

Original paper

Ethics committee membership selection: a moral preference tool

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How the diversity of membership of research ethics committees is arrived at has, to date, largely been fairly arbitrary. However, a tool to help determine one's moral preference is now available and it is introduced here as, arguably, having the potential to assist with ensuring a more meaningful diversity amongst an ethics committee's membership. The tool is seen to be easily applied – but, it is argued, may be conceived on at least two false premises. Firstly, despite different theories of ethics, none can be proved to give the 'right' answer other than in its own terms. Secondly, if there is an ethical hierarchy, as the model suggests, then ethical diversity must become redundant for the possibility of achieving ethical excellence.

Keywords: membership, diversity, lay member, history, theories of ethics, ethicability®

Introduction

Nowadays it is usually considered important that an ethics committee (REC) is comprised of as wide a range of 'types' of members as possible. Presumably this is to attain either a balanced ethical opinion or perhaps to ensure community representativeness – or both. The rationale is nowhere clearly stated and I choose not to argue for either logic here, because both goals are potentially problematic. A balanced view can be a position to which no one truly subscribes (although reaching suboptimal decisions does not seem to be the typical experience of members of RECs), and, at best, it is difficult to see that the argument that a member of a REC represents 'the community' has been made with any conviction.

Nor am I convinced that an 'ethical' diversity, the theories behind which form the basis of many introductory 'ethics' textbooks [eg 1-3], is particularly useful. In an early editorial, Rawbone [4] argued that 'the ethical decision will, for each committee member, be, at least to some extent, dependent on that member's individual school of philosophy.' This led him to ask 'Should committee members thus be expected to analyze their own 'way of thinking'... And if the answer to this is 'yes' then should the research ethics committee have a balance of members between the differing perspectives?' West and Butler [5] appear to have answered 'yes' to the first question (indicating that their REC favoured ecological ethics and the ethics of caring) but then argued for a consistent ethical perspective so that applicants could select

the committee whose theoretical persuasion suited the researcher. This suggestion strikes me as being highly problematic – not least how does such a committee hope to adapt to changes in personnel?

Whilst the need for a diversity of representation on RECs is clearly stated in standard operating procedures, quite how that spectrum should be arrived at remains unclear, and this would be particularly so in the case of moral diversity. One can strive to include persons whose 'labels' suggest they are different – the disabled, those from a range of ethnic groups and religious convictions, males and females, scientists, ethicists, lawyers, ex-trial participants, pharmacists, researchers, medics, etc – but such labels do a poor job of distinguishing people's moral diversity.

It might be true that we do not want amoral individuals on RECs, but other than that should we seek people whose moral preferences differ at least to some degree from those of others on the committee? Theories of ethics can be considered as emphasising aspects of approach to a 'problem', and not necessarily in arriving at different conclusions. What is 'right', after all, tends to be the same after applying any ethics approach because what is judged 'right' is often determined by a social consensus.

So perhaps the primary question as to whether we should actively seek moral diversity remains to be argued; but such argument is not the substance of this paper. Here, I simply describe a tool which may offer a way to determine how a moral diversity might be recognised amongst members of an REC should such

differences be considered either relevant or desirable – but before considering the tool it may be helpful to sketch how membership of ethics committees has developed over time.

Early ethics committees

Early medical research ethics committees were dominated by medical men, researchers and those in authority. An early account of a prototype REC seems to appear in the fictional work of Sinclair Lewis's 'Arrowsmith' [6]. Dr Martin Arrowsmith has isolated a bacteriophage that seems effective against pneumonia and the plague bacilli, and he wants to test it on an island community ravaged by the bubonic plague:

Martin [Arrowsmith] was able to present his plans to a Special Board composed of the Governor, the temporarily suspended Board of Health, Inchcape Jones [the island's Surgeon General], several... members of the House of Assembly, and Sondelius [an authority on preventative medicine] ...Sondelius even brought in the Negro doctor, Oliver Marchand, not on the ground that he was the most intelligent person on the island (which happened to be Sondelius's reason) but because he represented the plantation hands...

