

“A form of Practical Machinery”: The origins of Research Ethics Committees in the UK: 1967-1972.

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Abstract

Despite their importance in the oversight of modern medical research, the history of Research Ethics Committees (RECs) in the UK has tended to be limited to a list of important events, rather than detailed exploration of how these bodies developed over time. This article uses archive material to highlight the importance of the Ministry of Health in the late 1960s, as it supported the Royal College of Physicians’ attempts to set up RECs, shape the interpretation of the College’s recommendations while at the same time attempting to remain at arms-length from these committees themselves. The central problem faced by the Ministry was the need for RECs to remain advisory bodies rather than formally part of hospital hierarchy, for fear of infringing on clinical autonomy and possibly making hospitals (and the broader NHS) liable for mistakes made during research. This paper traces the development of RECs from their origins to the announcement in 1972 of a study surveying these committees and their membership.

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 researchers¹, it is curious that little attention has been paid to these organisations by medical historians² in contrast to the work looking at the role of institutions such as the BMA and GMC in the development of medical professional ethics³, and the general development of medical

¹ Robinson L, Murdoch-Eaton D and Carter Y ‘Editorial: NHS research ethics committees’ *British Medical Journal*, 2007, 335: 6; Wainwright P and Saunders J ‘What are local issues? The problems of the local review of research’ *Journal of Medical Ethics*, 2004, 30: 313-317; Martyn C ‘The ethical bureaucracy’ *Quarterly Journal of Medicine*, 2003, 96:323-324; Chalmers I ‘Letter: Lessons for research ethics committees’ *The Lancet*, 2002, 359:174; Dunn NR, Arscott A and Mann RD ‘Costs of seeking ethics approval before and after the introduction of multicentre research ethics committees’ *Journal of the Royal Society of Medicine*, 2000, 93:511-512; Stacey TE ‘Ethical review of research in the NHS: the need for change’ *Journal of the Royal College of Physicians of London*, 1998, 32(3): 190-192; While AE ‘Research ethics committees at work’ *Journal of Medical Ethics*, 1996, 22:352-355; Eichler H ‘Letter: Hazards of misguided ethics committees’ *The Lancet*, 1995, 346: 1115-1116; Harries U.J. et al ‘Local research ethics committees: Widely differing responses to a national survey protocol’ *Journal of the Royal College of Physicians of London*, 1994, 28(2): 150-154; Watling MIL and Dewhurst JK ‘Current experience of central versus local ethics approval in multicentre studies’ *Journal of the Royal College of Physicians of London*, 1993, 27(4): 399-402; Berry T.J., Ades T. and Peckham C ‘Letter: Too many ethics committees’ *British Medical Journal*, 1990, 301: 1274; Anon. ‘Editorial: Research Ethics Committees’ *The Lancet*, 1983, May 7, p.1026; Lewis PJ ‘The drawbacks of research ethics committees’ *Journal of medical ethics*, 1982, 8:61-64.

² The best work on the context and early stages of REC development is offered by Jenny Hazelgrove: Hazelgrove J ‘The Old Faith and the New Science: The Nuremberg Code and Human Experimentation Ethics in Britain, 1946–73’ *Social History of Medicine*, 2002, 15(1): 109-135; Hazelgrove J ‘British research ethics after the second world war: the controversy at the British Postgraduate Medical School, Hammersmith Hospital’, in V Roelcke and G Maio (eds.) *Twentieth Century Ethics of Human Subjects Research*, Stuttgart, Fran Steiner Verlag, 2004, pp. 181-197

³ Smith RG ‘The development of ethical guidance for medical practitioners by the general medical council’ *Medical History*, 1993, 37:56-67; Morrice A ‘“Honour and interests”: medical ethics and the

professionals' ethical values.⁴ Thus while some work has explored the origins of modern medical ethics teaching in the UK⁵ and the parallel development of academic bioethics⁶ very little attention has been paid to how the specific institution of Research Ethics Committees were set up and developed 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.⁷ 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 development of multicentre 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

British Medical Association' in AH Maehle and J Geyer-Kordesch (eds.) *Historical and Philosophical Perspectives on Biomedical Ethics*, Aldershot, Ashgate 2002, pp. 11-33.

⁴ Waddington I 'The development of medical ethics – A sociological analysis' *Medical History*, 1975, 19:36-51; Halpern S *Lesser Harms: The Morality of Risk in Medical Research*, Chicago, Chicago University Press, 2004.

⁵ Whong-Barr M 'Clinical Ethics Teaching in Britain: a history of the London Medical Group' *New Review of Bioethics*, 2003, 1(1): 73-84.

