Is the NHS research ethics committees system to be outsourced to a low-cost offshore call centre? Reflections on human research ethics after the Warner Report

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The recently published *Report of the AHAG on the Operation of NHS Research Ethics Committees* (the Warner Report) advocates major reforms of the NHS research ethics committees system. The main implications of the proposed changes and their probable effects on the major stakeholders are described.

The Ad Hoc Advisory Group (AHAG) on the operation of NHS research ethics committees, set up in November 2004 by Lord Warner on behalf of the Department of Health, submitted its report in June 2005.¹ The report advocates major reforms of the research ethics committee (REC) system. The primary aim of the report is to streamline the processes around the approval of research projects and to pursue conformity of governance across Europe. Implicit in the report is the contention that failure to achieve this objective would be harmful to everyone with vested interests in improving health and social care. Moreover, it is stated that the reforms will enhance the mechanisms that protect the interests of all parties concerned.¹

Being mindful of two published critiques of the Warner Report, we suggest that its alleged benefits should not be taken at face value.^{2,3} In fact, the reformed system will give rise to moral failings akin to those of the existing system, but will differ from the existing system in its effect on the stakeholders. Thus, whereas the outgoing system has given each stakeholder a unique mixture of benefit and harm, the incoming system offers benefit only to sponsors and researchers and nothing but detriment to participants in research and consumers of its products.

In the light of this conclusion, we finally suggest that the Warner Report be construed not merely as an ill-considered document, but rather as an ideological reflection of a long-established hegemonic contract fine-tuning itself to contemporary global challenges.

To avoid any misunderstanding, one point must be clarified at the outset. This paper is about the social implications of the Warner Report and the historical context in which it has been conceived. It does not provide a moral judgement of the report or its implications and should not be confused with a moral judgement. Precisely for this reason, we also avoid offering any moral alternative. We believe, however, that although our analysis has no necessary moral ramifications, it can help the reader make an informed judgement, whatever it may be.

THE PROBLEMS

The problems, which the AHAG is determined to resolve, may generally be described as unacceptable "regulatory blocks impeding research".¹ These could be further classified as follows.

Methodological bias

The AHAG asserts that RECs often conduct the scientific review inadequately (they fail to understand particular forms of research or have preferences for certain clinical research methods), when they are not supposed to be responsible for scientific review in the first place.¹

The AHAG attributes this flaw primarily to the membership of RECs, which—despite recent changes—is said to be largely drawn "from a relatively narrow spectrum of society, members tending to be professional in background and from an older age group".¹ The AHAG considers such membership to be incompatible with the ethical principles of independence and broad public representation of the RECs, because it is "rather parochial, strongly influenced by

association with particular research environments and disparate in direction and quality".^{1,4}

Disparity

While recognising that some inconsistency in decisions made by RECs is inevitable, the AHAG emphasises that the extent of inconsistency has become an "irritation".¹ The AHAG attributes this inconsistency mainly to an incomplete assimilation of quality assurance measures and insufficient exchange of members.¹ The methodological bias and the large number of local RECs may also be contributory.

Cumbersome procedures

The AHAG points out that the large number of local RECs complicates procedures for researchers who wish to carry out multisite studies.¹ Overcapacity is identified as a problem, which is attributed to changes in the nature and distribution of research, as well as the geographical patterns of applications.¹ This may be amplified by the preoccupation of the RECs with issues that should arguably be beyond their remit. One example is the scientific review. Another example is the site-specific assessment—that is, the assessment of the suitability of the local researcher and facilities, which, the AHAG claims, as performed by the RECs, adds "little value" to local approval by the host organisation.¹

An additional source of frequent dysfunction of the RECs is said to be the increasing incidence of inquorate meeting, attributed by the AHAG to the voluntary unpaid status of members.¹

THE REFORM

To tackle these problems, the AHAG introduces changes in the remit, membership, number and financial support of the NHS RECs. Implicit in these changes is the following rationale: to make the REC system more efficient, one would need to make it more ethical, and vice versa. The main points are outlined as follows.

Change in remit

To exclude the methodological bias and shorten the time spent per application, the AHAG introduces two changes in the remit of the RECs.

