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How to judge the value of innovation

More evidence is needed but "promise" is important early on

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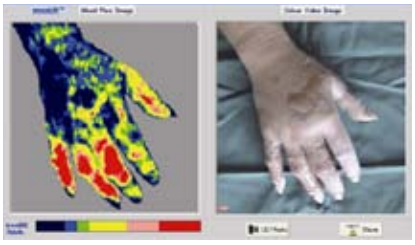
The NHS chief executive's report, *Innovation Health and Wealth*, which sets out the government's current strategy on innovation in healthcare, highlights the importance of adopting innovative technologies in a rational way.[1] Some new devices and diagnostics may offer important benefits to patients and health services, but it can be difficult to judge which they might be and to influence their uptake by clinicians and healthcare commissioners. Few of the many initiatives aimed at encouraging innovation have succeeded in driving the well reasoned adoption of new technologies.[2] The poor evidence base for medical technologies (more so than for drugs) hampers decision making.[3] Given current financial pressures that may deter the adoption of new technologies by payers, who are understandably reluctant to meet increased costs, how can a clear proposition be made for the value of a technology?



A new technology assessed by NICE

Medical technologies are often evaluated using limited evidence. This is partly because the regulation of medical devices worldwide does not require as much research data as does the regulation of drugs; partly because new technologies are often developed by small companies that have little experience in research; and partly because new technologies typically reach market early, before many research findings are available. More well conducted trials of medical devices are undoubtedly needed, but evidence from research also needs to be supplemented by better data collection using registers and improved and more transparent post-market surveillance of devices.[4-6]

After the introduction of a new procedure (some of which will involve a new device), there is a need for consistent and appropriate reporting of outcomes, and a clear framework is now available for this.[7] Regulators (such as the Medicines and Healthcare Products Regulatory Authority in the UK and the Food and Drug Administration in the United States) are separate from health technology evaluators like the National Institute for Health and Clinical Excellence (NICE), but their requirements for evidence overlap substantially, particularly with regard to the collection of data once new technologies are in use.

Since 2009, NICE has been engaged in selecting and evaluating medical technologies notified by manufacturers.[8] If the benefits for patients and health services are judged to be supported by evidence then NICE publishes guidance on the adoption of the new technology, which explains its advantages over current management.[9 10] Decision making processes are complicated because many factors need to be considered—not least the balance between risks and benefits. It can be difficult to define precisely what current management (the comparator for the new technology) comprises, and both the consequences of introducing new technologies into complex care pathways and clinicians' attitudes to their introduction need consideration.

The NICE committee that selects and evaluates new technologies uses NICE's rigorous processes and methods, together with published criteria, to guide its decisions.[9] The committee considers the amount and quality of published evidence to support claims of benefit, together with advice from experts and from patients. In addition, the committee seems to make a qualitative judgment, which will be familiar to all professionals who, when using a new tool, judge that it looks and feels right and does the job well; this characteristic is perhaps best termed "promise." Early experience suggests that amount of promise that a technology is perceived to have and the amount of evidence required by the committee to make a positive judgment interact to produce a decision. A technology's promise seems to comprise the nature of the benefits it is claimed to have, the size of these benefits, and their plausibility. An element of uniqueness and novelty may be recognised subjectively or, more objectively, by an associated patent.[11]

Benefits for patients may range from increased survival to some kind of cosmetic improvement; for the health service benefits may range from needing less staff time to obviating other tests; and benefits for all could range from fewer visits to hospital to reduced length of hospital stay. The size of the benefit has two dimensions—the degree of benefit for the patient compared with current management (By how much does it prolong survival? How much is pain reduced? How much shorter might length of stay be?) and the degree of benefit for the entire patient population. In a very large patient population a small benefit to each individual may be important.

Plausibility can be assessed by looking at its clinical utility. Does it look as though the technology will really work as claimed? Does it look straightforward to use for clinicians or patients (or both)? Are there any reasons why it might not work as well in everyday practice as in test environments described in studies? Is it likely to achieve in practice all the benefits that have been suggested? Will it fit into existing care pathways or might they need to be changed to accommodate it?

