Incentives to quit smoking in primary care

Spirometry with pictorial feedback on lung age, not just raw data, improves quit rates

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In the accompanying randomised controlled trial, Parkes and colleagues assess the effect of telling patients over 35 years of age their estimated spirometric lung age as an incentive to quit smoking.[1] Support for conducting the trial comes from a recent Polish observational study on the potential association between smoking cessation and participants' spirometry results, as communicated using Fletcher and Peto's diagram (a pictorial representation of how smoking ages the lungs).[2] The Polish study showed higher smoking cessation rates at one year in smokers with airway obstruction than in those with normal spirometric parameters. However, the study had no control group without spirometry testing or without feedback on such testing. The authors called for a large randomised controlled trial comparing the effect of providing spirometry results versus no spirometry results on smoking cessation.

In Parkes and colleagues' trial, participants in the intervention group received comprehensive information about their spirometry results including individualised interpretation, estimated lung age, and Fletcher and Peto's diagram. People in the control group received written results as raw data on forced expiratory volume in one second, with no further explanation. Participants in both groups were advised to quit smoking and were offered an optional referral to an intensive support service. Smokers randomised to the intervention group were about twice as likely to be not smoking at 12 months' follow-up than those in the control group. A subgroup analysis found no evidence of a dose-response relation between "lung age deficit" (lung age minus chronological age) and the outcome, as quitters and non-quitters had similar lung age deficits. This study did not look at the potential health benefit of screening for chronic obstructive pulmonary disease because all participants underwent spirometry testing.

Another recent randomised controlled trial investigated a closely related research question in smokers aged 18-24 years.[3] It focused on intermediate psychological outcomes, based on health behaviour theories such as the "health belief model." This model states that people are likely to follow a particular health action if they think they are susceptible to a condition that they consider serious, and if they believe that the benefits of the action outweigh the costs.[4] The intervention group received a smoking cessation booklet plus feedback about their spirometric lung age and respiratory symptoms, and the control group received only the smoking cessation booklet. Perceived risks, worries, and desire to quit smoking were assessed using 7 point Likert-type scales at study entry and after delivery of the intervention. No significant differences were found between groups at either time point. They also assessed the perceived relevance of lung age and feedback on respiratory symptoms in the intervention group using the "10 item personal involvement inventory." A significant inverse correlation was seen between lung age deficit and perceived relevance of lung age feedback, perhaps as a defensive reaction against potentially worrying information..

A systematic review explored the effect of biomedical risk assessment as an aid for smoking cessation.[5] It included trials in which a measurement—such as exhaled carbon monoxide, spirometry, or genetic testing—was used to increase motivation to quit. For trials to be eligible, the control group had to receive all parts of the intervention except for the biomedical feedback. Only one trial of spirometry was eligible for this review.[6] It found no significant difference in smoking cessation at 12 months' follow-up between participants receiving spirometry feedback and repeated counselling and those receiving counselling but not spirometry testing (odds ratio for 7 day abstinence at 12 months in the intervention group compared with the control group 1.21, 95% confidence interval 0.60 to 2.42). An ongoing updated search found another eligible paper that had similar results.[7] Parkes and colleagues investigated a slightly different research question (comprehensive, illustrated, and individualised oral feedback versus short, raw, and written feedback) than these two trials where participants did not undergo spirometry if they were allocated to the control condition.

On the basis of the evidence so far, general practitioners have to decide whether to wait for a trial comparing the potential benefit for smoking cessation of spirometry testing using lung age feedback versus no spirometry testing or whether to adopt the strategy suggested by Parkes and colleagues. In making this decision they should be aware of the limitations of the trial—for example, the lack of information about the comparability of the study sample with the entire recruitment population, the longer duration of contact between participants and caregivers in the intervention group than in the control group, and outcome data that are limited to point-prevalence abstinence.[8] Despite these limitations, however, providing feedback on lung age with graphic displays seems to be the best option

so far for communicating the results of spirometry. This strategy might also be an opportunity for general practitioners to tailor smoking cessation messages to the individual, as recommended in the recent National Institute for Health and Clinical Excellence (NICE) guidance on smoking cessation.[9]

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Giving antioxidants to infants with Down's syndrome

Does not improve psychomotor development

RESEARCH, p 594

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Competing interests: TR is currently director of prenatal screening for the Sheffield sub-regional Down's syndrome screening programme and has been paid to speak at conferences on screening for Down's syndrome. He has also received consulting fees from several manufacturers of analytical reagents.