The Special Board met in Parliament House, all of them trying not to look like their simple and domestic selves but like judges. With them appeared such doctors of the island as could find the time. (Ch. 34: III)

This pattern of expert dominance survived into the early 1960s and the arrival of bodies named as RECs and Institutional Review Boards (IRBs). These bodies are likely to have been modelled on the need for prior ethical review of research which had been a preference of the US National Institute for Health (NIH) since its inception in 1953 [7], apparently as an alternative to the 'ethical code' approach offered by the Nuremberg Code, and thus perhaps more suited to the situation in contemporary US human subjects research [8]. This preference became a requirement in 1966, possibly following the experience of the Seattle Artificial Kidney Center under Dr. Scribner in the early 1960s. The Center had more patients awaiting dialysis than it had facilities to cope with them, so 'Dr Scribner established two selection panels, the first of physicians to determine medical eligibility and the second...of seven laypeople who made the "final decision"...[T]he last committee was meant to provide objective answers but also to ensure community support...' [9]. If researchers in other countries wanted NIH funding they would need a similar review process, so not surprisingly a number of committees

sprang up in several UK hospitals in the aftermath of this requirement – and these committees seemed unable to satisfy themselves with just reviewing NIH-funded research. In this 'ad hocery', the Royal College of Physicians set up a Committee on the Ethical Supervision of Clinical Investigations in Institutions to seek some consistency amongst the committees, and this reported in July 1967. It recommended 'that all projects were [to be] approved by a *group of doctors* including those experienced in clinical investigation' (emphasis added), and that each hospital authority was to have 'a responsibility to ensure that all clinical investigations carried out within its hospital or institution are ethical and conducted with the optimum technical skill' [(ibid)]. 'Hospital authorities' meant the Board of Governors and so composed a number of non-medical personnel, indeed a majority of the members now tended to be lay. Thus eventually lay members got on to ethics committees, but it was an unclear and indeed confused process [8, 10]. The US Congress decided to favour lay membership of IRBs from the late 1960s: 'For the proper regulation of the powerful professionals of modern society, we need a combination of insiders and outsiders, of professionals and citizens' [11] and the guidelines were refined on May 1st 1969 to indicate that a committee entirely composed of medics or scientists would be inadequate to perform the functions expected of it.

GAfREC

The current requirement for RECs under the Governance Arrangements for Research Ethics Committees (GAfREC) [12] is that:

5.1 RECs should be constituted to ensure the competent review and evaluation of all ethical aspects of the research projects they receive, and to ensure that their tasks can be executed free from bias and influence that would affect their independence in reaching their decision.

Section 6 elaborates on this by indicating a need to obtain 'a sufficiently broad range of experience and expertise' (6.1), 'a balanced age and gender distribution ... [and] also... members from black and ethnic minority backgrounds, as well as people with disabilities. This should apply to both expert and lay members' (6.2). 'At least one third of the membership should be 'lay' members who are independent of the NHS, either as employees or in a non-executive role, and whose primary personal or professional interest is not in a research area' (6.3).

Group think

The independent ethics committee of which the current author is a member includes at least one of each of the following: expert in toxicology and pharmacol-

ogy, general practitioner, the disabled, ethnic minorities, ordained members, legally qualified, trained in medical and research ethics, participant in clinical trials, and experience of NHS RECs. Perhaps, however, it is not our different skills, experiences and backgrounds that are important for a comprehensive perspective on the question of the ethical acceptability of the protocols put for our consideration so much as that we are able to avoid 'group-think'. Over time a committee, no matter how 'diverse', may gravitate to a common position for thinking about the issues before it. If we all tend to think alike then no matter how diverse we can be presented as being, by adopting 'group-think' there would only be the appearance of the diverse membership which GAfREC encourages – and this appearance of diversity can suggest a fair, even-handed, approach.

But 'group think' may be more than just gravitating to a common position. Sunstein [13] for example suggests that 'when people with similar views debate an issue, they end up with more extreme positions than any of them previously held'. On first meeting this notion it may not be obvious that any discussion in a REC ever tends anywhere near an extreme view, but Sunstein is not suggesting that 'more extreme' necessarily equates to extremist. The point is that as REC members reach the consensus they need, then the more alike their views are to start with, the more the consensus position they reach is likely to be just a little more, or less, than some of them had individually thought about that position before the debate. This may be thought of as a 'subtle extreme'. It may, however, be difficult for a member to see this occurring in practice – yet surely all REC members have experienced themselves agreeing with others about a situation which they did not quite so clearly believe to be the case before discussion, and then mulling over the issue in their own minds recognising that they had shifted a bit in a direction they had not expected.

