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What has happened to the UK Confidential Enquiry into Maternal Deaths?

Following review a new consortium is charged with improving its output

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On 13 June the Healthcare Quality Improvement Partnership (HQIP) in England and Wales announced that MBRRACE-UK (Mothers and Babies—Reducing Risk through Audits and Confidential Enquiries across the UK) had been appointed to run the national maternal, newborn, and infant clinical outcomes review programme, the latest incarnation of the Confidential Enquiry into Maternal Deaths. MBRRACE-UK is a collaboration of members from the National Perinatal Epidemiology Unit (NPEU) and several universities and charities, and it is now faced with improving the quality of this long running programme and making sure its future recommendations are more evidence based.

The Confidential Enquiry into Maternal Deaths was the world's longest running clinical audit, originating in the mid-19th century. Local health board audits in the 1920s became a national (England and Wales) three yearly report funded by the Ministry of Health in 1952.[1] Its most recent purpose has been to monitor causes of maternal death, improve safety, and reduce mortality using a system of anonymised case records and regional and national assessors, with review, standardisation, and recommendations. The inquiry has engendered loyalty and respect and has been emulated around the globe.

Various structural reincarnations have included expansion to the whole of the United Kingdom (in 1985), inclusion under the umbrella of the National Institute for Health and Clinical Excellence (in 1999), and the adoption of independent charity status while incorporating the Confidential Enquiry into Child Health. In 2003 it became the Centre for Maternal and Child Enquiries (2003). Recently the inquiry was put out to competitive tender and was suspended for more than a year.[2 3] In 2011, as the new programme was about to be placed under the umbrella of the National Perinatal Epidemiology Unit (NPEU), the Department of Health initiated a further review.[2] The department sought justification for the costs of the inquiry, and for its differences in management compared with other specialties within the framework of generic Department of Health structures.

MAURO FERMARIELLO/SPL

Still important to know why mothers die

Among the challenges facing the programme's new hosts is a requirement to make the audit and its recommendations more robust. Although the UK has one of the lowest rates of maternal mortality in the world, and such deaths are few when set against a vast and rising burden of morbidity, changes in causes of death and demographic changes must still be audited. Some deaths are inevitable, but avoidable ones are unacceptable. The latest Department of Health review concluded, after wide consultation, that it was essential to continue the programme, but that quality improvements—including prompt reporting, multidisciplinary involvement, and inclusion of morbidity measures—were needed.

Despite being highly regarded, highly cited, and linked to 35 national standards in the Clinical Negligence Scheme for Trusts, the old confidential inquiry was widely criticised. Its critics argued that it dealt with "anecdote," did not fulfil audit criteria, and involved experts giving their opinion on the data collected rather than formal peer review. Thus its recommendations could not be properly implemented.[4] Epidemiologists criticised it for its expense, lack of denominators, and scanty scientific evidence of benefit.[5] Counter arguments highlighted that evidence does not always lend itself to formal scientific evaluation, and proponents of the inquiry have pointed out that its recommendations are drawn from multiple sources, which is a strength.[6]

Changing demography and the effect of this on measurable maternal outcomes presents another challenge to the new hosts of the programme. Shifts in the causes of maternal deaths have been identified by recent inquiries, which have highlighted poor mental health, cardiac disease, and sepsis as the major culprits, while deaths after assisted reproduction and elective caesarean section for breech birth, as well as deaths as a result of changes in the management of appendicitis have appeared as emerging problems.[7-10] Evidence of substandard care, especially in the areas of haemorrhage and hypertension, implies that there is room for improvement.[11] However, maternal mortality rates are rising in several high income countries and demographic changes, such as age, obesity, and migration from countries where maternal mortality is high, threaten maternal outcomes in the UK.[12] A foreseeable lack of improvement in maternal outcomes may in turn affect the perception of success of MBRRACE-UK and its chances for future funding.

