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Implementation of the Health and Social Care Act

Dogged by financial pressures, role uncertainty, and gaps in leadership

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The reforms that come into place after implementation of the Health and Social Care Act on 1 April represent the largest set of changes the NHS in England has seen since its formation. The pre-election promise notwithstanding, there have been two huge top down reorganisations—in the NHS and in public health. A vast amount of time and money has been spent on reorganisation and redundancies. Even if the NHS were in a robust financial position this would be a major concern.

The first striking feature is the number of organisations that are new or that have substantially redefined roles. There are 211 clinical commissioning groups (CCGs), 27 area teams, 23 clinical support units, 12 clinical senates, 13 local education and training boards, and 152 health and wellbeing boards. Few of these exactly match any previous jurisdictions and the talk of restructuring further has already begun. The national Commissioning Board (now renamed NHS England), Trust Development Authority, Public Health England, HealthWatch, Health Education England, and academic health science networks are all new. In addition, local authorities will take responsibility for health and wellbeing boards and public health, including sexual health. Monitor and the Care Quality Commission have had their responsibilities redefined, and the Office of Fair Trading and the Competition Commission take on new responsibilities for market regulation.

There is much uncertainty about the relations between these new organisations and the rules of engagement and accountability. Responsibility for commissioning has been fragmented, and in some cases CCGs will be accountable for outcomes that will be commissioned by other bodies. Although this will provide an impetus for more collaborative working, such approaches take time to develop and depend on having the time to build relationships. This will be difficult in the many places that have vacancies: even the NHS Commissioning Board has two director level vacancies.

Although the Department of Health continues to assert that the reforms are the solution to the NHS's problems, it offers little more than assertion and pious hopes

Several areas require large scale change that has been led by regional authorities in the past. Because these no longer exist, either CCGs will quickly need to learn to collaborate or the regional offices of the NHS Commissioning Board will need to expand into this power vacuum and in doing so will reassert traditional hierarchies. In some cases there will be stasis, and change will be driven by providers themselves or by invoking the failure regime—the process used for the first time recently in response to longstanding financial problems in south east London.

The rules of the new system are still being written. For example, guidance on safeguarding children has been issued less than two weeks before the start of the new system. Rules relating to procurement and competition (section 75) remain contentious and confusing, with reassuring messages from government being contradicted by experts just days before they come into effect. Some CCGs are unclear about exactly what resources they have because money and control have been clawed back as the NHS Commissioning Board has redefined its scope, particularly in the area of specialist commissioning (vascular surgery and cancer, for example).

Trusts that have not yet achieved foundation trust status will probably experience pressure to change, merge, or otherwise accelerate their progress. Whether this is possible is doubtful, and mergers are increasingly being questioned by the competition authorities because of their poor record. The act brings new powers for Monitor to use a failure regime, and it already seems to be preparing to spend a large amount of money to bring this to bear on several distressed foundation trusts. This is compounded by the problem of key leadership roles not being filled.

Relatively little attention has been paid to the transfer of public health responsibilities to local government, which will be trying to incorporate these services at a time when it is also under unprecedented pressure. There is concern about whether local authorities will protect the budget, whether posts can be filled, and whether smaller authorities can sustain the infrastructure needed to deliver appropriate public health services.

There are, however, reasons to be positive. It seems that CCGs are bringing a new perspective to their role. Creative and productive conversations are taking place, although there are questions about the level of engagement by general practitioners.[1] Health and wellbeing boards working with CCGs offer the prospect of new and positive approaches.

Even the most charitable would admit that NHS structures are now in an incoherent mess, and that the process that produced this mess was close to disastrous. Even now it is not clear how the reforms will improve the service delivered by the NHS, and the Health Select Committee has found that the pressure to improve efficiencies and reduce costs is cause for profound concern.[2] Although the Department of Health continues to assert that the reforms are the solution to the NHS's problems, it offers little more than assertion and pious hopes. Integration is seen by many as an important part of the solution to many of the challenges facing the NHS, but the new rules on competition and procurement, and the fragmentation of commissioning, work against this.[3] The promise of liberation of the NHS through reduced central control seems to be slipping away. Time that could have been better spent on tackling the serious outstanding challenges is consumed by reorganisation.

