National Patient Safety Agency

National Research Ethics Service

Research Ethics Committees in the News

Issue 64, February 2010

Purpose of publication: To alert everyone in the National Research Ethics Service (NRES) to articles and news items that may be of interest and provide useful background information.

Disclaimer: All entries are to inform readers of the different views and opinions in published in media as part of their ongoing training and development. Inclusion does not signify recommendation, or endorsement by NRES or the National Patient Safety Agency (NPSA).

General information: This publication can be accessed on the NRES website. http://www.nres.npsa.nhs.uk/news-and-publications/publications/recs-in-the-news/ NHS Research Ethics Committee (REC) members can obtain free access to many journals electronically via a NHS Athens Account; REC coordinators have details for setting up a NHS Athens account. REC coordinators can also download articles so that lay members do not incur printing costs, or for members without internet access. NRES NPSA does not have the copyright or the resources to supply full text articles. Please contact your local healthcare library http://www.hlisd.org/ for articles which can not be downloaded without a charge.

Further information: There is also a keyword-searchable resource of hundreds of articles relating to research ethics, the Ethics Research Information Catalogue (ERIC). ERIC was created and is managed by NRES Ethics Advisor, Dr Hugh Davies.

Sandra Tapping
NRES Policy and Information Specialist

TRIAL REGISTRATION AND TRANSPARENCY

(TR & R 1) **Should protocols for observational research be registered?**
The Lancet, 30 January 2010:375, 348

Reflecting on a recent meeting to discuss whether observational trials should be registered, an editorial considers the benefits and drawbacks of this practice, including whether registration lends greater credibility to research findings.
http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(10)60148-1/fulltext

(TR & R 2a) **Preparing raw clinical data for publication: guidance for journal editors, authors, and peer reviewers**
Iain Hrynaszkiewicz, Melissa L Norton, Andrew J Vickers, and Douglas G Altman
BMJ, 28 Jan 2010:340; 181

Practical guidance for those involved in the publication process, by proposing a minimum standard for de-identifying datasets for the purposes of publication in a peer-reviewed biomedical journal, or sharing with other researchers.
http://www.bmj.com/cgi/content/full/340/jan28_1/c181?papetoc

(TR & R 2b) **Preparing raw clinical data for publication: guidance for journal editors, authors, and peer reviewers**
Iain Hrynaszkiewicz, Melissa L Norton, Andrew J Vickers, and Douglas G Altman,
Trials 29 Jan 2010: 11

Same paper as the *Trials* paper above to ensure wide and free access to the guidance.
http://www.trialsjournal.com/content/11/1/9

(TR & R 2c) ***BMJ* policy on data sharing**
Trish Groves, *BMJ 28 Jan 2010; 340 c564*

An editorial on the Hrynaszkiewicz *et al* guidelines.
http://www.bmj.com/cgi/content/extract/340/jan28_4/c564

(TR & R 3) **Ensuring integrity in science**
Ralph J. Cicerone, *Science,* 5 February 2010: 327; 5966, 624

An editorial calls on the scientific community to take firm action to restore public trust in the conduct of science by ensuring that the data underpinning published research is made available for scrutiny.
http://www.sciencemag.org/cgi/content/summary/327/5966/624

(TR & R 4) **The truth about Tamiflu? Data access is matter of trust**
Alan R Maryon-Davis**,** *BMJ,* 13 January 2010;340:c134

In a letter the UK Faculty of Public Health strongly supports the *BMJ*'s call for mandatory disclosure of raw data of all trials cited in drug licensing applications and marketing claims. Full disclosure and openness to scrutiny of evidence on efficacy and safety are crucial if the pharmaceutical industry is to maintain the full trust and confidence of patients, practitioners, policy makers, and the wider public.
http://www.bmj.com/cgi/content/full/340/jan13_3/c134

REGULATIONS AND GUIDANCE

(R & G 1a) **Commission's review of the Clinical Trials Directive**
MHRA website January 2010

The Medicine and Healthcare Regulatory Agency (MHRA) asked for comments so that they could respond to the Commission's review of the Clinical Trials Directive.

