

## A framework for discussion

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There are three broad questions to tackle:

### 1 *Do you think that Britain needs some sort of national body to respond to research misconduct?*

There may be a whole lot of people out there who think that the answer is clearly “No,” but I suspect that that is not the majority view here. None the less I think there ought to be some quick discussion about this.

### 2 *What might this body look like?*

#### **How might it function?**

It might just provide broad leadership. It might be a discussion forum. Would it advise employers? If it is to have some sort of investigative role, how will it do that? Will it do it by legal right? Should it conduct hearings? Should it be in the business of sanctions? Should it be auditing what's going on? Should it be about prevention, education? Should it be doing research? Should it produce an annual report? Should it be some kind of clearing house, collecting data?

#### **What should its scope be?**

Should it cover all research, including the humanities? Should it be restricted to scientific research? Or biomedical research? Should it just be research done by doctors? Should it cover Britain or Europe or beyond? Should it cover England or the UK?

#### **Who should own this body?**

Should it be part of government? Should it belong to the academic bodies? What should be its link to the NHS? Should it belong to patients in some way?

#### **What should its legal status be?**

Should it be created by acts of parliament? Should it be a part of government, or like the GMC, report to the privy council? Should it predominantly act on behalf of other bodies by their consent? What might its governance be like?

#### **How would it be funded?**

#### **What might it be called?**

### 3 *How are we going to make this happen?*

Who is going to do what, with whom, when, where, and how?

#### **Workshop sessions**

#### **Group 1 facilitated by Dr Peter Wilmshurst, Royal Shrewsbury Hospital**

*Is a national body needed?*

Everyone agreed that a national body was required, but the term misconduct needed to be defined. The body should be national, not European because of different legal systems, and should include Scotland and Wales. The panel should look to Commonwealth countries whose law is more like that of the UK, rather than the EU.

To gauge the scope of the problem, a survey could be undertaken or the government could commission a report to investigate data from the stakeholders, decide on a model, and then report to a minister. Every time an internal enquiry was undertaken this should be notified to the national body. The participants thought that the yellow card system was not very effective.

Ethics committees could take a larger role. They already have a role in preventing unethical research from going ahead, but they are not properly constituted nor do they have the power or ability to look at fraud. Most ethics committees are very overworked as it is and only cover medical research.

#### *Scope*

- education
- policing research
- investigating fraud

The new body should be proactive and include training, for example, on how to supervise, with certification on completion. It was considered the duty of institutions to undertake this.

Fraud or misconduct are not viewed as criminal offences in the medical community as they would be in a commercial environment. There would need to be different grades of offence with corresponding fines/sanctions. There could be guidelines for institutions, for which legislation would not necessarily be required.

Define penalties and policy from the start. The body should span biomedical research, and all types of

research, if national. There could be an overarching panel with subpanels. If limited to biomedical research, the new body must include non-clinical scientists. It could act as a model for others to use in other fields.

A good idea would be to look at the US and Scandinavian systems and cherry pick after proper appraisal.

#### *Status*

It should be a GMC type regulatory body. One function would be to promote research integrity. Powers would compel an employee to co-operate or, when required, deploy an investigative team. A lot can be achieved without legislation, so the new body could start without statutory powers but with an advisory role. It could collect data on the number and type of complaints logged, encourage participation, and then see if the next step should be to formalise. But it must be totally independent from government, with a lay person to run it: there had already been too much posturing by the colleges and everyone wanted to be in charge.

#### *Governance*

Parliament or a minister should oversee the body. This would involve co-ordination with the Department of Health, DTI, DEFRA and Department for Education. It should also include representatives from the MRC, NHS, Wellcome, universities, members of public, and include an ethicist.

#### *Funding*

It would primarily be funded by central government, with each institution also paying a membership fee. It could operate along the same lines as the quality control scheme for laboratories where each institution pays an annual fee. This could be levied as a direct cost against each research grant or as a percentage of the amount of research being done. Institutions may find that money is more difficult to get for research if they haven't signed up. There would have to be benefits. It will be both expensive and time consuming to police and investigate misconduct. Fees could be charged for training courses, which could be a lucrative source of revenue.