⁶ Cooter R 'The Ethical Body' in R. Cooter and JV Pickstone (eds.) *Medicine in the Twentieth Century* (Harwood), 2000, pp. 451-468.

⁷ Foster C *The Ethics of Medical Research on Humans*, Cambridge, Cambridge University Press, 2001, pp.140-146; Ashcroft R 'The Ethics and Governance of Medical Research: what does regulation have to do with ethics?' *New Review of Bioethics*, 2003, 1(1): 41-58.

Michael Alison, the Under-Secretary of State for Health and Social Security, could inform Parliament that all teaching hospitals and over 70 percent of other hospitals had set up such committees to oversee clinical research, a total of 238 RECs. What interests and forces underpinned the rapid expansion of organisations which, according to current thinking, are so inimical to the interests of biomedical researchers and doctors as a whole?⁸ How did such an expansion take place when the Ministry of Health deigned to formally get involved in setting the rules for their composition or acknowledging a role in their oversight? This latter point is of particular interest, since, as I will show, the Ministry, while remaining at arms length from the need to set up RECs and control their function, sought, through the actions of others' such as the RCP and members of Parliament, and through controlled release of information to bodies such as the Patients Association, to maintain some semblance of control 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 emphasises the need for nuanced, empirically detailed analysis in researching the role of institutions involved in research ethics. UK

⁸ With regard to the impact on biomedical science see: Derbyshire SWG 'The rise of the ethics committee: regulation by another name?' in J Panton and OM Hartwich (eds.) *Science vs. Superstition: the case for a new scientific enlightenment* (Policy Exchange and University of Buckingham Press), 2006, pp.35-50; Warlow C 'Editorial: Clinical research is under the cosh again' *British Medical Journal*, 2004, 329:241-242; Jamrozik K. 'Research Ethics paperwork: what is the plot we seem to have lost?' *British Medical Journal*, 2004, 329:286-7. Similar claims have been made about the impact of ethics review on social science: Dingwall R. 'Editorial: An exercise in fatuity' *Journal of Health Services Research and Policy*, 2006, 11(4): 193-194; Dingwall R. ' "Turn off the oxygen..." Comment on the presidential Address' *Law and Society Review*, (2007), 41(4):787-795.

Research Ethics Committees originated within the NHS, and to examine their development without taking due account of that context, is to fail to offer up a full explanation for how these bodies developed in the way they did. As well as emphasising 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 development⁹ – whereby the “simple fact that a scandal happened is used to explain subsequent developments in the human subjects review system”.¹⁰ 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).¹¹ 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 area¹², and as such leads to histories that mirror, rather

⁹ van den Hoonaard WC ‘Is research-ethics review a moral panic?’ *The Canadian Review of Sociology and Anthropology*, 2001, 38(1): 19-36; see also Fitzgerald MH ‘Punctuated equilibrium, moral panics and the ethics review process’ *Journal of Academic Ethics*, 2005, 2(4): 1-24.

¹⁰ Stark L ‘Morality in Science: How research is evaluated in the Age of human subject regulation’ Ph.D. Thesis, Princeton University, 2006, p.32

¹¹ Whong-Barr op. cit. note 5; Lederer S.E. ‘Research without borders: the origins of the Declaration of Helsinki’ in , in V Roelcke and G Maio (eds.) *Twentieth Century Ethics of Human Subjects Research*, Stuttgart, Fran Steiner Verlag, 2004, pp. 199-217.

¹² Jonsen AR *The Birth of Bioethics*, New York, Oxford University Press, 1998.

than examine, bioethical thinking.¹³ As Roger Cooter has pointed out, “Contemporary medical ethicists...constitute a part of the historical problem” rather than the solution.¹⁴

1967: A responsibility that the College cannot shirk

As Laura Stark has shown, in 1966, the idea of some sort of ethical peer review of research prior to it taking place was not new, and had been in place in the Clinical Centre of the US National Institutes of Health since its beginnings in 1953. The purpose of such ‘Group Consideration’ (as this review was called) was to emphasise 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 put this system in place clearly wanted an alternative to the ‘ethical code’ approach embodied in the Nuremburg Codes which were “not intended to discipline the majority of investigators, but to discredit the rare and egregious abuser”. Rather they “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”.¹⁵ 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.

¹³ E.g. Rothman D J *Strangers at the Bedside: A history of how law and bioethics transformed medical decision making*, New York, Basic Books, 1991

¹⁴ Cooter R ‘Review article: The resistible rise of medical ethics’ *Social History of Medicine*, 1995, 8(2): 257-270 on p.270.