Although they have to work within new cost constraints, a higher expectation of quality, and an expectation that they should show evidence of impact, the programme's new hosts, and their independent advisory groups, must not forget the traditional ethos of the confidential inquiry, which recognised that worthwhile clinical lessons can still be learnt from attending to the detail of individual tragedy and that careful unpicking of the circumstances surrounding avoidable deaths requires the engagement of front line clinicians who deliver care. Expert evaluation, peer opinion, and subjective judgment of substandard care—passed on through powerful narratives innovatively acquired (for example, through requesting relatives' views)—must still have a place in determining and motivating best practice alongside more quantifiable outcomes. The unique impact of the confidential inquiry that engendered support from clinicians and galvanised the maternity community must not be lost in an inundation of guidelines and performance monitoring.

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In future Monitor will be able to agree with commissioners that providers in areas where the costs of operating a clinically safe service are higher than their income received under the payment by results tariff should receive additional payments

Tackling the problems of seriously challenged NHS providers

Requires moving away from the usual solutions and applying the right remedies

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The experience of South London Healthcare NHS Trust highlights the inadequacies of existing approaches to dealing with failing healthcare providers.[1] The trust, which was created from a merger between hospitals that had well known financial and quality challenges, had a deficit of £65m (€81m; $101m) in 2011-12, and a similar deficit is projected for the current financial year.

One of three remedies has usually been applied to NHS providers who face challenges in delivering care of an acceptable standard within budget. The first approach is often to appoint a new chief executive and senior team. The problem with this approach is that the causes of failure may not be a result of poor management or weak governance. The scale of the difficulties facing the most challenged providers today is without precedent, and even the most able leaders will struggle to overcome them. Only when the underlying causes are properly understood can appropriate interventions be developed.

The second approach is to merge challenged providers with organisations that are performing well. Although this may help in some situations, well performing organisations may find their own performance dragged down by the work involved in supporting providers with which they merge. The evidence on mergers suggests that caution is needed, not least because of the time and effort required to bring together different cultures and realise the potential benefits in practice.[2]

A third solution involves franchising the management of challenged providers to the private sector. This is the approach adopted at Hinchingbrooke Hospital where Circle, a recently established private sector provider, has taken over the hospital's management after a competitive procurement process. Although other challenged trusts may go down a similar route, it is not clear whether private companies will be more effective than NHS managers in turning around the performance of "failing" trusts, particularly where the reasons for failure go beyond poor management and inefficient operations.

The scale of the difficulties faced by the most seriously challenged NHS providers is such that none of these approaches is likely to be adequate. The merger that resulted in the South London Healthcare NHS Trust was a compromise that the chief executive of the strategic health authority acknowledged would be difficult to make work.[3] The appointment of a new chief executive in 2009 to run the trust was an attempt to improve performance, but although quality of care has improved on some measures its finances remain problematic. A major reason for the continuing deficit is the cost of the private finance initiative hospitals run by the trust.

The UK government has recognised that the usual strategies haven't worked and has invoked the unsustainable provider regime developed by the previous government in the case of South London. Andrew Lansley, the secretary of state for health, has written to the chief executive of the trust to indicate that he is considering using the regime to deal with its current problems.

If Lansley decides to go ahead in this way, a trust special administrator will be appointed to take over the running of the trust and the board's directors will be suspended. The administrator will ensure continuity of patient care at the trust while he or she advises on options for dealing with its financial problems. A range of options is available to the administrator, including dissolving the organisation and transferring its services to other providers. It will be for the secretary of state to decide whether to take the administrator's advice, whatever this may be, or to reject it in favour of taking some other action.

The government has already announced that it will provide additional help to a small number of NHS hospitals with private finance initiative liabilities that they cannot afford, but in the case of South London it seems that this will not be sufficient for the trust to survive in its current form. The size of the trust's deficit means it may not be possible to maintain the full range of services currently provided, and a solution that entails a wider reconfiguration of services in the whole of south east London seems highly likely. This has the potential to bring about further improvements in the quality of care as well as dealing with the trust's financial challenges.

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South London NHS Trust's deficit is £65 million

Several other NHS trusts with serious challenges may find themselves subject to the unsustainable provider regime if other options for dealing with their difficulties, such as mergers, are not feasible. The same applies to NHS foundation trusts with deep seated problems, which are subject to a similar failure regime overseen by their regulator, Monitor. It might help that in future Monitor will be able to agree with commissioners that providers in areas where the costs of operating a clinically safe service are higher than their income received under the payment by results tariff should receive additional payments.

