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Editorial

Report on EQUATOR Network launch meeting 26th June 2008 "Achieving Transparency in Reporting Health Research"

> "Poor reporting cannot be seen as an isolated problem that can be solved by targeting only one of the parties involved. A well-coordinated effort, with collaboration between the research and publishing communities, strongly supported by research funders, will likely have a better chance of leading to improved reporting of health research."[1]

Reporting quality of randomised controlled trials is a topic that is taken seriously in the *International Journal of Surgery*. In 2007, Riaz Agha and colleagues undertook a systematic review of the reporting quality of randomised controlled trials in surgery.[2] The covering editorial[3] queried who should take the responsibility for generally educating all those involved so that they might achieve a more conscientious approach to improving the quality of reporting. It is pleasing to be able to report that this responsibility has been acknowledged, is being debated, and has been claimed, steered by a group of people well experienced in these matters. A new initiative, the EQUATOR Network, is directed by an international Executive Group that brings together leading experts in health research methodology, statistics, reporting and editorial work (www.equator-network.org). It aims to improve the reliability of scientific publications by promoting clarity, transparency and accuracy in health research reporting. The Launch Meeting took place on 26th June 2008 at the Royal Society of Medicine and was attended by about 170 participants from a wide range of leading organisations and institutions.

Sir Muir Gray, Director of the National Knowledge Service, Oxford, recently given the role of Chief Knowledge Officer for the NHS, opened the meeting by sharing good news received only that morning that the MRC (www.mrc.ac.uk/) had agreed to add its financial support to that already provided by the NHS Library for Health (http://www.library.nhs.uk) and the National Institute for Health Research (http://www.nihr.ac.uk/). He outlined the benefits of the growing trend towards digital publication. The IJS has been a front-runner in recognising the benefits of rapid handling and online publication of accepted articles within days of acceptance. The BMJ sees continuous publication as 'the next logical step'[4]: as from July 2008 all articles are published online as they become ready prior to being selected for a subsequent print issue.

Why should we all be concerned about achieving transparency in reporting health research? Perhaps we should remember the main goal: the relief of people's illness and pain.[5] The purpose of undertaking research is to reduce uncertainties about treatments and interventions so that clinicians and patients can decide together what is the best course of action to take. Doug Altman, Director, Centre for Statistics in Medicine, University of Oxford, presented summarised evidence that showed that many published articles omit vital information: this demonstrates a collective fault of authors, peer reviewers, and editors. Reporting guidelines should help all these groups to ensure proper reporting of research, which is an essential component of good research. If authors of research reports fail to give a full description of the treatment or intervention, doctors will not be able to help patients as they should. Paul Glazsiou, Director, Centre for Evidence-based Medicine, University of Oxford, UK, and GP, left us with no illusions about the effects of inadequate reporting as it affected his ability to advise and treat his patients. Not only will patients be short-changed, but also without adequate descriptions, "tens of millions of pounds of research effort could be wasted each year because effective treatments cannot be implemented or will lack fidelity when applied".[6] A further consequence of poor reporting of trials is felt when compiling systematic reviews. As Ian Needleman, Director, International Centre for Evidence-based Oral Health, UCL, London, UK, explained, the totality of evidence in a critical summary, as called for by Archie Cochrane, is only meaningful as a concept if potentially contributing studies are reported in sufficient detail to allow evaluation and inclusion. In his view, because of the potentially profound impact of poor reporting both on the understanding of the totality of evidence and on the delivery of health care, adequate reporting should be considered as an ethical responsibility.

