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bmj.com News: Serious errors and neglect in the NHS should be a criminal offence, says safety expert (*BMJ* 2013;347:f4973)

Improving the safety of patients in England

Berwick's report should be required reading for everyone

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The health service in England has been subjected to unprecedented scrutiny in recent years, with the Francis report,[1] Keogh review,[2] and now a report from a panel chaired by the American patient safety guru, Don Berwick.[3] Although all deal with the same problem, the reports are quite different. Whereas Francis, a lawyer, produced a document stretching to more than 1700 pages, with 290 recommendations, Keogh and Berwick, both doctors, wrote concise analyses, with Berwick's amounting to only 46 pages and 10 recommendations. For those unwilling to read even that, Berwick adds three letters, to senior government officials, to NHS staff, and to the people of England. Each emphasises four fundamental principles, that quality and safety must be placed above all else, that patients and carers must be empowered and heard, that staff should be developed and supported, and that there should be thorough and unequivocal transparency.

Unfortunately, despite its brevity, the immediate responses suggested that those commenting on it had failed to read it thoroughly. The health secretary claimed that it supported the government's reforms, whereas patient groups believed that it ignored some of their key demands.[4] Neither conclusion is justified. This is a report whose every word requires careful study, not superficial scanning.

Berwick recognises that healthcare is political, and he was clearly aware of the current sustained ideological campaign to denigrate the NHS.[5] Thus, he states unequivocally that it is a "world-leading example of commitment to health and healthcare as a human right" that should be emulated and that, although the NHS does have patient safety problems, so does "every other healthcare system in the world." He agrees that "big changes are needed" but notes how its "achievements are enormous" and catalogues ways in which it continues to improve. No doubt mindful of how "zombie statistics" were misused to attribute 13 000 excess deaths to failings in the hospitals Keogh reviewed,[6] Berwick suggests that "drama, accusation, and overstatement" are best avoided.

A powerful weapon in the fight against those who seek to undermine the NHS and denigrate its staff in pursuit of ideology or profit

He shows his independence by challenging the prime minister's ambition of zero harm, noting how patients must often balance the harms and benefits of treatment. He understands that many risks could be eliminated if resources were infinite but knows that they are not. He calls for "constant vigilance against reductions in resources" but also a mature and open dialogue in which trade-offs must be explicit when goals such as cost savings are being pursued.

He is emphatic that most health professionals seek to do a good job and calls for them to be spared the now too common "generalised criticisms of their intentions, motivations, skill, or dedication." When things go wrong it may be as a consequence of wilful or reckless neglect or mistreatment, but this is extremely rare, and when it happens he accepts the need for criminal sanctions. Much more often the cause will be failings of the system or human error and "it makes no sense at all to punish a person who makes an error." Instead, the organisation should learn from it.

This view underpins his approach to regulation, which "alone cannot solve the problems highlighted by Mid Staffordshire" as "in the end, culture will trump rules." Describing the existing regulatory system as one of "bewildering complexity," he calls for a regime run by "true experts" who can "apply thoughtful judgment," a model that seems far removed from the tick box culture that has characterised the Care Quality Commission. It is unfortunate that many of the public health professionals with skills in healthcare evaluation have been pushed out of the NHS in the recent reforms. He also reflects widespread concerns about lack of patient involvement,[7] asking whether the concept of community health councils should be revisited.

Berwick's report has, however, attracted some criticism. One relates to his reluctance to recommend minimum nurse staffing levels. Yet, he shows how the reality is more complex. He knows that low staffing levels threaten patient safety,[8] noting that a medical or surgical ward with fewer than one trained nurse for every eight patients, plus one in charge, is likely to increase risks substantially. However, mindful of the potential for this to become the norm, he notes how more nurses will be needed if patients are sicker. He states that staffing levels must be informed by a more sophisticated real time system to ensure that they match patient needs. This is a warning to those hospitals saddled with large private finance initiative liabilities that are currently shedding staff.

A second criticism is his rejection of a legally enforceable duty of candour. Again, his words require careful examination. He is clear that patients have a right to have all their questions answered and that professionals must notify all serious incidents. However, he cautions against the immense bureaucratic burden, as well as the anxiety that would result, if patients had to be told of every error, no matter how minor. He also calls for research about how best to communicate these matters to patients.

Berwick's clarity of writing, logical flow, and at times subtle phrasing might lead some to think that he has said little that is new. But he has put forward a clear vision for a new set of relationships between patients and health professionals to ensure continuing improvements in quality and safety based on trust, not fear. He has given them a powerful weapon in the fight against those who seek to undermine the NHS and denigrate its staff in pursuit of ideology or profit. It is now up to them to seize it.

Competing interests: None declared.

Provenance and peer review: Commissioned; not externally peer reviewed.

References are in the version on bmj.com.

