

The way forward

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Do we need a national body?

The first question is the question of need and I detected some reservation as to whether you felt the need was there. I would suggest that this largely comes from a degree of uncertainty and insecurity. The notion of another body looking at what we do is always unwelcome initially.

But there are ways of getting around that problem, which were referred to by the various groups. Namely, you could start by having some less formal body and then move on to a more formal mechanism. On the other hand, we have been reminded today that this is often the resort of those who want to slow things up.

Formal vs informal

The Americans have written into legislation what are called “sunset” clauses. This allows something to be set up and funded for a limited period of time, such as five years, at which point it is re-examined. That would not be impossible in the UK. For example, the US President’s Commission on Bioethics was funded for only a certain amount of time after which it had to come back to congress for more funding. This was refused.

So either move from the informal to the formal model or think about a limited lifespan. But you do have to solve the problem of need, if you are going to go to government, and persuade them to even take this issue seriously.

Evidence first and foremost

The very evidence you need to establish whether or not there is a problem is the evidence that doesn’t exist, because we are talking about fraud and misconduct. But the Department of Health, and certainly the Treasury, would need to be persuaded very seriously that there was a problem before government embraced the idea and committed funds.

Therefore, I would suggest that you should start with some very senior civil servants. And you will need evidence to substantiate your claims. Any public policy to be made by government depends on good, reliable data, and if good reliable data are not available from commercial sources or from evidence of misconduct, then government is rendered that bit more insecure in its making of public policy.

Who will take the issue forward?

The next question is: who are you talking to here? To

whom is this seminar addressed? Put another way: who is to take this issue forward? You may be talking to government, as it were, through senior civil servants; you may be talking to yourselves, as interested professionals. You have to decide who is going to be the standard bearer to take the messages from here elsewhere and to whom they are going to be directed.

There seemed to be quite considerable disagreement. A lot of you just wanted to talk amongst yourselves—you are all professionals who all understand one another. Then there are some who feel that if you talk amongst yourselves you’ll be doing it for a very long time, and that’s what you’ve done already, and now is the time to talk to the movers and shakers. I happen to agree with that stance, and I think that senior civil servants ought to be engaged very soon.

What is the scope going to be?

The next question is, what are you going to talk to them about? What is the scope of the enterprise that you have in mind? I completely agree with the idea that if you have got to start somewhere you ought to start small and relatively well contained. And then if the argument is seen to be a sound one, you can always extend into science as a whole. You can begin with biomedicine without too much difficulty. Of course, there are always going to be arguments at the edges as to whether something constitutes biomedicine, but that’s in the nature of all these issues.

It was clear to me that although you all thought it was a very good idea to have something, you weren’t at all sure what the something should be. And there was a certain professional insecurity about being overseen by someone who isn’t “one of us.” I hear the word “lay” often used, to define those who would otherwise presume to comment on what we do.

We are talking about misconduct in dealing with volunteers in a healthcare system and so we all have a vested interest in it. It isn’t a professional matter alone. And even if you tried to make it so people would resist that. And if you believe this is important isn’t it important for all of us? And you have to say that it’s important or you won’t get it through the door of the civil servant.

We have moved on, we are in the twenty first century. We don’t leave things to cartels or to professional groups we want to get engaged. So I think you just have to recognise that there will inevitably be tension between the ideas of “professional corporatism” and the involvement of the citizenry at large.

Accreditation vs self regulation

It wasn't quite clear how this independent body might emerge. Would it be a membership model, through the process of accreditation by the institutions? Or would it be a kind of looser confederation of professional and other interested groups and institutions?

I can see weaknesses in both, because both hinge on voluntary participation. And you will have to find a way around this if you want an independent body with the teeth to require membership and compliance. But it means ensuring that all those institutions feel that the requirement isn't imposed but collectively agreed. Membership should include all those institutions involved in research and also those who are volunteers in research, with requirements laid down for proper conduct. The Wellcome Trust is doing it; the Department of Health is doing it. Overarching clinical guidance or clinical governance are the ways forward

I have recently become a member of a council concerned with forensic practitioners. There is a body that accredits anybody giving evidence on fingerprints or toxicology, for example. It is currently an internal self-regulatory body, but will no doubt extend further in due course. That is a way in which you can begin to take steps to regulate or accreditate.

Funding

I have already said that all funding decisions made by government are mediated through the Treasury, who largely demands that everything they fund should be cost neutral. That will be a difficult case to argue unless you can persuade the NHS research and development budget to fund you. I happen to agree with Richard Smith that multiple funding is a very good idea. If the institutions, the research foundations, the government perhaps the royal colleges, etc, all contribute all the various stakeholders themselves will be committed to the welfare of this institution. They don't resent paying for all of it, but they will feel that as part of it they can have their say, and it won't cost them more than they can afford.

Powers

What powers and duties should this new body have? Here the devil really is in the detail of these powers and equally the reciprocal duties. You seemed to be discussing at least three models.

One is the maximal model of an independent body that is not only reactive to allegations of misconduct, but also proactive. It would have an inspectorate arm, a training arm, and a guidance arm. That option is going

to be more expensive and more onerous to launch from scratch.

The minimal model is simply to liaise with the institutions and employers to encourage them to disseminate information about research guidance and governance and to get people to agree certain standard forms.

The middle way is to insist that all institutions sign up to a certain constitutional form, which binds everybody involved in research. That contract gives you the power to discipline any improper deviations. And it provides guidance that is national and overarching. This model keeps things close to the institution, close to the employer, and close to the funding. This would seem to be the best course to adopt, with a view to developing further with guidelines, etc, as the need arises.

National vs international

What reach should this body have? I think that the tendency here was to start small and make it applicable only to the UK. But the problem with this as Michael Farthing will tell you, is that a lot of research is submitted from all over the world and you need to have some powers to deal with that. My own view is that you should think very much in terms of internationalising through, for example, the Council of Europe.

The Council of Europe has several international conventions on biomedicine. And, in fact, they have just produced an international convention on research. It would not be too late even now to try to make some representation as regards the conduct of research. Forty three European countries now embrace the Council of Europe. It is a way forwards that is less narrow than pursuing an entirely UK based system.

Accountability

Lastly, how should such a body be held accountable because whoever pays for it must be accountable, and must be seen to be accountable? I would have thought that one mechanism, irrespective of whether it is created by legislation or not, should be that it reports annually to a select committee within the House of Commons. This could be the select committee on science and technology or on health. The new body should also produce an annual report, to be circulated to all the institutions concerned.

All of us think that this is a very good idea but translating that idea is very hard because there are divisions within this room, and there will be divisions outside. I think the way forward is to now sit down with pivotal people within the relevant government departments and with people from the Wellcome Trust, and others, to move on to the next stage.