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Standards of care in research

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established disease control programmes may help.[9] Harris advocates the same approach to expanding HAART in Malawi (p 1163).

That health gains can stem from supporting and educating women is a clear message that emerges in several guises. Priority setting based on listening and learning from individuals and communities who with support work creatively to provide their own solutions is another. The health sector in rich countries can also learn from the achievements of non governmental organisations, and the Bangladesh Rural Advancement Committee is a shining example (p 1124).

Difficult circumstances and scant resources fuel innovation, and strong inspirational leadership achieves a lot as many illustrative snapshots in this issue show (p 1125). Examples of successful health advocacy also exist. The People's Health Movement is a beacon in this respect (p 1127), and input from civil society is now seen as vital in the compilation of new strategies to strengthen health systems.

One of the unspoken messages of this week's issue is that we can't learn from things we don't hear about. The global conversation on health needs to be more equitable and extend beyond the health sector (p 1189). New initiatives are needed to give low income countries a stronger voice and better access to reliable relevant information.[10]

A final and important message health professionals and policy makers in rich countries can learn from observation of poorer ones is the importance of acting outside the health box. Health improvement in all countries depends on a concerted effort to tackle the global forces that undermine health (p 1192). It also depends on wider recognition of the determinants of health, foremost among which are poverty and inequity. Rich countries need to honour pledges made in grand international health arenas and pay more attention to how money is spent and who benefits.

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Standards of care in research

Should reflect local conditions and not the best western standards

Education and debate p 1179

The interpretation of "standard of care" in research has generated a lot of controversy among researchers. It has underpinned much of the debate on the use of placebos in randomised controlled trials such as the one around the zidovudine trials, which were proposed to prevent mother to child transmission of HIV infection in Africa. These trials entailed an evaluation of a short course treatment regimen in comparison with a control population receiving nothing.[1–3] A high profile debate ensued that led to a reconsideration of guidelines on international research as well and spurred initiatives to make low cost antiretroviral treatment available in developing countries.[4 5]

In October 2000, the World Medical Association modified the Helsinki declaration to state that "the benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods."[6] The Council for International Organizations of Medical Sciences guidelines took the debate a stage further by using the term "established effective therapy" to indicate a degree of consensus and acceptability among health professionals about the nature of treatment [7] But crucially, these guidelines did not specify if established effective therapy applies to a local or global context. Given the paucity of relevant health research in developing countries, aspiring for best standards of care may make research in these countries irrelevant and unsustainable.[8]

Total absence of care or health services cannot be considered a suitable control standard. Nor can harmful practices in a dysfunctional system, such as unsafe injections or female circumcision. Whether best

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standards of care should reflect the best available western care or an international standard of care is undecided. Recommendations and management protocols from the World Health Organization, the closest we have to international standards, do not cover all disorders and circumstances and assume a certain level of performance of health systems.

Two aspects of the debate need further consideration. Firstly, should the standard be a prevalent local standard or one that is ideal for that setting? Pragmatists regard this debate as one between what can be done versus what ought to be done in a given situation. Secondly, standards of care often refer to specific interventions or drugs that are being used in a trial and not to the overall care in a health system where other factors, such as support of the health system, may be equally important.

Standard of care therefore depends on the context. Furthermore, established interventions in the developed world may not withstand the scrutiny of cost effectiveness and sustainability in the developing world. For example, in the United States health expenditure per head is several times higher than in Sri Lanka, but does not yield proportionately greater health gains.[9] The prevalent standards of care in the United States cannot qualify as gold standards elsewhere on the basis of cost effectiveness alone.

This debate needs to be resolved in a manner that does not preclude further development of health systems through targeted research. It should permit pragmatic improvement rather than waiting for revolutionary changes in health systems that may never happen. The development of low cost alternative interventions is only possible through such a process.

Not doing locally relevant research deprives poor populations of the benefits of incremental improvement of care, and this is unethical. If a rigid yardstick had been used for research on oral rehydration therapy—at a time when intravenous rehydration was considered the gold standard—one of the greatest advances of the past century would not have been discovered. Similarly, Kangaroo Mother Care of low birthweight infants in Colombia and studies of domiciliary or community management of neonatal illness by community health workers in India evaluated innovative methods of caring for high risk infants, which fell below prevalent standards of care.[10 11 12] They were designed to research the benefits of low cost feasible alternatives. The existing public health system was the standard for comparison, and this was less than what could be provided in affluent urban settings. Other projects, such as cluster randomised trials or trials of vaccine effectiveness, are designed specifically to provide the kind of evidence that can move programmes forward in local settings.

The best way forward is to adopt a more flexible and pragmatic approach that allows existing guidelines to be interpreted in the context of the standards and quality of care available in local or comparable public health systems. Better still, the existing Helsinki and Council for International Organizations of Medical Sciences guidelines must suggest a contextual interpretation of the guidelines for standards of care in research.[6 7] The current stalemate among ethicists is not acceptable as it could impede the development of low cost alternatives in developing countries.

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Lessons from thalassaemia screening in Iran

Screening programmes must consider societal values

Primary care p 1134

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Most of the recent advances in medical genetics have been in basic science and technology. Experience of translating these into effective, population based interventions is limited, but the potential is great, especially for lower resource countries.[1 2] This is well illustrated by the experience of the national thalassaemia screening programme in Iran (p 1134), a comprehensive, primary care based programme for screening and genetic counselling. Since the programme's inception in 1996 premarital screening of 2.7 million couples has been carried out over five years, followed by genetic counselling of more than 10 000 couples who were found to be positive. This has resulted in a 70% reduction in the expected annual birth rate of affected infants.[3] For a vast, lower-resource country with a population of 68 million, this is a considerable achievement.

As low and middle income countries undergo demographic and epidemiological transition and infant mortality falls below 50/1000 live births,