¹⁵ Stark (2006) op. cit. note 10, p.48

As Stark suggests, the “Group Consideration guidelines bear the marks of having been written by investigators for investigators”.¹⁶

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 time of reflection on the ethics of clinical research and broader medical practice, both on the part of professionals and the public. While, as Jenny Hazelgrove suggests, the Nuremberg Code of 1947 may have been largely ignored by British researchers¹⁷, ethical concerns on the part of various medical researchers had not gone away in the post-war years, and had prompted various institutional responses. The best example of this is the debate within the 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, downplaying written at the expense of verbal 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 Councils’ 1962-63 Annual report.¹⁸

¹⁶ Ibid. p.56

¹⁷ Hazelgrove, op. cit. (2002) note 2.

¹⁸ Medical Research Council, ‘Responsibility in Investigations on Human Subjects’, in *Report of the Medical Research Council for the year 1962-1963* (HMSO: London), 1964, pp.21-25. For a detailed exploration of the origins of this report see: Bolton T. *Consent and the Construction of the Volunteer:*

That old, paternalistic, certainties were being questioned is emphasised 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’¹⁹), criticising 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?”²⁰ 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”²¹ – and letters defending Bradford Hill and Hodgson in turn.²² The debate was closed, not with the tacit acceptance of Bradford Hill’s paternalistic position but rather a highly critical editorial, suggesting that “If any proof were need of the

Institutional Settings of Experimental Research on Human Beings in the Cold War, unpublished PhD Thesis, University of Kent, 2008.

¹⁹ World Medical Association. *Ethical Principles for Medical Research Involving Human Subjects*, 1964, (Helsinki: World Medical Association).

²⁰ Bradford Hill A. ‘Medical Ethics and Controlled Trials’ *British Medical Journal* 1963, April 20, pp:1043-1049 on p.1046

²¹ Hodgson H. ‘Letter: Medical Ethics and Controlled Trials’ *British Medical Journal*, 1963, May 18, pp.1339-1340 on p.1339

²² Murley RS ‘Letter: Medical Ethics and Controlled Trials’ *British Medical Journal*, 1963, June 1, pp.1474; Grimshaw PN ‘Letter: Medical Ethics and Controlled Trials’ *British Medical Journal*, 1963, June 29, pp.1736.

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.²³

Such unity between the editors of an establishment journal such as the *BMJ* and a new pressure group, like the PA, underlines the breadth of concern about the ethics of such research 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 1967 book (both called *Human Guinea Pigs*), blew the whistle on what he felt were unethical research practices in both the UK and US, and who suffered intense public criticism from other doctors as a result.²⁴ Yet while this context explains why researchers and medics 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 is pushed by some form of ‘moral panic’, gives prominence to Pappworth, and his

²³ Anon. ‘Editorial: Ethics of Human Experimentation’ *British Medical Journal*, 1963, July 6, pp.1-2

²⁴ Pappworth MH ‘Human Guinea Pigs: A warning’ *The Twentieth Century*, Autumn 1962. pp.68-71;

Pappworth MH *Human Guinea Pigs: Experimentation on Man*, ([1967] 1969) London, Penguin;

Pappworth MH ‘“Human Guinea pigs” – a history’ *British Medical Journal* 1990, 301:1456-1460;

Booth C. ‘Obituary: Maurice Pappworth’ *British Medical Journal* 1994, 1994;309:1577-1578; Lock, S

‘Obituary: Dr Maurice Pappworth’ *The Independent* November 12, 1994, page 42; Edelson PJ ‘Henry

K. Beecher and Maurice Pappworth: Honor in the development of the ethics of human

experimentation’, in V Roelcke and G Maio (eds.) *Twentieth Century Ethics of Human Subjects*

Research, Stuttgart, Fran Steiner Verlag, 2004, pp. 219-233.

whistleblowing activities.²⁵ 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 his 1967 suggestion that hospitals needed committees to oversee the ethics of research²⁶ attention rather needs to turn to a memo from the US Surgeon General from the previous year to all recipients of grants from the US Public Health Service (PHS). This memo confirmed that in order to remain in receipt (or to get 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".²⁷

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 disorganised nature of the situation led Desmond Laurence, Fellow of the Royal College of Physicians, to approach Max Rosenheim, President of the Royal College of Physicians of London (RCP) (and Professor of Medicine at University College Hospital of which Laurence was a member). Max Rosenheim told Laurence to recruit two senior Fellows of the College distinguished for their research in different areas to

²⁵ Hazelgrove, *op. cit.* (2004), note 2 above, p.191.

