Clinical Medicine 2011, Vol 11, No 1: 44–7

Paper use in research ethics applications and study conduct

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ABSTRACT – Application for Research Ethics Committee (REC) approval and the conduct of medical research is paper intensive. This retrospective study examined all applications to a single REC in the south of England over one year. It estimated the mass of paper used, comparing the proportional paper consumption of different trial types and during different stages of the research process, quantifying the consumption in terms of carbon dioxide emissions. In 2009, 68 trials were submitted to the REC. Total paper consumption for the REC process and study conduct was 176,150 sheets of A4 paper (879 kg), equivalent to an estimated 11.5 million sheets (88 tonnes, 2,100 trees) a year for the UK; the REC process accounted for 26.4%. REC applications and the conduct of approved trials generate considerable environmental impact through paper consumption contributing to the NHS's carbon footprint. Paper use might be reduced through the implementation of digital technologies and revised research methods, namely changing attitudes in both researchers and ethics committees.

KEY WORDS: climate change, environment, medical research, paper consumption, research ethics

Introduction

Climate change is a significant challenge to public health in the 21st century,[1,2] prompting research aimed at health protection from global warming.[3,4] An estimated 1–2% of global carbon emissions originate from paper production and paper consumption is expected to increase by 5% annually until 2015.[5] In the UK, the NHS produces approximately 21 million tonnes of carbon dioxide (CO_2) per year and medical research contributes to this.[6] Furthermore, 3.9 tonnes of CO_2 is produced in the manufacture of one tonne of office paper.[7] Previous studies assessing the environmental impact of medical research[8,9] have focused on fuel use; a single multicentre international trial is estimated to be responsible for annual emissions the equivalent of 126 tonnes of CO_2.[8] However, while reducing paper consumption makes a simple contribution towards achieving EU carbon emission targets, no studies have directly addressed this issue.[7,10,11]

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Application for Research Ethics Committee (REC) approval is an essential component of good clinical practice during medical research. The process appears to be paper intensive and, as such, the environmental burden may be large: in 2007/8, 7,257 REC applications were made to more than 100 RECs in the UK.[12,13] The aim of this study was to quantify the mass of paper used during all applications to a single REC over a period of one year. The mass of paper necessary to conduct approved studies was also calculated and paper usage between different types of research study compared.

Methods

The head of operations for England at the National Research Ethics Service (NRES) gained permission from the strategic health authority for the authors to view relevant REC applications on NHS property. Confidentiality agreements were signed. Ethical approval was not required.

Study design

A retrospective study was conducted and all data gathered by a single researcher (AC) in January 2010 at Brighton East REC (Brighton and Hove NHS, Brighton, East Sussex). The REC administrator provided details of all studies reviewed between 1 January to 31 December 2009, and numbers of REC members present for each meeting. Each study application had a unique identifying number, which was used to locate and examine hard copies of individual studies in date order. For each study, the researchers recorded the type of study and proposed sample size, and the number of sheets of A4 paper distributed to committee members and used during requested amendments or resubmissions. The types of documentation counted included research protocols, sponsors' letters, participant information sheets, consent forms, and the Integrated Research Application System (IRAS) form.

Paper use during the REC process

For each REC meeting, all members received a copy of all documents, except for clinical trials of investigational medicinal products (CTIMPs) as only the submitted documents are used. It was assumed that only attending members received copies of documents. For non-CTIMP applications, all submitted paper is sent to a printer for duplex printing on 80 gsm (grams per meter squared) A4 (210 mm × 290 mm) paper. To calculate the paper consumption for each study, the number of sheets of A4 paper submitted initially to the REC was counted, multiplied by the number of REC members attending that month's meeting, and divided by two (duplex printing).

After consideration by the REC, the following outcomes are possible: further information required, favourable opinion (FIFO), favourable opinion with conditions (FOC), provisional opinion (PO), favourable opinion (FO), unfavourable opinion (UFO) and withdrawn after REC meeting. For studies receiving FIFO, FOC and PO, documents sent after the meeting to gain a FO had their pages counted – these are not copied. Those studies receiving FO and UFO did not submit additional information.

Paper use during study conduct

For studies that received a FO, the researchers calculated the paper use for study conduct. From the submitted documents, the A4 paper use for invitation letters, participant information sheets, consent forms (three copies per patient), letters to general practitioners, interview schedules, questionnaires, data collection forms, case report forms, and additional letters were calculated and multiplied by the proposed study size to estimate the minimum paper use for study conduct. If double-sided participant information sheets, folding leaflets, consent forms, letters or data collection forms were submitted, it was assumed that this format would be distributed and the page count adjusted accordingly. Small CTIMPs with no investigator's brochure and short protocols (defined as less than 30 pages of A4 by the REC administrator) were treated as non-CTIMPs for the purpose of paper use calculations.

Sheets of paper were hand-counted, and data transferred directly to a spreadsheet for analysis. Calculation accuracy was verified by SE and SW. The cost of A4 paper was determined from the purchasing department of Brighton and Sussex University Hospitals (BSUH) NHS Trust. The number of trees required to manufacture paper was estimated from online resources.[14,15] Only three sheets of A4 paper were used in the design and conduct of this study.

