Management of blood pressure in primary care

New evidence raises questions about current practice

RESEARCH, pp 1245, 1260

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Two studies provide new insights into the monitoring and control of blood pressure.[1 2] In recent years, emphasis has shifted away from treating hypertension as a separate entity towards treating it in the context of the risk of cardiovascular disease.[3] This shift has informed randomised controlled trials, such as the PROGRESS trial, which have looked for (and found) benefits of treating people at high risk (in this case, those with a previous stroke or transient ischaemic attack) with blood pressure lowering agents regardless of their blood pressure.[4] It has also influenced guidelines that have recommended lower blood pressure treatment targets for people at higher risk of cardiovascular events.[5 6] Within this new paradigm, we continue to titrate the use of antihypertensive drugs against blood pressure measurements. The two studies both provide data to challenge this orthodoxy.

Hypertension is perhaps the most common form of chronic disease managed in primary care and routine review is costly. Follow-up is recommended every six to 12 months for people with controlled blood pressure, and in the United Kingdom pay for performance remuneration requires that blood pressure has been measured within the past nine months.[5-7] Actual attendance seems to be even more frequent, however—a recent study found that patients receiving usual care for hypertension saw their general practitioner for such care more than four times in a year.[8]

Keenan and colleagues' findings suggest that much of this activity is misguided. They used data from patients in the active, two drug, treatment arm of the PROGRESS study to evaluate variability in blood pressure from three months after the patients started treatment.[1] Over the next 33 months they estimated long term and short term variability with the aim of differentiating true changes in blood pressure over time from random variation and measurement "noise." They found that, if someone had a blood pressure of 130 mm Hg at baseline, there was only about a 1% chance that a subsequent blood pressure reading three months later of 140 mm Hg or above was a "true" increase. This figure rose with time, but even after 21 months there was only a 50% chance that such an increase was real.

These data suggest that we need to rethink how we monitor the control of blood pressure. We could use techniques that reduce the effect of the inherent variability of blood pressure and increase the chance that an observed increase in blood pressure is a true one. For example, self monitoring allows multiple measurements to be taken over several days.[9] Recent European guidelines have described self monitoring schedules, but the evidence base to support these schedules or self monitored treatment targets is not strong.[10] Intermittent use of self monitoring would require careful education of patients and doctors, but modern automated sphygmomanometers are simple enough to require minimal instruction. Ambulatory monitoring could be an alternative for those unable to self monitor, but it is expensive and not widely available in primary care. Alternatively, less frequent monitoring may be more appropriate and cost effective. Adverse effects of treatment rather than blood pressure control would then be the main driver of the frequency of monitoring.

Law and colleagues conducted a wide ranging meta-analysis of trials of blood pressure lowering, and their findings will contribute to debate on the management of hypertension in several areas.[2] For example, in contrast to other reviews, the authors conclude that β blockers are as effective as other blood pressure lowering agents.[5 11] Their finding that antihypertensive drugs have no major effects on cardiovascular risk independent of their effect on blood pressure concurs with previous analyses.[12] They also found that the effect of lowering blood pressure on risk of cardiovascular disease was independent of the pretreatment blood pressure; this reinforces the view that treatment to lower blood pressure should be offered on the basis of risk, regardless of blood pressure.[3]

Perhaps the most controversial aspect of their analysis is their comparison of combination blood pressure therapy at half standard doses with combination therapy at standard dose. For example, they conclude that patients with a systolic blood pressure of 150 mm Hg would achieve a 20 mm Hg drop in pressure if they took three drugs at half standard dose, or a 16 mm Hg drop if they took two drugs at standard dose. No trials have tested combinations of three drugs at half standard dose, and their analysis assumes that the effects are additive. Taken at face value, these findings provide tacit support for the use of a "polypill" to lower the risk of cardiovascular disease in people likely to be at high risk (such as all people over the age of 55) without first checking their blood pressure.[13]

If antihypertensives differ little in their efficacy, then acceptability becomes a key driver for treatment choice, along with the presence of comorbidities, such as diabetes or benign prostatic hypertrophy. Law and colleagues argue that reduced dose combination therapy is likely to reduce dose related side effects, and that patient specific factors such as comorbidity are generally of minor importance in determining antihypertensive therapy—a view that runs counter to current guidelines.[5-7]

Taken together, these two studies may herald a new era of blood pressure management. The place of the sphygmomanometer in the doctor's office for monitoring blood pressure lowering treatment no longer seems secure—it may perhaps be replaced by intermittent but infrequent blood pressure measurement at home supplemented by periodic enquiry about side effects as treatment choices become determined by tolerability rather than algorithm.