These views have now been incorporated into an overall response for the UK. Many parts are relevant to RECs (e.g. whether there should be European Commission-wide assessment of clinical trials; reporting of Suspected Unexpected Serious Adverse Reactions (SUSARS).

MHRA draw attention to the Integrated Research Application System (IRAS) developing in the UK which provides for a "one stop shop" within the UK which MHRA believe will deliver significant benefits for sponsors of all research to be conducted in the UK, but which, for reasons explained in the document, would not be appropriate for implementation across Member States.

MHRA expect that the Commission will now consider the responses that it has received before putting forward any proposals for change, the process for which is likely to begin in spring 2010. http://www.mhra.gov.uk/Howweregulate/Medicines/

(R & G 1b) **UK response to EC review of the Clinical Trials Directive**
CRAdvisor, 8 February 2010:256; 2-3

A summary of the responses of UK stakeholders to a European Commission (EC) consultation on the functioning of the EU Clinical Trials Directive.
http://www.canarybooks.com/

(R & G 2) **Council of Europe Steering Group on Bioethics consultation**
Council of Europe Steering Group on Bioethics, Dec 2009

The Council of Europe Steering Group on Bioethics (CDBI) has produced a draft Guide for Research Ethics Committee Members. This document is intended to be used as a tool for research ethics committee members. The Guide does not provide new principles but highlights the ethical basis for the principles laid down in the European instruments covering biomedical research and indicates operational procedures to facilitate their implementation.

NRES invite all REC members and NRES staff to comment on the proposal and send comments to Christine Holmes, Research and Development at the Department of Health (via email: Christine.Holmes@dh.gsi.gov.uk) by Friday 19 March 2010.
http://www.coe.int/t/dg3/healthbioethic/

(R & G 3) **MHRA pharmaceutical industry advice**
MHRA website, Feb 2010

The Medicine and Healthcare Regulatory Agency (MHRA) has updated the pharmaceutical pages of their website.
http://www.mhra.gov.uk/Pharmaceuticalindustry/Clinicaltrials/index.htm

IRAS

(IRAS 1) **Embedding Research in the NHS Culture**
David Cox, *Advances in Clinical Neuroscience & Rehabilitation,* 01 Jan 2010, 29- 31,

A description of the work of the National Institute for Health Research (NIHR) including reference to its part in the inception of the Integrated Research Application System (IRAS) - a one-stop portal for providing information needed to secure ethical and other approvals for research.
http://www.acnr.co.uk/

PHASE 1

(Phase 1, 1) **Paying the Phase I Volunteer**
Stephen Humphreys*, Applied Clinical Trials*, Feb 2010

A question that arises in Phase I research among healthy volunteers is how much to pay the participants. The sum must be sufficient to attract and fairly reward them, but not such as to unduly induce participation. The author (a lay member of non-NHS Phase 1 REC) puts forward a suggestion for a lottery type payment model, which by both deferring and subjecting part of the reward to further contingent events attempts to mitigate undue inducement.

There is reference to the TGN1412 trial and the subsequent increase in the numbers expressing an interest in joining clinical trials—the sums on offer as had been revealed were just too attractive
http://appliedclinicaltrialsonline.findpharma.com

RESEARCH IN CHILDREN

(Child 1) **Pediatric Trials: A Worldwide View**
Philippa Smit-Marshall, *Applied Clinical Trials,* January 2010

Paediatric research is increasing in volume and has become a global phenomenon. The author writes of special challenges of clinical studies in children.
http://appliedclinicaltrialsonline.findpharma.com/

(Child 2) **How to Improve Children's Research**
Adam Svobodník, Amparo Alemany, Antoine Cournot, Jürgen Schäfer, Martine Dehlinger-Kremer, Marta Mas, Michel Levy and Philippa Smit-Marshall, *Applied Clinical Trials,* February 2010