²⁶ Pappworth ([1967] 1969) *op.cit* note 24, p.252.

²⁷ 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.

write to him formally at the RCP.²⁸ 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 organisation 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 the interests of society at large with the needs of medical knowledge was “peculiarly suited to consider actively the whole of this important topic.”²⁹

By the end of October, Rosenheim had replied to the three physicians, pointing out that the topic 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.”³⁰ By January, the President had decided to set up a committee of the college to consider this issue³¹, 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.

²⁸ Interview, Desmond Laurence, July 2007.

²⁹ 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 September 1966.

³⁰ RCP, Letter from Max Rosenheim to from F Avery Jones, AC Dornhorst and DR Laurence, 24 October 1966.

³¹ RCP Archive, Letter from Registrar of RCP to FA Jones, 9 January 1967.

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 between different institutions, the Committee refrained from giving detailed guidance on how these bodies should operate.³²

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.³³ Rather, RECs were first mooted in the UK as a response on the part of professional medical researchers to funding requirements from the US PHS. This point is even clearer when one considers the MRC’s response to the RCP report. While Sir Harold Himsworth, Secretary of the MRC, approved of

³² Royal College of Physicians of London (1967) *Report of the Committee on the Supervision of the ethics of Clinical Investigations in Institutions* (London: RCP), page 4.

³³ 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 Dornhurst and Avery Jones in 1966”: Wellcome Trust Archive, 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.

the report – “I can say straightaway that I like it and agree with it”³⁴ – 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 with their own committees.³⁵ 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.³⁶ The 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.³⁷ International ‘echoes’ of the impact of the Surgeon Generals memo can be found in Sweden, where the first ethics committee was started in 1966 at the Karolinska institute, for exactly the same reasons.³⁸

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

³⁴ National Archives, Kew (hereafter NA), FD 9/869, Letter from Harold Himsworth to Max Rosenheim, 22 June 1967.

³⁵ Although the MRC debated the issues raised by the report for its practices and policies: NA, FD 9/869, Memo to Sir Harlod (Himsworth), 20 October 1967.

³⁶ 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 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 September 1970.

³⁷ NA, FD 9/869, Letter from Brandon Lush to JS Weiner, 30 April 1968.

³⁸ Westman-Naeser S ‘Current experiences in the Nordic Countries’ in P Bennett (ed.) *Good clinical practice and ethics in European drug research*, Bath, Bath University Press, 1994, pp. 27-35

following the publication of his book a few months later³⁹) but also that the report 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 considerable concern on the part of the Ministry of Health (MH).

Response to the RCP report

Following the publication of the report and its announcement in the *British Medical Journal*⁴⁰ the Patients’ Association – set up in January 1963 in direct response to Pappworth’s original 1962 allegations⁴¹ – 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). They 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’

³⁹ Pappworth MH ‘Letter: Experiments on Man’ *British Medical Journal* 2 September, 1967, 3(5565): 616.

⁴⁰ Rosenheim M ‘Supervision of the Ethics of Clinical Investigations in Institutions’ *British Medical Journal* 1967 12 August 3(5562): 429-430.

⁴¹ Wellcome Trust Archive PP/MHP/C.1/6. Letter from Helen Hodgson to Maurice Pappworth c. March 1963.

Association, the ultimate responsibility for the ethical conduct of research lay with the hospital, rather than the doctor.⁴²

Initially, the Ministry of Health was supportive of the College's report, for it came at a time when they were under considerable pressure over the issue of human experimentation. Pappworth's 1962 article and 1967 book had caused unease on the part of members of the public, and the Patients' Association 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 1962-1963 Medical Research Council's (MRC) annual report, which addressed issues of research on humans and especially the need for fully informed consent.⁴³ In the letter to consultants that accompanied the report Sir George Godber, the Chief Medical Officer, emphasised a theme that came to underpin the Ministry's position with regard to 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".⁴⁴

⁴² National Archives, Kew (hereafter NA), MH 160/883 Letter from Helen Hodgson to Rt. Hon. Kenneth Robinson, Minister of Health, 18 August 1967.

⁴³ MRC, *op. cit.* note 18.

⁴⁴ NA, MH 160/883, Letter from GE Godber to All consultants in the Hospital Service ref: H/R125/22, 17 July 1967.

