

# “A Form of Practical Machinery”: The Origins of Research Ethics Committees in the UK, 1967–1972

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## Introduction

Given the centrality of ethics review by independent committees (called Research Ethics Committees, or RECs, in the UK) to modern biomedical research, and the ubiquity of complaints about such review on the part of researchers,<sup>1</sup> it is curious that little attention has been paid to these organizations by medical historians<sup>2</sup> in contrast to the work done on the role of institutions such as the British Medical Association (BMA) and the General Medical Council (GMC) in the development of medical professional ethics, and the general evolution of medical professionals' ethical values.<sup>3</sup> Thus while some work has explored the origins of modern medical ethics teaching in the UK and

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<sup>1</sup>Louise Robinson, Deborah Murdoch-Eaton and Yvonne Carter, 'NHS research ethics committees', *Br. Med. J.*, 2007, **335**: 6; P Wainwright and J Saunders, 'What are local issues? The problem of the local review of research', *J. Med. Ethics*, 2004, **30** (3): 313–17; Christopher Martyn, 'The ethical bureaucracy', *Q. J. Med.*, 2003, **96** (5): 323–4; Iain Chalmers, 'Lessons for research ethics committees', *Lancet*, 2002, **359**: 174; N R Dunn, A Arscott and R D Mann, 'Costs of seeking ethics approval before and after the introduction of multicentre research ethics committees', *J. R. Soc. Med.*, 2000, **93** (10): 511–12; T E Stacey, 'Ethical review of research in the NHS: the need for change', *J. R. Coll. Physicians Lond.*, 1998, **32** (3): 190–2; A E While, 'Research ethics committees at work', *J. Med. Ethics*, 1996, **22** (6): 352–5; Hans-Georg Eichler, 'Hazards of misguided ethics committees', *Lancet*, 1995, **346**: 1115–16; U J Harries, P H Fentem, W Tuxworth and G W Hoinville, 'Local research ethics committees: widely differing responses to a national survey

protocol', *J. R. Coll. Phys. Lond.*, 1994, **28** (2): 150–4; M I Watling and J K Dewhurst, 'Current experience of central versus local ethics approval in multicentre studies', *J. R. Coll. Phys. Lond.*, 1993, **27** (4): 399–402; T J Berry, T E Ades and C S Peckham, 'Too many ethics committees', *Br. Med. J.*, 1990, **301**: 1274; Editorial, 'Research ethical committees', *Lancet*, 7 May 1983, **i**: 1026; Peter J Lewis, 'The drawbacks of research ethics committees', *J. Med. Ethics*, 1982, **8** (2): 61–4.

<sup>2</sup>The best work on the context and early stages of REC development is offered by Jenny Hazelgrove, 'The old faith and the new science: the Nuremberg Code and human experimentation ethics in Britain, 1946–73', *Soc. Hist. Med.*, 2002, **15** (1): 109–35; *idem*, 'British research ethics after the second world war: the controversy at the British Postgraduate Medical School, Hammersmith Hospital', in Volker Roelcke and Giovanni Maio (eds), *Twentieth century ethics of human subjects research*, Stuttgart, Franz Steiner, 2004, pp. 181–97.

<sup>3</sup>Russell G Smith, 'The development of ethical guidance for medical practitioners by the General Medical Council', *Med. Hist.*, 1993, **37**: 56–67; Andrew A G Morrice, "'Honour and interests": medical ethics and the British Medical Association', in Andreas-Holger Maehle and Johanna Geyer-Kordesch (eds), *Historical and philosophical perspectives on biomedical ethics*, Aldershot, Ashgate 2002, pp. 11–33; Ivan Waddington, 'The development of medical ethics—a sociological analysis', *Med. Hist.*, 1975, **19**: 36–51; Sydney A Halpern, *Lesser harms: the morality of risk in medical research*, Chicago University Press, 2004.

the parallel development of academic bioethics,<sup>4</sup> there has been very little consideration of how Research Ethics Committees specifically were set up and evolved in the late 1960s and early 1970s. Although some scholars have discussed the development of the British REC system, this work tends to provide little beyond an outline of major events.<sup>5</sup> These might include a report from the Royal College of Physicians (RCP) in 1967, the Department of Health's 'Red Book' of 1991 outlining the responsibilities of Local Research Ethics Committees (LRECs) and, more recently, the introduction of multi-centre RECs (MRECs) in 1997.

This article explores in depth the role of the Ministry of Health in the early years of the REC system; although RECs were unknown in the UK in 1966, within six years Michael Alison, the Under-Secretary of State for Health and Social Security, could inform Parliament that all teaching hospitals and over 70 per cent of other hospitals had set up such committees to oversee clinical research, a total of 238 RECs. What were the interests and forces that underpinned the rapid expansion of organizations which, according to current thinking, are so inimical to the interests of biomedical researchers and doctors as a whole?<sup>6</sup> How did such an expansion take place when the Ministry of Health had no wish formally to get involved in setting the rules for their composition or acknowledging a role in their oversight? This latter point is of particular interest, as I will show. The Ministry, while remaining at arm's length from setting up RECs and control of their function, sought, through the actions of others, such as the RCP and Members of Parliament, and through careful release of information to bodies such as the Patients Association, to maintain some semblance of authority over ethics review policy, while at the same time balancing it with the need to remain "hands off" with regard to clinical activities.

Methodologically, this paper upholds the need for nuanced, empirically detailed analysis in researching the role of institutions involved in research ethics. UK Research Ethics Committees originated within the National Health Service (NHS), and to examine their development without taking due account of that context, is to fail to provide a full explanation for how these bodies developed in the way they did. As well as emphasizing context, such an approach also rejects what Laura Stark calls the "critical event" model—roughly analogous to what has been called the "moral panic" view of REC development<sup>7</sup>—

<sup>4</sup> M Whong-Barr, 'Clinical ethics teaching in Britain: a history of the London Medical Group', *New Rev. Bioeth.*, 2003, 1 (1): 73–84; Roger Cooter, 'The ethical body', in Roger Cooter and John Pickstone (eds), *Medicine in the twentieth century*, Amsterdam, Harwood, 2000, pp. 451–68.

<sup>5</sup> Claire Foster, *The ethics of medical research on humans*, Cambridge University Press, 2001, pp.140–6; R E Ashcroft, 'The ethics and governance of medical research: what does regulation have to do with morality?' *New Rev. Bioeth.*, 2003, 1 (1): 41–58.

<sup>6</sup> With regard to the impact on biomedical science, see S W G Derbyshire, 'The rise of the ethics committee: regulation by another name?', in James Panton and Oliver M Hartwick (eds), *Science vs. superstition: the case for a new scientific enlightenment*, London, Policy Exchange and

University of Buckingham Press, 2006, pp. 35–50; Charles Warlow, 'Clinical research is under the cosh again', *Br. Med. J.*, 2004, 329: 241–2; Konrad Jamrozik, 'Research ethics paperwork: what is the plot we seem to have lost?' *Br. Med. J.*, 2004, 329: 286–7. Similar claims have been made about the impact of ethics review on social science: Robert Dingwall, 'An exercise in fatuity: research governance and the emasculation of HSR', *J. Health Serv. Res. Policy*, 2006, 11 (4): 193–4; *idem*, "'Turn off the oxygen . . .": comment on the presidential address', *Law and Soc. Rev.*, 2007, 41 (4): 787–95.