If available evidence indicates that the nature, size, and plausibility of benefit from a technology are sufficient, then the stage is set for formulating a value proposition. On the basis of plausible assumptions and cost modelling, what will the new technology cost to deliver defined benefits compared with current practice? It may cost more to buy, but do savings over a reasonable time frame suggest that the new technology offers better value if other components of a care pathway become unnecessary, for example?[12]

The early evaluation of innovative technologies will remain challenging and complex. All initiatives for fostering more and better research into new medical technologies including better coding, good registers, and systematic data collection when new technologies start to be used may increase the evidence available to decision makers. But the accrual of data takes time.[4 8] Manufacturers, users, and commissioners should recognise what evaluators of technologies see as promise and must appreciate the importance of making realistic value propositions.

Competing interests: None declared.
Provenance and peer review: Not commissioned; externally peer reviewed.
References are in the version on bmj.com.
Cite this as: *BMJ* 2012;344:e1457

A better understanding of the barriers to changes to dietary and physical activity behaviour in women of differing pre-pregnancy BMI is needed before we abandon interventions that include physical activity

How should women be advised on weight management in pregnancy?

There is not yet sufficient evidence to support any particular intervention

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Obesity in pregnant women has considerable resource implications, with increased odds of caesarean or instrumental delivery, haemorrhage, infection, longer duration of hospital stay, and need for neonatal intensive care.[1] At a time when more than half the women of reproductive age in the United Kingdom are overweight or obese,[2] any analysis of weight management interventions in pregnancy is timely and welcome. In the linked paper, Thangaratinam and colleagues present a comprehensive and well conducted meta-analysis of studies that have tried to improve maternal weight and obstetric outcomes through dietary and lifestyle interventions across the body mass index (BMI) range.[3] However, many of the included studies are of small size and limited quality. The authors conclude that interventions can improve some outcomes for the mother and baby and that dietary advice, rather than advice on physical activity, is most effective. Importantly, there was no evidence of harm.

Internationally, the guidelines for weight management in pregnancy vary. Because the US Institute of Medicine (IOM) recommends limits for gestational weight gain (table),[4] most published intervention studies focus mainly on this parameter. In the UK, however, the National Institute for Health and Clinical Excellence (NICE) guidelines for weight management in pregnancy do not advise regular weighing of pregnant women beyond their first visit because evidence for an effective intervention to improve clinical outcomes in a UK population has been lacking.[5]

Does the meta-analysis by Thangaratinam and colleagues provide the evidence needed for NICE to reassess the guidelines? We think that this would be premature. Although the findings suggest that interventions in pregnancy are safe and can produce modest reductions in gestational weight gain, control and intervention groups did not differ in the proportion of women who achieved IOM gestational weight gain limits. It is therefore not surprising that there was no effect on clinically relevant outcomes, including birth weight or macrosomia, and no reduction in the caesarean section rate.

New recommendations for total weight gain during pregnancy, by prepregnancy body mass index[4]

Body mass index category	Recommended weight gain	
	Weight (kg)	Weight (lb)
Underweight (<18.5)	12.5-18	28-40
Normal (18.5-24.9)	11.5-16	25-35
Overweight (25.0-29.9)	7-11.5	15-25
Obese (>30.0)	5-9	11-20

Although a positive benefit was reported for pre-eclampsia and gestational hypertension, the quality of evidence for these measures was rated as low or very low. The authors did not include evidence for an effect on postpartum weight retention (presumably through lack of adequate data), which has been shown to be robustly associated with excessive gestational weight gain.[4]

The authors undertook a subanalysis of overweight and obese pregnant women and found a reduction in gestational weight gain for this group, but with no change in pre-eclampsia or birthweight indices, an important determinant of adverse obstetric outcomes. This has been confirmed by another recent systematic review of randomised controlled trials in obese and overweight women, which reported a significant reduction in gestational weight gain of 2.21 kg, but again with no concurrent improvement in clinical outcomes, except for a lower incidence of gestational diabetes, for which the strength of evidence was low.[6] Most overweight and obese women gain weight above the IOM limits, as was shown in the recent meta-analysis by presentation of the absolute weight gain in the experimental and control arms of each trial; both groups gained weight even though the increase may have been less marked in the experimental arm.[6] (Thangaratinam and colleagues presented the mean difference only.) Thus a lack of any convincing improvement in relevant clinical outcomes was not unexpected.