The next two sessions provided suggestions about what might be done to improve the quality of research reports. John Hoey, Queen's University, Kingston, Canada, defined the qualities of good research reporting as accuracy, transparency, and efficacy. Having defined these principles in detail he reminded us of the published research evaluations of quality that are available: CONSORT, STROBE, STARD, and others (see 'reporting guidelines' www.equator-network.org). David Moher, Director, Chalmers Research Group, University of Ottawa, Canada, gave a brief historical perspective of the development and use of guidelines for health research. He described how to develop a reporting guideline, and their current use, uptake, endorsement, and adherence within journals. He concluded by considering the future optimal use of reporting guidelines for a wide variety of stakeholders. He drew attention to the front page of The Independent of Wednesday, 25th June 2008, with its picture of a clipboard, and the headline: 'A SURGICAL REVOLUTION' – a surgical safety checklist that could prevent thousands of deaths.[7]

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Iveta Simera, Project Manager of EQUATOR Network, Oxford, UK, described how the EQUATOR Network acts as an umbrella organization bringing together not only guidance, but also all important stakeholders that influence the quality of health research reporting: researchers, research funders; journal editors, peer reviewers and publishers; reporting guideline developers; and other organisations and individuals involved in the publication of health research. She also described the major goals of EQUATOR which include

- The development of an Internet-based resource centre.
- Assistance in the development, dissemination and implementation of reporting guidelines.
- Development of educational and training programmes relating to the use of reporting guidelines.
- Assessment of journals' implementation of reporting guidelines.
- Audit of reporting quality across health research literature.

A major problem is securing sufficient funding for the development, evaluation and dissemination of reporting guidelines, and a lack of strategies to accomplish these essential activities. Iveta also drew attention to the need to harmonise methods used in the development of reporting guidelines.

Altruism is often the motive for patients to volunteer to participate in trials. They do so in the expectation that their participation will contribute to the sum of human knowledge. It follows that there is a scientific, ethical and moral duty incumbent on those involved in producing and publishing research reports to do it fully and transparently. Davina Ghersi, Co-ordinator of the International Clinical Trials Registry at WHO, Geneva, vividly upheld and illustrated this obligation.[4] She called for the accountability from funders and ethics committees, who should ensure that research proposals conform to the highest possible standards, ultimately capable of producing full data that are usable, meaningful and accessible. Funders should not enforce restrictions on reporting in contracts or agreements.

Rapid access to research reports proves vital. Paul Ayris, Director of Library Services at University College, London, and UCL Copyright Officer, contrasted the traditional model of, say, the British Museum Reading Room **pulling** people into its library space, with today's networked and global environment, where the library is just one of the content providers. Researchers no longer have the need to set foot in a library: the world is their oyster. He suggested that academic libraries should therefore **push**[8] stuff out to where the user is. He cited Matthew Cockerill survey, submitted to the House of Commons Science and Technology's Committee Inquiry that showed how few texts are currently accessible to the general public:

> "*Our results indicate that although the majority (90%) of the resulting research articles now exist in online full text form, less than a third (30%) of the online full texts are accessible to the general public immediately upon publication. Perhaps more surprisingly, despite the NHS's major recent program of electronic journal procurement, only 40% of the online full texts of these NHS-funded research articles are immediately accessible to NHS staff at the hospital we studied. These preliminary results suggest that the current system of scientific publishing is failing to make NHS research fully accessible to those who could benefit from it, including staff within the NHS.*"[9]

An important role for publishers is to ensure reliability of scientific publications. Chris Graf, Publisher, *International Journal of Clinical Practice*, Wiley–Blackwell Publishing, Oxford, UK, jolted delegates with details from the report of a survey undertaken by the Office of Research Integrity[10] showing just how prevalent research misconduct is. The report suggests that many research misconduct incidents in the United States go unreported. Most editors surveyed were not very concerned about publication ethics: they thought problems were rare. They were also unaware of good publication ethics guidelines, indicating just how much work there is for publishers to do. The authors of the report concluded that "falsified and fabricated research records, publications, dissertations and grant applications are much more prevalent than has been suspected to date." Help is at hand. COPE (http://www.publicationethics.org.uk/) is a forum for editors of peer-reviewed journals to discuss issues related to the integrity of the scientific record; it supports and encourages editors to report, catalogue and instigate investigations into ethical problems in the publication process. Formed in 1997, the Committee on Publication Ethics' (COPE) major objective is to provide a sounding board for editors who were struggling with how best to deal with possible breaches in research and publication ethics. There is also a co-operative publisher service – CROSS CHECK (http://www.crossref.org/01company/pr/press061908.htm) – a plagiarism detection service that was launched on 19th June 2008 by Elsevier. It provides a reliable way to verify the originality of scholarly content in work submitted for publication. Best Practice Guidelines on Publication Ethics, promoting research integrity and responsible publication practices, are for everyone engaged in the publication process: editors, authors, manuscript reviewer and referees.

