NHS rethink: charade or cause for new hope?

We asked a range of commentators for their thoughts on the proposed changes to the NHS Health and Social Care Bill. Do the changes move us to a healthcare model we can be proud of or do they take us back to pre-1948 inequity and a "return to fear"?

Kate Arden, director of public health, Wigan

I've been a chief officer in the local authority for three years now. If you are a doctor who has "grown up" in the NHS don't underestimate what a big culture change it is moving to local government. You will need to influence cabinet and understand how local authorities work. Public health professionals will be coming into local government at a time of huge cutbacks and will have to negotiate that change and continue doing their job. It is going to be a real leadership challenge to keep them motivated. But I do think public health's proper home is in local government—the key thing is not to lose precious links with the NHS.

I'm glad that Public Health England is to be an executive agency. Public health has to be seen as independent—you sometimes have to give advice, even when people don't want to hear it.

Kambiz Boomla, chair of City and East London Local Medical Committee

This bill arose as the latest stage in a plot against the NHS, as enabling legislation to allow for its gradual dismemberment and piecemeal privatisation.

We have won concessions that might slow down the privatisation project. Yet most of the proposed amendments are neither as important nor as welcome as might first appear.[1 2]

While the commitment to retain the responsibility on the secretary of state for a comprehensive health service is welcome, this duty is watered down into "securing" rather than "providing," an important distinction as it allows further privatisations.

It's good that clinical networks are retained and that commissioning groups must be responsible for whole borough based populations. Yet commissioning managers, although now "more valued," can still be drawn from the private sector.

Monitor's main duty is no longer to promote competition, but instead "patient choice" has been chosen as the new battering ram the private sector will use to increase its NHS market share. Commissioners now have an obligation to "make markets," if patients complain. "Supporting choice, competition, and integrated care" is not a change of direction, simply a slowing of pace.

Not removed is Andrew Lansley's pledge that there will be "no toleration of financial failure." As austerity cuts inevitably drive provider units into deficit, we still face the prospect of debt problems forcing hospital closures, with the only alternative on offer being private sector buy-out.

The BMA should retain its opposition to the bill. Greater clinical involvement in commissioning can be achieved without a bill at all.

Andy Haines, professor of public health and primary care, (left) and Liam Smeeth, professor of epidemiology, London School of Hygiene and Tropical Medicine

While the recommendations by the NHS Future Forum deal with many concerns, there remains a stark lack of evidence to support the proposed reforms and no clear plan of evaluation. Vast sums of public money and the energy and commitment of thousands of talented people could be wasted implementing policies with little or no evidence base.

Elected governments rightly determine the resources allocated to and the overall priorities of health services. However, the means of achieving their objectives should be scrutinised by—and ideally developed in collaboration with—an independent body equipped with the necessary technical capacity. The Future Forum set a precedent, but it was convened as an afterthought in order to respond to a crisis in public and professional confidence and had neither the time nor the resources to examine the evidence base for the reforms. The proposed new independent body should be empowered to systematically review the evidence for the most cost effective strategies to meet the government's objectives and could work closely with the National Institute for Health and Clinical Excellence (NICE), which has many of the skills required. Major policies should be implemented on a trial basis with mandatory evaluation using the best available designs through a competitively commissioned research programme.[3] The results of evaluative research would determine whether a policy was implemented nationally.

Stephen Lawrence, general practitioner with a special interest in diabetes, Kent

I'm glad Monitor's wings have been clipped and that nurses and doctors will be represented in commissioning groups. But they've watered down the 2013 deadline. This deferral is one of the greatest threats to these reforms. The government should have learnt from fundholding, where the early adopters did very well for patients but not so well by the third and fourth waves. They should have stuck to their guns and said 2013, that's it.

GPs have worked with the private sector for years. What is different now is there is going to be more emphasis on the private sector providing care. It's important to ensure a level playing field so that the health economy is not destabilised by companies picking the low hanging fruit, then claiming they have a good track record in providing NHS care and picking up lots of national contracts as a result. The problem is that GPs may get left with the more difficult high hanging fruit to be provided for hard to reach groups. This may give the perception that GPs are not being as successful as the private sector.