Gestational weight gain, which incorporates fetal and placental weight, amniotic fluid volume, and maternal plasma volume expansion in addition to maternal fat accretion, varies substantially from woman to woman. For obese women, pre-pregnancy BMI may contribute as much to the determination of adverse pregnancy outcomes as excessive gestational weight gain. This may explain the lack of clinical benefit in obese and overweight women reported in the linked meta-analysis despite the larger reduction in gestational weight gain compared with women of any pre-pregnancy weight. Moreover, recent studies have challenged the IOM weight gain limits for obese pregnant women.[7]

The systematic review shows that dietary interventions achieved a greater reduction in gestational weight gain than physical activity interventions or those with a mixed approach but the significant effect on birth weight was seen only in trials of physical activity. A better understanding of the barriers to changes to dietary and physical activity behaviour in women of differing pre-pregnancy BMI is needed before we abandon interventions that include physical activity. Women with a lower pre-pregnancy BMI may have lower barriers to changing physical activity than those with a higher BMI,[8] so more emphasis of effective interventions to promote physical activity in overweight and obese women is needed.

The focus on gestational weight gain at the expense of adequate power for clinical outcomes and the heterogeneity between the many different study populations and protocols limit the interpretation of the current meta-analysis, as the authors acknowledge. We agree with the authors that future effectiveness studies should focus on clinically relevant outcomes and provide information that will enable the role of individual components of the intervention to be assessed.

Ongoing randomised controlled trials that are adequately powered for clinical outcomes and rigorously assess the different elements of the intervention include the Australian LIMIT trial in overweight and obese pregnant women[11] and the UK UPBEAT trial in obese pregnant women.[12]

Both trials are also assessing body composition in the child in control and intervention arms. Work on developing a core set of outcomes for studies in pregnancy has recently started under the COMET initiative at the University of Liverpool and will inform future work (www.comet-initiative.org).

Competing interests: LP is chief investigator on the UPBEAT trial; LCC has no other relationships or activities that could appear to have influenced the submitted work.
Provenance and peer review: Commissioned; not externally peer reviewed.

References are in the version on bmj.com.

Cite this as: *BMJ* 2012;344:e2774

RESEARCH, p 14

2008 poll on bmj.com
Should influence immunisation be mandatory for healthcare workers?
Votes: Yes 493 (62%); No 302 (38%)

Vaccinating healthcare professionals against influenza

Should be mandatory

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There is clear evidence that healthcare workers play an important role in transmitting infections to their patients.[1] The World Health Organization and national immunisation guidelines in 60% of developed and emerging economies strongly recommend annual vaccination against seasonal influenza for all healthcare workers in acute and long term care facilities.[2] However, unlike other prophylactic measures targeted at healthcare workers, such as hepatitis B vaccination, the uptake of flu vaccine has been generally poor. In the United States, two decades of consistent advocacy by the Centers for Disease Control and Prevention achieved a self reported vaccine coverage of only 64% among healthcare workers by 2010-1.[3] In the United Kingdom, despite recommendations by the Department of Health, uptake of seasonal flu vaccine was a dismal 35% among frontline healthcare workers in the same year.[4]

Flu contributes greatly to global mortality and morbidity and has important economic consequences. Each year, seasonal flu affects 5-10% of the world's population, causing 3-5 million severe infections and resulting in 250 000-500 000 deaths. Young children (especially those under 1 year); pregnant women; people over 65 years (especially those in institutional care); people with chronic medical conditions such as diabetes, asthma, chronic obstructive pulmonary disease, and chronic kidney disease; and those who are obese or immunocompromised are at a higher risk of severe influenza and associated mortality. These vulnerable patient groups are also at high risk of acquiring nosocomial flu infections and have a high case fatality rate.[1]