<sup>7</sup> W C van den Hoonaard, 'Is research-ethics review a moral panic?', *Can. Rev. Sociol. Anthropol.*, 2001, 38 (1): 19–36; see also M H Fitzgerald, 'Punctuated equilibrium, moral panics and the ethics review process', *J. Acad. Ethics*, 2005, 2 (4): 1–24.

whereby the “simple fact that a scandal happened is used to explain subsequent developments in the human subjects review system”.<sup>8</sup> The critical events approach would overlook the 1960s as a period of intense change and introspection on the part of the medical profession, as suggested by events both nationally (the setting up, in 1963, of the London Medical Group to teach medical ethics to students) and internationally (the World Medical Association’s Declaration of Helsinki of 1964).<sup>9</sup> A key problem with the critical events model, with its focus on individuals, whistle-blowers and scandals, and its avoidance of context and continuity in ethical thinking, is that it is exactly the approach offered by bioethicists to explain developments in this area,<sup>10</sup> and as such leads to histories that mirror, rather than examine, bioethical thinking.<sup>11</sup> As Roger Cooter has pointed out, “Contemporary medical ethicists . . . constitute a part of the historical problem” rather than the solution.<sup>12</sup>

### **1967: A Responsibility that the College cannot Shirk**

As Stark has shown, in 1966, the idea of some sort of ethical peer review of research prior to its taking place was not new, and had been in position in the Clinical Centre of the US National Institutes of Health (NIH) since its beginnings in 1953. The purpose of such “Group Consideration” (as this review was called) was to emphasize the good standing of research at the Clinical Centre, and to insulate its work from oversight and interference by policymakers and lawyers at the NIH. The medical board which established this system clearly wanted an alternative to the “ethical code” approach embodied in the Nuremberg Codes, which were “not intended to discipline the majority of investigators, but to discredit the rare and egregious abuser”. Rather the board “had in mind a more routine type of human subjects protection that, unlike the adoption of an abstract code, would be part of everyday practice and thus would not imply that they might doubt the honor of their colleagues”.<sup>13</sup> The origins of ethical peer review of research lie not in the knee-jerk reaction of policymakers and bureaucrats to some research scandal, but in the realms of professional social control. As Stark suggests, the “Group Consideration guidelines bear the marks of having been written by investigators for investigators”.<sup>14</sup>

The obvious question then is one of timing: given that the idea of such review had been around for over a decade, why did it come to prominence in the UK in 1967, as opposed to any other time? The 1960s were clearly a period of reflection on the ethics of clinical research and broader medical practice, by both professionals and the public. While, as Jenny Hazelgrove suggests, the Nuremberg Code of 1947 may have been largely ignored by British researchers,<sup>15</sup> the ethical concerns of various medical researchers

<sup>8</sup> Laura J M Stark, ‘Morality in science: how research is evaluated in the age of human subjects regulation’, PhD thesis, Princeton University, 2006, p. 32.

<sup>9</sup> Whong-Barr, *op. cit.*, note 4 above; Susan E Lederer, ‘Research without borders: the origins of the Declaration of Helsinki’, in Roelcke and Maio (eds), *op. cit.*, note 2 above, pp. 199–217.

<sup>10</sup> Albert R Jonsen, *The birth of bioethics*, New York, Oxford University Press, 1998.

<sup>11</sup> For example, David J Rothman, *Strangers at the bedside: a history of how law and bioethics transformed medical decision making*, New York, Basic Books, 1991.

<sup>12</sup> Roger Cooter, ‘The resistible rise of medical ethics’, *Soc. Hist. Med.*, 1995, **8** (2): 257–70, p. 270.

<sup>13</sup> Stark, *op. cit.*, note 8 above, p. 48.

<sup>14</sup> *Ibid.*, p. 56.

<sup>15</sup> Hazelgrove, ‘The old faith and the new science’, *op. cit.*, note 2 above.

had not disappeared in the post-war years, and had prompted various institutional responses. The best example of this is the debate within the Medical Research Council (MRC) over the role of informed consent. In 1954 the MRC canvassed unit directors on the correct treatment of human subjects in medical experiments; the directors, with rare exception, rejected the Council's suggestion that written consent should be sought from patients enrolled in research, claiming that such a formal approach would undermine the trust at the heart of the doctor-patient relationship. This position, favouring verbal over written consent, fed into formal MRC policy, and was included in the Council's statement on 'Responsibility in Investigations on Human Subjects' published as part of the Council's 1962/63 annual report.<sup>16</sup>

That old, paternalistic certainties were being questioned is made clear in the debate in 1963 over informed consent in the *British Medical Journal*, sparked by the publication of a lecture on 'Medical ethics and controlled trials' by Sir Austin Bradford Hill, one of the founding fathers of the clinical trial. In this piece, Bradford Hill mounted an attack on the draft code of ethics on human experimentation which had recently been drawn up by the World Medical Association (the code became the 'Declaration of Helsinki'<sup>17</sup>), criticizing its requirement for informed consent in all cases: "Surely it is often quite impossible to tell ill-educated and sick persons the pros and cons of a new and unknown treatment versus the orthodox and known?"<sup>18</sup> The article generated a scathing response from Helen Hodgson, chair of the newly formed Patients Association (PA)—"It is astonishing to a layman to read a commentary on medical ethics which appears to advocate a doctor/patient relationship based upon deceit"<sup>19</sup>—and letters defending Bradford Hill and Hodgson in turn.<sup>20</sup> The debate was closed not with the tacit acceptance of Bradford Hill's paternalistic position but by a highly critical editorial suggesting that, "If any proof were needed of the necessity for devising a code of ethics on human experimentation it was" Bradford Hill's "dangerous" and, with regard to his arguments against the WMA's draft code, "somewhat specious" ideas.<sup>21</sup>

This unity between the editors of an establishment journal such as the *British Medical Journal* and a new pressure group such as the PA, underlines the breadth of concern about the ethics of clinical research on patients in the early 1960s. In terms of public awareness of these issues, perhaps the pre-eminent figure of this time was Maurice Pappworth, who in a 1962 article for the literary magazine *Twentieth Century*, and a 1967 book (both called 'Human guinea pigs'), blew the whistle on what he felt were

<sup>16</sup> Medical Research Council, 'Responsibility in investigations on human subjects', in *Report of the Medical Research Council for the year 1962-1963*, London, HMSO, 1964, pp. 21-5. For a detailed exploration of the origins of this report, see Talitha Bolton, 'Consent and the construction of the volunteer: institutional settings of experimental research on human beings in the cold war', unpublished PhD thesis, University of Kent, 2008.

<sup>17</sup> *World Medical Association declaration of Helsinki: ethical principles for medical research involving human subjects*, Helsinki, World Medical Association, 1964.

<sup>18</sup> Austin Bradford Hill, 'Medical ethics and controlled trials', *Br. Med. J.*, 20 April 1963, i: 1043-49, p. 1046.

<sup>19</sup> Helen S U Hodgson, 'Medical ethics and controlled trials', *Br. Med. J.*, 18 May 1963, i: 1339-40, p. 1339.

<sup>20</sup> Reginald S Murley, 'Medical ethics and controlled trials', *Br. Med. J.*, 1 June 1963, i: 1474-75; Peter N Grimshaw, 'Medical ethics and controlled trials', *Br. Med. J.*, 29 June 1963, i: 1736.

<sup>21</sup> Editorial, 'Ethics of human experimentation', *Br. Med. J.*, 6 July 1963, ii: 1-2.

unethical research practices in both the UK and the USA, and who suffered intense public criticism from his medical colleagues as a result.<sup>22</sup> Yet while this context explains why researchers and doctors might have been receptive to the idea of research ethics review, it does not explain why RECs appeared *when* they did.