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 "Even 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)".⁴⁵

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

⁴⁵ NA, MH 160/883, Memo from MR Edwards to Mr Morris, ref: H.S.1A A517, 25 August 1967.

doctors to do what they thought right for individual patients”,⁴⁶ 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 area 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”.⁴⁷ One obvious solution was for such committees “not [...to...] 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”.⁴⁸

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.⁴⁹ 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

⁴⁶ Klein R *The New Politics of the NHS*, Harlow, Pearson Prentice Hall, 2001, 4th edition, p. 64

⁴⁷ NA, MH 160/883, Memo from DJ Morris to Mr Hales, 31 August 1967.

⁴⁸ NA, MH 160/883, Memo from JC Hales to Mr Morris, 7 September 1967.

⁴⁹ Op. cit. note 32.

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".⁵⁰ 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 mistake⁵¹ or what should happen in the case where hospitals actively funded research, rather than just employ the doctors carrying it out,⁵² 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".⁵³

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

⁵⁰ NA, MH 160/883, Letter from GE Godber to Sir Thomas Holmes Sellers, 8 June 1967.

⁵¹ NA, MH 160/883, Memo from JC Hales to Mr Morris, ref: P.S.O./823/20, 7 September 1967.

⁵² NA, MH 160/883, Memo from DJ Morris to Mr Hales, 8 September 1967.

⁵³ NA, MH 160/883, Memo from DJ Morris to Mr Salter & Dr Cohen, 6 October 1967.

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".⁵⁴ 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"⁵⁵ – 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]...neither the hospital authority nor the group [i.e. REC] is however responsible for the experiment and that the doctor cannot hide behind either".⁵⁶

In the end, there was no need for a public disagreement with the Royal College. The Chief Medical Officer, Sir George Godber, contacted Sir Max Rosenheim, President of the RCP and Chair of the Committee on the Ethical Supervision of Clinical Investigations in Institutions. Sir Max 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

⁵⁴ NA, MH 160/883, Memo from HC Salter to Dr Cohen, 1 November 1967.

⁵⁵ NA, MH 160/883, Memo from RHL Cohen to Mr Salter and CMO, 14 November 1967.

⁵⁶ NA, MH 160/883, Memo from HC Salter to CMO, 17 November 1967.

investigations”.⁵⁷ By the time the Ministry’s circular was being re-drafted, this ‘reinterpretation’ 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 “It is the firm view in the Department that the Committee’s *intention* should be followed rather than their *words*” (emphasis added).⁵⁸

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 the report.⁵⁹ The actual wording of the circular caused considerable debate among officials. Given that the note’s purpose was to recommend the RCP report to consultants and hospital managements, and that the circular was to be distributed with copies of the Report there was obviously the delicate matter of how to point out that the Ministry did not endorse the wording of the Report with regard to the responsibilities of competent authorities. While some officials sought to

⁵⁷ NA, MH 160/883, Memo from GE Godber to Dr Cohen, 27 November 1967.

⁵⁸ 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.

⁵⁹ The origin on the decision to circulate the RCP report itself (rather than a summary, for example) is unclear. Writing 2 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 December 1969.

acknowledge the differences with the RCP report⁶⁰, the Minister of Health at the time, Kenneth Robinson, felt that such an admission went “unnecessarily far in inviting trouble” and suggested its omission.⁶¹ 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 to be made aware of this disagreement.⁶² There were even concerns among some as to whether 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”.⁶³

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 “It is envisaged that the groups would be informal advisory bodies

⁶⁰ NA, MH 160/883, Memo from DJ Morris to Dr McGregor & Dr Evans, 8 March 1968.

⁶¹ 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.

⁶² NA, MH 160/883, Memo from HC Salter to Mrs Hauff, 15 March 1968.

⁶³ NA, MH 160/883, Memo from NJ Evans to Mr Morris, 12 March 1968.

rather than committees of hospital authorities”.⁶⁴ Thus in three short paragraphs the Circular embodies not just the Ministry’s view (in contrast to the letter of the RCP report) that clinical autonomy and liability issues devolve ethical responsibility for the conduct of research to individual doctors, but also that RECs must be distanced from formal association with hospitals.

By the 3rd of 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 consultants⁶⁵ and ten days later thousands of papers were sent out for SAMOs and Teaching hospitals to distribute.⁶⁶ By the 16th of May the Patients Association had responded to the Circular in a way that, for Officials “comes as no surprise”.⁶⁷ 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 emphasised 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”.⁶⁸ For the Association, HM68(33)’s

⁶⁴ Ministry of Health (1968) *Supervision of the Ethics of Clinical Investigations* HM68(33)

⁶⁵ NA, MH 160/883, Letter from GE Godber, CMO to SAMOs, 3 May 1968.

