pursue any additional requirements of Food and Drug Administration that might lead to such labelling. Thus, though this process exists it has rarely been used to alter labelling.

Recognising this failure and with the encouragement of the American Academy of Pediatrics, the FDA Modernization Act of 1997 (FDAMA) provided that manufacturers of drugs under patent could seek a six month patent extension for performing studies leading to labelling in children. Although six months may seem short, the financial windfall for many of these drugs is a strong incentive. Some manufacturers may choose to wait until patents are about to expire to initiate these studies. Concerns were raised over this approach when omeprazole (Prilosec, Losec) was studied in children after its success was well established in adults and received a patent extension giving them a potential "two billion dollar sales windfall."[5] This gives them more opportunity to pick drugs that are sure to be profitable to study in children. Unfortunately, drugs with limited potential for financial gain will not be studied even though they may have a potential benefit for children.

To level the playing field further, the Food and Drug Administration rules went into effect in 1999 permitting the agency to mandate paediatric studies if the product is likely to be used in a substantial number of children.[5] They may also decide that a meaningful therapeutic benefit to children exists and mandate studies.[6] As these regulations come into effect, President Bush is considering reversing these requirements under pressure from the pharmaceutical industry. We can only hope that the best interests of children are put first in his consideration.

The outcome of these changes at the Food and Drug Administration thus far is slightly encouraging. Several new drugs have included studies in children leading to labelling. On the other hand, some disappointing decisions have hurt the process. For example, recombinant activated protein C was approved for adults and had ample safety and pharmacokinetic data in children but was rejected for paediatric labelling on the presumption that mechanisms of severe sepsis were sufficiently different in children that efficacy could not be extrapolated from the data in adults. As a paediatrician, I find that an extreme view that may inhibit the use of a potentially beneficial therapy for children. Furthermore, there is increasing pressure by healthcare insurance providers to limit reimbursement only to labelled indications and populations. High technology drugs such as this come at a high price and limitations on payment will not help children.

Off label use of drugs is expanding for the paediatric population rather than decreasing.[7] The use of psychotropic drugs has literally exploded in behavioural and psychiatric practices in the United States. In some cases the off label use may be based on both age and diagnosis such as in attention deficit in children. Unfortunately it will take a concerted effort and a great deal of funding to correct this problem. For new drugs reaching the market we can hope that the Food and Drug Administration will continue to receive the authority to mandate consideration of children in addition to the carrot of patent extension to promote appropriate labelling for children and other disenfranchised populations.

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The FDA has announced that it will suspend the enforcement of the paediatric rule for two years while it examines its necessity. (*Pediatric News* 2002;36(4):60.)

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Quality care at the end of life

Should be recognised as a global problem for public health and health systems

Worldwide, 56 million people die each year, 85% of these in developing countries.[1 2] Yet little is known about the quality of care they receive at the end of their lives. The movement for improving the quality of care at the end of life is primarily focused on industrialised countries. Until it is seen as a global problem for public health and health systems, efforts to improve it will not make much impact in the world.

Public health

Quality of care at the end of life is a global public health problem because of the large number of people involved. If each death affects five other people in terms of giving informal care and grieving relatives and friends, the total number of people affected each year by end of life care is about 300 million, or 5% of the world's population.

Some of the interventions that could be used to improve care are in the realm of public health. These include large scale, culturally specific, educational programmes for public health workers and the public; population based strategies to destigmatise death and put it into the mainstream of health systems; and changes in social policies in relation to care for orphans.

BMJ 2002;324:1291–2

Improving care at the end of life will require research in public health. Of the many papers published on care at the end of life in the past decade, only a few have dealt with this problem in developing countries.

Health systems

Care at the end of life is a global problem for health systems because most people die in hospitals—at least in some countries[3]; research in palliative care has involved the organisation and delivery of palliative care services[4]; techniques such as rapid cycle change have been applied to improve the quality of care at the end of life; and accountability of managers of health systems and healthcare professionals is an important part of the solution.

More fundamentally, however, care at the end of life is a problem for health systems because improving its quality will rely on health information. Information about quality is recognised as a central concern of the health system, as exemplified by the report card movement. We have never seen information on care at the end of life on quality report cards. Why? Just as clinicians once put dying patients in the room at the end of the hall and never made rounds on them, health policy makers have kept the issue of care at the end of life outside the mainstream of their concerns.

There are data on mortality and other measures of quality of care, but there is no information on quality indicators for end of life care in the statistical appendices of the Word Health Organization's world health reports. There were also no measures related to end of life care among the performance measures of health systems in the world health report for 2000.

Even in Canada, which is recognised as a leader in health information, no information is available on the quality of care at the end of life for the 222 000 Canadians who die each year. In 2000 the Canadian senate recommended that the Canadian Institute for Health Information develop indicators for end of life care.[5] To our knowledge this is the first such recommendation, but it has not yet been implemented.

Two caveats

Simply applying Western perspectives on end of life care to developing nations is unrealistic and apt to fail. Any effort to improve the quality of care at the end of life in developing countries must be culturally based and include people from these countries. For example, traditional healers may serve as effective champions of care at the end of life in some settings because they are closely connected with shared values and community beliefs.

We live in a world where the life expectancy is about 80 years and rising for people in many developed countries and about 40 years and probably falling for people in some developing countries.[6] We have been asked, "In such an unjust world, where apparently the lives of many people in developing countries do not matter, why should their deaths?" This sets up a false dichotomy. If someone is condemned to a premature death because of the injustice of global health inequality, it is doubly unjust for that person to be condemned to an agonising death racked by preventable pain.

Way forward

We can improve the quality of care at the end of life in the world by (1) *Recognising care at the end of life as a global problem for public health and health systems*—The very conceptualisation of care at the end of life as a problem for global public health and health systems brings this issue into the mainstream of global public health. It then also falls under the scope of the WHO's initiatives on the performance of health systems.

(2) *Capacity strengthening*—We have recently outlined a vision for strengthening capacity in global health ethics, and this too should include attention to care at the end of life.[7] The Open Society Institute has made a major impact on capacity for addressing care at the end of life in the United States through its project on death in America. The time is right for a global effort at strengthening capacity in care at the end of life by creating a project on death in the world.

(3) *Information strategies*—No national health system to our knowledge systematically collects information on the quality of care at the end of life of its citizens. Countries with well developed health information structures, such as Canada, could make an important contribution. Case studies of developing countries would provide useful evidence on which to base any global effort to improve end of life care. We will know that the problem of care at the end of life has truly been globalised when the WHO devotes a world health report to care at the end of life and when indicators for such care are routinely included in its annual indicators of the performance of health systems.

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PS is supported in part by an investigator award from the Canadian Institutes of Health Research. We are grateful to Meg Droney for research assistance, Susan Murley for editorial assistance, and Eduardo Bruera, Miriam Hirschfeld, James Tulsky, and an anonymous reviewer for providing comments on an earlier draft of this article. A longer version of this paper was written as a working paper at the request of WHO.

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