The most obvious explanation, in accordance with the idea that REC development was pushed by some form of “moral panic”, gives prominence to Pappworth, and his whistle-blowing activities.<sup>23</sup> Yet while Pappworth was a major figure in the broader British debates around medical ethics and research, he played only a marginal role in the development of research ethics committees. Rather than focusing on his 1967 suggestion that hospitals needed committees to oversee the ethics of research,<sup>24</sup> attention should be directed at a memo of the previous year from the US Surgeon General to all recipients of grants from the US Public Health Service (PHS). This memo confirmed that in order to remain in receipt of, or to be awarded new, PHS grants for clinical research, applicants’ institutions had to provide prior review “of the judgment of the principal investigator” in terms of “the rights and welfare of the individual . . . of the appropriateness of the methods used to secure informed consent, and . . . of the risks and potential medical benefits of the investigation”.<sup>25</sup>

As a consequence of this, at a number of leading UK teaching hospitals, where researchers were in receipt of such grants, ad hoc committees sprang up, as British researchers attempted to remain eligible for US funding. Dissatisfaction with the disorganized nature of the situation led Desmond Laurence, a Fellow of the Royal College of Physicians, to approach Max Rosenheim, president of the Royal College of Physicians of London (and professor of medicine at University College Hospital of which Laurence was a member of staff). Rosenheim told Laurence to recruit two senior Fellows of the College distinguished for their research in different areas, and to write a formal letter to him at the RCP signed by them all.<sup>26</sup> Laurence was joined by Professor Tony Dornhorst and Sir Francis Avery Jones, and the letter, sent in September 1966, outlined the problem, pointing out that such committees were already being formed and that “it seems unlikely that they [the committees] will feel they can sensibly confine their attentions solely to cases where research is sponsored by a foreign country”. There was thus a need for some organization to “undertake to consider whether the present supervisory arrangements for human experimentation, or the lack of them, are satisfactory”, and the RCP, given its access to senior researchers and clinicians, and its ability to balance

<sup>22</sup> M H Pappworth, ‘Human guinea pigs: a warning’, *The Twentieth Century*, autumn 1962, pp. 66–75; *idem*, *Human guinea pigs: experimentation on man*, Harmondsworth, Penguin, 1969 [1967]; *idem*, “‘Human guinea pigs’—a history”, *Br. Med. J.*, 1990, **301**: 1456–60; Christopher Booth, ‘Maurice Pappworth, MD, FRCP’, *Br. Med. J.*, 1994, **309**: 1577–78; Stephen Lock, ‘Obituary: Dr Maurice Pappworth’, *Independent*, 12 Nov. 1994, p. 42; Paul J Edelson, ‘Henry K. Beecher and Maurice Pappworth: honor in the development of the ethics of human experimentation’, in Roelcke and Maio (eds), *op. cit.*, note 2 above, pp. 219–33.

<sup>23</sup> Hazelgrove, ‘British research ethics’, *op. cit.*, note 2 above, p. 191.

<sup>24</sup> Pappworth, *Human guinea pigs*, *op. cit.*, note 22 above, p. 252.

<sup>25</sup> Office of the Surgeon General (1966), ‘Investigations involving human subjects, including clinical research’, Memo to the Heads of Institutions Receiving Public Health Service Grants from the Surgeon General, 1 July 1966. Policy and Procedure Order 129.

<sup>26</sup> Interview, Desmond Laurence, July 2007.

the interests of society at large with the needs of medical knowledge, was “peculiarly suited to consider actively the whole of this important topic”.<sup>27</sup>

By the end of October, Rosenheim had replied to the three physicians, pointing out that the issue of human experimentation had been discussed by the College a number of times and that further guidance in this area “is clearly a responsibility to the public that the College cannot shirk, and I am bringing your letter to the notice of the Council at its next meeting”.<sup>28</sup> By January, the president had decided to set up a committee of the College to consider this issue,<sup>29</sup> and in May 1967, the Committee on the Ethical Supervision of Clinical Investigations in Institutions (of which all three signatories of the original letter were members) met for the first time.

The Committee reported in July 1967, producing two pages of commentary and recommendations, the most important of which was that each hospital authority had “a responsibility to ensure that all clinical investigations carried out within its hospital or institution are ethical and conducted with the optimum technical skill”. The way to do this was to ensure “that all projects were approved by a group of doctors including those experienced in clinical investigation”, although, given the variation of practices and interests among different institutions, the Committee refrained from giving detailed guidance on how these bodies should operate.<sup>30</sup>

A number of key points emerge from the College’s report. The first is that, although public concern about medical research was widespread, specific scandals did not initiate the move towards ethics review.<sup>31</sup> Rather, RECs were first mooted in the UK as a response from professional medical researchers to funding requirements from the US PHS. This point is even clearer when one considers the MRC’s reaction to the RCP report. While Sir Harold Himsworth, Secretary of the MRC, approved of the report—“I can say straightaway that I like it and agree with it”<sup>32</sup>—there was little need for the Council to concern itself with *setting up* RECs, since most of its research would be carried out in NHS institutions that had their own committees.<sup>33</sup> Yet the lack of an ethics committee at the MRC-funded National Institute for Medical Research (NIMR) became a problem a few months later in the spring of 1968, when it became clear that the NIH was unwilling to fund the visit of a Colonel Kaufman to collaborate with researchers at the NIMR, unless some form of ethics review of the research could be provided.<sup>34</sup> The

<sup>27</sup> Royal College of Physicians Archive (hereafter RCP), letter to Professor Max Rosenheim, President Royal College of Physicians from F Avery Jones, A C Dornhorst and D R Laurence, 5 Sept. 1966.

<sup>28</sup> RCP, letter from Max Rosenheim to F Avery Jones, A C Dornhorst and D R Laurence, 24 Oct. 1966.

<sup>29</sup> RCP Archive, letter from Registrar of RCP to F A Jones, 9 Jan. 1967.

<sup>30</sup> Royal College of Physicians of London, *Report of the Committee on the supervision of the ethics of clinical investigations in institutions*, London, RCP, 1967, p. 4.

<sup>31</sup> Years later Desmond Laurence wrote to Pappworth, pointing out that although the RCP report predated Pappworth’s recommendations concerning RECs in his book, “I have no doubt your 1962 *article*

prepared people’s minds for it, including mine when I drafted the letter signed by Dornhorst and Avery Jones in 1966”: Wellcome Library, Archives and Manuscripts, PP/MHP/C.5, letter from Desmond Laurence to Maurice Pappworth, 10 May 1990. This point was reiterated to me in an interview with Laurence in July 2007.

<sup>32</sup> National Archives, Kew (hereafter NA), FD 9/869, letter from Harold Himsworth to Max Rosenheim, 22 June 1967.

<sup>33</sup> Although the MRC debated the issues raised by the report for its practices and policies: NA, FD 9/869, memo to Sir Harold [Himsworth], 20 Oct. 1967.

<sup>34</sup> NA, FD 9/869, letter from Brandon Lush to Sir Peter Medawar, 9 April 1968. The opportunistic, researcher-led nature of the setting up of this

solution was to set up an ethics committee within the context of the NIMR, the role of which was to review applications from the MRC's "non-clinical" centres and the Institute itself.<sup>35</sup> International "echoes" of the impact of the Surgeon General's memo can be found in Sweden, where the first ethics committee was started in 1966 at the Karolinska Institute, for exactly the same reasons.<sup>36</sup>

It is also worth noting, not just that the RCP report does not offer a role for lay members on the proposed committees (something that Pappworth could exploit following the publication of his book a few months later<sup>37</sup>) but also that the document places responsibility for the ethical conduct of research on the "competent authority" of a hospital (i.e. its board of governors, hospital management committee or medical school council)—an issue which was soon to cause the Ministry of Health (MH) considerable concern.

### Response to the RCP Report

Following the publication of the report and its announcement in the *British Medical Journal*,<sup>38</sup> the Patients Association—set up in January 1963 in direct response to Pappworth's original 1962 allegations<sup>39</sup>—responded with cautious optimism, welcoming the idea of prior review by a group of doctors, "provided such groups would not at any time include doctors involved in the project under consideration". Yet the Association's main point was to endorse "the placing of responsibility for ensuring that investigations are ethical and conducted with optimum skill and safety *on the hospital authority*" (emphasis added). The PA noted that while an ethics committee might be able to assess the possible risks and benefits of clinical experiment, "This still leaves the question of whether the project is carried out in an ethical way", especially with regard to informed consent. Thus for the Patients Association, the ultimate responsibility for the ethical conduct of research lay with the hospital, rather than the doctor.<sup>40</sup>

Initially, the Ministry of Health was supportive of the College's report, for it came at a time when the medical establishment was under considerable pressure over the issue of human experimentation. Pappworth's 1962 article and 1967 book had caused unease among some members of the public, and the PA had applied constant pressure on the Ministry of Health through a campaign of letter writing and parliamentary questions from sympathetic MPs.