The Health and Social Care Act 2012 places a requirement on Monitor to publish annually a list of providers about which there are concerns. It is vital that these providers are given enough time and support to deal with their problems and turn their performance around. As this happens, the NHS must find ways of rewarding and recognising experienced management teams for taking on providers in difficulty and resist the temptation to blame newly appointed leaders for not delivering quick results.

Before the problems of seriously challenged providers can be dealt with, the nature and scale of the problem must be recognised, its precise cause in individual trusts diagnosed, and the remedies matched to the diagnosis. The alternative is to collude in the mistaken belief that available solutions will be sufficient to deal with difficulties that usually have a long history and have defied the best efforts of a succession of leaders from different backgrounds. That the government has invoked the use of the unsustainable provider regime for the first time indicates a welcome recognition of the scale of current problems. It is far better to begin to implement new solutions now than to wait for another catastrophic failure.

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Mountaineers and organisers of commercial expeditions do not always appreciate the importance of taking time to acquire fitness and skills

Climbing the Himalayas more safely

Fitness and mountaineering skills are most important, and they take time to develop

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Each expedition requires extensive preparatory training

Mountains are attracting a steadily increasing number of visitors. Each year, about 40 million tourists visit the mountainous areas of the Alps, and more than 100 million travel to high altitude regions all over the world.[1] For example, the number of trekkers in Nepal rose by 450% between 1994 and 2000, and a similar increase has been seen for climbers reaching summits higher than 6000 m.[2] In the linked paper, Westhoff and colleagues show that the number of climbers taking part in "traditional" (non-commercial) expeditions to high Himalayan peaks has remained relatively consistent since the 1990s, whereas the number of participants in commercial expeditions has increased continuously.[3]

Westhoff and colleagues aimed to determine whether previous participation in Himalayan expeditions reduced the risk of death associated with the climb and whether commercial expeditions are safer than traditional ones.

Although mountaineering activities may contribute to the well established health benefits of physical activity and to the inverse and independent relation between physical activity and overall mortality,[4] the study reports an extremely high risk of death for traditional climbers and those taking part in commercial expeditions who attempt to climb Nepalese Himalayan peaks.[3] The unadjusted mortality during the 40 year observation period (1970-2010) was 1.63% on Himalayan peaks of 8000 m or higher; if we assume 30 days of exposure per climb this equals 544 deaths per one million days of exposure. The risk of death varied from 170 deaths per million days of exposure on a "low risk" 8000 m mountain (such as Cho Oyu) to 1334 on a "high risk" 8000 m mountain (such as Annapurna).[3]

Compared with downhill skiing, mountain hiking, rock and ice climbing in the Alps, or trekking in Nepal, climbing in the high regions of the Himalayas is associated with a huge increase in death (table).[5-8] Compared with downhill skiing, which is a relatively high risk sport,[6] the risk of dying on Himalayan peaks of 8000 m or higher is increased on average by a factor of 495. Although Westhoff and colleagues found a trend towards a lower risk of death among those participating in commercial expeditions, the finding was not statistically significant.[3] Especially with regard to commercial expeditions, two main questions arise: which types of preventive measure have the potential for reducing the extremely high risk of death and which level of risk can be considered acceptable?

Climbing on low risk 8000 m mountains (rather than higher risk ones), improved logistics, modern equipment, appropriate acclimatisation and medical advice, and optimised weather forecasting may all help reduce mortality. Westhoff and colleagues found a significant trend towards reduced odds of death from 1970 to 2010, suggesting that such innovations and preventive efforts are already at work.[3] As reported by Huey and colleagues earlier,[9] experience in the form of previous climbs in the Himalayas had no beneficial effects.[3]

Frequency of death in relation to type of activity

Activity	Frequency of death (per 1 000 000 days of exposure)
Downhill skiing (Alps)[5]*	1.1
Mountain hiking (Alps)[5 6]*	5.7
Rock and ice climbing (Alps)[5]*	9.7
Trekking (Nepal)[7]	11
Climbing (Denali, 6194 m)[8]	100
Climbing (Cho Oyu, 8201 m)[3]†	170
Climbing (Himalayan peaks, ≥8000 m)[3]†	544
Climbing (Annapurna, 8091 m)[3]†	1334

*Calculations are based on an average of 7 days' exposure per year.[6]
†Calculations are based on reported unadjusted mortality and assume 30 exposure days per climb.