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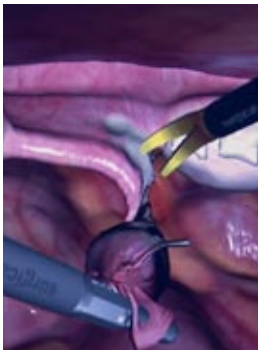
Surgical training using simulation

Early evidence is promising, but integration with existing systems is key



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Surgery was traditionally learnt by repeated practice on patients. Trainee surgeons were exposed to innumerable operative cases over many years, with supervision tailored to their needs. This provided experience in coping with a wide range of operative approaches and complications, and it balanced trainees' levels of experience with the demands of the procedure.

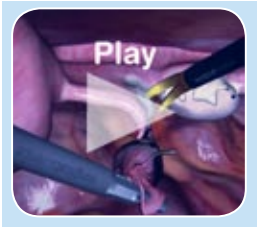
This process has changed radically in recent years. Minimally invasive surgical techniques have led to fast track and ambulatory surgery; service targets and reductions in working time have reduced training opportunities for young doctors; and strong ethical imperatives have made it unacceptable for novices to learn "on patients."[1] Traditional approaches are therefore no longer tenable. How then should surgeons learn their craft? In the linked randomised controlled trial, Larsen and colleagues assess the effect of virtual reality training on surgical performance in laparoscopic surgery.[2]

Simulation offers obvious benefits, especially in mastering counterintuitive techniques such as minimal access surgery. Sophisticated virtual reality simulators can provide anatomically realistic re-creations of many operations, with inbuilt metrics that enable technical performance to be recorded, measured, and used for feedback. Practice on such simulators, to a predefined level of proficiency, enables inexperienced trainees to acquire skills in a structured, educationally oriented manner without risk of harming patients.

Although simulation based training has been explored within the craft specialties since the 1970s, high quality evidence to support its widespread adoption within the curriculum is lacking.[3] A key question is whether skills learnt on a simulator translate to improved performance on patients.

It is here that Larsen and colleagues make an important contribution to our understanding.[2] In their trial of junior gynaecology registrars, an intervention group (with no clinical experience of advanced laparoscopy) was trained to proficiency on a virtual reality simulator. When the registrars performed their first laparoscopic salpingectomy on a patient (under senior supervision), the virtual reality trained group performed to the level of intermediately experienced laparoscopists (20-50 patient cases), whereas the control group performed at the novice level (less than five cases) and took twice as long to complete the procedure. The inexperienced surgeons needed to perform 28 simulated salpingectomies to attain the same level of proficiency as those in the virtual reality training group, who were given seven hours of dedicated training outside the service setting.

If simulation based practice can accelerate progress along the learning curve, it has obvious educational benefits.[4,5] But caution is needed when interpreting the results of this study. Firstly, the study investigated manipulative surgical skills. Although these are essential, they are only a part of a wider set of skills that are fundamental to safe practice, such as communication, decision making, judgment, and leadership.[6] Simulation based training that takes place outside the clinical setting risks isolating the trainee from the rest of the team and creating a misleading oversimplification of a complex reality.[7] Secondly, Larsen and colleagues studied routine salpingectomy in selected patients who had no complications. But a major challenge of surgery is being able to cope with the unexpected. Would simulator trained surgeons be able to deal with scenarios such as distorted anatomy, unexpected bleeding, missing equipment, a dysfunctional team, or the pressures of operating in the middle of the night? Thirdly, this study is limited to one procedure in one specialty, so



Follow trainee surgeon Sofie Leisby through laparascopic surgery—from practising in VR to a real life procedure—in a video to accompany this study on bmj.com.

generalising the results to other procedures and specialties is unwise. And lastly, recently acquired skills deteriorate rapidly unless consolidated through repeated practice, so snapshot studies can provide only a partial picture.