In 1967, just prior to the publication of the RCP report, the Ministry's response was to re-issue the 1962/63 MRC's annual report, which addressed issues of research on

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committee is supported by the fact that in the autumn of 1970 the NIMR committee was closed down, partly because it had so little work to do: NA, FD 9/869, memo from Brandon Lush, 30 Sept. 1970.

<sup>35</sup> NA, FD 9/869, letter from Brandon Lush to J S Weiner, 30 April 1968.

<sup>36</sup> S Westman-Naeser, 'Current experiences in the Nordic countries', in Peter Bennett (ed.), *Good clinical practice and ethics in European drug research*, Bath University Press, 1994, pp. 27–35.

<sup>37</sup> M H Pappworth, 'Experiments on man' *Br. Med. J.*, 2 Sept. 1967, iii: 616.

<sup>38</sup> M Rosenheim, 'Supervision of the ethics of clinical investigations in institutions', *Br. Med. J.*, 12 Aug. 1967, iii: 429–30.

<sup>39</sup> Wellcome Library, Archives and Manuscripts, PP/MHP/C.1/6, letter from Helen Hodgson to Maurice Pappworth, c. March 1963.

<sup>40</sup> NA, MH 160/883, letter from Helen Hodgson to Rt. Hon. Kenneth Robinson, Minister of Health, 18 Aug. 1967.

humans and especially the need for fully informed consent.<sup>41</sup> In the letter to consultants that accompanied the report, Sir George Godber, the Chief Medical Officer (CMO), emphasized a theme that came to underpin the Ministry's position regarding the impending RECs, that the "real safety of patients of course rests securely upon the ethical standards of the profession" and the letter itself "is not intended to trespass upon these in any way or to purport to give guidance from the Ministry".<sup>42</sup>

The RCP report arrived soon after this and provided a useful opportunity for the Ministry to prove that it was taking these issues seriously. Yet it also presented officials with a number of problems. Like the Medical Board of the NIH's Clinical Centre over a decade earlier, the Ministry accepted the limits of ethical codes and saw ethics review in principle as a "form of practical machinery as opposed to written guidance", a form of machinery that meant that "ethical responsibility for approving experiments would rest with doctors". Yet,

What is puzzling is the view [of the RCP] that the creation of such supervisory bodies would discharge the responsibility of the "competent authority" [e.g. the Hospital Board] to ensure that all clinical investigations are ethical . . . which the Committee contend is necessary.

The core of the issue was that hospital boards were not made up solely of doctors, but were predominantly lay, and since "[e]ven if there were to be lay representation on these bodies [i.e. RECs], their understanding of the minutiae which might be the crux of the ethical problem in a particular case would necessarily be limited". Thus, given these limits to lay understanding *within* RECs, "the suggestion that responsibility for such experiments should be put on the shoulders of the 'competent' lay authority is very questionable". Therefore "it is essential that ethical and legal responsibility should be kept firmly on the shoulders of the medical profession (where it lies at the moment)".<sup>43</sup>

The key point underpinning this attitude is what Rudolph Klein calls the "bargain between the State and the medical profession" concerning clinical autonomy. In the original 1948 settlement that created the NHS, such autonomy, "the right of individual doctors to do what they thought right for individual patients",<sup>44</sup> was secured at the cost of allowing economic decisions to be taken at a political level. Within the Ministry of Health, this "arms length" attitude regarding individual clinical decisions extended to other areas of medical practice, including clinical research. Thus some officials took exception to the Patients Association's interpretation of the RCP report (that competent authorities are ultimately responsible for the ethics of research) since "it runs counter to the line we have taken on clinical investigations—that the decision to carry them out and the getting of true consent are medical matters coming within the responsibility of the doctor concerned". While such authorities had a duty to ensure, when recruiting staff, that doctors had the appropriate qualifications, "they have no responsibility for oversight of the detailed clinical work undertaken by the doctor once appointed".<sup>45</sup> One obvious

<sup>41</sup> MRC, *op. cit.*, note 16 above.

<sup>42</sup> NA, MH 160/883, letter from G E Godber to all consultants in the Hospital Service ref: H/R125/22, 17 July 1967.

<sup>43</sup> NA, MH 160/883, memo from M R Edwards to Mr Morris, ref: H.S.1A A517, 25 Aug. 1967.

<sup>44</sup> Rudolph Klein, *The new politics of the NHS*, 4th ed., Harlow, Prentice Hall, 2001, p. 64.

<sup>45</sup> NA, MH 160/883, memo from D J Morris to Mr Hales, 31 Aug. 1967.

solution was for such committees “not [...] be a sub-committee of the H.M.C. [Hospital Management Committee] but an informal body to whom the doctor proposing an experiment should refer for advice. The setting up of such committees would be a matter for the doctors themselves”.<sup>46</sup>

The Ministry’s concerns about the RCP report were not just founded on the issue of clinical autonomy. There was also the matter of whether hospitals (and the broader NHS) would become, at least partly, liable for mistakes that occurred during clinical research. The political problems associated with who was responsible for unethical research in NHS hospitals had already been noted in June 1967, when in reference to concerns raised by Pappworth’s book, the CMO noted that ultimately: “The Minister can’t escape the point that the things complained of may be done in the hospitals for which he is responsible, but none of us wants this to get to the point where there could be any suggestion of making rules about it from here.”<sup>47</sup> Thus, if correctly positioned within the NHS hierarchy, RECs could provide a means of public reassurance, while avoiding incurring liabilities for hospitals and infringing clinical autonomy.

Thus within the Ministry, while concerns were also raised over liability issues should a nurse involved in a research project make a mistake,<sup>48</sup> or what should happen in the case where hospitals actively funded research, rather than just employed the doctors carrying it out,<sup>49</sup> it was the twin concerns—the importance of clinical autonomy and the need to protect hospitals from liability—that led to disagreement over whether RECs should be formally set up by the hospital management or whether they should remain informal medical bodies. The resulting draft circular recommending the RCP report to hospitals was written in such a way as to “avoid bringing out too boldly the difference of opinion between us and the Royal College on the ‘competent authority’s’ responsibilities”.<sup>50</sup>

Within a month, a solution was beginning to form that the answer to the problem of the ethical responsibilities of competent authorities lay not in trying to accommodate the RCP’s position but rather in highlighting the errors present in the Committee’s recommendations. Thus while the RCP Committee’s “suggestion that a group of doctors should be set up to advise on experiments” was useful, “we are agreed that the Cttee [*sic*] are mistaken in their view . . . that hospital authorities have a responsibility to ensure that clinical investigations are ethical and are carried out with the optimum degree of skill and safety”. Any circular to hospitals “should correct the impression they give”.<sup>51</sup> While some officials were reluctant to go into this kind of detail in a circular—“we are surely under no obligation to accept or comment on every sentence of the report”<sup>52</sup>—the general consensus was that while:

the situation we want to create is that it is recognised that doctors should not undertake these experiments without submitting them first to a group of their colleagues . . . [at the same time] . . .

<sup>46</sup> NA, MH 160/883, memo from J C Hales to Mr Morris, 7 Sept. 1967.

<sup>47</sup> NA, MH 160/883, letter from G E Godber to Sir Thomas Holmes Sellers, 8 June 1967.

<sup>48</sup> NA, MH 160/883, memo from J C Hales to Mr Morris, ref: P.S.O./823/20, 7 Sept. 1967.

<sup>49</sup> NA, MH 160/883, memo from D J Morris to Mr Hales, 8 Sept. 1967.

<sup>50</sup> NA, MH 160/883, memo from D J Morris to Mr Salter and Dr Cohen, 6 Oct. 1967.

<sup>51</sup> NA, MH 160/883, memo from H C Salter to Dr Cohen, 1 Nov. 1967.