David J Hunter, professor of health policy and management, Durham University

The outcome of the "pause and listen" charade is a masterly lesson in wordsmithing worthy of the BBC political satires *Yes Minister* or *The Thick of It*. True, some cosmetic changes have been made to mollify critics of the bill. But on the more contentious and worrying aspects of the proposals, it's a case of smoke and mirrors. The media have largely been duped, and those Liberal Democrat MPs who rose up in anger back in March seem to have dutifully accepted the prescription of Steve Field and his Future Forum.[1] The giveaway lies in both prime minister David Cameron and deputy prime minister

Nick Clegg claiming victory. Surely they can't both be right? Take the Future Forum's report on choice and competition. Largely accepted by the government, it takes few hostages, arguing vigorously in favour of more pluralism and diversity in provision. The contested desire for choice and competition is swept aside in favour of an insistence, based on flimsy evidence, that both are essential. Make no mistake, the proposals are virtually indistinguishable from those in the bill. Soothing words about slowing the pace of change and ensuring that nice cuddly mutuals take the strain rather than nasty for-profits (even if it is often hard to distinguish the two) amount to a clever attempt to deflect attention from the charge of privatisation. Monitor's modified remit is designed to reassure, but as long as those appointed to head up the original version remain then the reality is unlikely to match the new rhetoric. And there's the rub. As ever, the devil is in the detail, and most of that is not yet in place. When it is, it may be too late.

Judith Lindeck, general practitioner, Cambridgeshire

To this grass roots general practitioner, the revised health bill is as unclear as the original, while promising yet more bureaucracy.

I am pleased to see the removal of "promoting competition" from Monitor's role. Personally I feel abandoning the purchaser-provider split would save a huge amount of money; all parts of the NHS should work together to improve patient care. At present, it feels as though the main aim of secondary care is to squeeze as much money from primary care as it can. Often the local provider obstructs commissioning of new community based pathways lest it lose money. Our local secondary care trust is effectively a monopoly and hence has considerable power.

With these changes, primary care trusts and strategic health authorities could be swept away before all consortiums are up and running. How many good administrators will leave during this period of instability? Many have already gone; in our area, one commissioning group has already gone live and is sucking up resources, destabilising services needed by other practices. This effectively creates a two tier system, something the government said it aims to prevent.

The paper states that no GPs will be compelled to get involved in running consortiums. However, as all practices must be involved, all will have to cover while a partner represents the practice at meetings. Everyone else will have to pick up the work, and my major concern—that with a more part time work force there won't be the capacity to do the work—is not addressed.

Allyson M Pollock, professor of public health research and policy, Barts and The London School of Medicine and Dentistry

The Future Forum report and the government response signal that the policy of switching to mixed funding and insurance pools and further privatisation of care is unabated.[1 2]

Redistribution underpins the 1946 NHS Act and the secretary of state's duty to secure and provide comprehensive care. If redistribution had been central to the forum's concerns it would have highlighted how the bill will allow commissioners to pick and choose patients and services, introduce user charges, and promote private health insurance by entering into joint ventures with private companies and equity investors. It would then have argued for the restoration of the 1946 duty to secure and provide comprehensive care and the mechanisms that this requires—namely, administrative tiers covering geographical populations; services integrated into the administrative structures; the abolition of billing, invoicing, and market transaction costs; and the denial of care by patient selection.

It did none of those. Instead Monitor, the health service regulator originally charged with promoting competition, is retained. Government assurances that market reforms do not change "the application" of EU law are unchallenged.

And the forum is silent on how primary care trusts, in advance of their abolition in 2013, are closing NHS hospitals and services and drawing up lists of services that will no longer be provided by the NHS. It recommends that clinicians and nurses be given a new "right to provide" and start-up funds to try their hand at turning tax funds into profits.

It amounts to a return to pre-1948 arrangements of inequitable provision and a return to fear.

Martin Roland, professor of health services research, University of Cambridge

I qualified 35 years ago. Maybe I was young and naive, but I remember being proud that we had the best healthcare system in the world. With the proposed changes to the NHS reforms, I think we are moving towards a model that we can again be proud of.

GPs will retain a large measure of control over commissioning. This will harness their enthusiasm and entrepreneurialism, but they will not be free agents. Commissioning groups will have at least one specialist and one nurse member on their board (not from local providers), and lay members will have an important voice. Commissioning boards will also have to listen to local "clinical senates" on which a wide range of disciplines will be represented. This all sounds like a good compromise.

