

limbs initiated and fuelled the process which mobilised unprecedented public opinion and led to the Ottawa Treaty of 1997. In two cases the cycle was completed early and the weapons never used. The effects of exploding bullets and blinding lasers only had to be foreseen before governments agreed to prohibit their use in war (in the St Petersburg Declaration of 1868 and the 1995 Protocol IV of the 1980 UN Convention on Conventional Weapons, respectively). Such conventions, declarations, protocols, and treaties together make up a part of international humanitarian law.⁶ In brief, it is the effects of weapons which have generated the need for legislation about them.

The two cycles described above have a common feature: observation and documentation of the effects of weapons. If health professionals document their observations of the effects of weapons which cycle are they going to turn? This dilemma and the responsibilities of health professionals beyond treating the wounded were recognised at a symposium in Montreux, Switzerland in 1996.⁷ The symposium examined the responsibilities of the medical profession in turning the second cycle and, in particular, applying and helping to develop international humanitarian law.

The symposium recognised that the subject of the effects of weapons, firstly, fell within the broad field of health and, secondly, occupied a central position in relation to other disciplines interested in weapons. Participants attempted to give a name to the subject which refers not only to the observation and documentation of the effects of weapons but also to all activities exclusive to the second cycle. Hence, the "Solferino cycle." By recognising the interdisciplinary nature of the Solferino cycle, different disciplines can identify better how their activities relate to those of others. The cycle should be recognised as an academic focal point and a section of any library where people study law, medicine, sociology, history, communications, strategic and peace studies, or military affairs. At the same time it provides the frame and the fuel for advocacy.

Observing and documenting the effects of weapons does not bring about changes in belief, behaviour, or law unless communicated compellingly to both policymakers and the public. Though the observation of the effects of weapons is an essential activity within the Solferino

cycle, health professionals can turn it one step further by communicating these observations in the context of the cycle. Examples include: establishing that acquiring a weapon does not bring the personal security that is intended⁸; documenting that weapons designed for war exact a human toll through indiscriminate use outside war^{9 10}; and arguing from casualty data that increased distance between the users of weapons and their victims increases the chance of civilian injury.¹¹ Turning the Solferino Cycle also includes, for example, pointing out that the effects of new weapons may not be understood¹²; the potential abuse of biomedical knowledge^{13 14}; and endorsing the SIFUS Project.¹⁵

The Solferino cycle has shaped human history in response to some of our worst moments; it continues to turn and is important for our future. It is the basis of all elements of restraint when humans go to war or, more importantly, think about going to war.

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On 5 October 1999 the BMA is holding a seminar on the role of the medical profession in relation to weapons and international law

Time to register randomised trials

The case is now unanswerable

The case for registering all clinical trials—first advanced a decade ago¹—is now unanswerable. The public has the right to know what research is being funded. Researchers and research funders don't want to waste resources repeating trials already under way. And those conducting systematic reviews need to be able to identify all trials begun on a subject to avoid the problem of publication bias. Otherwise, clinicians may be deceived on what the evidence shows. Next week the *Lancet*, the Association of the British Pharmaceutical Industry, and the BMJ Publishing Group will hold a joint conference to promote the registering of trials.

Each year a vast financial investment is made by national funding agencies, medical research charities, and drug and device manufacturers in randomised controlled trials. Unfortunately the process is chaotic and takes little account of concurrent research. Several case studies have shown how the manipulation of trial data can provide a seriously misleading picture of an intervention's effectiveness. In a systematic review of trials using ondansetron to treat postoperative nausea and vomiting Tramer et al² found that "a false impression of ondansetron's efficacy may arise because a quarter of all relevant published reports are duplicates." Huston and Moher found it almost impossible

to complete a systematic review of risperidone's efficacy in schizophrenia for the same reason.³ These studies show that we have to find better ways of identifying and tracking clinical trials.

The history of this effort shows much good intention but only limited progress. One attempt to link research to practice in the setting of an entire health service began in the United Kingdom in 1991 with the launch of the NHS research and development initiative.⁴ That programme placed the systematic collection of data from randomised trials at its intellectual centre. The Cochrane Collaboration has been its most important and successful partner and has focused its work on published clinical trials. But this leaves untackled the large amount of unpublished trials.⁵ Chalmers famously described this underreporting of research as scientific misconduct,⁶ and publication bias remains a pervasive problem. The medical editors' trials amnesty tried to flush out that evidence, with only partial success.⁷

Rather than treat the problem of hidden research retrospectively, a more sensible approach might be to prevent it.¹ Based on their original investigations of publication bias, Dickersin and Min have argued that one "possibility is to require registration of all clinical trials prior to initiation. While this is widely agreed to be a good approach, widespread registration has not yet been effected....Who will take the lead?"⁸

Apart from the NHS national research register and the Cochrane controlled trials register, the most significant recent lead has been taken by the pharmaceutical industry. For example, Schering Health Care and GlaxoWellcome have committed themselves to registering information about their own trials. Richard Sykes (chairman of GlaxoWellcome) argued that he and his colleagues understood "the value of information, and we want to create a climate of openness where the evidence for prescribing our products is clear."⁹ Not all in the pharmaceutical sector agree, and Sykes has been ridiculed by some who see his step as opening up a window of vulnerability in GlaxoWellcome's commercial armour. But how can this be so when all that GlaxoWellcome is doing is releasing administrative information about continuing work (objective of the trial, end points, numbers, groups, and expected data of closure), not the actual data?

Editors also have a part to play. During peer review, editors increasingly find themselves requesting copies of the original trial protocol to check against the final submitted report. That "protocol culture" has led one of us to begin (and the other to plan) a protocol registration scheme.¹⁰ Editors are unwilling to fill their jour-

nals with promises of what might be, but they can publish these protocols on their web sites, perhaps linking them to a central registry.

Publishers could also help this process by collaborating with one another to construct such a free online database. The lead here has been taken by *Current Science*, which launched a metaregister of randomised controlled trials in October 1998. Trials depend on patient participation and are often funded with public money. Publishers make money from reprints of clinical trials, so it is reasonable to expect them to contribute to an initiative from which they ultimately benefit. A valuable partner might be PubMed Central, a project launched by director of the National Institutes of Health to create a free electronic archive of biomedical research.¹¹

The pressure to register trials will rise when research ethics committees, medical research charities, and drug and device manufacturers start to encourage trialists to register, especially since the responsibility for not publishing trial results seems to rest more with investigators than editors.⁸ A further challenge is to devise an internationally agreed method for assigning each trial a unique identifier. One such scheme is being piloted in cancer, with the help of the Cochrane cancer network.

Taken together, these efforts might bring shape to a presently formless clinical research enterprise. Such a structure should help to deliver high quality evidence to the clinical setting.

Richard Horton *editor, Lancet*

Richard Smith *editor, BMJ*

A version of this editorial also appears in the *Lancet* this week.¹²

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Improving access needs a whole systems approach

And will be important in averting crises in the millennium winter

A population that can do trivial things like shopping 24 hours a day in a variety of ways does not expect that doing serious things like accessing health care should be as difficult as it often is. Optimal access means providing the right service at the right time in the right place. Simplifying and

improving access according to need is evident in recent initiatives by the British government, such as NHS Direct. Good access arrangements in the NHS will be central to averting crises in the millennium winter. Access should therefore be treated as part of a whole system of formal and informal care,¹ ensuring that

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