<sup>52</sup> NA, MH 160/883, memo from R H L Cohen to Mr Salter and CMO, 14 Nov. 1967.

neither the hospital authority nor the group [i.e. the REC] is however responsible for the experiment and that the doctor cannot hide behind either.<sup>53</sup>

In the end, there was no need for a public disagreement with the College. Godber, the CMO, contacted Rosenheim, who in addition to being president of the RCP was chair of the Committee on the Ethical Supervision of Clinical Investigations in Institutions. Rosenheim agreed with the CMO's interpretation that the Committee "were trying to say that the hospital authority had a responsibility to see that appropriate machinery was available for the guidance of doctors undertaking clinical investigations ... [but] ... They did not mean to go further and suggest that the Board or Committee should satisfy itself about the conduct of individual investigations".<sup>54</sup> By the time the Ministry's circular was being re-drafted, this "re-interpretation" of the RCP report had become the standard line, with Ministry of Health officials eventually being confident enough to tell representatives from teaching hospitals that "what the [RCP] committee *wanted* to say was that the competent authority has a responsibility to see that appropriate machinery is available for the guidance of doctors" and thus "[i]t is the firm view in the Department that the Committee's *intention* should be followed rather than their *words*" (emphasis added).<sup>55</sup>

### 1968: Recommending the Report

The Ministry then began the process of preparing to print off thousands of copies of the RCP report to send to consultants and hospitals, along with the still undecided circular note recommending it.<sup>56</sup> The actual wording of the circular caused considerable debate among officials, given the delicate matter of how to point out that the Ministry did not endorse the RCP's wording with regard to the responsibilities of competent authorities. While some officials sought to acknowledge the differences with the RCP report,<sup>57</sup> the Minister of Health at the time, Kenneth Robinson, felt that such an admission went "unnecessarily far in inviting trouble" and suggested its omission.<sup>58</sup> Ministry officials were acutely aware of the possible problems arising from the contrast between the RCP report and the circular—"it may excite Press comment and will certainly cause a reaction from the Patients Association"—and had asked that the Minister be made aware of this disagreement.<sup>59</sup> There were even concerns among some as to whether

<sup>53</sup> NA, MH 160/883, memo from H C Salter to CMO, 17 Nov. 1967.

<sup>54</sup> NA, MH 160/883, memo from G E Godber to Dr Cohen, 27 Nov. 1967.

<sup>55</sup> NA, MH 160/883, meeting with Secretaries of Board of Governors of Provincial teaching hospitals, Supplement to brief, ref: SEC. B.G.4/68, 1 May 1968.

<sup>56</sup> The origin of the decision to circulate the RCP report itself (rather than a summary, for example) is unclear. Writing two years later, one official suggested that the idea "seems to have come from us [i.e. the Ministry], nudged by the Patients Assn": NA,

MH 160/884, memo 41, from Chambers to Mr Taggart, 3 Dec. 1969.

<sup>57</sup> NA, MH 160/883, memo from D J Morris to Dr McGregor and Dr Evans, 8 March 1968.

<sup>58</sup> NA, MH 160/883, memo from Kenneth Robinson, 21 March 1968. This is an interpretation of the memos (which refer to additions to the "penultimate paragraph" or "paragraph three" of the circular) without actual sight of the draft circular itself, which is not included in the records.

<sup>59</sup> NA, MH 160/883, memo from H C Salter to Mrs Hauff, 15 March 1968.

the circular should be sent to consultants *at all* since “although we may ‘interpret’ the report for hospital authorities (our creatures) we should not do so for consultants who are independent”.<sup>60</sup>

The final version of the circular, numbered HM68(33), introduces the RCP report, and then reminds readers of the MRC annual report of 1962/63 and its focus on “true consent” and how the getting of such consent “must clearly be the responsibility of the doctor who is to conduct it”. The third paragraph notes that the Report suggests that hospitals are responsible for ensuring “that facilities exist by which clinical investigations . . . are subject to appropriate scrutiny” and that “to this end they should secure that a group of doctors . . . is set up and that projects are subject to the approval of this group”. The final piece in the separation of ethical responsibilities is the statement that “[i]t is envisaged that the groups would be informal advisory bodies rather than committees of hospital authorities”.<sup>61</sup> Thus in three short paragraphs the circular embodies not just the Ministry’s view (in contrast to the RCP report) that clinical autonomy and liability issues devolve ethical responsibility for the conduct of research to individual doctors, but also the idea that RECs must be distanced from formal association with hospitals.

By 3 May the Ministry had alerted Senior Administrative Medical Officers (SAMOs) across the country that it would be sending out letters, circulars and copies of the RCP report to all consultants,<sup>62</sup> and ten days later thousands of papers were sent out for SAMOs and teaching hospitals to distribute.<sup>63</sup> By 16 May the Patients Association had responded to the circular in a way that came “as no surprise” to officials.<sup>64</sup> The Association felt that simply asking hospitals to implement the RCP report failed to meet any of the concerns raised in its letter of the previous August. In particular, the Association emphasized the inadvisability of “placing final responsibility on the hospital authority while instructing it to rely entirely on the medical groups”. Even the colour of the circular was wrong: “it is universally understood in hospital administrative circles that only pink circulars need be acted upon and white circulars are liable not to be read”.<sup>65</sup> For the Association, HM68(33)’s pale complexion was an indication of how lightly the Ministry took the issue of protection of human subjects. The Ministry’s response was to play a straight bat, reject the idea that there was a colour-based hierarchy for circulars and clearly spell out its position regarding the responsibilities of different groups: “though a hospital authority has power to permit experimental activities in its hospitals . . . it has no responsibility for oversight of the detailed clinical work done by a doctor once appointed.”<sup>66</sup>

<sup>60</sup> NA, MH 160/883, memo from N J Evans to Mr Morris, 12 March 1968.

<sup>61</sup> Ministry of Health, *Supervision of the ethics of clinical investigations*, 1968, HM68(33).

<sup>62</sup> NA, MH 160/883, letter from G E Godber, CMO to SAMOs, 3 May 1968.

<sup>63</sup> The printing orders suggest that 11,500 copies of the circular, 11,200 copies of the CMO’s letter to consultants and 25,000 copies of the RCP report were printed off. Distribution lists suggest that copies of

the CMO’s letter and the RCP report were actually sent to 8094 consultants via SAMOs and 2867 consultants at teaching hospitals in the first instance.

<sup>64</sup> NA, MH 160/884, memo from D J Morris to Mr Hales and Dr Gregor, 29 May 1968.

<sup>65</sup> NA, MH 160/884, letter from U Miller (Hon. Secretary PA) to R S Mathews, 16 May 1968.

<sup>66</sup> NA, MH 160/884, letter from M I Brabant to U Miller, 3 June 1968.

For the Ministry, the circular was a convenient tool in its response to wider public concerns about medical experimentation. Newspaper reports about medical research led members of the public to ask, “What sort of a country are we getting to be to allow the old and the helpless to be shockingly exploited in this way”, drawing comparisons with “Hitler’s gas chambers” and noting that “[f]or too long so-called scientists have been having a field day”.<sup>67</sup> The standard reply could now refer, not just to the MRC annual report from 1962/63 (and its re-circulation to doctors in mid-1967) but also to the RCP report and its wide distribution across the Health Service.<sup>68</sup>

Compared with that of the Patients Association, the response of the medical profession and NHS was more positive. By early July, 500 more copies of the circular had been ordered, and by August the Ministry, having distributed 25,000 copies of the RCP report was obliged to order 5000 more of what was clearly a “best seller”,<sup>69</sup> to allow distribution to Scotland. Yet the issue of the responsibilities of hospital management would not go away. A letter from Springfield Hospital in Tooting, in November 1968, suggests that members of hospital management committees were not satisfied with merely ensuring that an REC was set up, but that they felt “a particular responsibility to patients and it is their opinion that any projects, although approved by the medical staff, should also be approved by them”.<sup>70</sup> In reply the Ministry (now the Department of Health and Social Security—the DHSS) sought to quash any such ideas on the part of hospital management, repeating the position made to the Patients Association earlier in the year that, in essence, “[c]linical decisions are for the clinician to make: ethical questions are for the profession to consider . . . it would not be in patients’ interests if hospital authorities were to interfere”.<sup>71</sup>

### 1969–1970: Following Up

Towards the end of 1969, Rosenheim approached the CMO with the suggestion that the RCP, with the Department’s approval, should instigate some form of questionnaire “follow up” to its report of two years earlier.<sup>72</sup> Godber’s reply was supportive—“I’m sure it would be a good idea”—and, while the CMO was open to the proposal that the Department itself carry out some form of enquiry through the regional hospital boards, given the (apparently) independent nature of the original report he thought “there was some advantage in the follow up also being seen to be yours and independent”, albeit with Departmental help.<sup>73</sup> Godber’s preference for the RCP to produce this information

<sup>67</sup> NA, MH 160/884, letter from Elizabeth Brooks to Mr Peel, 16 May 1968. This letter was forwarded to the Ministry by John Peel, the author’s MP.