The obvious answer to this 'problem' of 'group think' is, perhaps, to retire and replace members of committees on a rota basis. This may help, but it may, just as likely, be no real solution. The new member will want to be accepted by the group (the committee) and so will want to appear 'reasonable' – and perhaps the best way to appear *reasonable* is to agree with other members, at least until such time as one becomes secure in the committee. By then, however, it might be very difficult to suddenly start to appear to be a different person, who last month believed such-and-such was satisfactory, and who this month is arguing the opposite.

Ethicability® framework

An alternative approach to achieving a diversity of REC membership in a relevant way might then be to

use a psychometric-type tool to assess a person's ethical thinking-style and to appoint individuals, at least in part, to capture a variety of moral perspectives for the committee. Steare's ethicability® framework [14] offers to analyse one's 'moral DNA'. By 'moral DNA' Steare does not actually mean that he believes people have a genetic predisposition to a particular moral position, but rather he uses the metaphor to draw attention to the fact that one has a preference as to moral approaches. He believes that a person's moral preference will be broadly towards 'rule following' (deontology), 'social conscience' (utilitarianism) or 'principled ethics' (Aristotelian virtue-ethics). Controversially, he advances Kohlberg's theory of moral development [15], at least in so far as to suggest that there is an ethical hierarchy amongst these theories of ethics, such that one might mature ethically by moving from rule-obedience, to appreciating the social value of morals, and may ultimately arrive at a more principled position when deciding the right thing to do in a given situation. Steare himself might therefore wish to recruit members from amongst those demonstrating a virtue ethics moral approach. One Independent Ethics Committee (IEC) which has been introduced to Steare's ethicability® tool to determine the ethics preferences of its members is Welwyn IEC.

Case study

The Welwyn IEC holds an Annual General Meeting (AGM) mid way through the year which serves a number of purposes. It allows the committee to consider any issues that have arisen and which need more time devoted to them if a resolution is to be achieved, it gives an opportunity to review its performance, and it has time within it for member training. In previous years it has included workshops covering such issues as new developments in pharmacology practice; toxicology testing; and SUSAR (suspected unexpected serious adverse reaction) reporting. In September 2009 Roger Steare, visiting professor of organisational ethics from the London City University's Cass Business School, was invited to provide some insight into how members consider matters from a moral point of view using his ethicability® framework.

Generally there is little overlap between business ethics and medical/research ethics because, whilst the latter is largely based on the principles of autonomy, beneficence, non-maleficence and justice [16], other principles tend to pertain with business ethics. However as what is right transcends disciplinary demarcations there seemed no reason why Steare's approach could not be used to help determine the moral preferences of members of ethics committees.

Taking the most simple version of Steare's ethicability® questionnaire (appendix) [17], and with all committee members' permissions, this was adminis-

tered to the members in such a way that only they would know their own results. This was conducted over a number of REC meetings in advance of the AGM. Members took a copy of the questionnaire and were invited to take a letter of the alphabet from a bag, only they would know which letter they had selected. They then completed the questionnaire, included their reference letter and returned the questionnaires in such a way as to maintain anonymity (indeed they could anonymously spoil their paper or simply return it uncompleted). Members' questionnaires were scored and the relative rankings tabulated.

It soon became apparent that it was possible to achieve the same score in two (and potentially all three) categories (rule compliance, social conscience, principled conscience – see appendix) and that this lack of a clear preference would not enable members to be assigned to a clear category. However because no member of the IEC had scored 'rule compliance' as their primary preference useful conclusions were still possible from the basic version of the tool.

A more detailed and validated version of the *ethicability*® framework is available on-line [18] where one can take an advanced test to determine more exactly one's 'ethicability' or moral preference.

In our situation, with none of the members falling into the rule compliance category it would seem that, in Steare's terms, the committee may be considered a morally sophisticated group compared with the average adult population [19].