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In their accompanying randomised controlled trial, Ellis and colleagues assess whether supplementation with antioxidants or folinic acid (or both) improves the psychomotor and language development of children under 7 months old who have Down's syndrome. The trial compared daily oral supplementation with antioxidants (selenium 10 µg, zinc 5 mg, vitamin A 0.9 mg, vitamin E 100 mg, and vitamin C 50 mg), folinic acid (0.1 mg), antioxidants and folinic acid combined, or placebo and found no significant difference in outcomes at 18 months.[1]

Antioxidants, vitamins, and miscellaneous food supplements are often believed to cure all manner of ills. In many cases, however, belief in food supplements flies in the face of the evidence.[2] Vitamins have been tested as a preventive measure for cardiovascular disease, but the heart protection study (vitamin E, vitamin C, ß carotene, 20 mg/d), the Norwegian vitamin trial (folic acid, vitamin B12), and a meta-analysis of the effects of fish oils on cardiovascular disease have failed to show benefit.[3-5] Trials continue into prevention of prostate cancer (the SELECT trial; selenium and vitamin E), Alzheimer's disease (the PREADVISE trial; selenium and vitamin E), and many other clinical conditions.[6 7]

The food supplement industry can use beliefs in the benefits of their products to support a profitable business. Understandably, parents will try any potentially effective treatment in an attempt to improve the health of their child with Down's syndrome. They may also feel pressured and guilty about not being able to afford expensive treatments.

Clinical trials are based on sound theoretical expectations that benefits should accrue, but often theory does not translate into clinical benefit. In theory, the genetic defects in Down's syndrome could act through excess oxidant stress that causes neurodevelopmental damage. It is therefore logical to investigate whether antioxidants could alleviate these defects.

One difficulty with researching infants with Down's syndrome is that the birth prevalence of the disease is decreasing as a result of antenatal screening and termination of pregnancy. Antenatal screening may identify the most severely affected fetuses, so the average IQ of infants with Down's syndrome who are not identified by screening may be higher than that of an unselected cohort. If the study had taken a long time to recruit, improvements in the NHS antenatal Down's screening programme might therefore have caused a false improvement in IQ. However, the study by Ellis and colleagues took a relatively short time to recruit the number of infants needed. Not all children could tolerate the treatment but for those who could compliance was good. Despite this no significant biochemical or psychomotor differences were seen between the groups. The findings are consistent with previous research.[8]

The NHS fetal anomaly screening programme is currently working hard to increase the efficiency of antenatal Down's syndrome screening by increasing the detection rate and decreasing the screen positive rate, which may encourage uptake of screening.[9] Screening programmes can do more harm than good, and ethical guidelines for screening include the concept that screening should only be carried out if an effective treatment is available.[10] When screening for Down's syndrome, the treatment is currently termination of pregnancy, which may be an effective treatment from one viewpoint, but may not be an acceptable treatment from the position of the fetus with Down's syndrome.

Antenatal screening for Down's syndrome identifies differences between fetuses with and without trisomy 21, as early as 10 weeks' gestation. This in itself indicates that postnatal supplementation would be unlikely to work. Folic acid supplements given before conception reduce the incidence of neural tube defects.[11] Perhaps supplementation with antioxidants before conception could reduce the neurobiological development damage caused by excess gene dosage in trisomy 21.

Giving vitamins to 6 month old babies with trisomy 21 does not improve their educational achievement, and until evidence of any benefit of expensive vitamin supplements is available, they cannot be recommended.