The strength of simulation is as an adjunct rather than an alternative to clinical experience. Several current developments will probably increase its potential. These include putting virtual reality and benchtop models into clinical context by using actors to create human simulator hybrids in a clinical setting,[8] using simulation for "warming up" before a procedure, and programming the patient's own imaging data into simulation software so that rehearsal is patient specific. Other suggested applications include using simulation to give surgeons experience of particular procedures before they perform them clinically, and using objective measurements within a standardised case. This principle could extend to regular revalidation of surgeons and surgical teams, and perhaps even to selection into surgical training. Before we embrace such high stakes applications, however, many questions need to be answered.[9]

A key challenge is to integrate simulation within existing curricular structures to ensure that practice takes place within a robust educational framework.[10] Simulation is costly in terms of equipment and teaching facilities. Although simulation centres can recreate operating theatres, delivery suites, endoscopy units, and interventional units, it is not feasible to provide a full range of settings in every medical centre. The establishment of simulation centres at key sites can enable trainees to participate in regular practice sessions which align with and reinforce their clinical training.

Simulation should be viewed as a parallel universe which mirrors and augments actual practice; it should place the learner at the centre of the process while ensuring patients do not experience avoidable harm. Mapping the dynamic association between the virtual reality centre, the simulated operating suite, and the real environment should become a priority for researchers and healthcare professionals.

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Folic acid fortification and congenital heart disease

More effective interventions are needed to target women of child bearing age

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In the linked study, Ionescu-Ittu and colleagues investigate whether the 1998 government policy for mandatory fortification of flour and pasta products with folate reduced the prevalence of severe congenital heart disease at birth in Quebec, Canada.[1] In 1997 the Teratology Society recommended folic acid supplementation to reduce the risk of neural tube defects through the fortification of staple foods. The aim was to ensure that 95% of women of child bearing age received 0.4 mg folic acid daily, with an additional 0.4 mg for those planning a pregnancy.[2] Although the potential role of folic acid in the prevention of neural tube defects was reported as early as 1980, public health campaigns resulted in preconception supplementation in only a third of pregnant women.[3]

The fortification policy was influenced by a Hungarian trial that reported a 90% reduction in primary neural tube defects in pregnancies supplemented by periconceptional multivitamins containing 0.8 mg folic acid.[4] Canada initiated mandatory food fortification in 1998, and fortification of wheat flour is currently practised in 67 countries (47 in response to national mandates or regional requirements), but it has not been adopted in Europe.[5] Folate is an important cofactor in homocysteine metabolism, and supplementation may reduce congenital malformations, including congenital heart disease, stroke, and coronary heart disease. Folate antagonists may increase congenital heart disease, particularly ventricular septal defect and conotruncal malformations.[6] Because congenital heart disease accounts for a third of infant deaths from malformations in industrialised countries and treatment is costly, complex, and unavailable to many children, primary prevention is vital.[7]

Ionescu-Ittu and colleagues assessed the effect of fortification with folic acid food on the prevalence of severe congenital heart disease in 1.3 million births between 1990 and 2005. They identified 2038 cases and compared changes in birth prevalence before and after fortification. Although they found no changes during the nine years before fortification, they found a 6% drop in the following seven years and concluded that mandatory fortification reduces severe congenital heart disease.[1]

Such studies raise important questions about whether food fortification is an effective strategy, and what its effect might be. Firstly, are the current levels of fortification sufficient to significantly reduce the rates of congenital malformations? In one Canadian study, only 14% of women of child bearing age had folate concentrations that protect against neural tube defects after food fortification alone.[8] Recommendations have therefore called for

increased fortification and additional supplementation with periconceptual folic acid and vitamins.[9]