A report of a European survey which indicates that there is a real need for better understanding of the design of paediatric clinical trials and the selection of appropriate and validated endpoints for paediatric use.
http://appliedclinicaltrialsonline.findpharma.com/

(Child 3) **Assessment of parental decision-making in neonatal cardiac research: a pilot study**
Aruna T Nathan, K Sarah Hoehn, Richard F Ittenbach, J William Gaynor, Susan Nicolson, Gil Wernovsky, Robert M Nelson, *J Med Ethics,* Feb 2010;36:106-110

The report of a pilot study to assess parental permission for a neonate's research participation using the MacArthur competence assessment tool for clinical research (MacCAT-CR), specifically testing the components of understanding, appreciation, reasoning and choice.
http://jme.bmj.com/content/36/2/106.abstract?etoc

HUMAN TISSUE

Human Tissue Authority statement on respectful interment of retained organs, foetuses and tissue samples
HTA website, 18 Jan 2010

The HTA code of practice on Disposal of Human Tissue is available from the HTA website
http://www.hta.gov.uk/media/mediareleases.cfm/

DATA PROTECTION

(DP 1) **Debating point: can a trial subject stop the processing of their personal data?**
CRAdvisor, 8 February 2010:256;6-8

A debate on the enforcement of the Data Protection Act and what happens when a subject wants to stop their trial data being processed.
http://www.canarybooks.com/

MISCELLANEOUS

(Misc 1) **A very public break-up**
Jonathan Gornall, *BMJ*, 340 23 January 2010; 340,180-183

A feature article examines the clinical trial conducted by the medical device company NMT Medical on the use of its STARFlex Technology for the treatment of migraine, which has led to a high-profile court case. The trial's principal investigator, Peter Wilmshurst, has accused the company of research misconduct while NMT has in turn lodged a libel complaint against Wilmshurst in the English High Court.
http://www.bmj.com/cgi/content/extract/340/jan18_1/c110

(Misc 2) **Questionnaires in clinical trials: guidelines for optimal design and administration**
Phil Edwards, *Trials* 11 January 2010, 11:2

Evidence-based developments in questionnaire design may help investigators minimize bias, improve data completeness and maximize precision in estimating

treatment effects when gathering outcome data from patients enrolled in clinical trials.
http://www.trialsjournal.com/content/11/1/2/

(Misc 3) **A lean mean research machine**
The Lancet, 16 January 2010: 375, 171

An editorial highlights a pre-election manifesto published by the UK Academy of Medical Sciences, which identifies a number of areas for Government action to ensure the UK can 'reap the rewards' of medical research. With the US National Institutes of Health also identifying major areas of scientific opportunity, the author suggests the challenge is to persuade politicians to invest for the long-term despite the current economic climate.
http://www.thelancet.com/

(Misc 4) **Do the right thing - unite**
Ron Iphofen*, Times Higher Education Supplement, 14 Jan 2010, p27,*

The author, who currently convenes the Social Research Association's forum on research ethics, writes that social science bodies must stop professional protectionism and draft a common research ethics code. He also writes that "there has been much progress in ethics review. The Department of Health's National Research Ethics Service now has an efficient system supporting quality research."
http://www.timeshighereducation.co.uk/

(Misc 5) **Death survey 'is insensitive' - Bereaved relatives to be quizzed on care**
Jamie Welham, *West End Extra,* 15 Jan 2010, p4,

An NHS survey by Kings College, London that will be sent to bereaved relatives who have died of a terminal illness has been criticised as "insensitive" by Cruse Bereavement Care. The journalist writes that 'the scheme was piloted last year and has been approved by the NHS ethics watchdog, the Research Ethics Committee'.
http://www.westendextra.com/news/2010/jan/

(Misc 6) **Research in the practice setting**
Martin King, *Practice Nurse,* 15 Jan 2010:39; 1,35-37

A beginner's guide to Good Clinical Practice in commercially-funded research, its regulation and ethics. However, out of date reference to LRECs doing the site-specific assessment.
http://www.practicenurse.net/