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Evaluating laboratory diagnostic tests

International collaboration to set standards and methods is urgently needed

NEWS, p 575
ANALYSIS, p 590

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Recent technological developments have created a new generation of laboratory diagnostics, which promise to provide better ways of detecting diseases and monitoring response to treatment. These tests create the possibility of earlier and more accurate diagnosis, and of shifting health care from hospitals to the community—making it more effective, efficient, and accessible. But two recent reports—one of which is published this week—highlight the relatively low importance given by clinicians and policy makers to evaluating laboratory diagnostic tests.[1 2] In an accompanying analysis, Melzer and colleagues outline the problems caused by this, specifically relating to the evaluation of genetic tests, and propose ways of overcoming them.[3]

So how should we evaluate tests? First, we must be clear about the purpose of the test—whether it is meant to diagnose, monitor, guide prognosis or treatment, or predict risk. Then the context in which it is used needs to be specified—for example, the disorder or disease, its prevalence in a particular population, and the care pathway that the test forms part of. Evaluating a test outside that care pathway is of limited use.

We can then use the ACCE framework[4]: the *A*nalytic validity (to what extent the test measures what it claims); its *C*linical validity (its ability to detect or predict the presence or absence of disease—its sensitivity, specificity, positive and negative predictive value); its *C*linical usefulness (does the test lead to better patient outcomes?); and any *E*thical, social, or legal implications (and perhaps economic implications in cost conscious health services).

Clinical usefulness should be the most important factor when deciding whether or not to adopt a test. But this is the least likely domain to be evaluated—to produce such primary evidence needs complex and expensive studies, often randomised controlled trials, with high quality of reporting to allow systematic review.[5] Some high profile tests are currently being fully evaluated, such as testing for human papillomavirus, which is being evaluated by the ARTISTIC study.[6] Such rigorous evaluation is not possible or necessary for all tests, but only for those that might lead to major changes in a care pathway and possibly substantial gain for patients. But the results of simpler forms of evaluation—at the very least of analytical and clinical validity—should be readily available, perhaps in a database of tests approved for use within health services. At present, even these results are often difficult to find.

A major reason for poor evaluation is that the regulatory framework for diagnostic tests is weak, with no international standards and no agreement on what evidence is required or by whom. Diagnostic tests are currently "CE" marked, which usually means that the manufacturer certifies that the product meets basic European Union safety and health requirements. In the UK, the Medicines and Healthcare Products Regulatory Agency expects the manufacturer to produce evidence for any clinical claims made for a test, but this lacks transparency and at best is limited to analytical and clinical validity. The NHS Centre for Evidence-based Purchasing reviews whatever evidence is available of clinical and cost effectiveness to advise NHS commissioners. But neither body can demand evidence of clinical usefulness, so manufacturers have little incentive to undertake such studies. Because diagnostics manufacturing companies are often small and lack experience in large scale trials or evaluations, they may need help with expertise and funding to produce better evidence.

Both reports agree on the need for more formal and systematic processes of evaluation and oversight of laboratory diagnostic tests.[1 2] They suggest the need for a body to take on this responsibility, but they are open on whether this body should be professional (for example, led by the Royal College of Pathologists), regulatory (like the Medicines and Healthcare Products Regulatory Agency), or advisory (like the National Institute for Health and Clinical Excellence). Such a

body would prioritise which tests need which level of evaluation and would have links to research funders, like the National Institute for Health Research health technologies assessment programme, to commission studies of clinical usefulness in the most important areas. It would also scan the horizon for developments that could greatly change patient care pathways and improve outcomes. The benefit of the advisory body taking responsibility would be that the tests would clearly be tied into a care pathway.

Exploration of the human genome seems to offer huge potential for genetic testing, and Melzer and colleagues describe how the problems outlined above all apply equally in this area. They call for harmonisation of regulatory standards internationally and for more transparency regarding the clinical evidence base for new tests. A realisation of how limited this is would lead to public and professional demand for better evidence and more formal evaluations, including trials. The valuable but voluntary UK Genetic Testing Network (www.ukgtn.nhs.uk) has evaluated over 89 tests, of which 70% were considered acceptable.