The risk of a market producing fragmented care has been reduced. Clinical commissioning groups will have a "duty to promote integrated health and social care," clinical senates will include experts "to support better integration of services," and Monitor will be required to "support the delivery of integrated services" where this improves care or efficiency. So although there will still be an emphasis on patient choice, the risks of an unfettered market have been reduced.

The speed of change will be slowed down, giving some prospect that the new model might get the five to 10 years that it will need to bed-in. Several important areas remain unclear. Proposed changes to medical education had few supporters and will be rethought. It is also unclear how public health will sit in the new NHS. However, overall, we now have an imaginative approach to organising healthcare that might just make the NHS the envy of the world once more.

Peter Watts, chief executive, The Practice (runs 60 general practices across England, employing 220 doctors)

There is massive scope for increased efficiency in the NHS. One example is outpatient clinics; you hear of patients making multiple visits to a hospital before they eventually get to see an appropriately trained senior specialist instead of a more junior clinician. It is nearly always more beneficial for a patient to be referred to a specialist who is appropriately experienced and for that person to be seen in a primary care setting, closer to a patient's home and outside of an acute environment. Not only is this more cost effective; it relieves pressure on hospitals, and patients prefer it. The NHS is an excellent model, but it is not a religion; there isn't just one way to provide healthcare.

I'd say to clinicians, don't try to do it all yourself. As professionals they need to do their day job; clinicians to do the medicine, not the information technology, European law, finance, etc.

GPs and all NHS providers should not be fearful of competition but embrace it in order to sustain the health ecosystem and drive standards. Integration is key to delivering 21st century healthcare—but integration and competition aren't mutually exclusive—they can and do sit successfully side by side. This is why data gathering, data interpretation, and data sharing are fundamental to the success of The Practice and future healthcare in the UK.

References are in the version on bmj.com

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See EDITORIAL, p 1

bmj.com
- Feature: Secrets of the MMR scare: The *Lancet*'s two days to bury bad news (*BMJ* 2011;342:c7001)
- Education and debate: Investigating the previous studies of a fraudulent author (*BMJ* 2005;331:288)

Calling time on research's Wild West

The only UK body dedicated to promoting research integrity had its funding withdrawn last year. So what is the future for policing research fraud? **Clare Dyer** reports

Eric Poehlman holds a unique place in the annals of medical research. Once a highly regarded US researcher on obesity, metabolism, and ageing, he published hundreds of papers and garnered millions of dollars in grants over his 20 year career. In 2006 he became the first biomedical scientist in the US to go to jail for falsifying research data.[1] Last year another US serial research fraudster, anaesthesiologist Scott Reuben, was jailed for conducting a series of fraudulent clinical trials of multimodal analgesia over six years.[2]

Prosecutors in Germany launched a criminal investigation this year after the editors of 16 medical journals retracted 88 articles by professor of anaesthetics Joachim Boldt because he failed to obtain ethical approval. He was stripped of his professorship, and the hospital where he was chief anaesthetist set up an investigating commission to review his work for data fabrication, falsification, or misrepresentation.[3 4]

In the United Kingdom, the Andrew Wakefield saga has highlighted the inadequacies in the country's system for tackling research misconduct. Dr Wakefield, a reader in experimental gastroenterology at London's Royal Free Hospital School of Medicine, sparked a worldwide scare by suggesting a link between autism and the MMR vaccine. He was struck off the medical register in 2010, and only then did the *Lancet*, which published the research in 1998, retract the article. Although he was ousted from his job in 2001 for refusing to replicate his controversial study, the medical school did only a cursory investigation in 2004 when the journalist Brian Deer raised substantial concerns about his work. And it took the same journalist to provide clear evidence that the study was not only unethical but fraudulent.[5]

The effects of the failure to tackle his wrongdoing more quickly and decisively are still being felt. Vaccination levels in the UK have still not fully recovered, and measles cases are on the rise around the world.[6] University College London, which merged with the Royal Free medical school a few months after the *Lancet* article was published, announced only three months ago that it would at last investigate the events behind the *Lancet* paper and Dr Wakefield's other work.[7]

Research misconduct can often take years to come to light. It can go undetected for decades, poisoning the evidence base on which doctors rely in choosing treatments for their patients. The scale of the problem is uncertain, although in 2009 the first meta-analysis of surveys questioning scientists about the incidence of research misconduct produced worrying findings. Around 2% admitted fabricating, falsifying, or altering data and up to 34% admitted other questionable research practices, with medical and pharmacological researchers the worst offenders.[8] Yet proposals by the Academy of Medical Sciences for a new Health Research Agency in the UK make no mention of integrity and skate over the need for measures to ensure that the research it hopes to facilitate is honest and reliable.[9]

