heavy truck problem . . . I've got a contact in Mercedes you know." There it was again, just like in the World Bank report, the link between motorisation and development. Cause or consequence, the motorisation of China will have important implications for the health of its people. Some effects will be beneficial, such as improved access to medical care, employment, and recreational opportunities. Others, notably traffic accidents and environmental pollution, will be detrimental. Adverse effects will be global as well as local. Worldwide, passenger cars account for 13% of the carbon dioxide—the most important greenhouse gas—emitted from fossil fuels. If China's 1·3 billion population attains a degree of personal motorised mobility approaching that in the United States, the contribution to global warming would be immense.

China, with its millions of bicycles, currently has one of the most equitable and environmentally friendly transport systems on the planet. However, European and North American car markets are reaching saturation point. Western car manufacturers are looking to the east. Little wonder China is one of Mr Clinton's "most favoured nations." Sadly, the answer to my question, "Will history repeat itself in China?" is almost certainly: yes, it will.

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Publication: an ethical imperative

John Pearn

Publication of medical research is both a monitor of the researcher's ethics and an audit of the local or regional ethics committee that approved it. Selectivity of publication or of the intention to publish lessens this audit. Opinions differ about what is ethically allowable in clinical and benchtop medical research. Ethical permission and ethical monitoring of medical research are subject to a hierarchy of pyramidal controls, starting in hospital and ending with the local, institutional, or regional ethics committee. Currently, such committees function with widely varying degrees of efficiency and quality of output, and with differing viewpoints on many ethical issues. Without an a priori insistence by institutional ethics committees that there be an intention to publish all medical research involving human subjects, ethics committees cannot routinely be subject to the scrutiny or audit which they themselves demand of researchers.

Divergent views on many ethical aspects of medical research are held not only by individuals[1-11] but by institutional ethics committees[12] and by the broader informed public as well.[13-17] Some ethics committees are startled by what others allow, and some committees, by contrast, are seen as overly conservative. Only a fraction of this divergence of collective viewpoints of ethics committees is ever printed. One celebrated exception was widespread comment about the recent study of HIV in children in Zaire—a study approved by the French national ethics committee but not by the United States National Institutes of Health.[14,15]

Local or regional ethics committees and institutional ethics committees undoubtedly function "at present with variable performance."[11] Such ethics committees act as watchdogs of patients' rights, but who watches over ethics committees? The best way in which institutional ethics committees can open their deliberations to scrutiny is through publication of the research that they allow. Rarely do they demand, as a condition of ethical approval, that any research project be submitted for publication. Both the Royal Children's Hospital (Brisbane) ethics committee and the Australian Defence Force medical ethics committee have adopted this requirement for all projects involving human or animal subjects. My own experience, following discussion in many ethics forums, is that this modus operandi is exceptional. This paper explores some themes and experience apposite to this topical and important subject.

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The chain of ethical supervision

The basic principle that underlies the ethical supervision of medical research is that of higher order sanction. The three primary technical evils of misconduct in medical research—piracy, plagiarism, and fraud[18]—are minimised by such a hierarchy of supervision. The fourth evil, that of unethical research, is partly mitigated by a traditional in house supervisory sequence of hierarchical control; but without the demand that research will be published, these modulatory overtones remain "in house," with all the historical evidence of the dangers of such a system.

The funding of most, but not all,[14] medical research is provided by public or private institutions, or by commercial companies which demand initial approval by the institutional ethics committee. Most committees do not monitor research, an omission that is not unique to medicine. One major national institution of engineers "for 70 years has never once investigated a case where an engineer failed to put the public interest first."[16] To ensure that societal values are upheld, even developed and clarified, the safety and quality of institutional ethics committees' judgments need to be subject to the audit that the committees demand of their client researchers.