⁶⁶ The printing orders suggest that 11,500 copies of the Circular, 11,200 copies of the CMOs 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.

⁶⁷ NA, MH 160/884, Memo from DJ Morris to Mr Hales & Dr Gregor, 29 May 1968.

⁶⁸ NA, MH 160/884, Letter from U Miller (Hon. Secretary PA) to RS Mathews, 16 May 1968.

pale complexion was an indication of how lightly the Ministry took the issues of human subjects protection. 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 regarding medical research:

“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”.⁶⁹

For the Ministry, the Circular provided a timely 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 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 “For too long so-called scientists have been having a field day”.⁷⁰ 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.⁷¹

Compared to the Patients Association, the response from 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”⁷², to allow

⁶⁹ NA, MH 160/884, Letter from MI Brabant to U Miller, 3 June 1968.

⁷⁰ NA, MH 160/884, Letter from Elizabeth Brooks to Mr Peel 16 May 1968. This letter was forwarded onto the Ministry by John Peel, the author's MP.

⁷¹ NA, MH 160/884, Letter from Julian Snow to John Peel MP, ref: A2788/18, July 1968.

⁷² NA, MH 160/884, Memo 12 from DJ Morris to CMO, 13 August 1968.

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 a 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”.⁷³ 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, “Clinical 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”.⁷⁴

1969-1970: Following Up

Towards the end of 1969, Max 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.⁷⁵ Godber’s reply was supportive – “I’m sure it would be a good idea” – and while the CMO was open to the idea of the Department itself carrying 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

⁷³ NA, MH 160/884, Letter from WJ Tarlton to DHSS, 19 November 1968.

⁷⁴ NA, MH 160/884, Letter from DJ Morris to WJ Tarlton 13 December 1968.

⁷⁵ NA, MH 160/884, Letter from Max Rosenheim to GE Godber, 24 October 1969.

independent” albeit with Departmental help.⁷⁶ Godber’s preference for the RCP to produce this information 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 organisations that thought that some kind of review of the new REC system was needed. In March 1970, the Patients Association wrote to the Department of Health 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”.⁷⁷ In discussing the reply to this letter, officials felt that, by and large, the Association could be referred back to the Ministry’s previous positions but the realisation that the Ministry could not maintain its arms length relationship with RECs (via the RCP) was dawning. 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”.⁷⁸

The reply to the Association simply mentions that the RCP were following up their report and that “When we hear from them the results of their investigations we shall

⁷⁶ NA, MH 160/884, Letter from George Godber to Max Rosenheim, 31 October 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 GE Godber to Dr Yellowlees & Dr Cohen, 31 October 1969.

⁷⁷ NA, MH 160/884, Letter from Helen Hodgson to PR Molineux, 11 March 1970.

⁷⁸ NA, MH 160/884, Memo 47 from DJ Clark to Mr Molineux 21 April 1970.

know the answer to your question on the setting up of committees”.⁷⁹ The PA maintained a tenacious pursuit of these results, sending letters in June, October and November 1970 to find out whether the RCP had reported back⁸⁰, 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.⁸¹ 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.⁸²

This letter 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?”⁸³ leading to a commitment from the RCP to let the Department know when the report might be produced.⁸⁴ 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.⁸⁵ Pressure also came from the Peel Advisory Group which had been set up in 1970 to investigate issues around fetal research, and which was expected “to

⁷⁹ NA, MH 160/884, Letter from PR Molineux to H Hodgson, 23 April 1970.

⁸⁰ NA, MH 160/884, Letter from C Cox to PR Molineux, 25 June 1970; NA, MH 160/884 Letter from General Secretary to PR Molineux 21 October 1970.

⁸¹ NA, MH 160/884, Letter from PR Molineux to C Cox, 3 July 1970.

⁸² NA, MH 160/884, Letter from H Hodgson to PR Molineux, 16 November 1970.

⁸³ NA, MH 160/884, Letter from CM Hallett to Secretary, RCP, 16 November 1970.

⁸⁴ NA, MH 160/884, Letter from GMG Tibbs to CM Hallett, 26 November 1970.

⁸⁵ NA, MH 160/884, Letter from GD Forwell to DJ Morris, 3 February 1971.

place heavy reliance on the ethical committees set up under HM(68)33 as a means of controlling future fetal research”. 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”.⁸⁶

In May 1971, the Royal College of Physicians finally released its report⁸⁷ to the Department, although the College pointed out that the report was “for limited release” and “should not be allowed to get into the hands of the Press”.⁸⁸ Overall, the College and the Department probably had reason to feel satisfied. The 345 questionnaires that went out produced a 58% response rate, split between an 86% response from teaching hospitals and a 55% 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 one and the other in reforming one 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 some comfort to the Department, some of the detail in the survey was perhaps more worrying. As the summary put it: “certain 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

⁸⁶ NA, MH 160/884, Memo 67 from V Poole to Dr J Wilson, 20 April 1971.