It must have individuals experienced in this type of investigation.

#### *Possible name*

Research Standards Agency

#### *Summary*

- A body is necessary for British institutions to cover dishonesty and serious scientific fraud.
- This should cover biomedical research to begin with and expand later.
- Could develop two models: one statutory and one non-statutory.

- Governance should come from institutions, possibly a quango.
- Money should also be contributed by funders of research and all stakeholders. Names of those who could possibly run it: Michael Farthing, national audit office, charity commissioners, Ian Gibson MP (also a scientist), Minister of Health, Lord Sainsbury.
- It must be independent of government.
- Local action at institutional level may not be enough and difficult to apply sanctions etc if not statutory.
- A clear definition of research is needed, and very good evidence of misconduct.
- Membership should be voluntary.

### **Group 2 facilitated by Dr Fiona Godlee, Biomed Central**

#### *Need for a national panel*

There were mixed feelings about whether a panel was needed, and whose problem this really was. The government does not own science. But it's important to publish science, otherwise there is no influence, so funders have an interest in making sure the research is credible.

The difference between deliberate undesirable practice and ignorance needed to be defined. This would depend on the severity of the sin, of which there are degrees: sending a paper to two journals is annoying, but not sinful. The seriousness of the crime would be dictated by the consequences to some extent.

#### *Scope*

This will depend on how much the panel will be dealing with non-medical and non-UK authors. Covering scientific sins by people employed only in British institutions ignores the fact that we operate in a global environment.

It was felt that the panel should cover all research aspects, including plagiarism and research grant applications. But it was much too ambitious to begin with an all inclusive set up; rather, starting with medicine and building from there would be preferable. But there was no logical reason for ultimately not including all of science. That must be the primary goal.

Its focus should be dishonesty, rather than all bad research, and it should concentrate on obvious rather than minor cases of misconduct, otherwise it risks being swamped.

#### *Function*

It needs to:

- Encourage whistleblowers and afford them some protection

- Structure the way research employers deal with misconduct
- If there is disquiet and reasonable grounds for concern, provide somewhere for people to go that is outside the institution, otherwise they have to rely on the integrity of employers who are not impartial and often have a vested financial interest.

A suggested scenario for bringing a case to book might start with the institution:

- To ask if there is a prima facie case
- If so, a nominated person to approach
- If there is a case to answer, a task force should have a dialogue with the institution
- Call in other people needed to give evidence

But it was felt that the institution might not take on this role, and how would pharmaceutical companies proceed?

#### *Sanctions*

Most crime does not get punished, so it would be unwise to expect this panel to do more. But it should publish an annual report in which it names names and implements heavy sanctions. Care would be needed to avoid libel, and so the standards of evidence should be beyond reasonable doubt.

What about whistleblowers on the receiving end of actionable insults, but who can't afford to sue? Whistleblowers should not be immune from libel because they could be motivated by malice. Should there be legal indemnity to protect the whistleblower/government/drug company? It should be remembered that anonymity could be hidden behind.

#### *Ownership*

Universities could take up voluntary accreditation and would have to submit to audit and quality control. They would have to be strong moral support from funding bodies

There could be a code of good practice published, a report written and action taken if they were revealed to be lacking. But that still leaves out commercial organisations, and they should be included.

Another suggestion was a no fault system with education as the prophylactic and random audit to prevent being scrutinised all the time. Any organisation signing up to it would know that they had a responsibility to investigate allegations. There could be a central body with an independent appeals court.

#### *Accountability*

- Wellcome
- NHS Research & Development
- MRC

Researchers could be answerable to them, and fun-

ders could apply sanctions if the recipients failed to comply. Any investigations, including the outcome, would be filed in a public report.