Trish Groves, Deputy Editor, BMJ, London, UK, described EQUATOR as a 'huge leap forward' making it easier to get reporting guidelines into practice. She saw provision of training as an important step. However, she emphasized that it was not necessarily about 'ticking all the boxes'. She suggested that perhaps EQUATOR could have flowcharts like COPE and 'how to' sections for editors, reviewers and authors. She encouraged EQUATOR to do more to market their guidelines to authors and editors, focusing on the aims and benefits. A balance should be struck between relevance and detail. The purpose of guidelines should be made clear: i.e. to provide guidance on reporting research transparently and fully so that readers (clinicians, learners, educators, other researchers, policymakers, patients) can understand what the investigators did and judge its quality, and so that systematic reviewers can select studies. She proposed her own 'CLEAR' statement: 'Concise Lists for Editors and Authors on Reporting' before we went for TEA – That's Enough Acronyms!

1. First annual EQUATOR Annual Lecture: "Meeting the research information needs of patients and clinicians more effectively"

Iain Chalmers, Editor, James Lind Library, Oxford, UK, www.jameslindlibrary.org, began the 1st EQUATOR Annual Lecture by clearly defining the problem: people are suffering and dying unnecessarily because of insufficient clinician and patient access to reliable, up-to-date information about completed and ongoing research. He used his early experience as a clinician and his later experience as a patient to describe why he has been obsessed for the past 40 years with the need to meet the research information needs of patients and clinicians more effectively.

He graphically described how, as a clinician in Palestine in 1969/1970, he could have served his patients better if he had had more humility, and if he had had access to systematic reviews of relevant clinical trials. He described how, because he had been taught not to administer antibiotics to children with measles, many lives were lost through ignorance. Most of the children he was treating were malnourished. But findings of a systematic review of clinical trials reported between 1939 and 1967, unavailable to him in Palestine, show that antibiotics prescribed for children with measles can reduce their risk of developing pneumonia. In October 2006, a paper about prophylactic use of antibiotics in measles published

online[11] concluded that "The group that received prophylactic antibiotics had less pneumonia and conjunctivitis and had significantly higher weight gains in the month after inclusion. The results indicate that prophylactic antibiotics have an important role to play in the management of measles infection in low-income countries." Precise details of the interventions and duration of use were provided in this report, thus enabling doctors to prescribe effectively.

As a patient, having experienced retained/impacted earwax[12] – a common problem causing impaired hearing and localised eczema, sometimes associated with serious complications, and costing the NHS £50 million per year – Sir Iain discovered that the only systematic review available was of little help. The authors of the report found that water and saline drops seemed to be as good as more costly commercial products, but concluded that "the quality of the research is generally low and more research is needed".[13]

He drew attention to the WHO International Clinical Trials Registry Platform (ICCTR), the mission of which is "to ensure that a complete view of research is accessible to all those involved in health care decision making" with the purpose of improving research transparency, ultimately strengthening the validity and value of the scientific evidence base. The WHO believes that "*the registration of all interventional trials is a scientific, ethical and moral responsibility*" (http://www.who.int/ictrp/en/). Additionally, to improve reports of research, compliance is required from many leading journals to guidelines already available.

As long ago as 1950, Marc Daniels[14] drew attention to the fact that essential details are omitted from reports. He was a member of the team that included Philip D'Arcy Hunt and Austin Bradford Hill who were responsible for designing, co-ordinating and reporting the MRC trial of streptomycin for pulmonary tuberculosis in 1947/1948 (see: www.jameslindlibrary.org/trial_records/20th_Century/**1950s**/**daniels**/**daniels**_biog.html).