Meanwhile the sole UK body dedicated to promoting research integrity is the UK Research Integrity Office (UKRIO). Set up in 2006 with the backing of the research community and the Department of Health, UKRIO is a low key independent body with no statutory basis and no investigatory powers. It was initially funded by the Department of Health, Universities UK, Research Councils UK, and others. But in a climate of economic stringency that funding has been withdrawn and it is now seeking new backers.

US Office of Research Integrity

The roots of the US Office of Research Integrity (ORI) date back to 1981, when congressional hearings followed a public furore over the discovery of research misconduct at four major US centres. It was created from the merger of two earlier offices in 1992.

The ORI lost its powers to initiate its own investigations more than a decade ago, and fact finding is carried out by the institutions where misconduct is suspected. But institutions receiving federal funds must have a policy on research misconduct that includes a proper investigation. Findings of investigations must be submitted to the ORI, which reviews them for "timeliness, objectivity, thoroughness and competence." The ORI may reanalyse the research data, publications, or other source documents, and make recommendations to the assistant secretary for health on administrative actions to be taken against the researcher.

Possible actions include corrections or retractions of journal articles and a ban on receiving federal funds or acting as a consultant to a public health body. The office saw Dr Poehlman jailed for a year for using fraudulent data in securing millions of dollars in federal research funds and in academic articles over a decade.

Limited powers

UKRIO's role is limited. It provides advice and assistance in investigations free of charge but relies on the institutions where research misconduct is suspected to carry out the necessary inquiries. With no power to instigate an investigation, it will advise when whistleblowers or institutions alert it to questionable research practices but can take no action on inadequate institutional investigations and cannot impose sanctions or publicise wrongdoing.

But universities, as a recent editorial in *CMAJ*, the Canadian Medical Association journal,




L to R: Andrew Wakefield and Malcolm Pearce, both struck off the register; Scott Reuben, jailed for fraudulent trials and Eric Poehlman, jailed for falsifying data

noted, have an inherent conflict of interest, concerned as they are with "academic reputation, high-profile faculty and the imperative to keep grant and sponsorship money flowing,"[10] The temptation is to get rid of the researcher (as happened in the Wakefield case), and often the whistleblower too, and sweep the mess out of sight.

Peer review and other mechanisms for ensuring the integrity of research wholly failed in Dr Wakefield's case. Some argue that only a statutory oversight body with investigatory powers conferred by parliament can properly safeguard the public reputation of science and the integrity of the research base. Peter Wilmshurst—a cardiologist and one man crusader against research misconduct who has reported around 25 doctors to the UK medical regulator, the General Medical Council (GMC), for research malpractice—would like to see "a statutory body with some powers to investigate to go into universities and compel people to produce their lab books and their results, so they can be investigated." Researchers found to have misbehaved should have all their results checked, and the universities employing them should face fines and be forced to repay grants, he suggests.

The UK is not the only country currently debating whether its research integrity mechanisms need beefing up. The issue has moved up the agenda worldwide. Canada, which has had its own scandals involving faked research, is currently considering introducing a new research integrity regime. The Council of Canadian Academies has proposed a federal agency without investigatory powers, focusing on education and prevention.[11] Not good enough, say *CMAJ* editor in chief Paul Hébert and colleagues in their editorial.[10]

They call for a new agency or an existing authority to be given "the power and mandate to investigate all allegations of research misconduct, along with the authority to compel researchers to come before panels and institutions to provide access to all necessary information to exonerate or find fault." For maximum deterrence, they insist, the authority must "publish the names of all individuals involved in serious misconduct, release the outcomes of all investigations and issue regular reports."

Such powers require legislation, and few countries so far have research integrity regulators set up by statute. Those that have legislated have usually done so in response to high profile scandals that have been seen as a threat to public confidence in science. But several countries are looking at their research integrity systems and debating the extent to which problems can be dealt with by advisory bodies, codes of conduct, and a focus on prevention and training, or whether stronger regulatory powers are needed.