Falls were the most common cause of death and are probably associated with insufficient fitness and mountaineering skills.[9 10] Previous climbs in the Himalayas may not be a good enough indicator of these attributes, the acquisition of which requires planned and long lasting (months to years) preparatory training, so participation in a previous expedition alone is unlikely to reduce the risk of falling. Mountaineers and organisers of commercial expeditions do not always appreciate the importance of taking time to acquire fitness and skills. Better and long lasting advice during the preparatory phase and a more rigorous selection process for participating in expeditions would probably help to reduce the risk of death

As Westhoff and colleagues show, it is the duty of researchers to analyse and highlight various aspects of the risks of death associated with climbing in the Himalayas, and it is the responsibility of expedition organisers to provide all the facts about the risks to their customers. Ultimately, the informed mountaineer has to decide whether the risks are acceptable and whether or not to participate. Continuing joint efforts of scientists, expedition organisers, and mountaineers will, hopefully, help to make climbing in the Himalayas safer.

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- Practice: Lessons from the Johns Hopkins Multi-Disciplinary Venous Thromboembolism (VTE) Prevention Collaborative (*BMJ* 2012;344:e3935)
- Research: Risk of recurrence after venous thromboembolism in men and women: patient level meta-analysis (*BMJ* 2011;342:d813)
- Research: Efficacy and safety of fondaparinux for the prevention of venous thromboembolism in older acute medical patients (*BMJ* 2006;332:325)

New oral anticoagulants for preventing venous thromboembolism

Are we at the point of diminishing returns?

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Orthopaedic surgery is known to be associated with a high risk of venous thromboembolism, and prophylaxis for orthopaedic patients is vital. In the linked systematic review and meta-analysis, Gómez-Outes and colleagues present a comparative effectiveness review that examines newer anticoagulant agents (dabigatran, rivaroxaban, and apixaban) in the prevention of venous thromboembolism after hip or knee replacement surgery.[1]

This review used randomised controlled trials that had directly compared one of the newer agents with enoxaparin to indirectly compare the effects of these drugs on venous thromboembolism outcomes and clinically relevant bleeding. This type of network meta-analysis in which multiple treatments are compared using both direct comparisons of interventions within randomised controlled trials and indirect comparisons across trials on the basis of a common comparator can be fraught with peril if not done with scientific rigour.[2] It found that rivaroxaban led to significantly lower rates of symptomatic venous thromboembolism than enoxaparin but at the cost of significantly increased bleeding. Both apixaban and dabigatran were as effective as enoxaparin in preventing venous thromboembolism, but apixaban had a lower risk of bleeding.

The four agents showed no difference in efficacy with regard to the "net clinical endpoint"—a composite of symptomatic venous thromboembolism, major bleeding, and all cause mortality.[1] Readers should take away four important conclusions.

Firstly, we are reaching the point of diminishing returns with newer anticoagulants for preventing venous thromboembolism. Pushing thrombosis rates lower (as was done with rivaroxaban) causes more bleeding. Unless new antithrombotic agents are developed that target pathological thrombus formation without disrupting normal postsurgical haemostasis, further reductions in venous thromboembolism will come at the cost of increased bleeding.

Secondly, patient preferences should be considered when making decisions about prophylaxis against venous thromboembolism. The four agents examined had different degrees of risk for venous thromboembolism and clinically relevant bleeding, yet all had similar overall outcomes as measured by the author's composite net clinical endpoint.[1] The authors weighted equally the negative consequences of a thromboembolism and those of a clinically relevant bleeding event. However, patients may not necessarily weight them the same. Some patients might prefer to receive a two unit blood transfusion rather than develop deep vein thrombosis, which requires months of anticoagulation and can result in post-thrombotic syndrome or pulmonary embolism. Others might prefer a symptomatic deep vein thrombosis, which can be identified and treated, rather than a devastating haemorrhagic stroke. The specific definition of "major bleeding" is crucial. The importance of including patient preferences and their impact on decision making have been emphasised by the National Institute for Health and Clinical Excellence (NICE),[3] the American College of Chest Physicians,[4] and the newly formed Patient-Centered Outcomes Research Institute (PCORI; www.pcori.org). When pooling different outcomes to determine the net clinical benefit of a given intervention for meta-analysis, it is important to appropriately weigh and balance the harms and benefits associated with the intervention.