<sup>68</sup> NA, MH 160/884, letter from Julian Snow to John Peel, MP, ref: A2788/18, July 1968.

<sup>69</sup> NA, MH 160/884, memo 12 from D J Morris to CMO, 13 Aug. 1968.

<sup>70</sup> NA, MH 160/884, letter from W J Tarlton to DHSS, 19 Nov. 1968.

<sup>71</sup> NA, MH 160/884, letter from D J Morris to W J Tarlton, 13 Dec. 1968.

<sup>72</sup> NA, MH 160/884, letter from Max Rosenheim to G E Godber, 24 Oct. 1969.

<sup>73</sup> NA, MH 160/884, letter from G E Godber to Max Rosenheim, 31 Oct. 1969. Godber clearly thought that the RCP would “get better co-operation from doctors themselves than the Department would”: NA, MH 160/884, memo from G E Godber to Dr Yellowlees and Dr Cohen, 31 Oct. 1969.

was to prove, in the long run, unhelpful, and, as the Department came under increasing pressure (particularly from the Patients Association) it would find itself having not only to defend the RCP's data, but also to repeat much of its work.

The RCP and the Department were not the only organizations that thought that some kind of review of the new REC system was needed. In March 1970, the PA wrote to the DHSS asking whether committees had been set up in accordance with the RCP report, whether they were reporting to hospital authorities, and whether these authorities were taking “an overall responsibility”.<sup>74</sup> In discussing the reply to this letter, officials felt that, by and large, the Association could be referred back to the Department's previous positions, but the realization was dawning on the Department that it could not maintain its arms-length relationship with RECs (via the RCP). It was clear that if hospital authorities were responsible for setting up RECs then “we for our part cannot abandon responsibility for knowing what they are doing”, and that if the ongoing RCP survey could not provide this information, “we should perhaps consider finding out for ourselves”.<sup>75</sup>

The reply to the Association simply mentions that the RCP were following up their report and that “[w]hen we hear from them the results of their investigations we shall know the answer to your question on the setting up of committees”.<sup>76</sup> The PA maintained a tenacious pursuit of these results, sending letters in June, October and November 1970 enquiring whether the RCP had reported back,<sup>77</sup> refusing to be put off by claims that the RCP faced the “enormous task” of analysing and collating the replies and that the Department could not say when the results would be available.<sup>78</sup> In its strongly worded November letter, the PA suggested that it was “unreasonable that four years later [i.e. after the RCP report] there is no information available as to what action has been taken”, and urged the Department to obtain its own data on RECs.<sup>79</sup>

This produced an immediate response from the DHSS with a letter going off the same day to the Royal College of Physicians asking for “some indication as to when the results of this enormous task are likely to be available”,<sup>80</sup> leading to a commitment from the RCP to let the Department know when the report might be produced.<sup>81</sup> By early 1971, even other parts of government, the Scottish Home and Health Department for example, were asking the DHSS how it was following up the 1968 circular.<sup>82</sup> Pressure also came from the Peel Advisory Group, which had been set up in 1970 to investigate issues around foetal research, and which was expected “to place heavy reliance on the ethical committees set up under HM(68)33 as a means of controlling future foetal research”.

<sup>74</sup> NA, MH 160/884, letter from Helen Hodgson to P R Molineux, 11 March 1970.

<sup>75</sup> NA, MH 160/884, memo 47 from D J Clark to Mr Molineux, 21 April 1970.

<sup>76</sup> NA, MH 160/884, letter from P R Molineux to H Hodgson, 23 April 1970.

<sup>77</sup> NA, MH 160/884, letter from C Cox to P R Molineux, 25 June 1970; NA, MH 160/884, letter from General Secretary to P R Molineux, 21 Oct. 1970.

<sup>78</sup> NA, MH 160/884, letter from P R Molineux to C Cox, 3 July 1970.

<sup>79</sup> NA, MH 160/884, letter from H Hodgson to P R Molineux, 16 Nov. 1970.

<sup>80</sup> NA, MH 160/884, letter from C M Hallett to Secretary, RCP, 16 Nov. 1970.

<sup>81</sup> NA, MH 160/884, letter from G M G Tibbs to C M Hallett, 26 Nov. 1970.

<sup>82</sup> NA, MH 160/884, letter from G D Forwell to D J Morris, 3 Feb. 1971.

The expectation was that if the RCP survey showed that response to the circular had been inadequate, “the Peel Group will probably feel bound to make some recommendation in their report urging that urgent steps be taken to ensure that these committees are set up and work effectively”.<sup>83</sup>

In May 1971, the Royal College of Physicians finally released its report to the Department,<sup>84</sup> although the College pointed out that the document was “for limited release” and “should not be allowed to get into the hands of the Press”.<sup>85</sup> Overall, the College and the Department probably had reason to feel satisfied. The 345 questionnaires sent out produced a 58 per cent response rate, split between an 86 per cent response from teaching hospitals and a 55 per cent response from Regional Hospital Boards (i.e. non-teaching). Of the 32 teaching hospitals that replied, 30 had ethics committees in place, one was in the process of forming an REC and the other in reforming a committee that had lapsed. Of the 169 non-teaching hospitals that replied, 125 had committees in place, and 44 had not. While these figures may have given a degree of comfort to the Department, some of the detail in the survey was worrying. As the summary put it: “[C]ertain replies gave reason to suppose that the function of an Ethical Committee in screening research projects for the protection of the public, the institution, and the research worker is not yet universally accepted.” The main problem was “a particularly common belief that there are two sorts of clinical investigation, one of which requires ethical supervision and the other of which does not, and that it is transparently easy to tell the one from the other”.<sup>86</sup> This is clear from the survey, which suggests that in only 74 per cent of replying hospitals with RECs in place were all clinical investigations referred to the ethics committee. Of even greater concern, in two hospitals, clinical drugs trials were given as an example of the kind of studies which did not require committee approval.

Although not flagged up in the summary, perhaps most interesting with regard to the long-term effects of the RCP survey, is the information the report offers on the membership of RECs. Question 5 of the survey asked hospitals to indicate “the constitution of your Committee, giving total Membership, and numbers of medically qualified members, non-medical scientists and other members”. Of the 126 hospitals that replied to this question, 101 had committees with only medical members, and of the 30 committees in teaching hospitals, only 6 had lay members. In the rare cases where non-teaching hospitals had lay members, they were always the hospital or group secretary. No committee had more than two lay members.<sup>87</sup> While the response to this question might seem mild, it is intriguing that these details are here at all. The 1967 RCP report made it clear that ethics committees should be made up of the medically qualified alone, and, as we shall see, the inclusion of this question and these responses puzzled the Department of Health when it came to deliberate the results of the survey.

<sup>83</sup> NA, MH 160/884, memo 67 from V Poole to Dr J Wilson, 20 April 1971.

<sup>84</sup> Royal College of Physicians of London, Committee on the Supervision of the ethics of Clinical Investigations in institutions, *A follow up enquiry for the College*, April 1971.