(Misc 7) **UK bolsters translational research effort with Capability Clusters**
Peter Mansell, *Pharmatimes*, 27 January 2010

The publication of the *Life Sciences 2010: Delivering the Blueprint* (January 2010) report, by the Office for Life Sciences (OLS), demonstrates tangible results and outlines a roadmap for the continued success of the life sciences industry in the

United Kingdom. This initiative, underpinned by a unique collaboration across government, the NHS, academia and the industry, has injected a fresh sense of urgency to the key challenge of securing a flourishing life sciences industry in the UK. Chapter 2 includes references to R&D offices and the development of Research Support Services in England.

Plans include for a network of Therapeutic Capability Clusters serving as “one-stop shops” for cutting-edge research mark a concrete step towards the formation of a UK Life Sciences Super Cluster aimed at establishing a world-leading presence in translational research. The clinical research infrastructure for the Capability Clusters will come mainly from the £160 million per year of support provided by the National Institute for Health Research (NIHR).
http://www.pharmatimes.com/clinicalnews/article.aspx?id=17291&src=EUKNews

Life Sciences 2010

(Misc 8a) **Wakefield was dishonest and irresponsible over MMR research, says GMC**
Clare Dyer, BMJ 29 Jan 2010 *BMJ* 2010;340:c593

The UK regulator held that Dr Wakefield abused his position, subjected children to intrusive procedures such as lumbar puncture and colonoscopy that were not clinically indicated, carried out research which flouted the conditions of ethics committee approval and brought the medical profession into disrepute.
http://www.bmj.com/cgi/content/extract/340/jan29_1/c593?papetoc

(Misc 8b) **Fall of Andrew Wakefield, ‘dishonest’ doctor who started MMR scare**
David Rose, *The Times*, 29 January 2010, and Brian Deer, *Sunday Times,* 31 Jan 2010, p18, plus most other newspapers

The result of the longest GMC medical misconduct inquiry ever held. The three men had been charged with offences relating to research they had conducted during the 1990s at the Royal Free hospital in Hampstead, north London, concerning the measles, mumps and rubella (MMR) vaccine and supposed links to autism in children.

The GMC ruled that Wakefield, who was a gastroenterologist at the time, did not have the ethical approval or qualifications to oversee the study, which involved children undergoing colonoscopies, lumbar punctures, barium meals and brain scans.
http://www.timesonline.co.uk/tol/news/uk/health/article7009882.ece
http://www.timesonline.co.uk/tol/life_and_style/health/article7006525.ece

(Misc 8c) **Retraction—Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children**
Editors, *The Lancet*, Early Online Publication, 2 February 2010 doi:10.1016/S0140-6736(10)60175-7

The reasons for the retraction include that "investigations were "approved" by the local ethics committee have been proven to be false."
http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(10)60175-7/fulltext

(Misc 9a) **PREDICT charter underlines trial bias against older people**
Pharmatimes, 03 February 2010

A charter supporting the rights of older people in clinical trials has been launched as part of the European PREDICT project co-ordinated by the Medical Economics and Research Centre (MERCS) in Sheffield, UK.

The argument is that too often clinical trials for conditions prevalent in older people, such as heart failure, hypertension, Alzheimer's disease, depression or colorectal cancer, are not sufficiently representative of this population.
http://www.pharmatimes.com/clinicalnews/article.aspx?id=17321&src=EUKNews

(Misc 9b) **Aging Under the Microscope in Europe**
Peter O'Donnell, *Applied Clinical Trials*, Feb 2010

A report of a workshop organised by the geriatric medicines working party of the European Forum for Good Clinical Practice with its own assessment of whether Europe is a ready to cope with the challenge of an aging population for medical research.
http://appliedclinicaltrialsonline.findpharma.com/

(Misc 10) **Do we want brain scanners to read our minds?**
Colin Blakemore, *Daily Telegraph*, 5 February 2010 p.27

An article by neuroscientist discusses the ethical implications of the news that researchers have used a brain scanner to successfully communicate with a patient in a persistent vegetative state. The potential for such technology to be used for Government surveillance or commercial marketing poses challenges for individual privacy.
http://www.telegraph.co.uk/science/7159464/

(Misc 11) **Are the odds stacked against today's young researchers?**
Michael Oliver *BMJ.*8 Feb 2010; 340: c646

A viewpoint that there are many reasons why opportunities for initiating new ideas are limited. Michael Oliver**,** professor emeritus of cardiology, University of Edinburgh writes that the chief reason is cost but he briefly refers to RECs.