Thirdly, in a real world setting effectiveness may differ greatly because adherence to drug regimens may vary as a result of differences in the route of administration, frequency, duration of treatment, and side effects.

Fourthly, the authors re-emphasised the fact that venous thromboembolism still occurs, even with current best practice prophylactic regimens in highly selected patient populations in clinical trials.[5] A zero rate of venous thromboembolism is an unattainable goal. Policy makers should not therefore designate it a "never event" or use venous thromboembolism rates alone for pay for performance or quality metrics, as proposed by the NHS Quality and Outcomes Framework in the United Kingdom and the Centers of Medicare and Medicaid Services in the United States.[5 6] Instead, a more reasonable and attainable goal is to eliminate preventable harm—defined as venous thromboembolism associated with suboptimal prophylaxis.[7]

Many organisations are creating guidelines for best practice in prophylaxis against venous thromboembolism in patients undergoing orthopaedic surgery, including NICE,[2] the American College of Chest Physicians,[4] and the American Association of Orthopaedic Surgeons.[8] These organisations rely on synthesised evidence, such as the accompanying article and a recent systematic review sponsored by the Agency for Healthcare Research and Quality,[9] to guide clinicians. However, even with published guidelines, shockingly few patients get optimal prophylaxis. In one US study only 42% of patients with deep vein thrombosis had received appropriate prophylaxis during a recent hospital admission.[10] The ENDORSE study, encompassing more than 68 000 patients in 32 countries, found similarly low adherence to prophylaxis guidelines.[11] A 2012 study reported that only 40% of Austrian patients in intensive care received prophylaxis in line with guidelines.[12]

Knowledge translation in medical care is a substantial gap in the medical literature. Pronovost and colleagues offered the "translating evidence into practice" (TRIP) scientific framework on which to base quality improvement interventions.[13] Using this structure, our multidisciplinary collaborative has successfully implemented interventions that have improved prophylaxis against venous thromboembolism at our institution, and we urge clinicians elsewhere to concentrate on implementing evidence based measures.[14]

Competing interests: ERH is the primary investigator of a mentored clinician scientist development award K08 1K08HS017952-01 from the Agency for Healthcare Research and Quality entitled "Does screening variability make DVT an unreliable quality measure of trauma care?", receives royalties from Lippincott, Williams & Wilkins for a book *Avoiding Common ICU Errors*, and has given expert witness testimony in various medical malpractice cases. MBS has received research funding from Sanofi-Aventis and Bristol Myers Squibb and honorariums for CME lectures from Sanofi-Aventis and Ortho-McNeil; has consulted for Sanofi-Aventis, Eisai, Daiichi-Sankyo, and Janssen HealthCare, and has given expert witness testimony in various medical malpractice cases; no other relationships or activities that could appear to have influenced the submitted work.

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Many patients with end stage renal disease still receive folic acid supplements, and this meta-analysis shows the futility of such treatment

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Homocysteine, the kidney, and vascular disease

Moderate differences in homocysteine concentrations do not cause vascular disease

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Chronic kidney disease is common and those who have it are at substantially higher risk of cardiovascular disease.[1] The association between these two diseases is partly explained by their shared causes (such as diabetes) and by disturbances in known vascular risk factors caused by chronic kidney disease (such as higher blood pressure and altered lipid metabolism).[2] However, these risk factors do not seem to fully explain the excess risk, and other risk factors, including homocysteine, have been implicated. The linked meta-analysis by Jardine and colleagues examines the relevance for cardiovascular disease risk of lowering blood homocysteine concentrations in people with chronic kidney disease.[3] If low cost and effective interventions to reduce homocysteine (such as folic acid supplements) could also reduce risk of cardiovascular disease in these patients then the benefits for public health could be substantial (in addition to explaining the link between these diseases).