Results

In 2009, 68 studies were reviewed by Brighton East REC in 11 meetings. The modal number of committee members attending was eight (range 8–12). Table 1 shows the type of research, expected sample sizes, the number of sheets and mass of A4 paper used.

Applications to, and subsequent conduct of studies approved by, Brighton East REC in 2009 were estimated to use 176,150 sheets of A4 paper; this paper consumption equates to 352.3 reams (one ream equal to 500 sheets of paper) and 879 kg of paper. Of the total estimated paper consumption, 26.4% (232 kg) was consumed during the ethics application process and the remaining 73.6% (647 kg) was during the subsequent conduct of approved studies. Paper copying by the REC consumed 32,789 sheets (18.6% of total). Questionnaire studies accounted for the greatest proportion of paper use (45.6% of total usage), followed by 'other clinical' trial types (29.7%) and CTIMPs (11.8%).

The REC submission process (not counting copying by the REC) consumed 13,741 sheets of A4 (29.5% of the total REC process paper use), and the 12 CTIMPs applications accounted for the highest proportion of this paper use at 6,678 sheets (48.6%).

Table 1. Calculations of paper usage at Brighton East Research Ethics Committee (REC) in 2009. The type of research, expected sample size, sheets of A4 paper used and mass of paper used in studies reviewed by Brighton East REC in 2009. Mass of 1 sheet of 80-gsm A4 paper = 4.9896 g.

Trial type	Number of study applications (studies approved)	Initial REC submission. Number of A4 paper sheets (mean; range)	Total sample size of approved studies	REC process*. Number of A4 paper sheets (mass, kg)	Study conduct. Number of A4 paper sheets (mass, kg)	Total A4 paper sheets used (mass, kg)
CTIMP	12 (9)	6,678 (557; 77–1,591)	635	9,661 (48.2)	11,207 (55.9)	20,868 (104.1)
Device trial	4 (3)	427 (107; 82–142)	156	2,687 (13.4)	1,464 (7.3)	4,151 (20.7)
Other clinical	16 (14)	2,280 (143; 34–313)	9,421	12,339 (61.6)	39,986 (199.5)	52,325 (261.1)
Questionnaire	16 (14)	2,229 (140; 44–287)	8,363	11,097 (55.4)	69,240 (345.5)	80,337 (400.9)
Qualitative only	7 (6)	1,000 (143; 65–208)	80	5,034 (25.1)	692 (3.5)	5,726 (28.6)
Database and human tissue	8 (6)	736 (92; 53–141)	772	3,445 (17.2)	5,124 (25.6)	8,569 (42.8)
Other	5 (3)	391 (79; 59–109)	193	2,267 (11.3)	1,907 (9.5)	4,174 (20.8)
Total	68 (55)	13,741 (203; 34–1591)	19620	46,530 (232.2)	129,620 (646.8)	176,150 (879.0)

*Process includes initial submission, REC paper copying and any further information provided. CTIMP = clinical trial of investigational medicinal products

Discussion

This analysis estimates that in one year applications to a single REC and subsequent conduct of approved trials consumed 879 kg of paper. This mass equates to more than 352 reams of paper – derived from 21.1 trees (average height, 12 metres and diameter, 15–20 cm)[14,15] – and 3.4 tonnes of CO_2 emitted during paper manufacture (excluding transport costs). To put this paper usage into perspective, this mass is equivalent to a line of A4 paper 37 kilometres long or a pile of paper more than 18 metres high (taller than a six-storey building or four London Routemaster buses).

Assuming that Brighton East REC is representative of other RECs in the UK, then nationally, it is estimated that successful applications to local RECs consume more than 11.5 million sheets (88 tonnes, 2,100 trees-worth) of paper in a year. The other, less-direct consequences of paper use, such as deforestation and water use, should also be considered as these augment the environmental effects of CO_2 production. For instance, the manufacture of 88 tonnes of paper is estimated to use greater than eight million litres of water,[16] enough to fill more than three Olympic-sized swimming pools.

Although paper is surprisingly cheap – 176,150 sheets of paper cost only £658 (approximately £65,800 nationally) – the cost of printing and photocopying is an additional expense for RECs and applicants (1.18 p per side, inclusive of toner, machine rental and maintenance (personal communication from the procurement department, BSUH NHS Trust, Brighton, East Sussex)), equivalent to £2,078 annually (£208,000 nationally) and has further environmental impact locally and nationally. Although paper is relatively cheap to purchase, vast quantities are consumed, and in the NHS (a large paper consumer) procurement of paper products accounts for greater than 5% of its total CO_2 emissions.[2]

The '6 R approach' suggested by Hutchins and White[11] provides a useful model for the development of environmental ideas and this format has been adopted in Box 1 to discuss a number of strategies for decreasing paper usage.