Norway, Denmark, and Croatia have independent bodies created by legislation, with some investigatory powers, and Poland's parliament last year adopted measures for a national commission to oversee research ethics. In Sweden, universities are obliged by law to investigate any allegations of research misconduct and can refer more complex investigations to a central body. The US has the Office of Research Integrity (ORI), a legislated body within the federal government's Department of Health and Human Services, which oversees the regulation of research funded by the federal public health service (box).

"Research misconduct can go undetected for decades, poisoning the evidence base on which doctors rely in choosing treatments for their patients"

Transparency is a major feature of the ORI's remit. Findings and actions taken are publicised and can spell the end of a research career. The ORI's openness contrasts with the practice of the UK office, which has not yet published any details of its cases. UKRIO has only an advisory role in investigations and its participation is absolutely confidential. It will provide experts if an institution asks but has no power to insist on a thorough investigation or require the findings to be published. It plans to publish a report on its first four years soon, with anonymised summaries and statistics of the types of cases it has handled, and suggesting lessons to be learnt.

Slow response

The impetus for setting up UKRIO can be traced back to a scandal in 1994 when Malcolm Pearce, a senior lecturer at St George's Hospital Medical School in London, reported that he had salvaged an ectopic pregnancy by transferring the embryo to the womb. The paper, which attracted worldwide attention, was published in the *British Journal of Obstetrics and Gynaecology*, of which Dr Pearce was an assistant editor, with his head of department, Geoffrey Chamberlain, listed as a coauthor.[12] Professor Chamberlain happened to be the editor of the journal and president of the Royal College of Obstetricians and Gynaecologists. An investigation found that—unbeknown to Professor Chamberlain—the patient never existed, and Dr Pearce's report in the same issue of the journal of a randomised trial of treating women prone to miscarriage with chorionic gonadotrophin was also shown to be a fiction.[13] Dr Pearce was struck off the medical register, and a *BMJ* editorial called on the UK "to abandon its lax approach to scientific fraud."[14]

Dr Pearce was at least unmasked quickly. A fraudulent paper and abstract by Anjan Banerjee, published in *Gut* in 1990, were not retracted until 2001, after he was suspended from the medical register and a year before he was struck off by the GMC.[15] In the intervening years he received various promotions and honours, including a Hunterian professorship from the Royal College of Surgeons. His medical school, King's College

1992
US Office of Research Integrity created

1995

Malcolm Pearce struck off by General Medical Council (GMC) over fictitious reports in *British Journal of Obstetrics and Gynaecology* in 1994

1997
Committee on Publication Ethics (COPE) founded by journal editors in response to growing concerns about the integrity of authors submitting papers to journals

1999
Edinburgh consensus statement on misconduct in biomedical research calls for a national panel to provide assistance for investigation of research misconduct and "collect, collate and publish information on incidents of research misconduct"

2001

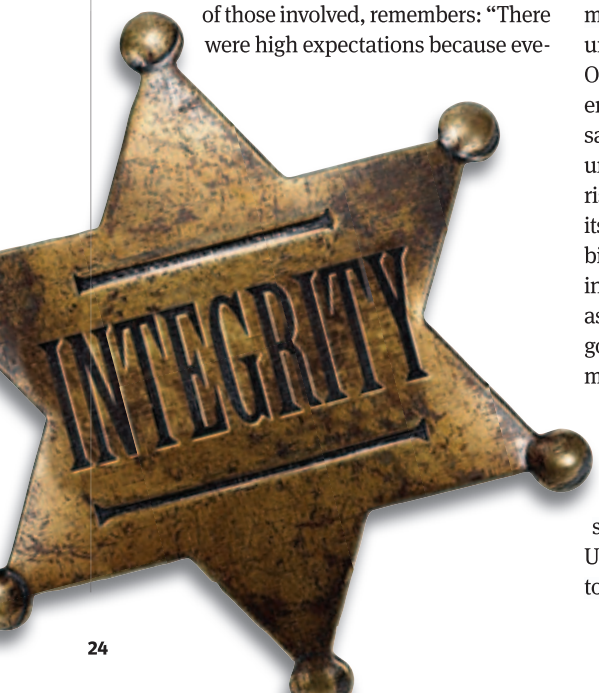

Anjan Banerjee struck off by GMC over fraudulent paper in *Gut* in 1990

2006
Revelations that research by Norwegian oncologist Jon Sudbo and South Korean cloning expert Hwang Woo-suk (below)


UK Research Integrity Office (UKRIO) set up on pilot basis as an independent advisory body without investigative or regulatory powers

London, had carried out an investigation in 1991 that concluded that his research was unreliable, but it failed to inform the GMC or *Gut* of this. The GMC was later told that the laboratory books from the time he carried out his research had disappeared, which impeded its investigation.[16] Dr Wilmshurst, who reported Dr Banerjee to the GMC, observes: "In my experience, when it comes to a choice between exposing misconduct in their institution or covering it up, the senior officials in the institution will usually choose cover-up."