<sup>85</sup> NA, MH 160/884, letter from G M G Tibbs to C M Hallett, 20 May 1971.

<sup>86</sup> RCP, op. cit., note 84 above, p. 2.

<sup>87</sup> *Ibid.*, p. 5.

### **1971: After the Survey**

In the meantime, the Patients Association had clearly decided to cut out the middle men, and approach hospitals directly to enquire about the presence or otherwise of Research Ethics Committees. On 24 May 1971, the Association sent out letters to many hospital boards, enquiring about the number of “‘ethical committees’ [that] have been established in the hospitals under your Board” as well as “how their membership is chosen and how they function”.<sup>88</sup> As a result, some hospitals contacted the Department for advice on what to say in reply. For many officials the response to an increasingly provocative Patients Association seeking access to a survey that was deemed to be confidential was not obvious.<sup>89</sup> One solution was to ask the RCP for permission to release the survey<sup>90</sup> although this was rejected by some in the Department because since the survey showed that the “RCP’s original report is not yet universally accepted”, the survey itself was not suitable for release to the Association; indeed “it would be difficult for the RCP to extract those parts which are suitable”.<sup>91</sup> In the middle of August events overtook officials when it became clear that “PA is in possession of the whole [survey] and the question of release of certain elements of the enquiry to them appears to be no longer pertinent”.<sup>92</sup>

What was not immediately obvious was that the release of the whole document to the PA had taken place at the beginning of June, on the advice of Godber, the CMO. In a letter to Rosenheim of the RCP, Godber suggested that “it seems highly likely that a copy of it [the survey] or an extract from it will eventually reach Mrs. Hodgson [the then president of the PA]” in which case the Association “would certainly make whatever use of it it wished”. A better alternative, Godber suggested, would be “to volunteer a copy, asking Mrs. Hodgson not to publish” and thus gain some sort of control over how the Association used the results of the survey.<sup>93</sup> Rosenheim clearly agreed with this approach: later correspondence between the RCP and the PA points out that while the Association can discuss the survey with the DHSS, and while the fact that a review had been carried out was not confidential, “the report itself is still regarded as a confidential document”.<sup>94</sup>

In the middle of this debate, the issue of the range and number of RECs in the country became public when, on 27 July, Joyce Butler, MP, asked the Secretary of State, “How many hospital authorities have now established an ethical committee . . . and how many committees include lay members?”<sup>95</sup> It is unclear from the archives what the relationship was between Mrs Butler and the Patients Association, but, given the timing (the PA would have received the RCP survey some time in the previous ten days) and the constraints on what the PA could say about this confidential document, getting

<sup>88</sup> NA, MH 160/884, letter from U Miller, no addressee, 24 May 1971.

<sup>89</sup> NA, MH 160/884, memo 1 from G R A Gill to Mr Smith, 11 June 1971.

<sup>90</sup> NA, MH 160/884, memo 2 from Mr Smith to Dr Archibald, 30 June 1971.

<sup>91</sup> NA, MH 160/884, memo 6 from Dr McGregor to Dr Archibald, 20 July 1971.

<sup>92</sup> NA, MH 160/884, memo 9 from Mr Yates to Miss Wavish, 13 Aug. 1971.

<sup>93</sup> NA, MH 160/884, letter from G E Godber to Max Rosenheim, 1 June 1971.

<sup>94</sup> NA, MH 160/884, letter from G M C Tibbs to H S U Hodgson, 14 July 1971.

<sup>95</sup> Parliamentary Question from Joyce Butler, Hansard, HC (series 5), vol. 822, col. 59 (27 July 1971).

a sympathetic MP to ask about the results of the survey (without mentioning it by name) was a useful way of bringing the results into the public domain.

The written response to Mrs Butler's question blandly reassured Parliament that "some 55% of all hospital boards responded . . . and that nearly all teaching hospitals and more than three quarters of others have now established such committees". The Patients Association reacted angrily to this reply, since it misrepresented some of the data in the survey, giving the impression that more RECs were in place than was the case.<sup>96</sup> The Department accepted its error—apparently the result of a last minute edit of the written reply<sup>97</sup>—and while it wrote to Mrs Butler to apologize and correct the information,<sup>98</sup> it felt that the Association's reaction had been overblown.<sup>99</sup> The Association itself was far from satisfied. In October 1971 it noted that Sir George Godber had just been quoted in the *Guardian* newspaper repeating the erroneous figure of 55 per cent of non-teaching hospitals having ethics committees (when, of course, 55 per cent referred to the survey response rate), sarcastically asking whether, "If the Department is incapable of interpreting the survey, could not some assistance be given to it?"<sup>100</sup>

It seems likely that the timing and the tone of the Association's letter were provoked by more public revelations (which the Association refer to obliquely in their letter) regarding the treatment of patients by medical researchers in the NHS. On Wednesday 13 October (the day before the PA letter) Dr John MacRae, a GP based in Fulham in London, named four London hospitals at which he said that unethical research was being carried out. MacRae was speaking out in support of Maurice Pappworth who, on a radio programme the previous Sunday, had made allegations about the treatment of patients at the Hammersmith and Royal Free hospitals. MacRae (who had been tutored by Pappworth) claimed that patients of his had been subjected to unnecessary investigations at Charing Cross, Westminster, University College and St Thomas's hospitals, all of which denied his claims, citing both the use of informed consent procedures and the approval of the hospitals' ethics committees prior to any research.<sup>101</sup>

In its own terms, Department officials knew that they could defend themselves against the PA's objections. The Department was confident in its approach to RECs and respect for professional autonomy, reminding Secretaries of the boards of London hospitals that its policy was "to encourage the establishment of ethical committees . . . [and to] . . . rely upon the well established ethical practices of the profession and the sanctions which the profession itself imposes". With regard to the allegations made by Pappworth and MacRae, unless details could be provided about specific cases, the Secretary of State had to accept the denials of the hospitals accused.<sup>102</sup> Yet at the same time, there was an acceptance among officials that they had to know what was actually going on in terms

<sup>96</sup> NA, MH 160/884, letter from Helen Hodgson to Sir Keith Joseph, 16 Aug. 1971.

<sup>97</sup> NA, MH 160/884, memo from Smith to Brandis, 13 Sept. 1971.

<sup>98</sup> NA, MH 160/884, letter from Michael Allison to Joyce Butler MP, 30 Sept. 1971.

<sup>99</sup> NA, MH 160/884, memo from L H Brandis to Mr Qades, 15 Sept. 1971.

<sup>100</sup> NA, MH 160/884, letter from H Hodgson to Sir Keith Joseph, 14 Oct. 1971.

<sup>101</sup> 'London hospitals reject new allegations of unjustified experiments on patients', *The Times*, Wed. 13 Oct. 1971, issue 58297, page 2.

<sup>102</sup> NA, MH 160/884, meeting of Secretaries of London Boards of Governors on 21 October 1971, Brief for Chairman (Mr J S Orme).

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of implementing the 1968 circular, and that because of the limited response to the RCP survey, this data was still lacking:

[W]e shall continue to be in a somewhat indefensible position on all matters relating to experiments if we do not discover quickly the extent to which hospital authorities have implemented the . . . Guidance given in HM(68)33 to set up ethical committees.