2. The importance of systematic reviews

Fifteen years ago, a paper in the Lancet taught that "good systematic reviews provide a valuable foundation for new research initiatives".[15] Yet the proportion of study investigations using systematic reviews is still very limited, resulting in trials being conducted long after adequate evidence was available, as was the case with the use of aprotinin in cardiac surgery.[16] Such failure to prepare and refer to systematic reviews results in harm and wasted resources in health care and health research. Sir Iain emphasized that discussion section of reports should begin and end with up-to-date systematic reviews of other relevant evidence.[17]

He traced how, following his salutary experience in Gaza in 1969/1970, he had become involved in improving the syntheses of research findings (systematic reviews), firstly through the electronic dissemination and maintenance of systematic reviews of controlled trials in perinatal care, from 1988 with the Oxford Database of Perinatal Trials (ODPT); then from 1993 to1995 with Cochrane Pregnancy and Childbirth Database (CPCD); following in 1995 with the Cochrane Database of Systematic Reviews (CDSR). His conviction that underreporting of research (which amounts to scientific misconduct)[18] by failing to provide adequate, publicly available reports of the results of clinical trials does injustice to the patients who have participated in them, and about the dangers of publication bias, have driven him to work to improve matters. He expressed his belief that EQUATOR should help to improve the quality and relevance of research. He spoke of his current work with the James Lind Alliance – '*tackling treatment uncertainties together*' (www.lindalliance.org) – improving the relevance of research to patients and clinicians. Currently, it is looking specifically at determining research priorities in asthma, bringing together Asthma UK (an organization representing people with asthma in the UK – www.asthma.org.uk/) and the British Thoracic Society (representing health professionals with an interest in respiratory disease – www.brit-thoracic.org.uk), to

- find out which unanswered questions are of importance to patients, carers and clinicians
- find out which outcomes are important to patients
- make uncertainties explicit (through DUETs – **D**atabase of **U**ncertainties about the **E**ffects of **T**reatment (www.duets.nhs.uk)
- do research to address uncertainties

He quoted from the General Medical Council's guidance for doctors, published on 13th November 2006, in particular, para 14:

> *"You must work with colleagues and patients to maintain and improve the quality of your work and promote patients safety. In particular you must:*
> *(f) help to resolve uncertainties about the effects of treatments."*

As an example, he drew attention to the terrible, enduring consequences caused by failure to address uncertainty over 30 years about whether to use caffeine in newborn infants to reduce apnoeic episodes. The results of a trial published in 2007 showed that "*caffeine therapy for apnea of prematurity improves the rate of survival without neurodevelopmental disability at 18–21 months in infants with very low birthweight.*"[19] Sir Iain went on to describe the report of the CRASH trial as an exemplar of what is needed.[20] It was exemplary because:

- It refers to the current uncertainty about the effects of a treatment, manifested in a **systematic review of all the existing evidence**, and in **variations in clinical practice**.
- It notes that the **trial was registered and the protocol published prospectively**.
- It sets out the new results in the context of **an updated systematic review of all of the existing evidence**.
- It provides readers with **all the evidence needed for action** to prevent thousand of iatrogenic deaths.

Sir Iain concluded by drawing attention to various ways of exploiting the possibilities offered by electronic publishing that have been proposed. For example, the review and electronic publication of research protocols, and electronic publication and archiving of medical research.[21–23] He emphasized that he believes it is a shared responsibility to meet the research information needs of patients and clinicians more effectively. He said that it is encouraging that an improvement to the evidence base has been promised in Lord Darzi's Interim Report, in which he expressed his wish to "shape the NHS for the 21st Century" with the creation of a "national clinical evidence base available to commissioners, practitioners, patients and public alike".[24]

> "***Teach thy tongue to say I do not know and thou shalt progress*" *Maimonides, Spanish philosopher 1135–1204***

Slides used by presenters at the meeting are available on the EQUATOR meeting website (http://www.equator-network.org/?o=1125).

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I declare I have no conflict of interest.
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