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Letter: The REF and UK academic medicine (*BMJ* 2012;344:e544)

The UK's Research Excellence Framework 2014

A tool with many uses including, now, assessment of the usefulness of research

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In 2014 the United Kingdom will conduct its seventh universities research assessment exercise in which it will assess, rank, and reward universities according to the excellence of their research between 2008 and 2013. As usual there are changes to previous processes, which include a new name (the Research Excellence Framework, or REF), an attempt to reduce costs, and an increased focus on the impact of research.[1]

As an exercise in accounting and rationing, the process enables the four higher education funding bodies in the UK to allocate nearly £2bn (€2.5bn; $3.2bn) of research funding—about 30% of all university research funding each year—on the basis of peer review of research outputs. The involvement of more than 140 of the UK's most senior health researchers in six subpanels will lend legitimacy and authority to the task.

The effect of serial university research assessment exercises has been to concentrate resources in centres of excellence

A researcher's four best publications (described as "outputs") during the period will be assessed for their originality, importance, and rigour. They will then be graded as world leading (4*), internationally excellent (3*), internationally recognised (2*), nationally recognised (1*), or unclassified. Only a small number of research studies can really be considered world leading or internationally excellent, especially in health services research, which is usually concerned with local issues. However, grades 4* and 3* are the ones that count in the REF. Anything below 2* will attract no funding and too many 2* papers will weaken a submission.

After the 2008 research assessment exercise, about 50% of the available research funding was allocated to the "top 10" universities.[2] A great deal of effort was therefore expended to produce fine gradations between universities and to distribute the remaining funding. Mindful of the cost of the exercise, assessed at £47m in 2008 (about 0.5% of the value of public research funding), with little change from the previous exercise, REF 2014 will involve half the previous number of panels and subpanels.[3]

UK research compares well internationally and produces more publications and citations per British pound of public funding than any other G8 country. Because other countries do not carry out national research assessment exercises, such comparisons do not depend on REF data. The "reputational yardsticks" and "valuable benchmarking information" that the REF produces are therefore for local consumption and are increasingly used to monitor and manage research activity within institutions. Although at a national level the REF results are not concerned with individual researchers, within institutions that are seeking to concentrate and prioritise their resources the focus is very much on individuals.

An important new feature of REF 2014 is its focus on research impact, which will account for 20% of the "quality profile" to be awarded to each submission.[2] After substantial piloting and consultation with universities and research users, it has been agreed that one example of research impact "outside the academic sector" should be described and assessed for every 10 researchers included in each submission. Impacts must be linked to at least one 2* paper published since 1993.

With 20 years of research findings to choose from and a broad definition of research impact ("any effect on, change or benefit to the economy, society, culture, public policy or services, health, the environment or quality of life, beyond academia"), it should not be difficult for universities to find examples of research impact to satisfy the public purse. This exercise will force researchers and institutions to consider the relevance and usefulness of their work and will require them to put systems in place to maximise their research impact. The examples should also inform wider discussion in the public domain.

One effect of serial university research assessment exercises has been to concentrate resources in centres of excellence, and for these centres to concentrate on smaller numbers of research areas. As universities become knowledge factories, producing particular types of knowledge, the question arises of how well the public is being served.

Whatever the excellence of medical knowledge, professional skills, and health policies, these are often irrelevant to the needs of patients, incompletely applied, or deployed in ways that provide poor value for money. Health systems around the world are struggling to find ways of coping with ageing populations, endemic multimorbidity, service fragmentation, resource constraints, and widening inequality. We will increasingly need well researched local solutions to these internationally prevalent problems.[4]

The REF has many uses, and it will soon be possible to add another, the assessment of usefulness. Peer review will sort out false claims, but when REF 2014 has reported, a wider discussion can begin—on what society needs and gets from its health research.

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- Analysis: Social determinants of health and the design of health programmes for the poor (*BMJ* 2008;337:a290)
- Analysis: Tackling social determinants of health through community based initiatives (*BMJ* 2006;333:854)
- Feature: Putting health inequality on the map (*BMJ* 2010;340:b5558)
- News: Avoid cuts that will widen gaps in child development, Marmot urges (*BMJ* 2011;342:d971)

Ensuring the health of future populations

Requires that social determinants are set within the wider biophysical environment

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Marmot's recently published review of health in Europe identifies people's social and economic conditions as fundamental determinants of their heath.[1] Like the larger World Health Organization report on which it builds,[2] the report singles out conditions in early life and urges governments to give priority to improving children's lives to promote both their future health and the health of future generations. The social determinants of health and a commitment to intergenerational equity are the cornerstones of the review.

