of the minimal amount of residual airway inflammation to overcome. The quality of prescribing may have contributed because doctors tend to prescribe insufficient numbers of renewals of inhaled corticosteroids compared with LTRAs.[11 12] Importantly, in line with other studies,[12] a differential rate of drug claims favoured LTRAs over inhaled corticosteroids (65% *v* 41%) and LTRAs over β2 agonists (74% *v* 46%). These findings raise an interesting question: in this context, is it better to prescribe a more potent treatment that may not be used well or often enough, or to prescribe a less effective treatment that is associated with higher use?

The open label design, variability in patients' adherence, and doctors' heterogeneity in prescription style that permitted treatment modifications maximised external validity, but at the cost of internal validity. The additional "noise" caused by these design problems decreased any real treatment effect towards the null hypothesis, when analysed by intention to treat. Therefore, before equating "non-significance" to "equivalence" these trials must be analysed per protocol—that

is, by restricting the analysis to doctors and patients who used the drugs as allocated by randomisation and censoring data at discontinuation, switch, or add-on of treatment. In these trials, statistical equivalence was not met in any of the per protocol analyses. In addition, the mild impairment of enrolled patients decreased the possibility of finding important group differences, resulting in a ceiling effect. The group comparisons of exacerbation rates in the monotherapy trial lacked power as demonstrated by the large confidence interval. Obviously, a per protocol analysis cannot compensate for problems in design—such as open label design, ceiling effect, or lack of power—that might introduce bias and reduce apparent group difference.

What should we prescribe now? Clearly, efficacy and pragmatic trials contribute different and complementary information to decision making and should be considered when making guideline recommendations. At this point, there is evidence, but not proof, that the difference in the clinical effect of opting for LTRAs versus inhaled corticosteroids as monotherapy or LTRAs versus long acting β2 agonists as adjunctive treatment is much smaller in general practice than in efficacy trials, particularly when treatment can be changed if control is unsatisfactory. Currently, there is no clear insight as to which link(s) in the sequence of events impaired efficacy in these trials, but many factors are likely to be involved, and the question needs to be explored further. However, these highly effective drugs should not be given up; instead the corrections needed to maximise their benefit should be identified and implemented. Moreover, it cannot be presumed that the same findings would apply in a specialty clinic or in children; a pragmatic trial in these settings, designed to minimise bias, that carefully documents doctors' prescription patterns and patients' adherence would provide important information. Yet, the lesson is learnt: it is timely to invest in pragmatic trials of proven effective treatments and take their findings into consideration when issuing guideline recommendations for the treatment of asthma. In mildly symptomatic patients seen in general practice, LTRAs as monotherapy or adjunctive treatment might not be such a bad second choice after all.

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Plain packaging for tobacco products

Minimising the emotional attachment to a cigarette brand could help smokers quit

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Australia going for plain cigarette packaging
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On 7 April 2011, the minister for health and ageing, Nicola Roxon, introduced legislation into the Australian parliament to mandate plain packaging for all tobacco products in Australia. Australia is the first jurisdiction to introduce such legislation, and—in keeping with previous initiatives—the programme will be evaluated prospectively to assess the contribution it makes to the community's smoking rates.

Smoking rates in Australia have declined over the past three decades as a result of progressively stronger tobacco control measures (box) and a concomitant change in behavioural norms. For example, today only 5% of non-smokers are exposed to smoking inside their homes.[1] Adult daily smoking rates in Australia in 2010 were 15% compared with 24% in 1991. However, Aboriginal and Torres Strait Islander people are twice as likely to smoke as non-indigenous Australians. People living in remote or very remote areas are almost twice as likely to smoke as those in major cities, and those in the most disadvantaged fifth of the population are more than twice as likely to smoke as those in the least disadvantaged fifth.[1] Other population groups who are more likely to smoke include those from culturally and linguistically diverse backgrounds, prisoners, people with mental health problems, and those with a history of substance misuse.[2 3] Smoking related morbidity and mortality still correlate with social disadvantage, and this contributes to disparities in health outcomes.