Genetic tests create particular concerns, but they may provide the stimulus to develop a better framework for evaluating and regulating all laboratory diagnostic testing in the public and the private sector. International collaboration to set standards and methods is essential. These reports have emphasised the need for such developments and have opened the debate on ways ahead.

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Illness in people with intellectual disabilities

Is common, underdiagnosed, and poorly managed

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This week a report published report by the Joint Committee on Human Rights highlights the widespread denial of fundamental human rights to people with intellectual disabilities by mainstream public services.[1] One reason why people with intellectual disabilities receive suboptimal care is diagnostic overshadowing, whereby a presenting symptom of mental illness or physical illness is incorrectly attributed to the person's intellectual disability.[2] Although people with intellectual disability have a higher prevalence of mental illness than people with a normal IQ,[3] medical professionals are less likely to diagnose psychiatric problems in this group.[2] People with intellectual disability are also more likely to have chronic disorders such as epilepsy, cerebral palsy, and genetic syndromes.[4 5] However, their health needs are often unmet.[5]

Two recent reports by the Disability Rights Commission and MENCAP have highlighted the importance of diagnostic overshadowing in people with intellectual disability in England and Wales.[6 7] They highlight the widespread inequalities encountered by people with intellectual disability or mental illness in the National Health Service and suggest that diagnostic overshadowing is one of the major barriers preventing people with intellectual disability from accessing adequate care. The Disability Rights Commission found that people with intellectual disability or mental illness were less likely to receive appropriate investigations, screening, and treatment than people in the general population and were more likely to die younger. Higher mortality in people with intellectual disability has also been found in other countries, especially in those with severe disability.[5]

MENCAP investigated the deaths of six people with intellectual disability and concluded that they were preventable and had occurred as a result of poor medical practice. The reports highlight the low priority given to the health needs of these people, the lack of appropriate training provided to medical staff, the disregard for the views of carers, and the lack of understanding of problems related to consent and capacity. Discriminatory judgments made by doctors about the value of the lives of people with intellectual disability—often based on misconceptions—were also recognised. The reports concluded that institutional discrimination is widespread within the NHS, and that the government and the NHS were failing the needs of one of the most vulnerable, stigmatised, and socially excluded groups in society. MENCAP recommended an urgent independent government inquiry into these deaths, which is now taking place. The problems were echoed by the Healthcare Commission's investigations into services for people with intellectual disability by the Cornwall NHS partnership[8] and the Sutton and Merton Primary Care Trust.[9]

So how can clinicians improve the situation? People with intellectual disability have complex medical needs and often cannot communicate their symptoms. A change in behaviour should raise the suspicion of a physical or mental illness and be investigated automatically. It is hoped that the new Mental Capacity Act 2005, which came into effect in October 2007 in

England and Wales,[10] will improve care. In patients lacking capacity, clinicians should ensure that all the necessary steps have been taken to improve capacity, such as presenting information in an accessible form, providing an independent advocate to represent the patient, and setting up "best interest" meetings where the views of carers and professionals are considered. This process will ensure that medical decisions are no longer made in isolation and are in the best interests of the patient.

The "Our Health, Our Care, and Our Say" white paper emphasises the need to give people with intellectual disability more control over their wellbeing, including access to regular health checks.[11] Currently, general practitioners in the United Kingdom receive incentives for generating a register of patients with intellectual disability as part of the quality outcomes framework. However, this is a voluntary scheme and is insufficient to meet the health needs of people with intellectual disability. When annual health checks for people with intellectual disability were introduced in New Zealand, 73% of those screened needed follow-up interventions. These interventions may not have been offered otherwise, which suggests that such a scheme would be beneficial.[12] The Disability Rights Commission has recommended several strategies for tackling health inequalities, including clear leadership from the Department of Health, strategic health authorities being held accountable for developing disability equality schemes, access to annual general practitioner health checks, and improved access to screening. The BMA and the royal colleges will need to play a more active role in implementing changes to undergraduate and postgraduate medical education, including training in communication skills for health professionals.