The review's concern with social determinants and generational equity aligns it with the broader mission of public health. In its classic formulation, the role of public health is to ensure the conditions in which people can live healthy lives, and its duty is to protect conditions for health over time and across generations.[3 4] The principle of moral equality—that no one individual or group is intrinsically superior to another—underpins this duty. This principle demands that "we treat the welfare of future generations on a par with our own" and do not discriminate against future populations simply because they are differently located in time.[5]

However, despite the stewardship responsibilities placed on those working for the public's health, it is widely acknowledged that there has been little sustained engagement with the conditions for the health of future generations. Most published research and policy endeavours are concerned less with environments than with lifestyles, and more with current risks at the individual level than with looming population level threats. Such a perspective identifies factors like tobacco use and physical inactivity as the leading global risks to health and as the primary targets for public health interventions.[6]

The series of WHO reports on the social determinants of health aims to move public debate and policy making beyond this concern with proximal causes and to focus attention on "the causes of the causes."[1 2] It is an approach captured in Dahlgren and Whitehead's iconic "rainbow" model of the main determinants of health,[7] and it is supported by a rich seam of epidemiological research.[2 6] In line with this evidence, the European review argues that the fundamental determinants of health—housing and sanitation, education and employment, welfare services, and healthcare—are produced by the societies in which people live.[1] The report notes the challenges presented by climate change; however, the biophysical environment does not figure among the causes of the causes.[1] As currently conceived, the social determinants of health appear to end where the earth's life supporting systems begin.

As Rose observes, the determinants that are most difficult to recognise are those that are universally present.[8] Over the last 10 000 years (400 generations) the stability of the earth's biophysical systems has been the universal presence, the taken-for-granted platform on which the economies of today have grown and flourished.[9] Across this geological era, the earth's climate, atmosphere, soil and water systems, biodiversity, and sea ice concentrations have stayed within a relatively narrow range of variability.

GMB AKASH/PANOS

Some efforts to improve health equality degrade the environment, which will affect future populations' health

However, this period of stability seems to be ending abruptly,[5 9 10] and we are now on the cusp of a new geological period that has been triggered and shaped by human activity. Economic growth, in particular reliance on fossil fuels and industrialised forms of agriculture, is damaging the earth's biophysical systems at an accelerating rate, moving them beyond their previously stable boundaries and triggering potentially irreversible and catastrophic damage to the earth's capacity to sustain life.[9-11] Indeed, some of the factors identified as the social determinants of health for today's populations are degrading the biophysical environments for tomorrow's populations. As a consequence, current generations are the advantaged minority, and the disadvantaged majority are those yet to be born.[12] The challenge of intergenerational equity extends well beyond tackling the generational transmission of disadvantage.

To deal with this challenge, the social determinants of health must be set within the wider biophysical environment. The boundaries of the causes of the causes must be extended to include the climate systems and ecosystems on which future health depends. It is difficult to quantify the value of stability in these systems using standard models of economic evaluation, where costs and benefits are measured in market terms.[5 10 13] Although useful for evaluating policies with limited temporal and spatial impacts, the models are ill suited to the ethical and policy challenges raised by systemic and irreversible changes in the prerequisites for survival.

A starting point for the public health community is to assume the position and perspective of future generations.[5 13] From this vantage point, neither the risk factor nor the social determinants approach is "fit for the future." Neither approach is designed to ensure that future conditions for health are at least as good as those today. The urgent need is to give substance to the call for equity across generations made in the European review of health determinants and enable public health to be the voice for the disenfranchised populations of the future.[1]

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Further care home scandals like Winterbourne are likely without action, warn campaigners (*BMJ* 2012;345:e5379)
General health checks in adults for reducing morbidity and mortality from disease (*BMJ* 2012;345:e7191)

Mortality from preventable causes is three times higher among people with moderate to severe intellectual disabilities than it is in the general population

Annual health checks for people with intellectual disabilities

Potentially an important step towards reducing health inequalities

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The recent convictions in the United Kingdom of 11 staff members from Winterbourne View Hospital of the criminal charges of abuse of adults with intellectual disabilities highlights the continued institutional weaknesses in caring for this vulnerable group.[1] However, most people with intellectual disabilities reside in the community, supported by primary care services. Substantial effort has been made in recent years to improve the care of these people through a change in legislation and financial incentives to general practitioners.

