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Objectives: To review the issues of publication of clinical trials with consideration of ethics and the incomplete evidence base.
Methods: A review of clinical trials and issues of communications and ethics. Several case studies of notable public health researchers will be discussed.
Results: Many of the major breakthroughs of public health practice, including the works of John Snow would not have been published under modern guidelines for scientific communication. The research - publication system of modern health care poses many challenges for editors. Journal editors need to include a balance of different types of studies where insufficient randomised controlled trials are available.
Conclusion: Clinical trials are a reliable source of evidence for health care practitioners. Journals need to uphold the integrity of the information provided by RCTs and synthesise and communicate health information. At the same time, editors must assess non-RCT evidence and be vigilant for many of the other potential problems in health and medical communication.
The Editor,
Preventive Medicine

Dear Editor

Re: Publications from Clinical Trials: Process, Conflict of Interest and the Evidence Base

Enclosed for your consideration is the invited lecture for the First Asia Pacific Clinical Epidemiology and Evidence-Based Medicine Conference, July 2012. As requested by the organisers we have abbreviated our paper to 1200 words.

Thankyou for considering our submission

Yours sincerely

On behalf of the authors

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1 March 2013
Publications from Clinical Trials: Process, Conflict of Interest and the Evidence Base

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Short running title: Publications from clinical trials
Word Count Text: 1195 Abstract 155
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Key words: Clinical trials, ethics, communication, evidence base.

Conflicts of Interest: The authors have no conflicts of interest to declare
Introduction

Clinical trials have been a part of medicine and public health since the beginning of time although the trials of earlier years fell far short of the standards of today. The great advance in life expectancy and health status seen in the past century has been largely due to research in public health, health services and medical sciences. Research requires communication to facilitate implementation. This paper will summarise some of the issues in communicating and publishing medical knowledge from the perspective of editors.

John Snow and Hippocrates are two of the most influential medical scientists of the past. Both published their works, but it is interesting to speculate if they would have passed the 21st century journal reviewers. Hippocrates’ writings were based on his clinical wisdom derived from years of experience. He wrote extensively about clinical treatments and healthy lifestyles, including the importance of nutrition and is best remembered for the principle “Primum non nocere” (above all do no harm) and the Hippocratic oath. Details of the fascinating history of this phase can be found in an article by Smith (Smith, 2005). In modern clinical practice and epidemiology, the principle of “do no harm” has been modified into the science of risk management acknowledging that every intervention carries a degree of risk.

John Snow is one of the heroes of public health and epidemiology, while working as an anaesthetist. During the cholera epidemic in the Golden Square area of London in 1854, he found that 70 workers at a local brewery drank water from a different source and had not contracted cholera (Brody et al., 2000). He removed the handle from the local Broad Street pump and the epidemic subsided. In fact the epidemic was already on the wane, but of course he may have prevented another outbreak (Rothman, 2004). Snow’s report began:

“On Imperfect Studies
The subject is capable of being decided by exact numerical investigation, but I have thought it better to publish my inquiry in its present imperfect state than to wait till I should be able to make such a complete research as I could wish, more especially as, by directing the attention of the profession to the question, it may be earlier decided.” John Snow (Paneth, 2004)

Probably neither of these greats would have been published in a high ranking journal as they were really writing commentaries of personal experience.

Communicating knowledge in the health sciences and public health
The chain of medical communication includes researcher (sender), journal article (message), publisher (channel) and reader/practitioner (receiver). This simple system may be influenced by funders and sponsors who may wish to change the study outcomes and recommendations.

The Researcher
In 1948, the world of medical research and publishing changed forever with the publication of the Medical Research Councils randomised controlled trial (RCT) on streptomycin in the treatment of tuberculosis (Streptomycin in Tuberculosis Trials Committee, 1948). In that year, there were 341 papers on streptomycin and TB published according to PubMed, but only one RCT. The process of undertaking RCTs was further developed and in 1972 Cochrane published his definitive monograph on evaluation leading eventually to the Cochrane Collaboration, metanalyses and the elevation of systematic reviews to be the gold standard for medical knowledge (Cochrane, 1972).

But while we have the benefit of RCTs for therapeutic interventions, some things cannot be tested using a RCT. For example in nutrition, the 80 year long trial of the effect of different infant feeding options followed by a strict diet on life expectancy would be of no practical value as food supplies change. In other cases, ethics prevent a true RCT and for example cannot be undertaken for breastfeeding, because of its known benefits. In Public Health, most policy decisions will be made without the benefit of RCTs for all options and other ways of research will have to be found (Victora et al., 2004). Ways must be found to improve the quality and reduce bias of other types of studies, including cohort and case-control studies. An important modern principle of medical ethics is not to undertake research that is poorly designed or has too small a sample size. Yet these faults are frequently found in modern research and are the two most common reasons that editors reject papers.

Journal Articles

As many questions in medicine and public health cannot be assessed by RCTs, journals then have an obligation to continue to publish other types of studies. There is a lot of pressure to undertake research and publish, but it is unethical to waste resources and the time of participants to do research that cannot be published. Journal editors are challenged by many issues including poor writing, multiple analyses of the same data, plagiarism and even fraud. The development of the ICMJE and the CONSORT protocols has raised the standard of journal articles (Moher et al., 2001).

The Publisher

In the 21st century, the publisher and editor face the challenges of citation rates and sometimes profits (Brown, 2007). Editors have a responsibility to recognise the importance of publishing papers that include a variety of methodologies.

The Reader/practitioner

Each health practitioner has an obligation to get unbiased information and to implement best clinical (and best affordable) practice for their patients or communities.
The Funder

Who funds the research or the article is not included in traditional models of communication - but is of increasing importance in the health field. Full and open disclosure of all is required of all publications, including the publications that rely on commercial sponsorship of articles and could be more appropriately called advertorials. Secondary publications can be influential and are often sponsored by commercial interests. A review of health publications in Korea found that a disproportionate number of articles about Viagra had been translated, compared to few articles related to health promotion and lifestyle change (Lee et al., 2000).

Developing the evidence base: Publication and knowledge

When does knowledge become, or at least approach, the truth? The basis of modern science is probability and the need for replication of studies, followed by synthesis (egmetanalysis). Publication of repeat studies and those with negative results is important.

Conflicts of interest

All components of the health communications system face potential conflicts of interest which can lead to bias in the availability of knowledge needed to improve the health and wellbeing of the citizens of our region. There are many types of conflict of interests: (1) financial ties, (2) academic commitments, (3) personal relationships, (4) political or religious beliefs and (5) institutional affiliations. For example, authors affiliated to a company that manufactures a particular drug or device, have a vested interest in publishing research papers on the company’s products (World Association of Medical Editors Editorial Policy and Publication Ethics Committees, 2009). Most journals now require authors to disclose any conflict of interest, but reporting standards vary.

Conclusions

The research – publication system of modern health care poses many challenges for editors. Clinical trials are a reliable source of evidence for health care practitioners. Journals need to uphold the integrity of the information provided by RCTs and synthesise and communicate health information. At the same time, editors must assess non-RCT evidence and be vigilant for many of the other potential problems in health and medical communication.

References