Spurred on by growing concerns about the state of research integrity in the UK, representatives of the medical establishment, including the GMC and royal colleges, convened in Edinburgh in 1999 and produced a consensus statement calling for action to tackle research misconduct.[17] UKRIO was one eventual result. Richard Smith, former editor of the *BMJ* and one of those involved, remembers: "There were high expectations because everybody came together, all the different groups. After years of people saying 'this isn't really a problem because it doesn't happen very much and no patients are ever harmed,' people sort of accepted that it was a problem and that something needed to be done. And then pretty well nothing happened."



Eventually, he says, Michael Farthing, a former editor of *Gut* and now vice-chancellor of Sussex University and vice-chair of UKRIO, "picked up the ball and cobbled together UKRIO. It wasn't really a consequence of that meeting. He just got so frustrated he began to do something himself."

Uncertain future

In the five years of its existence UKRIO has had some success. Its code of practice for research and its manual for the investigation of research misconduct have been adopted by more than 50 universities, as well as NHS bodies and others. Originally contacted mainly by whistleblowers, it is called in increasingly by institutions, says its chair, Ian Kennedy. But it is hopelessly unequal to the scale of the task. Its caseload has risen each year, reaching over 60 last year, and its remit now covers all fields of research, not just biomedicine. With the end of its original funding in October 2010, UKRIO reconstituted itself as a company limited by guarantee and plans to go on trying to fill the gaps, with a subscription model of support as one possibility.

Why wasn't its funding continued? The UK Research Integrity Futures Working Group was convened by Universities UK and Research Councils UK in Spring 2009 to consider what research integrity arrangements the UK should have for the future. One option was to further fund and expand UKRIO. The independent science policy consultancy People Science and Policy was commissioned to produce a report on the various options. The consultancy interviewed 42 individuals from 36 organisations involved in research, mainly universities and research councils, and concluded that there were "some disadvantages" in continuing and extending support for UKRIO. The consultancy was told that UKRIO had "started very slowly," leaving concerns about its capacity to deliver. The greatest risk was that "UKRIO would continue to be seen as an offspring of the biomedical world and fail to win wider support."[18]

The Futures Working Group produced proposals for a national body with a £400 000 a year budget "to succeed and build on the work of UKRIO."[19] While acknowledging that the UK system "does not offer sufficient assurance to the public or research funders that existing research integrity systems function effectively or are robust," the report shies away from the idea of regulation and argues that investigation of individual cases is best left to organisations employing researchers. "Consultations on research integrity have shown that there is no perceived requirement or appetite in the UK for a new body which would have regulatory or investigatory functions," concluded the group, chaired by Janet Finch, vice-chancellor of Keele University.

Modest though its proposals were, they coincided with financial cutbacks, and there was no consensus on taking them forward. The report argues that misbehaving researchers who are on the medical register can be taken to the GMC and "any new regulatory function would be likely to create overlap, uncertainty and inefficiency."

The GMC has dealt with dozens of cases of research misconduct over the years, but typically comes on the scene only when investigations

2009

UKRIO produces code of practice for research which is adopted by many institutions but is not mandatory

First meta-analysis of surveys questioning scientists about the incidence of research misconduct finds around 2% admit fabricating, falsifying, or altering data and up to 34% admit other questionable research practices[8]

2010

Andrew Wakefield struck off by GMC for "irresponsible and dishonest" conduct over case studies published in the *Lancet* in 1998; *Lancet* retracts paper

UKRIO loses funding

UK Research Integrity Futures Working Group recommends a national body to succeed UKRIO without investigatory or regulatory powers, with a budget of £400 000 a year, but no consensus emerges on taking it forward

Publication of European Code of Conduct for Research Integrity by the European Science Foundation

2011

Brian Deer's articles on Wakefield in *BMJ* produce evidence his work was fraudulent. University College London announces it is investigating Wakefield's work