The NHS is good at making flawed arrangements work. The question is whether it has been so badly disrupted by the current reforms that it will no longer be able to do this effectively. Was this the intention all along? Strong and visionary leadership is usually the answer to this type of problem, but this time the lack of such leadership is part of the problem.

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Letter: Bacterial meningitis and lumbar puncture (*BMJ* 2013;346:f361)

Taking the sting out of lumbar puncture

Ultrasound guided procedures seem less likely to fail

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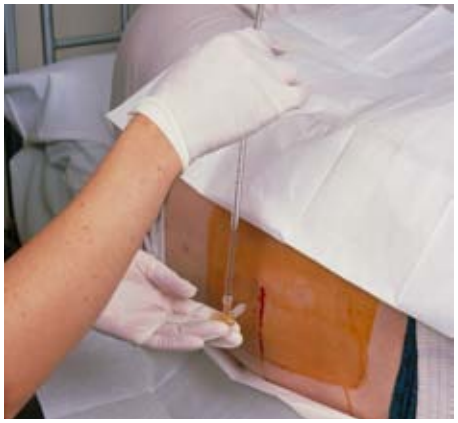
Lumbar puncture remains an important and commonly performed diagnostic procedure,[1] but training for its performance is not standardized.[2] Although most diagnostic lumbar punctures are performed by neurologists, hospitalists, emergency department physicians, and pediatricians, physicians in many different specialties should have some experience with lumbar punctures and may on occasion need to perform one.

A well designed linked systematic review and meta-analysis by Shaikh and colleagues investigates the benefit of using ultrasound guidance when performing lumbar puncture in routine diagnostic and therapeutic settings and in the performance of epidural catheterizations, mainly for giving anesthesia.[3] The meta-analysis looked at 14 randomized studies with results from more than 1300 participants. It found a significant risk reduction for the primary outcome measure of failed procedures for ultrasound guided compared with the traditional anatomic approach to lumbar puncture. Failed procedures were defined conservatively as any failure to achieve the goals intended for the procedure. Epidural catheterizations were judged equivalent to subarachnoid punctures for assessing ultrasound guidance, and studies of either when combined achieved statistical significance. Six of 624 procedures failed in the ultrasound group compared with 44 of 610 in the control group (risk ratio 0.21, 95% confidence interval 0.10 to 0.43). Summary estimates for secondary outcomes of traumatic procedures, needle reinsertions, and needle redirections all supported the primary outcome finding. Time considerations in performance of the procedures could not be assessed owing to variability of reporting in the component studies.

Strengths of this meta-analysis include its comprehensive search for relevant studies and the high quality and low (modest) heterogeneity of the included studies. Methodological limitations involved variability in reporting of outcomes in the included studies. Complete blinding was logistically difficult. Most studies included young women receiving obstetric anesthesia administered by highly experienced practitioners, so generalizability to non-obstetric populations is limited. However, ultrasound guidance for lumbar puncture might offer even more benefits in non-obstetric populations. In these groups, lumbar puncture is more likely to be performed by practitioners with less procedural experience than obstetric anesthetists. The benefits shown may underestimate the potential benefits of a more general application of ultrasound guidance.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Better performance could widen indications

The authors point out that ultrasound guidance is now used at the bedside in the performance of many medical and surgical procedures, so its extension to lumbar puncture seems an inevitable trend towards improving procedural outcomes. Lumbar puncture is probably underused in the investigation of many problems, including chronic headache disorders, where identification of low or high pressure headaches with the measurement of opening pressure (which should almost always be obtained) may strongly affect treatment. Though the baseline failure rate for lumbar puncture was low in the studies even without ultrasound guidance, the same may not be true for less experienced operators. Furthermore, this analysis cannot provide information about lumbar punctures that were indicated but not performed. Because lumbar punctures may be refused by patients out of fear, or deferred by reluctant providers, ultrasound guidance may improve patient acceptance and reduce failure rate in this wider population.