#### *Funding*

Institutions could price it into their funding applications or the MRC could levy a small tax.

#### *Statutory powers*

The new body would need strong statutory controls to have any teeth. These could be under the aegis of the Secretary of State/Office of Science and Technology/Office of Fair Trading/Department of Trade and Industry.

Membership should be periodically renewed.

It should be some sort of quango with statutory powers and central funding. It could be a special health authority for stakeholders in other fields. It could be developed along the lines of the National Cancer Research Institute (NCRI).

#### *Name*

- Committee for Research Integrity (CRI)/ Council on Research Integrity
- Serious Research Misconduct Office

#### *How are we going to make this happen?*

First steps:

- Public involvement
- Get the following to sign up:
- Council of deans and medical schools
  - Principals and vice chancellors
  - NHS R&D
  - All major employers and research funders

Signing up to it would not mean membership. Local research ethics committees should be kept informed.

The chair of COPE could pull everything together into a consortium that would include Ian Gibson MP, who is also a molecular biologist, Lord Hunt, and Lord Sainsbury, to build up a broader action group of movers and shakers.

Look at different models of bodies who could help action it:

- National Audit Office
- Audit Commission
- Research Councils
- NCRI

#### **Group 3 facilitated by Dr Sabine Kleinert, *The Lancet***

The overall feeling was that there should be a national panel, but that it must have an impartial adjudicator.

Institutions can't or won't deal with research misconduct. But current libel laws could cause problems.

#### *What might it look like?*

There should be one body to deal with all institutions. Its role would be to:

- Provide leadership
- Produce guidelines in training and research
- Educate
- Boost morale

And to be effective, everyone would have to sign up to it, including groups like the forensic pathologists, for the peer pressure effect. If its investigations have legal powers an Act of Parliament would be required.

#### *How would it work?*

The panel should be tried out on a voluntary basis first, and if that fails, then it should be given legal teeth. It could have a rapid response team comprising independent investigators, but what would their remit be and who would fund them? COPE stops short of investigations, but surely the institution should have someone to call on. But would institutions pay for this?

Could it be run along the lines of a counter fraud office within the NHS?

The body should have a list of independent investigators who could be called on, if required. A report should be published which the institution would not be able to buy.

The report and its consequences should be dealt with in secret by human resources.

There would be a contractual relationship between researcher and institution and the funder, and if this were flouted, this would constitute breach of contract, and would be part of NHS research governance.

#### *What about sanctions?*

There should be a framework from minor to major breaches; human resources can also get involved

#### *Scope*

It would be better to start small with biomedical research and then widen it out to include humanities, engineering, etc. And it should be applicable only to the UK.

#### *Ownership*

The government should not own it. This could be undertaken by funding bodies like the NHS, Wellcome Trust, the MRC etc, but all stakeholders must be involved

#### *Governance*

This was not a job for the royal colleges, and it would be too complex to leave to one.

#### *Funding*

- Subscriptions
- Centrally funded
- Would individuals sign up to it or learned societies?
- All stakeholders should go into the funding pot  
Institutions would call in investigators; perhaps funders should get involved. But what about whistleblowers? Protecting them is very difficult.  
Would insurance premiums cover this type of investigation for an institution?

#### *Name*

UK Biomedical Research Standards Council

### **Group 4 facilitated by Sir Cyril Chantler, Guy's, King's College, and St Thomas' Hospitals Medical and Dental School**

It was unlikely that a national charity, such as the Wellcome Trust, could take on the role of a national body, as it could not act both as a funding agent and deploy governance. Care must be taken to ensure that bureaucracy does not get in the way of research. The new body must not be just a mass of red tape.

There was some debate about whether the research misconduct was confined to medicine only or whether the rest of science needed to be included. And some felt that the stimulus for the panel came from embarrassing stories in the press.