Before plain packaging, several initiatives were brought into force (box). Of these initiatives, increased prices through taxation or excise have had the most effect on people with the greatest socioeconomic disadvantage.[5 6]

There are three key groups to consider when trying to reduce the impact of tobacco: current smokers, former smokers (who want to remain non-smokers), and non-smokers at high risk of taking up smoking. Plain packaging will enhance existing tobacco control policies and programmes by further reducing the appeal of tobacco products to smokers and increasing the effectiveness of pictorial health warnings, especially in young people.[7]

Health, fitness, and cost remain the primary reasons cited by Australian smokers for wanting to quit.[1] In New South Wales two out of three current smokers have indicated they would like to give up in the next six months.[8] Cigarette packs are an important marketing vehicle because they connect personal characteristics, social identity, and aspirations to tobacco brands.[9] Tobacco advertising and promotions influence the

PREVIOUS INITIATIVES TO PREVENT SMOKING

- Ban on advertising (1973; television and radio) and phasing out of tobacco sporting sponsorship (from 1988)
- Introduction of written (1973) and pictorial health warnings (2006)
- Excise increases above the rate of inflation, which have resulted in an estimated 3-6% reduction in demand for tobacco for every 10% price increase[4]
- Public education campaigns (from the 1980s)
- Increase in the numbers of smoke-free environments (indoor and outdoor), smoke-free public transport (from mid-1970s), and ban on smoking in cars carrying anyone under 16 years of age (from 2007)
- Enforcement of the prohibition of sales to minors (from 1990s)
- Removal of tobacco products from sight in retail outlets (from 2010)
- Introduction of subsidised nicotine replacement treatment for all smokers (2011)

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- Plain packaging for tobacco products (*BMJ* 2011;343:d5693)
- From brand to bland—the demise of cigarette packaging (*BMJ* 2011;343:d4376)
- The cancer emperor's new clothes: Australia's historic legislation for plain tobacco packaging (*BMJ* 2010;340:c2436)

uptake of smoking among young people.[10 11] Anything that can be done to minimise the emotional attachment to a cigarette brand could help smokers to quit their addictive habit.

Article 13 of the Framework Convention on Tobacco Control states that countries should "undertake a comprehensive ban of all tobacco advertising, promotion and sponsorship."[2 12] Given the money spent on creating brands to promote one cigarette over another, this must include cigarette packaging. Branding is a form of advertising covered under this convention.

The world will watch to see if this legislation is enacted, and to see the magnitude of its effect on smoking related cognition and behaviours in consumers. The end goal must be in sight at all times—to reduce the burdens of smoking on the community so that rates of cancer, chronic obstructive pulmonary disease, and ischaemic heart disease can continue to be reduced. The 50% chance that smoking contributes to premature mortality from at least one of these diseases has not changed for smokers; it is just that fewer people are now exposed to that risk.

Lower rates of smoking can be achieved by using a range of interventions and support to help current smokers to quit and stay quit such as price increases to discourage youth from smoking,[13] and to ensure that any attraction for non-smokers to start is systematically minimised.

Legal challenges to plain packaging have already been voiced. The opposition to the legislation may come as strongly from other commercial sectors in retail and marketing, which are worried about the value attributed to their brands, as from the tobacco industry itself. An unlikely coalition of dissenting voices may be born as a result.

Ultimately, the successful reduction of smoking across the community will rely on people making informed decisions before they start smoking alongside mechanisms that actively encourage smokers to quit. Prohibition will not work, but changing cultural and behavioural norms to smoking by changing its acceptability has achieved outcomes that were thought impossible even 20 years ago. Plain packaging is another logical step in reducing the appeal of tobacco.

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Teaching trainees about management and leadership

New frameworks help, but old obstacles hamper progress

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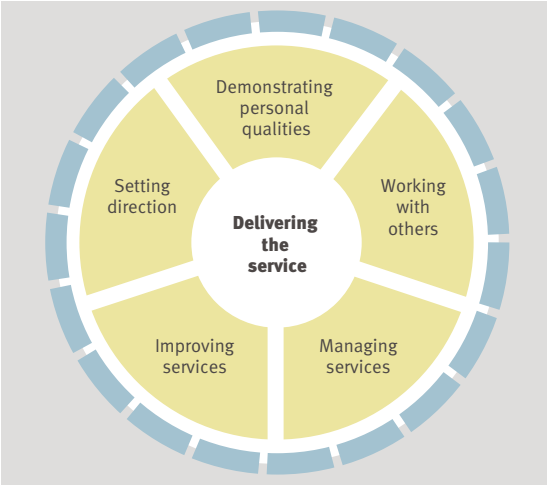
Various trends demand ever greater involvement of doctors in management roles. Several factors have changed the ways in which health professionals are monitored, paid, and regulated. These include the expansion and systemisation of medical knowledge, constrained health service budgets, informed users, and changing attitudes towards the professions. Doctors everywhere must be prepared to engage in the continual transformation of the services they provide throughout their career. However, medical training has traditionally emphasised clinical autonomy in decision making and allegiance to professional rather than organisational values. The need to strengthen the training of students and young doctors in management and leadership is therefore widely accepted. The General Medical Council and the royal colleges now emphasise the importance of management related training goals.[1] What should be taught and learnt, and how?