This analysis provides no data on the impact of ultrasound guided lumbar puncture on the common complication of postdural puncture headache. This is a question of great clinical interest that merits further research. Unconfirmed clinical impressions suggest that cleaner less traumatic taps may paradoxically increase the risk of such headaches. This might be due to lower levels of clotting factors in the area of the tap that could help prevent a spinal fluid leak. Though this matter should be investigated in future research, other factors such as needle type may be more important determinants of this complication.

Identification of anatomic landmarks before lumbar puncture does not seem to be as accurate as ultrasound guidance, and it does not provide adequate information about optimal angle of needle insertion or required depth for the procedure. Pre-procedural static ultrasound can help by showing the midline, optimal vertebral level, and target depth. Dynamic ultrasound scanning allows the operator to follow progression of needle insertion. The use of ultrasound guidance does not mean that the performance of lumbar punctures will become the province of specialized clinicians. Ultrasound guided lumbar puncture is not difficult to master and does not greatly increase the time needed to perform the procedure.[4]

The results of this analysis suggest one way to modernize and standardize the performance of lumbar puncture. Further research should investigate potential barriers to its implementation, confirm and quantify benefit, identify appropriate settings and patient populations, and investigate appropriate protocols and possible amendments to practice standards. Taken as a whole, the findings of this meta-analysis are compelling and support further investigation of the routine use of ultrasound to aid the performance of lumbar punctures. Ultrasound guidance shows promise as a way to "take the sting" out of lumbar punctures for patients and clinicians.

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1 Lavi R, Rowe JM, Avivi I. Lumbar puncture: it is time to change the needle. *Eur Neurol* 2010;64:108-13.
2 Williams J, Lye DC, Umapathi T. Diagnostic lumbar puncture: minimizing complications. *Intern Med J* 2008;38:587-91.
3 Shaikh F, Brzezinski J, Alexander S, Arzola C, Carvalho JCA, Beyene J, et al. Ultrasound imaging for lumbar punctures and epidural catheterisations: systematic review and meta-analysis. *BMJ* 2013;346:f1720.
4 Nomura, JT, Leech SJ, Shenbagamurthi S, Sierzenski PR, O'Connor RE, Bollinger M, et al. A randomized controlled trial of ultrasound-assisted lumbar puncture. *J Ultrasound Med* 2007;26:1341-8.

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- Research: Effect of weekly vitamin D supplements on mortality, morbidity, and growth of low birthweight term infants in India up to age 6 months (*BMJ* 2011;342:d2975)
- Research: Calcium supplements with or without vitamin D and risk of cardiovascular events (*BMJ* 2013;342:d2040)
- Research: Effects of vitamin D supplementation on bone density in healthy children (*BMJ* 2011;342:c7254)

Vitamin D sufficiency in pregnancy

Better evidence is required to establish optimal levels and need for supplementation

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One year ago, the chief medical officers of the United Kingdom recommended that "All pregnant and breastfeeding women should take a daily supplement containing 10 µg (400 IU) of vitamin D," to counter the high prevalence of vitamin D deficiency in pregnant women. This was aimed at reducing the associated consequences of deficiency, such as rickets in children and osteomalacia in adults.[1]

In a linked meta-analysis, Aghajafari and colleagues look beyond bone health to other adverse health outcomes for mother and baby.[2] Previous systematic reviews have highlighted challenges in combining data from different studies, including diverse definitions of vitamin D deficiency, variations in vitamin D assays used, use of non-representative samples, and varying study designs and study quality.[3 4]

A review published in 2011 found insufficient high quality studies to conduct quantitative meta-analysis[3]; in the qualitative review the evidence was inconsistent. In a subsequent review, rigorous assessment of study quality resulted in quantitative meta-analyses of only two observational studies and five randomised controlled trials, with additional studies reviewed qualitatively.[4] Combined data from trials suggested that bolus high dose vitamin D supplementation (but not daily dosing) was associated with reduced risk of low birth weight (risk ratio 0.40; 95% confidence interval 0.23 to 0.71). Combined trial data found no significant protective effect of vitamin D supplementation on the outcome small for gestational age (0.77, 0.35 to 1.66), although observational studies supported a protective effect. Results for maternal outcomes were inconsistent. In a 2012 Cochrane systematic review, meta-analysis of three trials of daily vitamin D supplementation during pregnancy found a reduced risk of low birth weight (0.48, 0.23 to 1.01), although this was not significant.[5]