Thus there was a pressing need to require regional health boards to compile lists of HMCs that already had research ethics committees, indicating when they had been set up and their composition, and to clarify with those that had not yet established RECs whether they intended to do so.<sup>103</sup> This position was supported within the Department—“we’ll never exorcise this spectre until we get a reply from *all* hospital authorities”<sup>104</sup>—although it was necessary to seek permission from Rosenheim to repeat the RCP’s work, this was duly received.<sup>105</sup>

At the same time, in late 1971, Parliament responded to the latest allegations about medical research with an adjournment debate on 3 November. Such debates are called by MPs at relatively short notice (usually a week) to respond to pressing concerns, and take place at the end of the day, after main parliamentary business has finished. This debate, on ‘Hospital Patients (Experiments)’ was called by William Molloy, MP for Ealing North, who had, in the past, asked a number of parliamentary questions on this topic and corresponded with the Department. The central themes of Molloy’s impassioned speech were that abuses of NHS patients appeared to have taken place and that the government was unwilling to launch a public enquiry into these events. Drawing on news reports of Pappworth’s recent radio interview, as well as private correspondence from patients and families who claimed to have undergone such experiments, Molloy noted that “the nation is disturbed” and called for a public enquiry.<sup>106</sup> In response, Michael Alison, the Under-Secretary of State for Health and Social Security, agreed that the public should be disturbed by such allegations, but that the trouble lay in their unsubstantiated nature. Referring to Pappworth, Alison noted that “the author of the allegations . . . has, I understand, not been prepared to support them with specific evidence. Certainly I can say that my Department has not been supplied with any such evidence”. In addition, important structures, such as the MRC annual report, were now in place to protect patients, and ensure informed consent. When it came to ethics committees, the 1967 RCP report was referred to as a good example of the responsible behaviour of the profession. That said, the College’s survey produced information that was “not complete and my Department is therefore making its own inquiries of hospital authorities in England—the results of which I shall be happy to make known to the hon. Member, as soon as they are available”.<sup>107</sup>

<sup>103</sup> NA, MH 160/884, memo 2 from Smith to Miss Wavish and Mr Brandis, 22 Oct. 1971.

<sup>104</sup> NA, MH 160/884, memo 3 from unknown to Dr Cohen, n.d (23 or 24 Oct. 1971).

<sup>105</sup> NA, MH 160/884, memo 5 from unclear to Mr Brandis, 26 Oct. 1971.

<sup>106</sup> William Molloy, Adjournment debate, Hansard, HC (series 5) vol. 825, cols. 320–323 (3 Nov. 1971).

<sup>107</sup> Michael Alison, Adjournment debate, Hansard, HC (series 5), vol. 825, cols. 324–328 (3 Nov. 1971).

Thus, two years after the CMO suggested that the RCP survey the state of UK RECs independently of the Department, a Minister of Health had to make a public commitment to carry out exactly the same kind of work. The resulting enquiries, labelled “DS 308/71” started on 10 November with a letter sent to hospital boards, and by late December 1971 the results had been collated and analysed. Of the 321 hospitals covered by the regional hospital boards that the Department had approached, 238 had ethics committees of some sort, 32 had decided that they did not need a committee, and 51 were still debating the issue. In terms of different kinds of hospital, “all teaching hospitals have total cover. On the least favourable reading of the returns just under 70% (69.8%) of HMCs [i.e. non-teaching] have complete cover; on the most favourable reading the percentage is 75.4%”.<sup>108</sup>

These results are generally in line with the RCP report, but the Department’s analysis of its own and the RCP’s survey highlights a peculiar change in the College’s position with regard to lay members. The Department’s survey followed the RCP in asking about the membership of committees: the DS 308/71 results suggest that 187 out of the 238 committees were made up of only medical members. Yet officials were confused as to why the RCP survey (which the Department mimicked) had asked about lay members at all, since the original 1967 RCP report had not mentioned lay members, indeed it had defined RECs in terms of exclusive medical membership. “It is curious, therefore, to find them in their 1971 survey assessing the number of ethical committees with lay members without attempting to relate this to their 1967 viewpoint.” Since in drafting its circular, the Ministry of Health had followed the College’s lead in suggesting that RECs consist of medical personnel, “It will be difficult to suggest to hospital authorities that absence of lay members makes an ethical committee unsatisfactory.”<sup>109</sup>

So where did this interest in lay members come from? DHSS officials speculated that it was prompted by the 1967 report and its suggestion—later rejected by Rosenheim of course—that hospital authorities (made up of lay members) should take ultimate responsibility for the ethics of clinical investigations:

[the] possible reason for the RCP apparent change of view, viz that they became confused about the intention behind the wording of Recommendation 2 of their Committee’s 1967 Report; that that Committees [*sic*] always intended that the hospital authority should play a major part in the oversight of clinical investigations; and that this is the reason for their interest in lay membership in their 1971 survey. Indeed, para 2 of the Survey’s Summary (page 1) is unequivocal in its statement of the hospital authority’s essential responsibility in the matter.<sup>110</sup>

The RCP’s survey summary does indeed refer to the original 1967 report as suggesting that “the responsible authority would be able to assure itself of the ethical propriety of every project for clinical research to be carried out there—something it had a duty to do”.<sup>111</sup> The problem for the Department was that “It is not clear whether the wording of this question reflected any change of view on the part of the RCP as to how these

<sup>108</sup> NA, MH 160/185, memo 3 from W E Wavish to Mr Smith, 21 Dec. 1971.

<sup>109</sup> *Ibid.*

<sup>110</sup> *Ibid.*

<sup>111</sup> RCP, *op. cit.*, note 84 above, p. 1.

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committees *should* be composed, nor as far as I am aware, do we know what further consideration the RCP have given to the whole subject”.<sup>112</sup>

This apparent *volte face* by the College (or return to its original position) was problematic for the Department, since, as we have seen, the RCP’s “medics only” policy for RECs was an important part of the official, arms-length position with regard to these committees. If one removed the support of the RCP for medical only RECs, then the lay membership of such committees would undermine the official position that such research was too complex for lay people—meaning members of hospital authorities—to understand. This in turn would sabotage the argument that such authorities could not take responsibility for research, and would thus undermine the Department’s maintenance of clinical autonomy and avoidance of legal liability.

The unexplained origin of this interest in lay members (although the Patients Association had raised this as an issue on a number of occasions) presented a threat to the Department’s position, but one which could be ignored for the time being. Thus on 28 January 1972, Alison issued his written answer to a question from Molloy, noting that “all teaching hospital authorities and over 70 percent of other hospital authorities” had RECs in place, of which about a fifth included a lay member.<sup>113</sup> This expansion, not just in academic centres such as teaching hospitals, but also in over two thirds of other hospitals emphasizes the status of RECs as NHS bodies. While their origins might lie in the needs of academic researchers, RECs swiftly became incorporated into the broader NHS context.

### **Conclusion**

In a short period of time, the Ministry of Health and its successor oversaw the development and expansion of RECs in the UK from zero to 238 committees. Using the Royal College of Physicians as a form of proxy, officials ensured the spread of such committees, which proved a convenient defence against claims that “more should be done” to protect human subjects, while at the same time protecting the concept of clinical autonomy and avoiding the need for hospitals to take responsibility for doctors’ research. This reliance upon the RCP had its limitations: the College’s lack of formal powers (for compelling response) meant that its survey of RECs had to be repeated and officials found themselves trying to disentangle RECs from the College’s attitudes towards the need for hospitals (and hence the NHS and its Ministers) to take responsibility for committees’ decisions (and the research that they approved). Lay members of RECs thus became a problem in attempts to erect a barrier between lay hospital management boards and clinicians’ research. Early 1972 saw the Department overseeing a REC system which, while impressive for its breadth and acceptance by the clinical community, was clearly in a state of flux and by no means finalized.

The main contribution of this article is to stress the importance of the role of the Ministry of Health in the early development of research ethics committees in the UK.

<sup>112</sup>NA, MH 160/185, memo 14 from E R Hammer to Mr Gidden, 3 March 1972.

<sup>113</sup>Michael Alison, written answer, Hansard, HC (series 5), vol. 829, col. 550 (28 Jan. 1972).

Previous work has tended to overlook the part played by the Ministry and, consequently, highlight the role of RECs as a form of—usually inadequate—self-regulation.<sup>114</sup> It is not that RECs were not a form of self-regulation, but rather that this informal status was less the result of *laissez-faire* “drift” on the part of policy makers than a deliberate, *active* decision to dissociate these committees from NHS bodies and thus help preserve the idea of clinical autonomy.

<sup>114</sup> Hazelgrove, both references cited in note 2 above.