"Fifty and more years ago it was possible to embark on a research project with advice from one's seniors and without much, if any, peer review interference, bureaucratic resistance, or obligatory referral to various ethics committees."
http://www.bmj.com/cgi/content/full/340/feb08_2/c646

(Misc 12) **Core competencies for clinical ethics committees**
Victor Larcher, Anne-Marie Slowther and Alan R Watson on behalf of the UK Clinical Ethics Network, *Clinical Medicine,* 01 Feb 2010, p30-33

Unlike RECs there is no regulatory framework of clinical ethics committees (CECs). This article may be of interest to REC members because the authors suggest defined educational requirements and core competencies for CEC members.
http://www.rcplondon.ac.uk/pubs/clinicalmedicine/

OVERSEAS

(Overseas 1) **FDA Issues Draft Guidance on IRB Continuing Review**
FDA website, Jan 2010

This draft guidance is intended to assist institutional review boards (IRBs) in carrying out their continuing review by providing recommendations regarding the criteria, process, and frequency of continuing review to assure the protection of the rights and welfare of subjects in clinical investigations. The draft guidance should also help clinical investigators and sponsors better understand their responsibilities related to continuing review.
http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ProposedRegulationsandDraftGuidances/default.htm

(Overseas 2) **China set for global lead in scientific research**
Clive Cookson, *Financial Times*, 26 January 2010 p.1

An article highlights the huge growth of scientific research in China over the past thirty years, with an increase in collaborative research, a 64-fold increase in peer-reviewed scientific papers and predictions that China will overtake the US output by 2020.
http://www.ft.com/cms/s/0/3d0c1606-0a19-11df-8b23-00144feabdc0.html

(Overseas 3) **Hidden risks associated with clinical trials in developing countries**
Cláudio Lorenzo, Volnei Garrafa, Jan Helge Solbakk, Susana Vidal, *J Med Ethics* Feb 2010:36**;**111-115

The purpose of this paper is to discuss forms of uncertainty involved in clinical trials in poor and low-income countries that are not addressed by conventional methods of risk assessment. The authors propose the involvement of research ethics committees in the risk evaluation process and the establishment of national ethics evaluation systems.
http://jme.bmj.com/content/36/2/111.abstract?etoc

(Overseas 4) **The use of placebo in a trial of rectal artesunate as initial treatment for severe malaria patients en route to referral clinics: ethical issues**
Andrew Kitua, Peter Folb, Marian Warsame, Fred Binka, Abul Faiz, Isabela Ribeiro, Tom Peto, John Gyapong, Emran Bin Yunus, Ridwan Rahman, Frank Baiden, Christine Clerk, Zakayo Mrango, Charles Makasi, Omari Kimbute, Amir Hossain, Rasheda Samad, Melba Gomes *J Med Ethics* Feb 2010: 36:116-120

Placebo-controlled trials are controversial when individuals might be denied existing beneficial medical interventions. The authors describe the ethical issues underpinning a placebo-controlled trial in severe malaria.
http://jme.bmj.com/content/36/2/116.abstract?etoc

(Overseas 5) **The Indian Pharmaceutical Environment**
Suprabha Naralkar, Kishor Karandeand Pratik Vasani, *Regulatory Rapporteur* February 2010

This article provides a perspective on the Indian drug regulatory environment, including research ethics committees and their timelines.
http://www.topra.org/sites/default/files/focus2_12.pdf