Although optimal maternal 25-OHD levels at different gestational times are not known, levels below 50 nmol/L are common during pregnancy

In a recent combined analysis of two randomised controlled trials, higher vitamin D (measured as serum concentration of 25-hydroxyvitamin D; 25-OHD) at delivery was associated with a significantly (P<0.006) decreased risk of "comorbidities of pregnancy." Comorbidities were gestational diabetes, hypertension, infection, bacterial vaginosis, and preterm birth without pre-eclampsia, but the study did not have enough power to analyse individual outcomes.[6]

Meta-analysis overcomes the problems of small sample sizes and insufficient power. But challenges arise in combining data from studies of different designs, inclusion and exclusion criteria, and definitions of exposure and outcome. Aghajafari and colleagues' review contains no primary data from vitamin D intervention studies.[2] Only one trial was considered, but was excluded from analysis. The largest effect sizes derive from case-control studies, some with minimal or no adjustment for confounding; comparisons of extreme groups (such as <50 *v* >75 mmol/L), so that data from most of the sample (the middle group) are omitted[7]; and blood sampling after "disease" onset. Serum 25-OHD concentration is labile. It depends on recent intake of vitamin D and sun exposure, both of which may change, and may even be affected by preclinical disease (disease induced vitamin D deficiency).

Gestational age at sampling is also relevant to causal interpretations if low vitamin D status at late sampling is linked to outcomes that are usually associated with earlier gestational onset. Aghajafari and colleagues found that "vitamin D deficiency"—variously defined and measured at different gestational ages—is adverse for maternal and infant health. If lower vitamin D status causes these outcomes in a linear way, more severe deficiency (<50 nmol/L) would be expected to have a stronger effect than less severe deficiency (<75 nmol/L). The opposite effect seems to occur for pre-eclampsia.[2]

Despite these challenges to interpreting the evidence, these studies have clear clinical implications. In 2010 the US Institute of Medicine recommended that a serum concentration of 25-OHD of 50 nmol/L or more should be considered sufficient for bone health.[8] Although optimal maternal 25-OHD levels at different gestational times are not known, levels below 50 nmol/L are common during pregnancy, particularly in populations at high latitudes and in specific subpopulations. Evidence of a causal association between vitamin D deficiency and some maternal and neonatal outcomes is insufficient, but the evidence for bone health is clear cut. The findings of this meta-analysis support a goal of vitamin D sufficiency for all pregnant women.[2] Supplements, diet, and sunlight exposure all influence 25-OHD levels and should be used together, with care, because U shaped dose-response curves are reported for a range of health outcomes, including small for gestational age,[9] with disease risk increasing at both low and high 25-OHD levels.

Most studies are undertaken in developed countries. Yet Asian and African countries have higher infant mortality and represent half of the global population. Where it has been measured, vitamin D deficiency is common in these countries, under the combined influences of darker skin, cultural practices that limit sun exposure, and, in some locations, urban air pollution blocking ultraviolet radiation. For example, median 25-OHD levels of pregnant women living in Beijing were only 26 nmol/L.[10] If there is a causal association between vitamin D deficiency and adverse maternal and neonatal outcomes, gains from ensuring sufficiency may be great in these countries.

Current evidence on vitamin D status and neonatal and pregnancy health derives largely from observational studies, small trials, low doses of vitamin D supplementation, unclear study processes of randomisation and blinding, or low adherence. In their editorial, Harvey and Cooper called for large well designed randomised controlled trials to clarify the causal association between vitamin D supplementation and health.[11] This is particularly needed to delineate the importance of vitamin D in pregnancy, with its potentially lifelong effects on the health of offspring.[12]

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- News: Death of baby with anencephaly after mother was refused an abortion sparks controversy in India (*BMJ* 2012;345:e7320)
- Feature: Is abortion worldwide becoming more restrictive? (*BMJ* 2012;345:e8161)

Sex selection and abortion in India

Efforts to curb sex selection must not retard progressive safe abortion policies

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Sex ratio in India continues to decline

Abortions for the purpose of sex selection in India have again caught the attention of Indian policy makers and the global press after the 2011 Indian census showed a decline in the sex ratio. The number of girls per 1000 boys dropped from 927 in 2001 to 914 in 2011 for children aged 0-6 years.[1] Most notable was Maharashtra state, which recorded a decline in the sex ratio from 913 in 2001 to 883 in 2011. Under an intense media spotlight, the state has set out to "save the girl child" under the tenets of the Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act. There have been waves of suspensions of doctors for violating this act.[2] However, a parallel stream of ill informed directives may result in the victimisation of women seeking abortion.