Brian Deer (R) tries to question Andrew Wakefield

2012

New health research authority to be set up by statute to streamline approvals for research. No decision yet taken on whether it will have investigatory and enforcement powers

have been carried out by others. MedicoLegal Investigations, a small company which acts mainly for the drug industry, has referred more than a dozen cases to it. Most of its referrals and those from Dr Wilmshurst have resulted in findings of misconduct, but exposing research fraud is not the GMC's forte. In Dr Wakefield's case the allegations focused on whether his research was ethical, not on whether it was genuine. "Often there is delay, sometimes the GMC has misinvestigated and I've had to go back and say 'you're missing that point,'" says Dr Wilmshurst. In many cases, he considers the sanctions imposed to have been "pretty lenient."

"High profile cases of research misconduct around the world and major retractions by journals stand as a warning against complacency in the UK"

The Commons science and technology committee, in its current inquiry into peer review, has been asking questions about the need for regulation of research integrity and recommendations on the subject could feature in its forthcoming report. Research bodies have long argued that the process for getting approval to do health research is too bureaucratic in the UK, leaving little appetite for more regulation. But the picture is about to be redrawn.

The UK government, which sees the life sciences as an important engine for economic growth, announced in March that a special health authority—the Health Research Authority—would be set up later this year, with the National Health Research Ethics Service at its core. It will work closely with the Medicines and Healthcare Products Regulatory Agency, which regulates clinical trials, to "promote proportionate standards for compliance and inspection," although as a body set up by statutory instrument it will have no investigatory powers.[20]

The next step in the plan is to establish this authority in primary legislation so that it can combine and streamline the approvals for health research, which are scattered across various bodies. The bill could also give the authority investigatory powers, but whether it will do so is still undecided, says Marc Taylor, deputy director of research and development and head of research systems and governance in the Department of Health.

"If parliament decides that the authority should exercise powers of inspection and enforcement, then that's how it will be. And if it decides that it should enforce through other bodies, then that's how it will be. But I'm sure there will be powers of inspection and enforcement in some of the areas it deals with. It is an open question at the moment exactly what role this new research agency should have in promoting or enforcing research integrity and exactly what relationship that would have to the kind of thing UKRIO has been doing to support good practice in individual organisations."

High profile cases of research misconduct around the world and major retractions by journals stand as a warning against complacency in the UK. "Anybody who sits in government in the UK and doesn't think there is going to be something happening here is clearly in cloud cuckoo land," declares Professor Farthing. When he became involved in the issue of research integrity back in the 1990s he favoured a statutory body. But as a pragmatist, when government is "cutting back on practically everything," he questions whether now is the time to push for such a body. "I've spoken to a number of ministers of different colours over the years and I have found it difficult to get any real interest or commitment."

Nicholas Steneck, director of the research ethics and integrity programme at the Michigan Institute for Health and Clinical Research, says the Research on Research Integrity Program set up by the ORI and the National Institutes of Health made a difference in the US for a time because it started to pinpoint where the problems lay. "That is what is missing around the world. Everybody is afraid of these offices because they're afraid of what's going to happen. What needs to happen is a systematic look at where the problems are and how you go about sensibly fixing them."

Professor Steneck, who had a long association with ORI, is on the board of UKRIO and is a member of Canada's Tri-Agency Research Integrity Advisory Group. He thinks a central office with overarching authority would strengthen research integrity in the UK. "I think a central office would make a difference. I think the knee jerk that we don't want more regulation is not necessarily a good idea. That said, I don't think that's going to happen in the UK—none of the players want it."

He says the failure to take the UK Research Integrity Futures Working Group report forward showed that the research institutions are happy with the authority they have. "You don't want anyone else to have the authority and therefore you don't move forward with it. That's the attitude that I think will prevail."

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COMMENTARY Iain Chalmers and Andy Haines

Skilled forensic capacity is needed

An editorial introduction to the series of *BMJ* articles about research fraud and the MMR scare ends by noting that the affair "raises important questions about . . . what can be done to prevent something like this happening again."[1] At least one of the answers to this question was identified a decade ago. Two years after a consensus conference on misconduct in biomedical research held in Edinburgh,[2] a proposed blueprint for the prevention and investigation of research misconduct was published by authors representing several medical royal colleges and the Faculty of Pharmaceutical Medicine.[3 4]

One of its pivotal recommendations was the need to establish a rapid response process through which institutions could call on independent teams of trained external assessors, to investigate allegations of research misconduct.[4] With the exception of one small private organisation, MedicoLegal Investigations,[4] no other capacity yet exists within the UK.[5] Meanwhile there continue to be scandalous and costly delays in investigating allegations and suspicions of research misconduct, and in identifying innocent as well as guilty researchers.