⁸⁷ 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.

⁸⁸ NA, MH 160/884, Letter from GMG Tibbs to CM Hallett, 20 May 1971.

ethical supervision and the other of which does not, and that it is transparently easy to tell the one from the other”.⁸⁹ This is clear from the survey which suggests that in only 74% of replying hospitals with RECs in place, were all clinical investigations referred to the ethics committee. Even more worrying, in two hospitals, clinical drugs trials were given as an example of the kind of studies which did **not** require committee approval.

Perhaps most interestingly in terms of the long term effects of the RCP survey, although it is not flagged up in the summary, 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 six 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.⁹⁰ While the actual response to this question might seem mild, the intriguing fact is that it is here at all. The 1967 RCP report made clear that ethics committees should be made up of medics alone, and, as we shall see, the inclusion of this question and these results puzzled the Department of Health when it came to its own deliberations about the results of this survey.

1971: after the survey

⁸⁹ RCP, op.cit. note 87, p.2

⁹⁰ Ibid. p.5

In the meantime, the Patient's 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 the 24th of May 1971, the Association sent out letters to a number of 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".⁹¹ As a result, a number of 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.⁹² One solution was to ask the RCP for permission to release the survey⁹³ 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".⁹⁴ 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".⁹⁵

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 Sir George Godber, the Chief Medical Officer. In a letter to Max Rosenheim of the RCP, Godber suggested that "it seems highly likely that a copy of it [the survey] or an extract from it will

⁹¹ NA, MH 160/884, Letter from U Miller, no addressee, 24 May 1971.

⁹² NA, MH 160/884, Memo 1 from GRA Gill to Mr Smith, 11 June 1971.

⁹³ NA, MH 160/884, Memo 2 from Mr Smith to Dr Archibald, 30 June 1971.

⁹⁴ NA, MH 160/884, Memo 6 from Dr McGregor to Dr Archibald, 20 July 1971.

⁹⁵ NA, MH 160/884, Memo 9 from Mr Yates to Miss Wavish, 13 August 1971.

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.⁹⁶ Rosenheim clearly agreed with this approach: later correspondence between the RCP and 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”.⁹⁷

In the middle of this debate, the issue of the range and number of RECs in the country became public, when, on the 27th of July, Joyce Butler MP asked the Secretary of State “how many hospital authorities have now established and ethical committee...and how many committees include lay members”?⁹⁸ 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 sometime in the previous ten days) and the constraints on what the PA could say about this confidential document, getting a sympathetic MP to ask about the results of the survey (without mentioning it in name) is a useful way of bringing the results into 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

⁹⁶ NA, MH 160/884, Letter from GE Godber to Max Rosenheim, 1 June 1971.

⁹⁷ NA, MH 160/884, Letter from GMC Tibbs to HSU Hodgson, 14 July 1971.

⁹⁸ Parliamentary Question (PQ) from Joyce Butler *Hansard* Vol 822 Col. 59, 27 July 1971.

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 of more RECs being in place than was the case.⁹⁹ The Department accepted its error – apparently the result of a last minute edit of the written reply¹⁰⁰, and while it wrote to Mrs. Butler to apologise and correct the information¹⁰¹, felt that the Association’s reaction had been overblown.¹⁰² 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% of non-teaching hospitals having ethics committees (when, of course, 55% refers 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?”¹⁰³

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 the 13th of 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. MacCrae 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.

⁹⁹ NA, MH 160/884, Letter from Helen Hodgson to Sir Keith Joseph, 16 August 1971.

¹⁰⁰ NA, MH 160/884 Memo from Smith to Brandis, 13 September 1971.

¹⁰¹ NA, MH 160/884 Letter from Michael Allison to Joyce Butler MP, 30 September 1971.

¹⁰² NA, MH 160/884 Memo from LH Brandis to Mr Qades, 15 September 1971.

¹⁰³ NA, MH 160/884 Letter from H Hodgson to Sir Keith Joseph, 14 October 1971.

MacCrae (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.¹⁰⁴

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 MacCrae, unless details could be provided about specific cases, the Secretary of State had to accept the denials of the hospitals accused.¹⁰⁵ Yet at the same time, there was an acceptance among officials that they had to know what was actually going on in terms of implementing the 1968 Circular, and that because of the limited response to the RCP survey, this data was still lacking:

"we 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."