The homocysteine hypothesis of coronary heart disease was initially prompted by observations of occlusive vascular disease in children with extreme increases in plasma homocysteine (>100 µmol/L; about 10 times the normal value).[4] A meta-analysis of retrospective observational studies in 1995 reported that a 5 µmol/L higher concentration of homocysteine was associated with a 60-80% higher risk of coronary heart disease.[5] However, a meta-analysis of prospective observational studies in 2002 reported that after adjustment for known cardiovascular disease risk factors, a homocysteine concentration 25% lower than usual (about 3 µmol/L, a difference typically expected with folic acid supplementation) was associated with a more modest 11% lower risk of coronary heart disease.[6]

The enzyme methylenetetrahydrofolate reductase, encoded by the *MTHFR* gene, uses folate to metabolise and remove homocysteine. Genetic variants in *MTHFR* result in lifelong differences in homocysteine concentrations, and "Mendelian randomisation" studies, which rely on the random assortment of alleles during meiosis, can provide an unbiased assessment of causality. The initial meta-analysis of *MTHFR* and coronary heart disease in 2002 reported that people who were TT rather than CC homozygotes for the *MTHFR* C677T polymorphism had a 16% (95% confidence interval 5% to 28%) higher risk of coronary heart disease.[7] The apparently concordant results of the observational and genetic studies increased interest in the results of randomised trials of homocysteine lowering B vitamins in people at risk of vascular disease (including those with chronic kidney disease).

CHARLES BACH/SPL

High homocysteine does not warrant folic acid treatment

However, the meta-analysis of eight large trials involving 37 485 people carried out by the B vitamin Treatment Trialists' (BVTT) collaboration reported in 2010 that, on average, lowering homocysteine concentrations by 25% for five years had no effect on risk of major vascular events (relative risk 1.01, 0.97 to 1.05).[8] Although some of the trials (and previous meta-analyses) had reported significant effects for some vascular outcomes or in particular subgroups, this meta-analysis robustly refuted any beneficial (or hazardous) effects of lowering homocysteine concentrations with folic acid treatment on cardiovascular disease, cancer, and all cause mortality.

The current meta-analysis examined the effect on cardiovascular disease in people with chronic kidney disease.[3] The authors identified 11 trials of 10951 people with chronic kidney disease and extracted data from the published reports. Given the greater exposure to homocysteine and higher risks of cardiovascular disease in people with chronic kidney disease, it was expected that this population might benefit from folic acid supplementation, but the results were again resoundingly null (risk ratio 0.97, 0.92 to 1.03). Indeed, the new results are consistent with the lack of heterogeneity in the effects of vitamin B treatment on cardiovascular disease by baseline kidney function in the BVTT meta-analysis. Many patients with end stage renal disease still receive folic acid supplements, and this meta-analysis shows the futility of such treatment. It also illustrates the requirement for large scale randomised trials to identify effective and safe strategies to reduce vascular risk.

An updated meta-analysis of *MTHFR* and coronary heart disease in 2012, involving 19 unpublished datasets, reported no association of *MTHFR* genotype with risk of coronary heart disease (odds ratio 1.02, 0.98 to 1.07).[9] By contrast, a meta-analysis of published studies (28 617 cases of coronary heart disease) had suggested an odds ratio of 1.15 (1.09 to 1.21). The discrepant results of *MTHFR* studies reflect the effects of publication bias and other methodological problems.[9] After two decades of research, meta-analyses of randomised trials of folic acid and the unbiased genetic studies have convincingly shown that moderate differences in homocysteine concentrations are not causally relevant to vascular disease.