Cite this as: *BMJ* 2013;347:f5038

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As with maternal undernutrition, maternal overnutrition and obesity are associated with definite changes in the intrauterine milieu, which may lead to an increased supply of nutrients to the developing fetus

Maternal obesity and heart disease in the offspring

Interventions may need to begin before pregnancy

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The prevalence of overweight and obesity in women of childbearing age and in pregnant women has steadily increased over the past 20 years.[1 2] Maternal obesity is associated with a variety of adverse outcomes for the mother, such as increased mortality, pre-eclampsia, and gestational diabetes. It is also associated with adverse outcomes for the child at birth (such as large for gestational age babies and fetal distress) and in later life (such as increased risk of later obesity, metabolic disorders including insulin resistance and dyslipidaemia, hypertension, asthma, and behavioural problems).[3] The linked paper by Reynolds and colleagues is the first to describe associations between maternal obesity and risk of cardiovascular morbidity and mortality in mid-life.[4]

What are the possible explanations for such associations? In 1992, Barker first proposed the fetal origins hypothesis, which, briefly stated, posits that an adverse intrauterine environment is associated with lifelong consequences.[5] In its first application, low birth weight as a result of maternal undernutrition was associated with cardiovascular risk factors such as raised blood pressure in the adult offspring.[6] This was probably due to a mismatch between programming for a "thrifty phenotype" and overnutrition in the postpartum period.

As with maternal undernutrition, maternal overnutrition and obesity are associated with definite changes in the intrauterine milieu, such as increased circulating cytokines, glucose concentrations, and lipids, as well as increased insulin resistance—all of which may lead to an increased supply of nutrients to the developing fetus.[3] Among the mechanisms of fetal adaptation to overnutrition are epigenetic changes in response to increased fetal exposure to glucose, lipids, and inflammatory cytokines.[3] Thus, offspring may experience permanent or transient changes in metabolic programming, leading to inappropriate appetite regulation and behavioural problems associated with obesity in adult life.

Data supporting such associations are observational. The Nurses' Health Study, for example, found a J shaped association between birth weight and later obesity[7]; this finding was replicated in the Health Professionals' Follow-up study.[8] Two systematic reviews also support this finding.[9 10]

While intriguing, Reynolds and colleagues' study leaves at least two questions unanswered. Firstly, what is the role of the early postnatal environment? A recent study from the 1958 British birth cohort found associations between parental body mass index and risk factors for cardiovascular disease among the offspring during mid-life. In that study, parental height and weight were measured when the offspring were 11 years of age.[11] Associations remained after adjustment for offspring lifestyle and socioeconomic factors but were reduced after adjustment for adult adiposity. These finding suggest intergenerational transmission of obesity, perhaps owing to postnatal circumstances reflecting parental and childhood obesity.

Secondly, what is the role of parental obesity? In the 1958 British birth cohort, results were not stronger for maternal obesity than for paternal obesity. Results were also similar when maternal prepregnancy weight was substituted for maternal body mass index at offspring age 11, suggesting a role for the postnatal environment.

If Reynolds and colleagues' findings are true, what are the implications? The US Institute of Medicine guidelines, adopted in 2009, recommend weight gains of 15 lb (6.8 kg) to 25 lb and 11-20 lb for overweight and obese pregnant women, respectively, with no more than 0.6-0.5 lb weight gain per week in the second and third trimesters. These guidelines were adopted by the American College of Obstetricians and Gynecologists in 2013,[12] with the caveat that appropriate diet and exercise be discussed throughout pregnancy. The goals of such management are to balance the risks of fetal growth, obstetric complications, and maternal complications. However, the results of studies of maternal obesity and offspring outcomes suggest that interventions should begin before pregnancy.

Too little too late

Competing interests: None declared.

Provenance and peer review: Commissioned; not externally peer reviewed.

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Cite this as: *BMJ* 2013;347:f4960

RESEARCH, p 10

- Research: Work stress and risk of cancer: meta-analysis of 5700 incident cancer events in 116 000 European men and women (*BMJ* 2013;346:f165)
- Observations: Job insecurity contributes to poor health (*BMJ* 2012;345:e5183)
- Feature: Metropolitan Police blues: protracted sickness absence, ill health retirement, and the occupational psychiatrist (*BMJ* 2011; 342:d2127)

The impact of the workplace on health

Job insecurity increases the risk of coronary heart disease

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In the continuing battle against coronary heart disease, attention is usually focused on behaviours over which people have direct control, such as regular exercise and diet. However, there are other important risk factors over which people often have little control. High on this list is the potential impact of the workplace on health.