In 2004 the *Sunday Times* published an article by the journalist Brian Deer alleging misconduct by researchers at the Royal Free Hospital medical school in London.[6] Six years earlier Andrew Wakefield and colleagues had reported an association between MMR vaccine and childhood autism in a paper published in the *Lancet*.[7] John Reid, the then health secretary, called for an inquiry by the General Medical Council (GMC) as a matter of urgency.[6] However, it was not until six years later, after extensive further research by Mr Deer, that the GMC's fitness to practise committee upheld the majority of Mr Deer's allegations. The committee found Dr Wakefield and his senior coauthor, John Walker-Smith, guilty of serious professional misconduct, including, in Dr Wakefield's case, dishonesty. Charges were proved against a third coauthor, Simon Murch, but he apologised to the GMC; he was deemed to have shown insight and was therefore discharged. The role of the remaining 10 coauthors, who were not arraigned by the GMC, has not been investigated. Nor have the failings at Dr Wakefield's institution, the Royal Free Hospital medical school, in its wholly inadequate response to serious allegations of misconduct in 2004.

In the late 1990s, another journalist, Brian Morgan, together with a pressure group and the then editor of the *Bulletin of Medical Ethics* Richard Nicholson, alleged that researchers associated with a controlled trial involving preterm infants in Stoke on Trent[8] were guilty of research misconduct, including forgery of consent forms.[9] A media frenzy followed.[10] This led to numerous unpublished inquiries and one requested by the health secretary, none of which found any evidence of misconduct, let alone forged consent forms.[9] However, the clinicians who had been targeted by the campaign had to wait 11 years before the GMC eventually judged that they had no case to answer.[9] This delay in justice had devastating effects on the doctors and nurses and their families who had been publicly vilified[11] as well as on clinical research in the UK.[9 12]

Apart from the failure to identify efficiently those guilty and those innocent of research misconduct, current inefficiency wastes millions of pounds. Taken together, the investigations of alleged research misconduct at the Royal Free Hospital and in Stoke on Trent have been estimated to have cost at least £12m (€13m; $19m).[9 13] In addition, many other costs may be incurred, as well as harm to patients, both because of failure to expose flawed research or because of unwarranted promulgation of doubts about reliable research.

These two examples show the consequences of the UK's failure to make efficient and effective arrangements for establishing the facts in response to allegations of research misconduct. The UK Research Integrity Office (UKRIO) may be able to resolve uncertainties about whether misconduct has occurred in some cases,[14] and it has issued useful guidance on how to undertake investigations. But UKRIO does not currently have the professional forensic expertise, the mandate, or the capacity needed to investigate allegations independently.[9 15]

Although institutions that employ researchers do sometimes mount and report credible investigations into allegations of research fraud, the default assumption should probably be that they are not sufficiently independent. They have an obvious conflict of interest because of the inevitable pressures on them to protect their reputations. These pressures may trump a duty to protect the integrity of science.[16]

In addition to the need for independence, however, some investigations require forensic expertise so that the facts can be established before attempts are made to reach safe judgments. Although it will sometimes be possible to establish relatively easily that research misconduct has occurred (in confirming plagiarism, for example), skilled forensic experience is needed to establish the facts in other, less easily investigated allegations, such as the two we have cited. As a member of staff at the GMC remarked during discussion of the allegations made about researchers in Stoke on Trent, most institutions "would not have any idea how to set up and carry forward an inquiry into a difficult and high profile case."[9] As noted by the Organisation for Economic Cooperation and Development's 2007 global science forum, "All those responsible for procedures to investigate research misconduct . . . should have received training in the application of the procedures and/or be experienced in their use."[17]

Proper procedures for investigating allegations of research misconduct, including skilled forensic capability, are needed without further delay. Furthermore, publication of the outcome of each investigation should be required for all research, whether publicly or commercially funded. Because organisations that fund research have a strong interest in its integrity, they could support these measures by small pro rata payments. The costs would amount to a tiny proportion of total UK research expenditure.

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