The reasons for low vaccine uptake among healthcare workers are manifold and none is supported by current scientific evidence. Firstly, many healthcare workers believe that they are not at risk of contracting flu. However, observational research has shown that even in a mild epidemic season about 23% of healthcare workers had serological evidence of flu, with 28-59% of these infections being subclinical.[5] Furthermore, most healthcare workers continue to care for their patients when ill, which increases the probability of nosocomial transmission.[6] Nosocomial flu infections have a high case fatality rate of 27%, especially in patients with comorbidities.[7]

Secondly, some believe that vaccinating healthcare workers with trivalent inactivated vaccine has no significant effect on nosocomial flu infection and its outcome (morbidity and mortality) in the vulnerable group of patients most likely to acquire flu. A review that found no significant difference in laboratory confirmed outcomes in elderly patients in long term care facilities may be responsible for this belief.[8] However, all studies included in the review were limited by several biases and strain mismatch between the vaccine and circulating virus. Studies from temperate and tropical regions have shown that vaccinating healthcare workers against flu reduces flu infections and sickness leave for flu-like illnesses, with the difference being significant when the vaccine strains and circulating strains are well matched.[9 10]

Finally, many healthcare workers refuse the vaccine because they are not convinced that it is safe and they fear adverse effects. However, good evidence shows that the trivalent inactivated vaccine is safe and has a vaccine effectiveness of 70-90% in the presence of a good strain match between the circulating and vaccine virus strains. A recent meta-analysis reported similar results for the pandemic vaccine.[11] The authors estimate that in the absence of a good strain match the efficacy ranges from 59% to 83%, depending on the type of vaccine used.

Uptake of seasonal flu vaccine was a dismal 35% among frontline healthcare workers in the UK


MARK THOMAS/SPL

Recommendations by health authorities and promotional campaigns for flu vaccination only marginally increase vaccine uptake by healthcare workers.[12] In light of accumulating evidence that flu vaccination in healthcare workers is an effective and useful strategy, there is therefore a strong case for mandating vaccination in healthcare workers who are in direct contact with patients. All healthcare workers should strive to "first do no harm." If vaccination can prevent harm to patients there is a clear ethical and legal argument that workers should be vaccinated. Moreover, employers are ethically bound to protect their staff from hospital acquired infections. There is also an economic case for vaccinating healthcare workers.[12] It is pointless to have a policy without the will to mandate it in the interest of patients. Adverse events are always possible after flu vaccination, and resistance to a mandatory vaccination policy is probably inevitable. However, 98% coverage has been achieved in the US among healthcare workers whose employers require compulsory flu vaccination,[3] and minor adverse reactions have been reported in less than 1% of vaccine recipients in the general population, similar to adverse events for other vaccines.

Although good quality studies (such as randomised controlled trials of a vaccine with a good strain match over several years in different settings) are still needed to firmly establish that vaccinating healthcare workers prevents nosocomial flu in patients, the current policy of strongly recommending annual flu vaccination to healthcare workers cannot continue. The English Department of Health needs to make flu vaccination mandatory in all healthcare workers who have direct contact with patients.

Competing interests: None declared.
Provenance and peer review: Not commissioned; peer reviewed.
References are in the version on bmj.com.
Cite this as: *BMJ* 2012;344:e2217

bmj.com

- Letter: The sin is not perfectionism but poor leadership (*BMJ* 2011;342:d1301)
- News: "Disruptive" doctors are often found to be perfectionists, agency reports (*BMJ* 2011;342:d876)

Perfectionism in doctors

Can lead to unhealthy behaviours in stressful work situations

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The launch of the UK Association for Physician Health (UKAPH) has brought together a group of doctors and other health professionals concerned with the care of doctors. Perfectionism is a common trait among doctors.[1-3] This is a good thing for patients and for healthcare organisations, but it can also leave doctors vulnerable to health problems and other difficulties.