In an extensive study of 174 438 participants followed for almost 10 years, Virtanen and colleagues provide persuasive evidence that one workplace characteristic, job insecurity, increases the risk of coronary heart disease (age adjusted relative risk for high versus low job security 1.32, 95% confidence interval 1.09 to 1.59).[1] This paper adds substantially to research reporting a link between job insecurity and adverse health events and negative behaviours,[2-4] including a recent paper by the same group that identified job strain as a risk factor for coronary heart disease.[5]

In a meta-analysis of 485 studies of 267 995 people we found a strong correlation between self reported measures of job satisfaction and health.[6] Poor job satisfaction was particularly associated with burnout, poor self esteem, depression, and anxiety. Job satisfaction is a multifactorial concept covering many aspects of the work experience, including job strain and job insecurity. Within this construct, a causal association is not difficult to hypothesise, because feelings of job insecurity reduce job satisfaction while increasing work behaviours and practices that are known to harm health.[7]

The most pernicious of these is working long hours, which persists despite initiatives such as the European Union Working Time Directive aimed at eliminating this practice. Employees who think that their job is insecure try to make themselves indispensable by working longer hours than contracted to do and by indulging in "presenteeism"[8]—coming in early and staying late so as to be visibly working when the boss arrives and goes home. The problem is more complex for part time workers, who often feel pressured into working hours that are not excessive legally but are longer than they wish to do and for which they are not paid. A common complaint is that "I am employed in a part time post but am doing a full time job." Such a situation is often tolerated because people fear that they will lose their job if they protest.

More recently, the "zero hour contract" has emerged, in which employees do not know how many hours, if any, they will be offered on any given day, a practice that takes job insecurity to a whole new level

Other forms of "presenteeism" include coming to work when on annual leave or when ill (lest sickness absences make them appear less committed than their colleagues). In a dataset of more than 39 000 workers in many different occupations, 28% were found to have some form of "sickness presenteeism."[9] All of these behaviours are about showing "face time" and are performed in a way that ensures the employee's boss knows about it. Analysis of a large series of studies from many occupational and geographical settings showed conclusively that long working hours equate to an increased risk of ill health and damage to social relationships.[10]

In recent years, working practices have been changing in ways that can only increase feelings of job insecurity. The "job for life" has long gone; fixed term contracts are the norm; employees are having contracts terminated and then being invited to reapply for their jobs at inferior grades/conditions; graduates are being advised that they may have to re-train several times during their working life. More recently, the "zero hour contract" has emerged, in which employees do not know how many hours, if any, they will be offered on any given day, a practice that takes job insecurity to a whole new level.

Against this background, Virtanen and colleagues' conclusions may be overcautious. Although they found slightly higher job insecurity levels in two groups with a known raised risk of coronary heart disease (people in lower socioeconomic groups and those with low physical activity levels), both differences were too small for the association between job insecurity and raised risk of heart disease to be dismissed simply as the result of confounding.

Job insecurity is no longer something that employees might experience occasionally but something that many now perceive as being ever present. This trend is being felt across all occupational and socioeconomic groups. The association between job insecurity and increased risk of heart disease cannot easily be dismissed as an artefact; the available evidence suggests that the link is causal.

To a large extent, the battle against the effects of a world recession and the problems of fragile economies are being fought in the workplace. Politicians and employers have difficult balances to achieve as they grapple with the decisions that need to be taken to protect jobs. Paradoxically, however, many of the practices being introduced to achieve this increase feelings of job insecurity while reducing real incomes. Employees are reluctant to fight against these changes for fear of losing their income and the stigmatisation that is increasingly being levelled at the unemployed.

Virtanen and colleagues' paper is a timely reminder that workplace practices have health as well as economic consequences, and that the wellbeing of the individual employee also needs to be weighed in the balance. Work, the activity most people still spend most time engaged in, is increasingly the source of harmful stresses that are outside the control of individuals but potentially within the control of those who manage our workplaces. The failure of politicians and employers to deal with this problem adequately could be storing up serious population health problems in the future.

Competing interests: None declared.

Provenance and peer review: Commissioned; not externally peer reviewed.

.References are in the version on bmj.com.

Cite this as: *BMJ* 2013;347:f4944

RESEARCH, p 9

Most people would probably consider that two or three systematic reviews on the same topic with similar eligibility criteria and outcomes is reasonable, whereas four or more would definitely be too many