In 2006 the Disability Rights Commission recommended the introduction of annual health checks for people with intellectual disabilities in England as a way to reduce the health inequalities experienced by this group.[2] Since 2008 general practitioners in England have been incentivised to perform a structured annual health check for adults with intellectual disability through an optional payment process (enhanced service).

The Learning Disabilities Public Health Observatory was set up in 2010 in response to a recommendation of the report of the Independent Inquiry into Access to Healthcare for People with Intellectual Disabilities.[3] The observatory has published a series of key reports on various aspects of healthcare for people with intellectual disabilities, including surveillance of the number of annual health checks being performed in primary care and local health profiles to help plan local social and healthcare services.[4]

Life expectancy is increasing in people with mild intellectual disabilities, as it is in the general population. However, mortality from preventable causes is three times higher among people with moderate to severe intellectual disabilities than it is in the general population.[5] People with intellectual disabilities also have considerable multimorbidity and have 2.5 times as many long term clinical conditions (excluding intellectual disability itself).[6]

Rates of admission for some conditions that are sensitive to ambulatory care (such as epilepsy, reflux, and constipation) are higher in people with intellectual disabilities. In addition, a substantially higher proportion of admissions to hospital occur as emergencies in this group compared with the general population (50% *v* 31.1%).[7] Recognising and managing ambulatory care sensitive conditions that are specific to people with intellectual disabilities in primary care should lead to fewer unnecessary hospital admissions.[8]

An Australian randomised controlled trial of people with intellectual disabilities reported that the detection of new disease was 1.6-fold higher in the regular health check group than in the no systematic health check group.[9] In addition, a recent systematic review concluded that the introduction of health checks typically led to the detection of unmet, unrecognised, and potentially treatable conditions, including serious and life threatening diseases such as cancer, heart disease, and dementia.[10] Ensuring that all people with intellectual disability receive an annual health check is one way of dealing with the additional unmet health needs of this population.

Although the number of health checks has steadily increased since their introduction, only 53% of people with intellectual disability received a health check in England in the last financial year.[4] Health checks are associated with substantial coding activity for incentivised health screening, health promotion, and disease finding related to the quality outcomes framework, but this is less so for processes specific for intellectual disability (visual and hearing assessment, for example), with considerable variation in recording.[11] However, there is marked inequality in uptake of health checks, with great variation between primary care trusts (the lowest 10% delivering less than 25%, and the upper 10% completing health checks on more than 69% of their eligible patients).[4]

It is not yet clear whether health checks lead to improved outcomes, such as fewer hospital admissions related to emergencies. In addition, although the NHS Outcomes Framework 2012-13 is committed to capturing excess mortality in people with intellectual disabilities,[12] the lack of substantial data linkage across healthcare settings makes this technically difficult.

The true impact of health checks can be assessed only through continued data gathering and improved surveillance across healthcare settings, and continued funding of the Public Health Observatory for Intellectual Disabilities is essential. However, gaps remain, such as identifying and dealing with the needs of people with intellectual disabilities and their carers; making reasonable adjustments in cancer screening programmes; identifying the needs of ethnic minority populations; and improving the care of children and young people, particularly through transition across healthcare settings.

Currently the programme of annual health checks is renewed on a yearly basis in England, but firm long term commitment to annual health checks and their evaluation is needed, with benchmarking of results at the practice level. Otherwise, we may continue to witness the cascade of disparities and a widening of the health inequality gap between those with intellectual disability and the general population.

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SPL

- Research: Risk of cancer with metal-on-metal hip replacements (*BMJ* 2012;345:e4646)
- Feature: How safe are metal-on-metal hip implants? (*BMJ* 2012;344:e1410)
- Feature: Ongoing problems with metal-on-metal hip implants (*BMJ* 2012;344:e1349)
- Practice: Diagnosing and investigating adverse reactions in metal on metal hip implants (*BMJ* 2011;343:d7441)

Metal-on-metal hip prostheses: where are we now?

Hip resurfacing may still have a role to play, but long term performance and safety data are needed

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In the late 1950s John Charnley, working in the north of England, introduced Teflon as a joint bearing surface material in his then visionary "low friction" hip joint replacement. Initial clinical success was soon followed by catastrophic mechanical failure and local tissue destruction owing to foreign body soft tissue reactions, and the use of Teflon in prostheses was abandoned by 1962.[1] Fifty years later this cycle of promising innovation followed by unforeseen complications seems to be repeating itself with metal-on-metal hip prostheses that use large diameter (≥36 mm) bearings.

