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

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,

BMJ 2004;329:1115–7

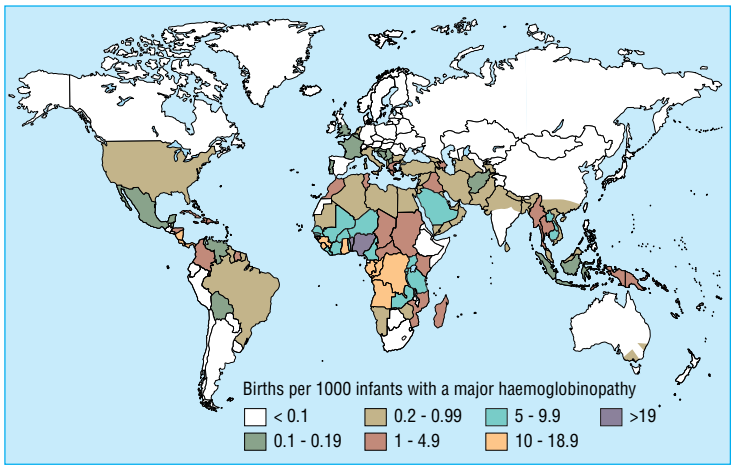
congenital disorders become increasingly visible and costly, contributing up to 30% of infant mortality in countries in the eastern Mediterranean region. Sickle cell disease and thalassaemia are a natural "point of entry" to genetics services for many such countries.[2] The thalassaemias are prevalent in the countries of the eastern Mediterranean region, South Asia, and South East Asia (figure). Thalassaemia major results in profound anaemia and death in infancy if untreated.

Regular monthly transfusions of red cells require much organisation and resources, and if death from iron overload is to be avoided in teenagers very expensive iron chelation treatment has to be offered in parallel. The burden on affected families is immense and the costs of treatments can overwhelm the health budgets of many countries where thalassaemia is common. In Iran, the estimated cost of treating 15 000 patients in 2000 was $200m.[5] Screening and offering termination of pregnancy provides a feasible practical option for such countries, although the challenge of organising comprehensive, effective programmes and gaining public acceptance is huge. The Iranian experience thus provides a good model to learn from.

Iran started its primary care thalassaemia prevention programme in 1996. The programme aimed to identify carrier couples before marriage and to offer counselling, thus providing them with the opportunity to separate. Prenatal diagnosis and the option of selective abortion were not available in the country at that time. By 1999, an audit showed that couples were still opting to marry rather than separate (which had been assumed would happen), and that the people affected wanted prenatal diagnosis and selective abortion. Widespread discussions ensued, and the law was amended in 2001 to allow the option of selective abortion up to 15 weeks' gestation for thalassaemia (a policy that is likely to be extended to include other serious congenital disorders). A national DNA laboratory network was therefore developed to offer prenatal diagnosis on chorionic villus samples.[3]

A key aspect of the programme was the holistic way in which the service was developed, with widespread public education, public health surveillance, and services developing in response to needs and wishes of the affected population and society in general. For example, the counsel of religious scholars informed the decision to accept 15 weeks as the limit at which a pregnancy could be terminated. The advice, based on the deliberations of Muslim scholars versed in Islamic law, is that the soul of the baby enters the womb at 120 days.[6] The debate regarding termination of pregnancy for thalassaemia is still in progress in several other Muslim countries including Egypt, Tunisia, and Maldives; Saudi Arabia as well as Pakistan have concluded that 17 weeks is the appropriate cut-off point.[2 7]

The Iranian programme provides lessons for high income countries too—for example, countries with minority ethnic communities that originate from areas of high prevalence, such as the United Kingdom, and countries with indigenous populations with high carrier rates, such as Italy. Western countries have been slow to adopt population based genetic screening. One reason for this may be that status and interest focus on "cutting edge" science rather than applying existing knowledge. Another reason may be the emphasis on the libertarian and individualistic meaning of "informed choice" without linking the societal debate to issues of the public's health and resources.



Distribution of haemoglobin disorders around the world

Services for haemoglobin disorders need to be equitable, accessible, and understood and accepted by all the subgroups involved. Services that are determined locally in a piecemeal fashion and vary according to the priorities of providers are far from ideal. In the United Kingdom late identification of risk and hence variable access to prenatal diagnosis has in effect limited choice to decide early in pregnancy whether to continue an affected pregnancy.[8] Iran adopted a well coordinated national approach in which screening is integrated with services for patients—an important lesson.