The problem of duplicate systematic reviews

Systematic reviewers should identify existing reviews as a compulsory first step

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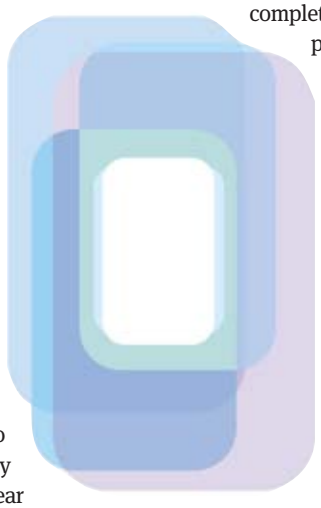
Systematic reviews occupy a central position in evidence based medicine. They are the starting point of a well developed practice guideline. Some funders of randomised trials ask investigators for a strong rationale for their proposed trial, indicating that the best evidence is likely to be a well conducted and completely reported systematic review.[1] These reasons, and others, probably explain the popularity and publication trajectory of systematic reviews.[2] Does this translate into duplication of effort and waste? In a linked paper, using sound methodology and complete and transparent reporting, Siontis and colleagues examined this question.[3]

Having selected 73 meta-analyses published during 2010, the authors identified two thirds of them as having at least one overlapping meta-analysis. The good news is that duplication does not seem to have been a major problem. The authors report a median of two overlapping meta-analyses per topic. However, for several clinical topics there were multiple duplicates, and in 17 instances at least one author was involved in more than one overlapping meta-analysis. These findings provide another opportunity to pause and reflect on the development of systematic reviews and meta-analyses.

Not all duplication is bad. Indeed, replication is essential and has uncovered some unfortunate behaviour by scientists.[4 5] With a judicious amount of duplication, clinicians—and other decision makers—can be more confident in the consistency, or lack thereof, of initially reported results. Regulators often require two randomised trials conducted in different jurisdictions as part of a drug's approval process. In the context of systematic reviews and meta-analyses, there is no magic number regarding the "correct" amount of replication: most people would probably consider that two or three systematic reviews on the same topic with similar eligibility criteria and outcomes is reasonable, whereas four or more would definitely be too many. The question that needs clarification is: when does replication become unnecessary duplication? Unnecessary duplication is usually associated with waste,[6] a big problem, particularly when funding comes from a shrinking public purse.

One factor that contributes to duplication is that systematic reviewers may not be aware of what their colleagues are planning. Until recently, there was no single source from which systematic reviewers (and others) could identify existing protocols of ongoing systematic reviews. However, an international prospective register for systematic review protocols now exists (PROSPERO; www.crd.york.ac.uk/PROSPERO/), funded by the National Institute of Health Research and administered through the Centre for Reviews and Dissemination.



The database contains 18 mandatory items and 22 discretionary ones.[7 8] This information can be used to search for existing systematic review protocols. At the time of writing, 1871 records of review protocols exist from 65 countries and duplication seems to be rare. This number will probably increase substantially later this year when Cochrane protocols are added to the register. With increasing international endorsement of the register by journals and funders,[9] it is likely to help reduce unnecessary duplication.

Another factor contributing to duplication is the relentless pressure on academics to publish. Many institutions still use the archaic system of publication quantity, rather than quality, as a measure for promotion and tenure. When income and professional advancement may ultimately depend on publication output, systematic reviewers may be unwilling to forgo publication, regardless of whether the review has already been done. Unnecessary duplication will be reduced only when researchers are evaluated on quality, and academic institutions come together, globally, to promote a policy whereby quality trumps quantity.

Expert peer reviewers of content might also be expected to help identify unnecessary duplication. However, in a fast moving clinical field, content experts may have a hard time keeping abreast of their own literature.[10] Better training for peer reviewers on ways to identify duplicate reports might help reduce the problem.

The best way to reduce unnecessary duplication of systematic reviews may be to make it compulsory for systematic reviewers to identify existing reviews, either protocols or completed reviews, before conducting their own review. This could form the first step of the review process. After the question has been clearly and precisely formulated,[11] systematic reviewers should search for existing systematic review protocols and completed reviews. PROSPERO is a good place to identify existing protocols and the Cochrane Library is an excellent place to identify high quality completed reviews.[12]

If existing protocols are identified, the review team should review the eligibility criteria and outcomes to see whether they meet their interest or whether there are relevant nuances, such as different patient subgroups or outcomes, that might warrant continuation of the review. Sometimes duplicate reviews are completed to satisfy sensitive political and jurisdictional needs. Even if completed duplicate reviews exist, their methodology might be weak,[13] and a new review might be conducted to overcome these deficiencies. Open access publication (or web posting of unpublished reports) will probably help reviewers examine identified protocols and completed reviews more thoroughly.

The PRISMA statement, which aims to help authors improve the reporting of systematic reviews and meta-analyses, does not specifically ask authors to report on existing duplicate reviews. However, item 3 (rationale) of the checklist asks authors to "describe the rationale for the review in the context of what is already known."[14] The PRISMA checklist and its background paper could be more comprehensive, flagging up the problem of unnecessary duplication in its guidance to authors.[15]

Competing interests: None declared.

Provenance and peer review: Commissioned; not externally peer reviewed.

References are in the version on bmj.com.

Cite this as: *BMJ* 2013;347:f5040

RESEARCH, p 12