The first change requires that the review of both the scientific and ethical aspects of research be institutionally as well as conceptually divorced.¹ The scientific review would have to be conducted before the application reaches the REC. The ethical review would not reach decisions based on the scientific review. Only in exceptional cases can it express concerns about scientific issues, but these

would have to be referred to, and dealt with by, a new body—the research ethics adviser at the Central Office for NHS Research Ethics Committees. The role of the RECs is to be confined to providing only ethical review. RECs are to assume “a secondary role—to facilitate ethical research”.¹

The second change pertains to the site-specific assessment: the responsibility for this task is to be transferred to NHS hosts.¹

Change in membership

As the modified remit of the RECs requires no scientific expertise, professionals are likely to either step down or become effectively irrelevant. The AHAG actively welcomes this trend and proposes that the membership be drawn from “a wider mix of society ...”.¹ This is deemed necessary to exclude methodological bias and enhance efficiency, independence and democratisation of the RECs.¹

Change in number

In the interests of efficiency and uniformity, the AHAG advocates reducing the number of RECs, the operations of which would be more intense, with a greater use of electronic communications.¹ The modified remit of the RECs may facilitate this step by reducing the average time required for each application.

Change in financial basis

The AHAG acknowledges that changes in remit, membership and number are likely to render the hitherto voluntary system of the RECs unsustainable. Moreover, it asserts that such a system “may no longer be appropriate”, as it may inhibit “application for membership by sections of society that should be better represented”.¹ Indeed, the AHAG regards paid membership as a sensible step towards increased efficiency, independence and democratisation of the REC system.

IMPLICATION I: SCIENCE WITHOUT ETHICS

The AHAG does not prescribe the nature of the scientific review. We may assume, however, that, like the scientific peer review required by journals, the main focus will be on methodological adequacy. The AHAG’s criticism of the outgoing system reflects a new diktat on the assessment of methodological adequacy. Reviewers are now expected to approve of any method if it is acceptable to any research discipline; philosophical assumptions about the validity of a specific method are unacceptable.

Further, the AHAG does not indicate who is to provide the scientific review, nor is it explicit about anonymity and

independence. “The RECs’ role is to be reassured that there has been adequate scientific review of the design” and that “[where] peer review has taken place, the RECs should accept this in all but exceptional cases”.¹ A subsequent document states that “the responsibility for scientific quality lies with the sponsor”.⁵

This vague guidance seems to imply that the new role of the RECs with respect to the scientific review is more or less that of ticking boxes. Applicants will be inclined to construe this guidance, among other things, as tacit permission to ask their departmental colleagues to provide the scientific review. Without the cloak of anonymity, they are likely to obtain a favourable opinion. After all, “colleagues have little to lose (and indeed often gain) from increased research activity in their department and have no wish to antagonise their colleagues”.⁶ Indeed, in a recent REC meeting, we recorded five applications out of a total of eight, in which close colleagues had provided the scientific reviews. The other three reviews were independent from the applicant’s institution, but two were provided by the funding agencies.

We may accept the AHAG’s claim that the RECs are not always competent in their conduct of the scientific review. They may rarely have been truly independent, unbiased and pluralistic. But “letting the cat (i.e. sponsors and researchers) watch over the cream”, as described above, is not about rectifying such weaknesses. Nor has it much to do with methodological pluralism, democratisation of science, production of good-quality research and preserving the principles of the RECs’ independence and non-bias. It only makes the assertion by the AHAG, that “it is unethical to conduct scientifically inadequate research”, look cynical.¹

IMPLICATION II: ETHICS WITHOUT SCIENCE

The AHAG makes two points in relation to the remit of the ethical review. Firstly, researchers will need to inform the REC about potential risks and how they propose to minimise them.¹ Secondly, the responsibility for site-specific assessment is to be transferred to NHS hosts.¹ The new remit of the ethical review may be deduced by subtracting these two points—the conceptual remit of the scientific review and the requirement that the RECs no longer reach decisions based on scientific review—from the outgoing remit. Thus it follows that the ethical review is to be confined mainly to issues of risk management, consent, confidentiality, indemnity and payments.