Institutional ethics committees and quality of decisions

Though the theme of medical ethics has a history of more than 2000 years, most local and regional ethics committees and institutional ethics committees have been instituted in the past decade and operate in the context of an evolving discipline. All who have served on such committees know that there can be widespread differences of opinion not only between individuals but between committees when specific research projects are being appraised. Sometimes a particular research project crosses boundaries of several institutions and sometimes one institution's ethics committee will

approve and another disallow a specific project. When different committees look at one project it is common for individual committees to demand quite different ethical modifications. Some researchers "shop around" after reviewing a "disallowed" verdict from one committee.

Inescapably, there is a spectrum of quality of institutional ethics committee decision making. Unethical research today tends not to be published, and the institutional ethics committees approving it cannot easily be subject to peer accountability or the potential for societal discussion and judgment.

An intention to publish

What is required is an universal condition among institutional ethics committes that there will be an intention to publish, and to monitor why research is not published, in the case of default. In the United States, currently some 16% of publicly funded, highly competitive medical research never sees the published light of day. Undoubtedly the non-publication rate of less stringently funded research is even higher.

The whole point about ethical decisions is the inherent difference of opinion. If there were total agreement it would cease to be an ethical problem.

Sir Raymond Hoffenberg[12]

In practice, many things go wrong with even the best planned research. Direction goes off the rails, individual researchers leave, and unexpected difficulties arise, causing the abandonment of projects. Furthermore, a significant corpus of research gets to the data collection stage, only to falter when the self discipline required for writing up and publication is found wanting. Many researchers take their research only to the stage of the in house report and then move on or are promoted to other positions. Much research submitted for publication is rejected by editors on grounds of poor methodology, unprofessional writing up, irrelevance to a journal's terms of reference, and a host of other reasons. The sum total is that much research is never disseminated, and other researchers or practitioners, let alone the general community, remain unaware of all but the sieved, best, and sometimes sanitised research. The question here is not what is ultimately published—it is what is not.

Commercial research

An increasing percentage of research is commercially funded, and there is pressure to keep research findings secret. This approach—that intellectual property resulting from medical research should remain a trade secret—is understandable, but dangerous. Using human subjects, if they are fully informed adults of normal intellect who are not "captive" or in the Third World may not involve ethical problems. There are, however, at least two unfortunate outcomes of any medical research which, a priori, is not going to be published. The first is obvious when there is no accountability or potential scrutiny at higher levels: the subjects themselves may not be aware of risks sequentially revealed as the research progresses. Problems surface only when royal commissions and similar bodies are investigating, retrospectively, research that has gone blatantly wrong.

The second unfortunate legacy of selective non-publication of commercial research is that anything that is potentially deleterious to a company's image or profit is suppressed. Commercially funded drug trials, in which the null hypothesis is not disproved, are almost never submitted for publication. This second problem means that all the inconvenience and risk to human research subjects is wasted, from the point of view of wider knowledge and future research. Again, the way forward is for institutional ethics committees to insist that ultimately the commercial enterprise undertaking the research will guarantee to submit the results, whatever the outcome, for the higher audit of publication in peer reviewed journals.

The role of journals

Medical journals hold the key role in any evolution to lift ethical standards of medical research.[18] This would seem to be straightforward, but there is a paradox: some journals accept for publication only those papers with local institutional ethics committee approval and that have passed the second echelon sieve of the journal's reviewers, themselves acting in ethical mode. Research of questionable ethical standards is thus unlikely to be published or tends to be published only in unrefereed journals or appears finally only as a letter to the editor.

This was illustrated by a recent report, finally published as a letter in the *Lancet*.[19] Some peers found the research—injecting blood infected with live HIV into 11 severely ill AIDS patients—of doubtful ethical acceptability.[14] Yet without its publication—an honest act by the researchers and a courageous one by the *Lancet*—the ethical points raised would not have been exposed for a subsequent wider ethical debate (in *New Scientist*[14]) and analysis by the broader audit of society.

Many bona fide researchers are publishing research papers passed by local ethics committees but of debatable ethicality. A postgraduate journal club that I jointly chair raises such ethical questions almost every week. Specific examples include the forceful collection of nasopharyngeal specimens from children with unrelated disease[23] and the use of agents untested for teratogenic effects and the injection of life viruses[14 15] in Third World populations.