Secondly, does fortification reduce the prevalence of severe congenital heart disease? Ionescu-Ittu and colleagues recorded cases from the physicians' claims database and Quebec death registry when severe congenital heart disease was documented as the main cause of death. An important factor is the antenatal detection rate for congenital heart disease during this period. Any change in live birth prevalence of a malformation must take into account changes in the detection rate at screening and rates of termination of pregnancy. Both these rates are high for neural tube defects in most European countries, which results in a low live birth prevalence of 11-14%.[10] In contrast, antenatal detection of congenital heart disease is low (about 30%), and termination of pregnancy rates have fallen for all but the most severe forms of disease. Unpublished data from St Justine Hospital's cardiac unit, which serves half of the Quebec population, show a 5% increase (from 20% to 25%) in the antenatal diagnosis of severe congenital heart disease between the pre-fortification and post-fortification periods. Termination of pregnancy for congenital heart disease remained stable at about 40%, so antenatal diagnosis could account for a 2% reduction in birth prevalence after fortification and reduce the effect of food fortification to 2.6-4%.

Population based studies have shown a year by year variation in congenital heart disease.[11] This, and the heterogeneity of congenital heart disease, make it difficult to ascribe causality and assess a potential gene-environment interaction—for example, the effects of no folate supplementation in families with single polymorphic mutations at nucleotide 677 of the *MTHFR* gene.[12]

Thirdly, is food fortification harmful to some people? Few European countries have implemented fortification and have cited unknown health risks and freedom of choice as the reasons for this decision. Although cognitive function is improved by lowering homocysteine concentrations, as long as vitamin B12 status is normal, this must be monitored in vulnerable groups, such as elderly people. Folate may play a dual role in cancer; low doses seem protective, but time trend analyses in countries with food fortification have shown an increased risk of colorectal and breast cancer, particularly in those receiving a higher dose of 1 mg/day. Firm evidence of its effects on cardiovascular diseases is awaited. It may also have adverse effects in the unborn baby. Theoretically the epigenetic regulation of DNA through methylation may be influenced by folate and vitamin B12 availability and hence may affect the expression of oncogenes or tumour suppressor genes in offspring supplemented in utero. However, research confirming this has not yet been published.

Mandatory food fortification has reduced the prevalence of neural tube defects by about 9%, and Ionescu-Ittu and colleagues describe modest reductions in congenital heart disease.[1 5] Substantial reductions in malformations have been reported only from additional periconceptual supplementation.[4]

As the population becomes more obese, rates of type 2 diabetes increase and nutritional habits remain poor, and the prevalence of congenital heart disease may increase. So, rather than considering fortification targeted at populations, should we find more effective interventions to target women of child bearing age?

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Children's health and the financial crisis

Children's services should not be an easy target for saving money

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In 2007, a Unicef report ranked the United Kingdom bottom of 21 developed countries in measures of child wellbeing.[1] The Children's Commissioner for England said that this had resulted in "a generation of young people who are unhappy, unhealthy, engaging in risky behaviour." Three further reports this year suggest that the care of British children is still falling short.[2-4]

The Good Childhood Inquiry, published in February 2009 by the Children's Society, received evidence from 30 000 children, adults, and professionals.[2] It concluded that British children are unhappy, largely because of parental behaviour, especially mothers going to work.

Children might be unhappy but are they healthy? A week later, the Department of Health and Department for Children, Schools, and Families launched Healthy Lives, Brighter Futures, the long delayed child health strategy for England.[5] A government child health strategy should be a big event and something to celebrate. Healthy lives,

Brighter futures claimed that children and young people growing up in England are healthier than ever.

The infant mortality rate is a quarter of what it was in 1960. Pneumococcal vaccine averted 470 cases and 28 deaths in its first 18 months. Vaccination against cervical cancer will save 400 lives a year, and some of the women saved will be under 30. Over the past quarter of a century, *Haemophilus inflenza* meningitis has been eradicated, "cot death" incidence has been halved, and survival from leukaemia has increased dramatically. Between 2000 and 2006 the number of consultant paediatricians increased from 1605 to 2232.