'Ethicability' in context

What Steare is concerned about is that everyone comes to understand where they are morally – and then act in accordance with that understanding. Not to have such a sensibility is to behave at whim, according to forces and factors about which one is essentially unaware. For Steare, one is thus more likely to act morally when one has considered what that might mean, and begun to think of oneself as a moral agent. For him, as for Kohlberg, morality is a developmental notion and thus an individual can be expected to develop from a rule-following mind-set, through a socially conscious approach to doing what is right, to finally become morally mature as a principled-ethicist (which Steare equates to virtue ethics). The principled person acts according to some inner sense of what is the right thing to do in a given situation and will come to that judgement on the basis of years of experience and a developed moral awareness. Following rules might usually lead to doing the right thing, but acting according to rules and procedures without having to think about one's behaviour is not moral goodness. Similarly, acting with a social conscience is a refinement of mere rule-following if one is prepared, on occasion, to act in a way that goes against the rules in order to achieve some higher (but

given) objective which one believes to be right. Steare gives the example of utilitarianism as a socially conscious approach – to do the right thing under this approach one must decide (probably unaided by any specific rules) what will give the greatest good to the greatest number. Finally, for Steare, the moral acme is achieved when one is able to act instinctively in the right way without having to consider an algorithmic rule-based approach, or by having to weigh up competing arguments and then deciding how to proceed on the basis of some prior objective. The virtuous person, or principled conscious actor, knows instinctively what the right thing to do is.

Steare points out that morality is not merely acting according to other's suggestions or requirements, and is much more to do with autonomous action rather than heteronymous behaviours. However, by comparing rule-following with deontology and social consciousness with utilitarianism these caricatures can help explain and contextualise the tool; they are not intended to be considered as exact equivalents.

Kant, for example, as perhaps the strictest of the deontologists, emphasised the need, whenever one acts according to a moral law, to always act freely, determining for oneself what one must do, unconditionally, in accord with pure reason. We thus do not follow moral rules imposed on us, but we ourselves are encouraged to act as if by our own maxims in every case, we are a legislating member of the kingdom of laws, or, in another formulation of the categorical imperative, one must 'Act only on the maxim through which you can at the same time will that it be a universal law' [20]. Unthinking obedience to an external moral authority is thus not a valid moral position for Kant. His deontology was not about pure rule-following, requiring each of us to act out of a personal conviction about what is right. In this light Kant advocates what Steare terms 'principled conscience'. The rational person is at all times morally responsible for their actions, and is always a free moral agent, never rule-bound (unless the rule is of their own devising in the kingdom of ends).

The comparison with utilitarianism (as least in some of its more 'advanced' versions) is similar, for utilitarianism would recognise the need not merely to act such that the greatest good is achieved for the greatest number because, as Mill [21] argues, utilitarianism could 'place virtue at the very head of the things which are good' and thus the greatest good could be exactly what the *virtuous* person aims at.

Conclusions

Steare's *ethicability*® tool is a quick and conveniently simple framework that can help individuals – and in this case, members of an REC – determine their moral approach. For the individual, perhaps untrained in ethics, this can be a starting point from which they

can develop their knowledge, and for committees it can help them understand the moral preference composition of its members. In the case study described, for example, members came out as a relatively morally sophisticated committee (compared with the 'all adults' population), but equally another committee might include rule-followers and thus be more typical of the general population. Steare seems to suggest that over time committee members would shift towards the virtue ethics approach. However in the absence of evidence either that this would happen (and if it did, seeking ethical diversity would seem a fruitless exercise) or that virtue ethics really is the most advanced approach to ethical thinking, then perhaps the only committees to be avoided are those whose members do not have a clear moral approach at all. But even then does it matter? So long as the members can think, and speak, and where the majority do not just concern themselves with unethical issues such as the investigator's punctuation and grammar rather than the ethical propriety of the research itself, then this is surely enough – and if so, perhaps this indicates that if diversity is to be sought, it could be a diversity in terms of a variegation in backgrounds and lifestyles, not just a diversity amongst those having NHS connections.

Members of RECs may wish to consider the use of an instrument such as the ethicability® tool and use the findings in conjunction with the more obvious facts about their membership to help them consider whether their committee is likely to be a sufficiently diverse one or not. In the absence of evidence that one moral approach is best or even that moral diversity is to be sought, such a tool can, however, do little more than help focus attention on such matters.