Improved communication and effective liaison between primary care, secondary care, and intellectual disability services is needed, together with joint working between medical bodies. This may help to reduce morbidity and mortality and improve quality of life. Research to date has used vignettes rather than actual patients, thus limiting the validity of findings in clinical practice.[13] Future research should involve extensive clinical audits of deaths and service usage, in addition to using videotapes of "real" patients rather than vignettes.

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Government's response to the Tooke inquiry into Modernising Medical Careers

Lacks a sense of urgency and an explicit timetable

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Unhappy at the Catholic Church's sale of indulgences, Martin Luther nailed his 95 theses to the door of the Castle Church in Wittenberg. While Rome eventually responded to some of his criticisms, it did not move fast enough to stall the protestant reformation.

At first glance, Sir John Tooke has been more successful than Luther, with England's secretary of state for health immediately agreeing to half his 47 recommendations to reform postgraduate medical education and training.[1-3] (Responses from Scotland, Wales, and Northern Ireland are awaited.) However, the vagueness of the government's timescale for implementation has left every spokesperson for the medical profession—starting with Sir John himself—unhappy. The government might want to reflect on the lessons of that church door.

Of Tooke's 23 other recommendations, four are matters for other organisations, two are being considered as part of Lord Darzi's next stage review of the NHS in England, and seven are consigned to the limbo of "further consideration."

In this limbo are most of the recommendations to alter the structure of training—the "visible face" of Modernising Medical Careers.[1] The rationale behind


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After me, the reformation

Tooke's new structure was to reinstate the principles of broad based beginnings and flexibility,[2] espoused in the chief medical officer for England's consultation document on senior house officers, *Unfinished Business*,[4] but eroded since then. Tooke recommended breaking the link between the two foundation years and incorporating the second foundation year as the first of three years of core specialty training. Higher specialty training would follow, with entry by competitive selection.[5]

Without an agreement on the early years, it is impossible to structure the remaining years of training. And until this is done, any new competitive selection process remains on hold. It was, of course, the very public failure of last year's competitive selection process, the medical training application service (MTAS), which triggered Tooke's inquiry.

So it hardly needs emphasising that these matters should be resolved with some urgency. Yet the government has decided to maintain the current training structure for a further, undefined period.

For England, the lynchpin of Tooke's recommendations was the formation of a new body, NHS: Medical Education England (NHS: MEE). Although it made its appearance only in the final version of Tooke's report (published 8 January 2008), the new body was to be intimately involved in the delivery of more than a third of the 47 recommendations.

The government's response was that the proposal for the new body needs to be considered alongside the work being done on workforce planning, education, and training as part of Lord Darzi's next stage review of the NHS. As this is due for publication in June, and must now be virtually complete, it is hard to see how sufficiently detailed consideration of an NHS:MEE can have happened in the past two months.

Such a body could mitigate the effects of the government's decision not to agree for England one of Tooke's recommendations—that the chief medical officers should be the senior responsible officers for medical education. In England the senior responsible officer will report through the director general of workforce to a subcommittee of the Department of Health that includes the chief medical officer. In his report, Tooke had strongly regretted that service imperatives had trumped educational ones in the training of doctors. If the routing of medical education is to continue through workforce planning (where the prime interest is not medical education but workforce needs), then a body such as NHS:MEE could provide an important counterbalance.

The government has also been vague about when (and if) general practitioner training will be extended to five years. And the merging of the Postgraduate Medical Education and Training Board with the General Medical Council, which Tooke wanted "as quickly as possible,"[2] won't be happening until at least 2010, when the government is prepared to allocate legislative time to it.

In his response to the Tooke report, the secretary of state accounts for the pace of implementation by "the need for policy development and implementation to be evidence based, and for change to be implemented only after careful testing and following co-production with professional and other key stakeholders." It will be fascinating to see whether the government holds to these tenets over the implementation of Lord Darzi's recommendations.

In the meantime, as the government is forever exhorting doctors to behave in a more businesslike fashion, it should set an example by providing SMART targets (those that are specific, measurable, achievable, realistic, and time bound) for the implementation of Sir John's recommendations. That would certainly banish any lingering suspicion that now that the hubbub over MTAS has subsided, the government is happy—as far as it can—to stick with the status quo.

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