Although the results of Iran's programme are comparable with island based screening programmes in Greece, Cyprus, Sardinia, and Sicily[9 10] the feasibility of implementing similar national screening programmes for haemoglobin disorders in countries whose geographical, economic, social, and political milieu is very different to Iran remains to be determined.

At national level, the Iranian study raises many interesting questions that warrant exploration, for example, what happened to couples who separated? What is the impact of being identified as a carrier? How are carriers viewed by society? Other options for screening need to be considered too, for example testing for carriers in early pregnancy to avoid women being stigmatised or concealing their carrier status.[11 12]

It is already evident, however, that screening programmes for haemoglobin disorders must comply with societal values. The messages conveyed in community education need to be clear for the public to understand the programme's aims and objectives. The sickle cell screening campaign in the United States in the 1970s failed because it was insufficiently planned and poorly communicated. The differences between carrier status and the homozygous condition were misunderstood, resulting in carriers being stigmatised and screening being rejected by the populations targeted.[13]

Samavat and Modell's understated article stands as a model by which to consider implementing genetic screening programmes in lower resource countries, working through primary care. Iran is now planning to develop genetic services building on this model of service.[3] Perhaps the message to wealthier countries is

that much can be achieved by adopting a holistic approach with an integrated community perspective that responds to community needs, and that such countries should consider seriously investing more in the public health application of basic genetic science and technology for the population's benefit.

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Competing interests: AS is currently seconded as the programme director for the NHS Sickle Cell and Thalassaemia Screening Programme. AC has an academic link with Bernadette Modell and has recently coauthored a book chapter with her on medical genetics in developing countries.

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Health systems and the community

Community participation holds the key to health gains

Education and debate p 1166

The need to strengthen health systems in developing countries in the drive to reach the United Nations' millennium development goals is under the spotlight.[1] But one key component of health systems, the activities that take place in the community that have an impact on health, gets insufficient attention.

The World Health Organization's definition of health systems includes "all the activities whose primary purpose is to promote, restore, or maintain health."[2] Community participation in activities that improve the health of individuals, families, and communities should be an integral part of the health system. Such activities should be at the centre of any concerted action to improve health. Yet the community's role and participation are sidelined in most top-down health programmes—a reason why many international and national programmes fail to deliver.

Engaging local communities to participate in identifying their own health priorities spurs the development of innovatory culturally acceptable solutions with locally available resources. In Bolivia, a study using such participation in planning services for mother and infant care reduced perinatal mortality from 117 to 44 per 1000 births.[3 4] Manandhar et al in Nepal report a reduction in maternal and neonatal mortality associated with a positive change in behaviour among women, which included seeking appropriate medical help, institutional delivery, and use of clean delivery kit.[5] In an uncontrolled project in rural Kanpur in India, a participatory learning approach led to improved birth preparedness, better birth spacing, early initiation of breast feeding, and improved care seeking for maternal emergencies.[5]

Weak demand for services seems to be a major obstacle in attaining the health related millennium development goals.[6] Interventions which promote the demand for appropriate services linked to improvement in their provision could be the key to decisive gains in the quest for millennium development goals.

In this issue, Costello argues that community based strategies must be harnessed to save maternal and newborn lives (p 1166). Research supports that this is an effective way to improve neonatal survival in resource poor settings.[4 7–9] Evidence is also trickling in to support the notion that important gains in maternal health could accrue through community based interventions. In addition to the Nepal experience,[4] the Gadchiroli home based newborn care initiative documented an unexpected 50% reduction in maternal morbidity associated with the introduction of a community based programme involving traditional birth attendants and village health workers (A Bang, personal communication, 2004).

Health services can be classified into three categories.[10] Services focused on individuals—for example, skilled obstetric care—which require well resourced health systems. Outreach services providing, for example, immunisation and vector control, require periodic input from healthcare providers. Family and community services—many such services depend on implementing strategies that are known to promote behaviour that improves health, for example, breast feeding or safe sex. Unlike the first two categories, these services can be provided by community based organisations and commercial networks.

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