Charnley's solution was to use high density polyethylene, and this is still a good choice of bearing material for older patients. However, in young patients with high physical demands, polyethylene prostheses wear out too quickly and often need to be revised. The introduction of hard wearing contemporary metal-on-metal bearings in the 1990s promised an end to prosthesis failure related to wear debris and better biomechanical function owing to the larger more natural diameter of the replaced joint. Initial enthusiasm led to about a million of these bearings being inserted worldwide during the past decade. However, reports of poor survival of prostheses, destructive local tissue reactions, and raised concentrations of cobalt and chromium metals in the blood of patients receiving these implants have now burst this bubble of optimism.

This episode has provoked reflection on the marketing authorisation process for new medical devices and raises several clinical questions. Does the clinical performance of these devices in most patients justify their role in the treatment of hip arthritis? What are the actual health risks of the technology? What forms of surveillance should we use to detect adverse effects, and how should we treat them?

The five year survival of large diameter metal-on-metal bearings placed above a standard femoral prosthesis has been substantially poorer than that of conventional hip replacement with a smaller femoral head component,[2] and their use has been largely abandoned in the United Kingdom and elsewhere. The short term survivorship of metal-on-metal hip resurfacing, in which only the hip joint surface (and not the head) is replaced, is also poorer than for conventional hip replacement.[3] However, the finding that the longevity of hip resurfacing in younger men with large (≥54 mm) hip joints is similar to conventional hip replacement for some brands of prosthesis suggests a place for this technology in selected patients.[3 4] But short term evidence is no substitute for long term survivorship data, and ongoing use of this technology will ultimately require demonstration of long term prosthesis survival at least equivalent to conventional hip replacement in this patient group.[5 6]

A recent clinical trial found that the 12 month functional outcomes of hip resurfacing are similar to those of conventional hip replacement and do not support claims of better hip function,[7] although the measurement tools used may have been subject to ceiling effects. Further randomised studies of longer duration—that target younger men and use outcome measures that are sensitive to performance differences at the higher end of the functional spectrum—are needed to clarify the efficacy of this intervention and inform models of its cost effectiveness.

What of exposure to metal debris? Toxicological studies and evidence from accidental exposure show that high concentrations of cobalt or chromium have genotoxic and other effects on multiple organ systems.[8] The consequences of prolonged systemic exposure to the mildly raised concentrations of these metals in patients with a well functioning prosthesis remain unclear. The Food and Drug Administration in the United States has responded by instructing prosthesis manufacturers to conduct cross sectional studies up to eight years after implantation to quantitate the adverse health effects associated with metal exposure (FDA, May 2012). The methods chosen will need to be appropriate and robust enough to confidently exclude general health effects that are likely to be subtle over this short exposure time. Recent findings that the short term risk of cancer and all cause mortality do not seem to be higher in patients with metal-on-metal bearing surfaces than in those with other bearings may instil confidence.[9 10] However, the anticipated long service life of these prostheses and the lead time for the development of disease mean that definitive answers will emerge only through ongoing surveillance.

The Medicines and Healthcare Products Regulatory Agency (MRHA) in the UK recommends measuring blood cobalt or chromium concentrations to detect the malfunction of prostheses in selected patient groups, followed by cross sectional imaging of the hip in patients with concentrations greater than 7 µg/L.[11] However, the value of this screening tool is unproved because the sensitivity of the chosen threshold is low (52%).[12] In addition, it is unclear how asymptomatic patients found to have raised metal concentrations or non-destructive lesions on imaging of the hip should be treated. The reliability of metal concentrations also needs to be assessed, given the lack of standardisation of collection and assay methods between laboratories. Furthermore, the cost of this additional device specific surveillance must be included in assessments of the cost effectiveness of this technology.

Metal-on-metal hip resurfacing may have a role to play in treating a subset of patients with high physical demands. However, investment in defining its long term outcomes and safety is needed before its cost effectiveness can be established. Meanwhile, other bearing materials continue to be developed and may provide an alternative solution to the problem of prosthesis wear and failure. These technologies will require similar scrutiny before we can be confident of their clinical value,[13] as history has a way of repeating itself in the innovation of joint arthroplasty.

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Correction

Call for worldwide withdrawal of tiotropium Respimat mist inhaler

In the print version of this Editorial we mistakenly used a picture of the HandiHaler (rather than the Respimat) device, which we accompanied with an incorrect caption (*BMJ* 2012;345:e7390, print publication 24 Nov, p 9). The caption "Use of the Respimat device confers greatest risk" is inaccurately applied to the picture of the HandiHaler device. We would like to clarify that the article refers to the risks of the Respimat device and that the authors do not question the use of the HandiHaler. We apologise for any confusion caused by this mistake.