"Clinical leadership" takes many forms. Some lead through local innovation; others lead through their professional bodies or through managerial involvement at various levels in the NHS. Successful medical managers are usually experienced clinicians with good "people skills." They are also strategic thinkers and visionaries who look beyond the boundaries of their own specialty; they exhibit passion and are prepared to take reasonable risks to achieve their goals. Most importantly, they know how to engage colleagues and effect change.[2]

Formal training is not always a prerequisite, but the idea that all doctors can just "manage" is hopelessly naive. It is one reason why, for example, previous iterations of primary care based commissioning have delivered less than their proponents anticipated.[3] The notion of clinical leadership can seem presumptuous, even patronising, to the health service managers who spend many years in training programmes



Five domains of the Medical Leadership Competency Framework

learning the technical tools of their profession. They know what we seldom acknowledge—that many doctors, without preparation, do not make natural managers.

The absence of an agreed curriculum presents a major challenge. Most doctors in management learn by experience. Their training in this field is usually piecemeal, delivered on the job, by a plethora of different organisations in short courses. The Medical Leadership Competency Framework, developed jointly by the Academy of Medical Royal Colleges and the NHS Institute for Innovation and Improvement, is therefore a worthy attempt at describing the territory. The framework describes the competencies doctors need to become more actively involved in the planning and delivery of health services. It comprises five domains (figure), each of which is subdivided into four competencies.[4]

The framework is built on the concept of "shared leadership." In most NHS organisations responsibility for the success of services is shared by many members of staff. Leadership is not restricted to those in designated roles. Sharing power requires trust and collaboration between doctors and managers. Collective leadership has been shown to assist successful implementation of, for example, new care pathways,[5] but it may not easily align with the individualistic culture of medicine.

The framework appears atheoretical, which points to a more fundamental problem. Much management lore is construed by medical scientists as inadequately evidence based. Doctors are concrete thinkers trained to think linearly, for whom traditional models of leadership and management, using military and industrial metaphors, make sense. Unfortunately, although the specification of work routines (for example, through evidence based guidelines and standard operating procedures) may be appropriate for dealing with regular processes with clear products, many healthcare outcomes are uncertain.[6] They depend to a large extent on the commitment of health professionals and service users with their individual perspectives, experiences, and motivations. More diffuse (distributed) models of leadership and management in healthcare may be appropriate. Unfortunately, much post-modern management theory is opaque, if not incomprehensible.

Various medical management courses and curriculums have been developed for postgraduates in several countries.[7] The Medical Leadership Competency Framework is unusual in trying to integrate development over the course of a professional career. It helpfully suggests what individuals will require at different stages of training. All doctors need to understand early on in their career the sciences of quality improvement. A finer appreciation of policy, change management, or business and financial planning may be useful in the different roles that doctors play later on in their careers. However, further research is needed to examine the behaviour of clinical leaders in practice and their training requirements.[8]

The current NHS reforms promise to return power to the front line (wherever that is),[9] but they are bound to strain working relationships between doctors and managers. The lives of NHS managers are hard and getting harder, as the decision to cut their numbers by 45% underlined. Current confusion over basic NHS structures, future roles and job prospects, and the impact of consultants from the private sector are just some of the uncertainties undermining their position as dependable role models. More opportunities for closer interdisciplinary training and working (such as "buddying" arrangements) are needed but may be harder to realise. This is potentially damaging in a period of such organisational turbulence.

Giving new managerial responsibilities to doctors therefore places new responsibilities on all undergraduate and postgraduate medical training institutions. We need greater clarity about curricular content and evaluative educational research on how and when to provide it.[10] Evidence shows that employing clinically qualified staff in hospital management yields better outcomes,[11] yet little is known about how and why this is the case.

We need more opportunities to share experience and learning with other disciplines, other sectors, and other countries. The proposed national Leadership Academy to accredit development programmes, support their delivery and evaluation, and investigate the effects of investment in this area makes sense.[12] The grooming of clinical leaders needs to be more clearly structured, grounded in evidence, and properly managed.

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