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References

1. Thompson M. *Ethics*. London: Hodder Education, 2006.
2. Benn P. *Ethics*. Abingdon: Routledge, 1998.
3. MacIntyre A. *A Short history of ethics* (2nd edn). Abingdon: Routledge, 1998.
4. Rawbone R. Editorial. *Research Ethics Review* 2005; 1(2): 37-8.
5. West E, Butler J. An applied and qualitative LREC reflects on its practice. *Bull Med Ethics* 2003; (185): 13-20.
6. Sinclair Lewis H. *Arrowsmith*. Harcourt, Brace & Howe, 1925.
7. Stark LJM. *Morality in science: how research is evaluated in the age of human subjects regulation*. PhD thesis: Princeton University, 2006.
8. Hedgecoe A. 'A form of practical machinery': the origins of research ethics committees in the UK, 1967-72. *Med Hist* 2009; 53: 331-350.
9. Emanuel EJ. The evolving norms of medical ethics. In Green RM, Donovan A, Jauss SA, eds. *Global bioethics*. Oxford: Clarendon Press, 2009.
10. Hazelgrove J. The old faith and the new science: the Nuremberg Code and human experimentation ethics in Britain, 1946-73. *Soc Hist Med* 2002; 15(1): 109-135.
11. Commission on Health Science and Society. *Hearings of 90th Congress, 2nd session*. 1968. Part IV, p.1265.
12. *Governance Arrangements for NHS Research Ethics Committees*. Department of Health. London: HMSO, 2001.
13. Sunstein CA. *Going to extremes: how like minds unite and divide*. Oxford: Oxford University Press, 2009.
14. Steare R. *Ethicability: how to decide what's right and find the courage to do it*. London: Roger Steare Consulting Limited, 2006.
15. Kohlberg L. Stage and sequence: the cognitive-development approach to socialization. In Goslin DA, ed. *The handbook of socialization theory and research*. Chicago: Rand McNally, 1969. pp347-480.
16. Beauchamp TL, Childress JE *Principles of biomedical ethics*, 6th edn. Oxford: Oxford University Press, 2009.
17. Jones C. How do you do the right thing? *Psychologies* 2009; Mar.: 62-67.
18. at www.ethicability.org
19. Steare R, Stamboulides P. *Who's doing the right thing?* London: Roger Steare Consulting Limited, 2008.
20. Kant I. *Groundwork of the metaphysics of morals*. Chapter II, section 421.
21. Mill JS. *Utilitarianism*. Chapter IV. London, 1863.

Appendix

[Key] 1 = strongly disagree; 2 = moderately disagree; 3 = neutral – neither agree nor disagree; 4 = moderately agree; 5 = strongly agree

Group R- Rule compliance	1	2	3	4	5
1 Breaking the speed limit is always wrong	[]	[]	[]	[]	[]
2 People who do the right thing should be rewarded	[]	[]	[]	[]	[]
3 Doing the right thing is the same as doing what is legal	[]	[]	[]	[]	[]
4 We can defeat terrorism by restricting civil liberties	[]	[]	[]	[]	[]
5 People who break the law should always be punished	[]	[]	[]	[]	[]
6 We need more laws and more police to solve youth crime	[]	[]	[]	[]	[]
					Total []

Group S – Social Conscience	1	2	3	4	5
1 The world would be a better place if we were all more considerate	[]	[]	[]	[]	[]
2 Doing the right thing is about what's best for others	[]	[]	[]	[]	[]
3 Do as you would be done by	[]	[]	[]	[]	[]
4 Empathy and good relationships are the key to living a good life	[]	[]	[]	[]	[]
5 Doing the right thing is about treating others fairly	[]	[]	[]	[]	[]
6 All we need is love	[]	[]	[]	[]	[]
					Total []

Group P – Principled conscience	1	2	3	4	5
1 Good people don't need laws to tell them what's right	[]	[]	[]	[]	[]
2 Virtue is its own reward	[]	[]	[]	[]	[]
3 Doing the right thing is all about character – our internal moral compass	[]	[]	[]	[]	[]
4 Sometimes we must all suffer in order to do what's right	[]	[]	[]	[]	[]
5 I believe in tough love, I'm tough on issues, but soft on people	[]	[]	[]	[]	[]
6 Moral principles are more important than the letter of the law	[]	[]	[]	[]	[]
					Total []

Now add up your scores for each of the groups and then rank the groups in descending order. For example, if your scores are Group R = 13, Group S = 26, Group P = 21, then your result is SPR. There are six types:

PSR – 'Philosopher': believe that moral principle, or virtue, is the most important ethical perspective.

SPR – 'Angel': believe that being good to others is the most important moral perspective.

RPS – 'Enforcer': the people we rely on to make sure that everyone obeys the rules.

PRS – 'Judge': believe that moral principle is the most important ethical perspective.

SRP – 'Teacher': believe that doing what is right for humanity is the right thing to do.

RSP – 'Guardian': believe that doing as we're told, following the letter of the law, is best for us all.