People who are perfectionists strive for flawlessness, set excessively high standards of performance, and tend to be overly critical of their behaviour.[4 5] There is continuing debate about whether perfectionism is "good" or "healthy," with the understandable view from the medical profession and the public that perfectionism is an essential driver of high quality patient care. But herein lies the rub: current pressures to do more, more quickly, and with fewer resources all militate against a perfectionist approach, and this can change vulnerable doctors into obsessive and frustrated people who make seemingly impossible demands on themselves and their colleagues. If patients expect their doctor to achieve the unachievable, this can result only in a fallen hero.

The characteristics of "unhealthy perfectionism" and "healthy perfectionism" have been the subject of some scrutiny.[6 7] Healthy perfectionism is not underpinned by the same level of anxiety as unhealthy perfectionism, and it produces more functionally useful outcomes. Unhealthy perfectionism can lead to reluctance to delegate and a tendency to micromanage and to be relentlessly critical—all of which can produce dysfunctional outcomes for the individual doctor and for the team. As an example, when treatment fails or the doctor cannot help a patient, a healthy perfectionist would probably accept that no more can be done, whereas a neurotic perfectionist might feel guilty and carry on relentlessly, regardless of the negative impact on himself or herself and on the patient.

It is perilous to collude with a culture of perfectionism in which doctors are expected to be infallible and errors are viewed as a "failure of character."[8] A compulsive triad of chronic doubt, chronic guilt, and an exaggerated sense of responsibility that burdens many doctors has been described.[3] These characteristics can act as brakes on rash decisions, but when they become chronic they can lead to indecision, which may undermine the confidence of patients and colleagues alike.


MONTY RAKUSEN, CULTURA/SPL

A fallen hero

Is perfectionism a trait or a learned behaviour? Personality research suggests that the tendency towards perfectionism is a consequence of extreme conscientiousness—the personality trait that most consistently predicts job performance.[9] High work demands and environmental pressures probably interact with personality to trigger perfectionism. Extreme stress causes strengths such as conscientiousness to become overplayed and to develop into dysfunctional behaviours.[10] Although conscientiousness is a stable trait that cannot (and, arguably, should not) be changed, more could be done to spot the early signs of maladaptive perfectionist tendencies and prevent them from developing further.

As a doctor becomes increasingly frustrated at being unable to tackle inefficiencies, work relationships can start to break down.

The following are some early warning signs of unhealthy perfectionism: all-or-nothing thinking ("no one understands how important this is"); failure to delegate ("no one will do it as well as I can"); inability to forgive oneself or others for small mistakes; procrastination to avoid the possibility of an error; dissatisfaction with success; and a continual striving for yet more achievement without praising others. As a doctor becomes increasingly frustrated at being unable to tackle inefficiencies, work relationships can start to break down.

How can the perils of perfectionism be dealt with? Effective team working acts as a buffer to the individual doctor who is trying to take on too much personal responsibility. Clinical leaders should establish a culture of constructive feedback that can help to identify doctors whose perfectionism is becoming a problem and provide boundaries for it. Timely feedback and coaching can help to increase the doctor's self awareness and to provide practical strategies for managing the more unhelpful aspects of perfectionism such as avoidance, procrastination, and reluctance to delegate. Cognitive behavioural approaches have been shown to be useful.[11] When their perfectionism is clearly causing a problem, individuals must be open to examining the effects of their behaviour on others rather than retreating into wilful blindness. To quote a recent *BMJ* letter: "It seems the sin is not the perfectionism that is demanded but . . . how the demand is communicated."[12] Finally, at an institutional level, managers need to recognise that excess pressure from external drivers and targets may have negative outcomes for doctors and for patients.

Competing interests: None declared.
Provenance and peer review: Not commissioned; externally peer reviewed.

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Cite this as: *BMJ* 2012;344:e1674