Children might be both unhappier and healthier, but many questions about the evidence need answering. Might the Unicef league table be flawed, as France came 16th, Austria 18th, and the United States 20th?[1] Do all 21 countries collect data as assiduously as the UK? Is a very preterm baby who survives for a few gasps counted as a live birth in the UK but not in other countries? The use of relative rather than absolute poverty indices by Unicef indicated that Hungary has fewer "poor" children than the US, although the average family income is three times higher in the US. For one of the six indicators (death rate from accidents), the UK has the second lowest rate—perhaps the UK would have fared better if alternative measures to the five other arbitrary indicators had been used?

The research from the Children's Society also has problems.[2] Firstly, nature versus nurture. If loving, firm parents have children with better "outcomes" (the inquiry's phrase), it may not be the result of this "authoritative" parenting style. It may just be that sensible, mature parents are more likely to have sensible, mature children. Secondly, reverse causality. It is probably easier to be authoritative when interacting with a cooperative child. The inquiry assumes that the successful child is produced by the parenting style. It may be the reverse. In contrast to the Good Childhood Inquiry, the 2006 British Household Panel Survey found that only 0.8% of 11-15 year olds described themselves as being completely unhappy and 4.2% were somewhat unhappy.[6]

But we should not be complacent. Apart from the welcome £340m (€380m; $500m) for children with chronic disorders, Healthy Lives, Brighter Futures offered no new resources. The strategy emphasised child health promotion and recommended managed networks (for example, for paediatric surgery and for safeguarding, which includes protecting children from abuse) but was not explicit about how these would be funded.

In March 2009, Lord Laming set out the progress made in improving the protection of children in England since the failures revealed by the death of Victoria Climbié.[3 7 8] The Laming review commented on the need for political leadership and particularly noted that training and workforce problems need to be resolved to support the use of the Working Together to Safeguard Children guidance.[9]

Staff in accident and emergency departments should be able to tell if a child has recently presented at any such department or is the subject of a child protection plan. Previously, children's medical notes could be "flagged" to indicate if they frequently attended with unusual "accidents." This was abandoned for fear of labelling a child and the implication that the parents might be assumed guilty until proved innocent.

The day after the Laming review, as if to reinforce its concerns, a Healthcare Commission report on hospital standards for children highlighted the inadequacies in training, including recognising and managing suspected child abuse. [4] The report assessed progress on children's services by 154 NHS acute trusts since 2005-6; the proportion of trusts classified as "deteriorated" or "consistently low performing" for basic training in child protection, paediatric life support, and managing children's pain was 29%, 41%, and 74%, respectively.

The report emphasised that all those involved in the care of children must be appropriately trained. When summarising the effect of the Healthcare Commission, its outgoing head, Ian Kennedy, said "following the collapse of banking, people in the sector that used to shout loudest about regulatory burdens feel more warmly towards regulation."[10]

In the public sector, performance indicators can have a role but do not serve children well if the priority targets do not include children, if case loads to meet targets overwhelm training and professionalism, and if the targets are not backed up by extra resources.

Over the past five years, the Healthcare Commission has not seen the improvements that Kennedy hoped "for those least able to look after themselves, who have historically been forgotten."[10] But what will make the next five years different? What is going to make all the new recommendations in these four recent publications happen? Other than the £340m for children with disabilities and chronic disorders, are these just fine words?

Words raise awareness, but people and resources help children. The UK is in a very tight financial squeeze, and the public sector deficit has increased. An election is looming and children have no votes—children's services should not be an easy target to save money. A child's school report would say of the government's performance, "On the right track but must try harder."

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Safeguarding NHS standards

Professional responsibility matters more than conforming to process

REX

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The inquiry of the Healthcare Commission into the failure of the Mid Staffordshire NHS Foundation Trust to provide adequate care for its patients continues to reverberate through the NHS.[1] Its publication in March has been followed by a succession of other reports, policy statements, and promises by regulators to do better in future. And rightly so, since the case suggests a wider systems failure.