The only, and less acceptable, alternative to introducing an "intention to publish code" to encourage openness of ethical viewpoints is to promote whistleblowing in selected projects that have manifestly gone wrong.[24]

Discussion

Revelations about misconduct such as fraud in medical research are followed by confusion and horror in the scientific community.[25] Both in Britain and in the United States awareness of research misconduct has led to healthy debate.[18-22 26-28] The medical and research professions of all modern societies have rightly bowed to the consumerist ethos in society to open questions of medical ethics to public scrutiny.

Very few institutional ethics committees monitor what happens to the research they approve. Their insistence on publication would undoubtedly put further pressure on a research worker, but the outcome will undoubtedly provide valuable feedback to the committee, feedback that in many instances is currently not available. If a submitted paper is subsequently rejected by a medical journal on ethical grounds, having previously been approved by an institutional ethics committee, the ensuing audit inevitably proves educative both for the researcher and for the ethics committee.

The best institutional ethics committees have a policy of encouraging research and do not see themselves as reacting negatively to submitted research

proposals.[29] In the best of all worlds the policy, "don't work just for your laboratory—contribute to society"[30] is common to community and client.

Codes of ethics are one hallmark of a profession[16] and are an informal but powerful contract between professions and the communities which they serve. Medical codes of ethics place the welfare, autonomy, and dignity of research patients first and maximise safety. The quid pro quo is that the general society allows the profession to regulate itself. A declaration of intent to publish all that is undertaken in the name of medical research is a logical and relatively easy next step along this path of quality improvement.

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What do I want from health research and researchers when I am a patient?

Iain Chalmers

See p 1318 and editorial by Goodare

I have attempted to adopt the perspective of a patient—albeit one with a rather atypical background—to explore what I want from health research and researchers. This has left me with the impression that health researchers could serve the interests of the public more effectively in a variety of ways, and that they would be helped to do so by greater lay involvement in planning and promoting health research.

Three years ago—a couple of decades after I first coauthored a research report—I was presented with an opportunity to wind up my career in health services research. An unexpected consequence has been that I have found it easier to ask myself how health research and researchers might serve lay people more effectively. I have begun to ask "What do I want from health research and researchers?"

Any personal view is inevitably shaped by personal experiences. Fairly soon after I qualified as a clinician I began to realise that my attempts to apply some of the therapeutic principles taught at medical school were sometimes resulting in unnecessary deaths. This sobering experience led me to be sceptical of received wisdom, an attitude that was reinforced when, as a health services researcher, I became aware of the quality of the evidence on which many therapeutic claims are based. It is against this background that, as a patient, I want decisions about my health care to be informed by reliable evidence.

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What do I want from research?

People are bound to vary in what they regard as reliable evidence. A leap of faith will always be required to make causal inferences about the effects of health care. For example, after about five treatments from a chiropractor to whom she had been referred by her general practitioner, my wife began to believe that chiropractic could help relieve her chronic shoulder and back pain. Although I was delighted that her longstanding symptoms had subsided, I did not begin to share her belief that chiropractic might have been responsible until a couple of years later when I read the report of a systematic review of the relevant controlled trials.

"Through seeking we may learn and know things better. But as for certain truth, no man hath known it, for all is but a woven web of guesses."

—Xenophanes, classical philosopher

For me "reliable evidence" about the effects of health care will usually mean evidence derived from systematic reviews of carefully controlled evaluative research. Sometimes, when the effects of care are dramatic, such research is unnecessary. For example, carefully controlled research is not needed to show that if my cardiac ventricles start fibrillating it would be worth using a defibrillator to try to persuade them to behave more normally; or that if I become crippled by osteoarthritis of the hip joint, a prosthesis will probably relieve my pain and immobility. But most forms of health care, including the important but less tangible elements such as suggestion, have less dramatic effects than these. If these moderate but important effects are to be detected reliably then systematic reviews of carefully controlled research