The act[3], passed in 1994 and amended before coming into effect in 2003, regulates prenatal diagnostic techniques in India and prohibits their misuse for sex determination. The act lays out minimum requirements for registration of clinics that use these techniques and the documentation that doctors must maintain. Designated authorities may conduct random "search and seize" operations at clinics and use decoys with hidden cameras or tape recorders to identify violations.

The act does, however, recognise its links with the Medical Termination of Pregnancy Act and reinforcement of its provisions. The Medical Termination of Pregnancy Act is a progressive piece of national legislation that ensures that the law will not hinder women choosing to terminate pregnancy. The core objective is to reduce anguish and health risks to women due to unintended pregnancies. The Prohibition of Sex Selection Act in no way infringes on the provisions of the Medical Termination of Pregnancy Act or permits state authorities to act in ways that may restrict a woman's right to abortion.[4]

In light of this, the Maharashtra government's recent spate of policy directives, aimed at curbing sex selection, seem to be misdirected. These directives include recommendations to reduce the abortion limit to 10 weeks[5]; introduction of a "silent observer" technology that relays ultrasound images from pregnant women to authorities to track potential sex selective abortions[6]; and the requirement that doctors take digital images of the fetus after abortion.[7] Such policies are a blatant intrusion of women's privacy and may drive them to seek unsafe methods of abortion.

Furthermore, policy directives seeking to restrict the availability of abortion pills have recently been proposed. In India a combination of mifepristone and misoprostol is approved for termination of pregnancy up to seven weeks.[8] The state, however, seeks to ban retail sale of these pills or place them on schedule X,[9] which requires rigorous record keeping of women who purchase the pills, with the potential to trace their whereabouts.[10] A clampdown on manufacturers and retailers of abortion pills has led to the withdrawal of these pills from the market and an ensuing shortage.[11] This has occurred despite World Health Organization recommendations to phase out surgery for first trimester abortions in favour of medical methods.[12] The government also seeks to mandate a three visit schedule to the hospital for termination using abortion pills. This flies in the face of current guidelines that permit doctors to prescribe these pills at their clinic, provided women have access to a registered facility for abortion.[9]

Such measures clearly have little to do with preventing sex selection but do hinder provision of safe abortion services. By seeking to implement them the state ignores recommendations from gynaecologists and social scientists, as well as the law as framed in the Prohibition of Sex Selection Act and Medical Termination of Pregnancy Act. The Federation of Obstetric and Gynaecological Societies of India has repeatedly advocated for access to abortion pills and extension of abortion limits. The National Commission for Women has recently recommended extending termination up to 24 weeks, from the current 20 weeks.[13] While the country looks towards liberalising abortion in the interests of the safety and health of women, regressive policies by the Maharashtra government to curb sex selection run the risk of criminalising abortion.

Evidence has consistently shown that liberal abortion laws coupled with government commitment lead to a decline in unsafe abortions and associated complications.[14] In 2011, more than 620 000 abortions were reported in India. The real numbers may be well over six million, largely performed in non-registered institutions, by untrained people, and in unhygienic conditions.[15] Unsafe abortions account for nearly 8% of all maternal deaths in India.[16] As India tries to reduce maternal mortality as part of the millennium development goals, fostering women's access to safe medical abortion is crucial.

With increasing availability of techniques such as preimplantation genetic diagnosis and blood tests to determine the sex of a baby,[17] [18] targeting abortion services would not solve the problem. Sex selection is common among the affluent and educated in India, as well as those of Indian descent who live abroad.[19] What really needs to change is the fabric of the patriarchal Indian society that undervalues girls and women.

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