None of the bodies who might have been expected to sound the alarm about poor standards of care come out of the affair with their reputation intact. Once satisfied about the trust's financial affairs, Monitor, the independent regulator of NHS foundation trusts, happily accorded foundation trust status to Mid Staffordshire at the beginning of 2008, relying on the Healthcare Commission's 2007 rating of the hospital as "good-fair." The Healthcare Commission launched its investigation into mortality rates at the trust in March 2008, but ignored earlier hints provided by staff and patient surveys that all might not be well and relied on the trust's own self assessment when making its 2007 judgment. The Strategic Health Authority and the relevant primary care trust did not, seemingly, raise as much as an eyebrow. Neither did those specifically charged with representing patient interests: the Public and Patient Involvement Forum and the elected foundation trust governors seem to have been remarkably passive. So was the local government scrutiny committee.

What are the lessons to be learnt? The first is that, as in the case of banking, the insistence on light touch regulation may have been overdone. In reaction to criticism of its predecessor, the Commission for Health Improvement,[2] the Healthcare Commission relied heavily on self assessment by trusts with only selective inspections. But, as the Audit Commission has pointed out, "Mid-Staffordshire [Foundation Trust] certified that it was compliant with all core standards except that relating to waste disposal, but it subsequently became clear that it was far from providing safe, high quality care."[3] So the challenge to the Healthcare Commission's successor, the Care Quality Commission, is to devise a system that is more sensitive to alarm signals that should trigger inspections: in the cacophony of available data and indicators, which should command instant attention? The need is not for more information—heaven forbid—but for a more precise focus on the information that really matters.

The challenge to Monitor is rather different. For Monitor to duplicate the Care Commission's role in monitoring quality would clearly be absurd, though it should recognise that its one eyed concentration on financial viability may have perverse effects: many of Mid Staffordshire's problems, such as inadequate staffing numbers, stemmed from the trust's preoccupation with meeting Monitor's financial requirements for foundation trust status. But Monitor should be concerned about why elected governors are not playing a more assertive role: its new consultative document on their role is a timid exercise in setting out the legal requirements, without asking why there might be a gap between expectations and reality.[4]

There are also lessons for the Department of Health, informed by a report from David Colin-Thomé, national director of primary care, that analyses the background to the Mid Staffordshire case.[5] The department's policy response is, predictably, a mixture of the sensible, the already-in-the-pipeline, and the rhetorical.[6] Thus the quality requirements for aspiring foundation trusts are to be tightened, NHS trusts will be required to publish quality accounts, and co-operation between the various regulatory bodies is to be tightened up. Most innovatively, and most questionably perhaps, NHS organisations will be required to publish a new annual statement of involvement to show how they are implementing the legal duty to involve patients and the public. In view of the evidence of passivity and ineffectiveness in the Mid Staffordshire case, involving public and patient opinion hardly seems a realistic policy option for safeguarding standards—however desirable it may be for other reasons.

There is a risk that a preoccupation with process will make the web of NHS regulation and monitoring ever more complex and baroque, and that even more time will be spent on defensive accountability as NHS organisations produce streams of documents designed to show their concern with standards. Yet the Colin-Thomé report sets out what is surely the key point when he writes: "All clinicians must speak up for patients when they witness poor quality care. It is our overarching duty." In other words, taking professional responsibility matters more than conforming to process; but although whistle blowing is protected in theory, it is not encouraged in practice.

The challenge to the NHS is to ensure that while clinical leaders are indeed involved in managerial decisions, they are not inhibited from speaking out if those decisions lead to unacceptable standards of care. Perhaps the proposed quality accounts should include signed statements by all clinical directors, medical and nursing, that they are satisfied with the standards of care being provided—with appropriate qualifications if necessary.

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4 Monitor. Guide for NHS foundation trust governance: meeting your statutory responsibilities. London: Monitor, 2009.
5 Colin-Thomé D. Mid Staffordshire NHS Foundation Trust: a review of lessons learnt from commissioners and performance managers following the Healthcare Commission investigation. London: Department of Health, 2009.
6 Department of Health. Government response to Alberti and Colin-Thomé reports. London: Department of Health, 2009.