#### *Function*

The new body should step in when an institution can't or won't do so. Initially there should be a voluntary agreement to work to agreed rules set out by the new body rather than handing responsibility over to it completely. Once critical mass had been achieved, then things could proceed to an audit body, and then to a more formal legal footing, if needed. But the issue was who would pay for such a body?

Many institutions have no guidelines at all and those that do have ones that are wide ranging. And guidelines do not necessarily mean that there are procedures in place. The new body could help standardise these and set up a process in the institution with things achieved through consensus. The new body could kitemark through audit.

Research misconduct should be built in by the funder and become part of current governance.

There needs to be a place for whistleblowers to go outside the institution, which must have teeth. The institution should have a named independent person within it.

#### *Investigations*

Employers or sponsors could do these, although most

sponsors would not have the money. Or the new body could do these either wholly or in a supervisory role for internal investigations. But it was felt that many institutions did not have the competencies to carry out investigations, and it was feared that if an institution were not compelled to call in the new body, it might not do so of its own accord.

#### *Audit*

The new body could become the auditor and audit year on year. But the institution must report any complaints to it, and once started these should be followed through even if the transgressor left and moved on elsewhere. Audit was thought to be a good idea but this should be anonymised unless the case was proven. It should be borne in mind that some people will call in legal advice once they leave employment.

#### *Register*

Some kind of register was needed. There is the GMC register, but the GMC is unlikely to make this public as they do in the US. And scientists who are not doctors would fall through the net.

There would need to be some kind of legal framework for it. Employers could search the register before hiring anyone. But what about European human rights legislation and protection of privacy? It was felt that it could become public on the grounds of public interest.

The problem is the retention of names rather than publication of "guilty parties." A register leaves the onus on the employer to get the references. Could this be under the auspices of the Commission for Health Improvement?

#### *Sanctions*

These should be applied by according to gravity of the offence. But where to draw the line between minor and major offences? And should the accused lose his or her job over major misconduct? If the panel is to be about prevention and advising on best practice, it is important to look at minor offences as these form the bulk of misdeeds.

How can sanctions revert to the funder or employer? The new body could let the institution know whether its sanctions are reasonable as part of its advisory and audit role.

The new body could be similar to other bodies such as the Association of British Travel Agents (ABTA) or the Association of British Pharmaceutical Industries (ABPI) to which organisations could voluntarily belong. The new body could have the power to remove the kitemark from institutions failing to adhere to guidelines. Funding bodies could use membership as a deciding factor for granting monies.

#### *Ownership*

- Owned by members as a mutual model
- Government?

- Royal Society if it is to go beyond biomedicine
- It should be seen to be evolving model where employers and researchers are members.
- Funding bodies need to be linked in as well as royal colleges.
- What about patient/lay membership?

#### *Funding*

Multiple sources are best. Fees could be proportionate to the means and size of the institution. Funding bodies could chip in.

#### *Scope*

The membership model would allow for expansion outside the field of medicine. But it should start with biomedicine and include non-medics.

#### *Legal status*

It would be acting on behalf of others who have legal responsibilities; therefore the legal framework lies with the employer.

It should just advise, audit, and produce reports, but it may need to form extra legal requirements.

Its strength should come through its mutuality: it's legitimate rather than having legal status.

Members should be drawn from legal, medical, pharmaceutical, genetics, government and public entities.

#### *Name*

Council of Research Integrity

#### *How do we make it happen?*

We have to get members to see that it is in their best interests. The Academy of Medical Sciences should take the lead. Wellcome's guidelines are on the right track; research councils should be shaken up as well. All universities should be on line by the end of the year. But we need to build on that momentum

## **Feedback from group sessions**

### **Group 1**

We thought that the new body should be called the Research Standards Agency.

We spent a lot of time talking about whether this body should be voluntary or statutory and, in the end, came to the conclusion that it would be best to work two models in parallel and then decide what was most suitable. We felt that it would be a good idea to look at the existing systems that have been developed, and cherry pick from those.

Whether this should be a statutory body or not seems to be very dependent on how long it would