Most important, however, is the conclusion that some issues, which have so far been deemed to reflect the mutual dependence of science and ethics, are to escape the remit of *any* body. Such issues pertain to the assessment of whether (1) the well-being of the human subject is taking precedence over the interests of science and society and (2) the importance of the objective outweighs the inherent risks and burdens to the subject.⁴

The history of recent pharmacological disasters and other failures may suggest that the regulatory system (RECs included) has not always met existing standards, or that the standards are inadequate, or both. But, it must be equally clear that the new modified remit of the RECs will only make things worse in this respect. This makes another statement of the AHAG—“[the] primary purpose of a REC when considering the proposed study is to protect the rights, safety, dignity and well-being of actual or potential participants”—look cynical as well.¹

IMPLICATION III: ONE MORE CAT TO WATCH OVER THE CREAM

As far as the site-specific assessment goes, the AHAG’s claim that the RECs have failed to add value to local approval by the host organisation seems to conceal a much more serious problem: their failure to carry out independent, unbiased and critical site-specific assessments. Transferring the task to the host—as the AHAG proposes—will, however, only make things worse. The fact that the AHAG finds no fault in allowing the host to assess its own suitability indicates once again that it cares about independence and non-bias only to the degree that they are compatible with streamlining the approval processes.

IMPLICATION IV: BUREAUCRACY IS DEAD! LONG LIVE BUREAUCRACY!

The modified shrunken remit of the RECs will effectively exclude doctors and scientists—who (biased and non-independent as they may be) happen to understand something about the science of research and its ethical implications—from the new membership. Interestingly, the new remit will probably have the same effect on any other stakeholders as well. After all, no one—apart from paid middle managers and pen pushers—stands to gain from serving on a committee with a remit that is essentially clerical (rather than critical). The expectations of the AHAG about the democratisation of new membership are problematic for at least three reasons. Firstly, no evidence exists that the present representation on the

RECs has, by itself, ever led to a situation where any group in society has been disadvantaged. Secondly, no evidence exists that payment can incentivise participation of under-represented groups; moreover, it may seem patronising to assume that it can. Thirdly, a paid clerical job renders independence, non-bias and wide representation essentially meaningless in the first place. We can only wonder whether a proposal with such poor empirical support could have been approved by any REC. More important, it should be noted that the proposed reforms seem to drive the review process towards the category of dialogue with low-cost offshore call centres that are becoming only too familiar in our society. What is perplexing, then, is the AHAG's belief that the RECs are to become more professional than ever.

CUI BONO?

The analysis of the AHAG's proposals yields the following conclusions:

1. The reform will increase the volume of research at the expense of its quality and safety.
2. The incoming system, with its greater division of labour, is to become even less accountable than the more centralised outgoing one.
3. These changes are advocated as an expression of improved ethics, enhanced accountability and concerns for the interests of all stakeholders.

How is this likely to affect the main stakeholders?

Private sponsors of research can only benefit from this situation. Researchers and their public sponsors would certainly be harmed by an increase in research of poor quality. If forced, however—because of funding, promotion, Research Assessment Exercise and performance-related pressures—to choose between research of high volume and low quality, and that of low volume and high quality, both would tend to opt for research of high volume and low quality. The proposed reform would give them the freedom to make this unpleasant choice, while avoiding moral dissonance and

alienation. In contrast, participants in research and consumers of its products will only be harmed by this situation.

THE WARNER REPORT IN HISTORICAL PERSPECTIVE

Human research ethics has been imposed on researchers and their sponsors since the end of World War II. Its flaws have been generally ignored, not because they did not exist, but rather because they embodied a hegemonic compromise, a coercive contract among social actors of unequal power that derives its legitimacy from the fact that it appears to them as no more than a product of their common interest, pure reason and free choice. This contract has derived its legitimacy and stability from the fact that it offered, or was deemed to offer, each stakeholder enough benefit to compensate for the harm.

The intensifying economic competition characteristic of contemporary global society, however, has transformed this social contract into a straitjacket for researchers and their sponsors. The formation of a new contract, of which the Warner report seems to be an ideological reflection, has become an existential imperative.

At first, the new contract will probably make human research in the UK more appealing for sponsors. This relative advantage, however, will not last long. Driven by competition, such contracts have a well-known tendency to spread to other countries. This process of privatisation together with deregulation has been referred to as globalisation, harmonisation or, to use David Korten's words, a "race to the bottom". Yet, even in its globalised form, the new contract is likely to be unstable.⁷ This is because, contrary to its predecessor, it offers subjects and consumers nothing but empty promises, nice words and many more disasters. A more acute destabilising factor, however, is the further intensification of the global competition. Sooner rather than later, sponsors and researchers will realise that the reformed system is no more than a bureaucratic nuisance. When competition is fierce, time is money, and every penny counts, then why insist on a procedure that adds "little value"? Why not close

down the REC system? After all, this would be cheaper than outsourcing it to a low-cost offshore call centre. But then, why not go one step further and abolish research altogether? Wouldn't this make the production of biomedical knowledge as streamlined as it can be?

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