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- News: Open access to research findings will deliver benefits but "will not be cost free" (*BMJ* 2012;344:e4248)
- News: Top science body calls for open access to research data to maximise their potential for public good (*BMJ* 2011;344:e4363)

Open science and reproducible research

New reports call for scientists to share data and publishers to embrace open access

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"Scientists should communicate the data they collect and the models they create, to allow free and open access, and in ways that are intelligible, assessable and usable for other specialists . . . Where data justify it, scientists should make them available in an appropriate data repository." So said the Royal Society last week, in its report *Science as an Open Enterprise: Open Data for Open Science*.[1] The report calls for more openness among scientists and with the public and media; greater recognition of the value of data gathering, analysis, and communication; common standards for sharing information to make it widely usable; mandatory publishing of data in a reusable form to support findings; more expertise in managing and supporting the use of digital data; and new software tools to analyse data. It is time for a big shift, says the report, from the status quo where "many scientists still pursue their research through the measured and predictable steps in which they communicate their thinking within relatively closed groups of colleagues; publish their findings, usually in peer reviewed journals; file their data and then move on."

A few days earlier the UK government's working group on expanding access to published research findings, chaired by Janet Finch, recommended a "clear policy direction to support publication in open access or hybrid journals, funded by article processing charges, as the main vehicle for the publication of research, especially when it is publicly funded."[2 3] The Finch report urges funders to establish more effective and flexible arrangements to meet the costs of publishing in open access and hybrid journals; publishers to minimise restrictions on the rights of use and reuse of text and other content, especially for non-commercial purposes; funds to be found to extend and rationalise licences and subscription arrangements for research generated in the United Kingdom and published in pay walled journals; and repositories to be developed to complement formal publishing. But the report warns that the transition to widespread open access publishing will take time and money, and meanwhile the effects of the transition on subscription based journals (which still provide the bulk of peer review and set standards for high quality publishing) must be carefully considered to minimise damage to the learned societies and publishers that run them.

As Finch explains in a podcast interview with *BMJ* editor Fiona Godlee, access to published articles and access to data are separate matters, but both can potentially benefit the public (www.bmj.com/podcast/2012/06/22/research-free-all). Indeed, major funders—including the Wellcome Trust, US National Institutes of Health, and UK Medical Research Council—have jointly stated their belief that "making research datasets available to investigators beyond the original research team in a timely and responsible manner, subject to appropriate safeguards, will generate three key benefits: faster progress in improving health, better value for money, and higher quality science."[4]

These funders do not yet, however, mandate data sharing. They should. The ability of doctors to make the right decisions with patients about the benefits, harms, and costs of treatments and tests depends increasingly on high quality learning and guidance, which, in turn, depend on a robust evidence base that is as complete and as transparent as possible. We cannot rely only on results in published research articles and trial registries because they are often incompletely and selectively reported.[5] Moreover, drug regulators often lack access to full data reported in confidence, let alone to publicly accessible data.[6]

Data sharing can greatly increase dissemination, meta-analysis, and understanding of research results; it can also aid confirmation or refutation of research through replication,[7] allow better implementation of research findings,[8] and increase transparency about the quality and integrity of research. It does bear some technical challenges and risks: these include potential invasion of participants' privacy and breaking of patients' confidentiality, inappropriate data manipulation, compromised academic or commercial primacy, and breach of intellectual property rights and journal copyright, but none of these should be insurmountable.[9]

So let's get on with it. Since 2009 the *BMJ* has asked authors to state at the end of their article whether they will allow their data to be accessed or even reanalysed by others.[10] Many authors have agreed to share their anonymised data. To make it easy for authors to do this, the *BMJ* is partnering the Dryad online repository (http://datadryad.org/), something that our sister journal *BMJ Open* (http://bmjopen.bmj.com/) has been doing for some time. Fifteen datasets from *BMJ Open* articles are already posted, as well as one from the *BMJ*.[11]

Meanwhile, we are stepping up the *BMJ*'s commitment to open access. After the success of last year's pilot, we have introduced article processing fees for all published research articles. Fee waivers and discounts are available for authors who are unable to pay, and editors will be unaware of whether a fee has been paid when making their decision on publication (www.bmj.com/about-bmj/resources-authors).

With these latest high level UK reports, and the growing support of research funders around the world,[4] the move towards open access has reached a tipping point. The *BMJ* was the first major general medical journal to make research articles freely available online and has maintained its commitment to open access ever since. We will continue to debate, test, implement, and promote new ways to support authors in the publication of their work, and to achieve worldwide access to research results and data (www.bmj.com/podcast/2012/06/22/research-free-all).

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