The authors accept that there are sources of error in this study. For example, paper used during follow-up correspondence between the REC and researchers (typically eight sheets of A4 per study), for amendment submissions, paper consumption in multicentre trials conducted outside the UK, minutes taken at REC meetings, or site specific application forms were not included. Nor were other paper uses in research, such as the printing out of reference articles, considered. Studies were assumed to have been completed once REC approval was granted, although this may not have transpired. This study was limited to a retrospective analysis and all of the errors this type of research encounters. The alternative of a prospective study would have been complex and resource intensive with very little direct control over data collection.

Energy costs incurred in procurement, postal distribution of documents, travel of committee members and researchers to and from REC meetings and NRES conferences can also have an impact on the environment. Under these circumstances, the possibilities of e-interactions involving e-paper, teleconferencing, and internet-based virtual meetings, are an important consideration; although the option of a physical meeting between the researchers and committee remains essential to the application process.

Box 1. Strategies to reduce paper consumption.

Responsibility, research, and rethinking

- As a public body, the National Research Ethics Service (NRES) has an extended duty to protect patients by minimising the environmental impact of its function.
- A 'paper trail' is an essential aspect of research governance, but, NRES is ideally placed to lead research and development of non-paper methods for Research Ethics Committee (REC) application and research conduct.
- The environmental impact of studies could be factored into the REC application.
- Individual sponsors, funding bodies and researchers must evaluate their personal, academic and clinical approach to paper use.

Reduce

- Complete cessation of paper use is unlikely and currently unrealistic but, where possible, electronic formats should be considered.[17] Photocopying by the REC accounted for 32,789 sheets of A4 paper in this study.
- REC applications currently involve completion of an online Intergrated Research Approval System (IRAS) form, which could be made available to REC committee members instead of paper copies and supplemental documentation could be viewed as a PDF.
- Internet-based 'online' questionnaire studies should be promoted as an alternative to paper questionnaires.
- REC meetings could be conducted using a single computer projection of all documents.
- Redesign of the IRAS form could minimise unused white space when printing.
- Double-sided printing on lower quality (eg 70 gsm) or recycled paper using smaller font size and margins should be encouraged.
- Documentation copies required by the REC could be reduced. Only one copy of a research protocol is required for non-drug trials and is currently advised on an *ad hoc* basis, but should be formalised by NRES on the IRAS checklist. The current checklist dictates that all documents be submitted single-sided and include six copies of the protocol and, in the case of clinical trials of investigational medicinal products, an additional three copies of the investigator's brochure.
- Researchers could avoid paper data collection through direct electronic transcription.

Reuse

- Novel technologies such as'unprinting' might make reuse of paper a viable concept in the future.[18]
- Distribution of REC submissions on rewritable CD or DVD-ROMs is an alternative to e-access but does require all committee members to have the necessary technology to view these.

Recycling

- All waste paper is potentially recyclable.[11]
- After three years, all paper submitted to RECs is destroyed.
- Recycling has an energy cost and financial incentives are limited, but this process avoids the environmental consequences of incineration and landfill.

Similarly, medical trials incur other environmental expenses with travel in various forms (eg staff commuting, participant travel, trial team travel) accounting for large CO_2 production.[8,9] The bureaucracy associated with ethics applications has been discussed previously[19] but individual researchers should take the responsibility to simplify trial design, data collection, and 'conduct systematic reviews of available research evidence in an effort to make best use of existing evidence to answer research questions'.[8]

The use of digital technologies is not without its own environmental impact as all stakeholders would require the means to access them. A discussion of the impact of computer manufacture on the environment is beyond the scope of this paper but online activity has a quantifiable CO_2 production, where 'it takes on average about 20 milligrams of CO_2 per second to visit a web site',[20] and an internet search produces 'about 0.2 grams of CO_2';[21] in December 2009, there were 'more than 131 billion [internet] searches' worldwide.[22]

Conclusion

This study has shown that both the REC application process and the conduct of approved research generate a considerable environmental impact in terms of paper usage. Allied to the energy cost of paper procurement and distribution, and travel to and from committee meetings, there seems to be considerable scope for reducing the environmental impact of ethics committees and research conduct through the extended use of existing digital technologies, new industrial techniques, and 'rethinking' on the part of both individual researchers and their sponsoring institutions or funding bodies. An entirely paper-free system is not practical and unlikely but paper reduction strategies are essential. A revised system of research ethics application where the environmental impact of proposed medical trials is considered by applicants and committees prior to approval is recommended.

Acknowledgements

The authors would like to thank the Brighton East Research Ethics Committee, in particular Mrs Nischinth Cherodian for facilitating the data collection process, and Joan Kirkbride, head of operations, England, NRES and team for seeking and gaining strategic health authority permission for this analysis. The authors would also like to thank Dr Katrina Ray and Professor Hugh Montgomery for their advice and assistance.

Competing interests

SE and SMW are voluntary members of the Brighton East Research Ethics Committee. SMW is the 'Anaesthesia and the environment' website coordinator for the Association of Anaesthetists of Great Britain and Ireland. AC has no competing interests. No author has any financial competing interests.

Ethical approval

This study was deemed to not require ethical approval by the National Research Ethics Service (NRES). NRES gained permission from the strategic health authority for the authors to view relevant REC applications on NHS property.

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