¹⁰⁴ Staff Reporter (1971) 'London Hospitals reject new allegations of unjustified experiments on patients' *The Times* Wednesday 13 October, Issue 58297, page 2.

¹⁰⁵ NA, MH 160/884 Meeting of Secretaries of London Boards of Governors on 21 October 1971, Brief for Chairman (Mr. J.S. Orme).

Thus there was a pressing need to contact Regional Health Boards to compile lists of HMCs that had set up committees, when they had been set up and their composition, as well as clarifying with those that had not yet set any committees up, whether there was intention to do so.¹⁰⁶ This position was supported within the Department – “we’ll never exercise this spectre until we get a reply from all hospital authorities”¹⁰⁷ – although the need to seek permission from Max Rosenheim to repeat the RCP’s work was pointed out, and duly received.¹⁰⁸

At the same time, in late 1971, Parliament responded to the latest allegations about medical research with an adjournment debate on the 3rd of 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 asked a number of PQs on this topic in the past, and who had corresponded with the Department previously. The central themes of Molloy’s impassioned speech were both that abuses of National Health Service 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.¹⁰⁹ In response, Michael Alison, the Under-

¹⁰⁶ NA, MH 160/884 Memo 2 from Smith to Miss Wavish & Mr Brandis, 22 October 1971.

¹⁰⁷ NA, MH 160/884 Memo 3 from unknown to Dr Cohen, n.d (23 or 24 October 1971).

¹⁰⁸ NA, MH 160/884 Memo 5 from unclear to Mr Brandis, 26 October 1971.

¹⁰⁹ William Molloy, Adjournment debate, 3 November 1971, Hansard Vol 825, No. 2, col. 320-323.

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”.¹¹⁰

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 carrying out exactly the same kind of work. The resulting enquiries, labelled ‘DS 308/71’ started on the 10th of 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 the Department 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

¹¹⁰ Michael Alison, Adjournment debate, 3 November 1971, Hansard Vol 825, No. 2, col. 324-328.

just under 70% (69.8%) of HMCs [i.e. non-teaching] have complete cover; on the most favourable reading the percentage is 75.4%”.¹¹¹

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”.¹¹²

So where did this interest in lay members come from? Speculation on the part of DHSS officials focused on the 1967 report and its suggestion – later rejected by Max Rosenheim of course – that hospital authorities (made up of lay members) should take ultimate responsibility for the ethics of clinical investigations:

¹¹¹ NA, MH 160/185 Memo 3 from WE Wavish to Mr Smith, 21 December 1971.

¹¹² Ibid.

“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”.¹¹³

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”.¹¹⁴ 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 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”.¹¹⁵

This apparent *volte face* on the part of 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 in turn the lay membership of such committees would undermine the official position that such research was too complex for lay people – meaning

¹¹³ Ibid.

¹¹⁴ RCP, op. cit. note 87, p.1

¹¹⁵ NA, MH 160/185 Memo 14 from ER Hammer to Mr Gidden, 3 March 1972.

members of hospital authorities – to understand. In turn this would put pressure on the argument that such authorities could not take responsibility for research, and in turn 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 January 28th 1972, Michael Alison issued his written answer to a question from William Molloy, noting that “all teaching hospital authorities and over 70 percent of other hospital authorities” had RECs in place, of which, around a fifth included a lay member.¹¹⁶ This expansion, not just in academic centres such as teaching hospitals, but also in over 2/3 of other hospitals emphasises the status of RECs as NHS bodies. While their origins might lie in the needs of academic researchers, RECs swiftly became incorporated into broader the 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. Through the use of the Royal College of Physicians as a form of proxy, officials ensured the spread of such committees, which proved a useful 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 limits: the

¹¹⁶ Michael Alison, written answer, 28th January 1972, Hansard Vol. 829 column 550.

College's lack of formal powers (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 finalised.

The main contribution of this article is to emphasise the importance of the role of the Ministry of health in the early development of research ethics committees in the UK. Previous work has tended to overlook the role of the Ministry and, consequently, highlight the role of RECs as a form of – usually inadequate – self regulation.¹¹⁷ It is not that RECs were *not* a form of self-regulation, but rather that this informal status was not the result of *laissez-faire* 'drift' on the part of policy makers but rather a deliberate, *active* decision to dissociate these committees from NHS bodies and thus help preserve the idea of clinical autonomy.

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¹¹⁷ Hazelgrove (2002) / (2004) op. cit. note 2.

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