

## Health policy, legislation and biomedical ethics

### Health policy and legislation

Many developing countries have adopted health policies on an ad hoc or informal basis, with the result that policies are not memorialised in legislation and therefore have no force of law. Enacting policies with no underlying legislation often means policy initiatives are short-lived and can be easily repudiated by successive governments. Even where a country is firmly committed to its policies, rule of law and existing international agreements, it is not bound by a policy, much less programmes, that has not been enacted in appropriate and enforceable legislation.

International policies and financing agreements, in conjunction with domestic policies and legislation, also govern the medium- and long-term viability of major health programmes in developing countries. National health policies are often adopted in response to pressure from international donor organisations, including obligations to restructure country debt. A developing country seeking to relieve debt under the Highly Indebted Poor Countries Initiative, including entering into Poverty Reduction Strategy Papers and related agreements, is by definition constrained by available resources and requires donor funding to meet its public health care obligations.

This situation can be compounded by additional international or external donor requirements defining terms of reference for funding of developing country programmes. Too often the net result for a country receiving donor funding is that policies and programmes are implemented without any enabling statutory infrastructure to ensure their medium- and long-term viability.

Health Partners International has worked closely with a number of national and state governments and ministries of health to develop legislative frameworks and incorporate health policies in law, including broad enabling legislation and more specific regulations. Despite general international acceptance of health principles, integrating health policies and developing an enforceable statutory framework are necessarily complex processes because each country has a unique constitutional, legal and health development history.

In the course of our work we identify the following steps towards crafting enforceable legislation:

- Consultation with the Ministry of Health and other relevant ministries
- An initial review of the country's structural constraints,

including those related to international financing requirements, the national constitution, national, state and local government policies, overarching legislation and regulations, as well as the country's health service structures and capacity for delivery

- Development of policy, including consultation with government and a broad range of stakeholders on policy drafts, revisions and the formal adoption of health policy
- Development of enabling legislation based on formalised policy, consultation with government and a broad range of stakeholders on legislative drafts and revisions, compliance with executive and parliamentary procedures and the passage and enactment of legislation
- Development of regulations to amplify enabling legislation
- Creation of underlying legal instruments, for example Performance Management Agreements, Service Level Agreements and Memoranda of Understanding, required for the day-to-day enforcement of legislation and ministry of health requirements
- Provision of training to implement legislation.

As examples, in **Nigeria** Health Partners worked with the Enugu state Government and Jigawa state Government to provide the legal infrastructure for a viable and functional district health system as part of the Partnership for Transforming Health Systems (PATHS) programme. In consultation with the relevant Commissioners, Permanent Secretaries for Health, and numerous other stakeholders, our consultant developed the draft Enugu State Health Bill in 2004 and the Gunduma Health Systems Act, 2007 for Jigawa state. During this process, our Consultant developed a comprehensive legal opinion on the constitutionality and legality of the Bill and Act under the Nigerian Constitution and related legal infrastructure, including the pending Federal Health Bill.

In **Malawi** Health Partners developed a comprehensive policy and statutory framework conducive to implementing reform to guide central hospital reform; reviewing the roles of academic institutions and research organisations in promoting service delivery; negotiating new agreements to operate at central hospitals; and reviewing control of research in Malawi. This included developing the National Health Policy and Malawi National Health Bill to address a wide range of issues, including international financing agreements, targets under the Highly Indebted Poor Countries Initiative, decentralisation of health service delivery, the use of the Sector-Wide Approach, control of health-related research (see below) and meeting Millennium Development Goal targets.

## Health legislation and biomedical ethics

With the international proliferation of clinical drug trials, multinational institutions in the private, non-governmental, educational and public sectors are seeking environments with willing research study participants, cheaper costs and less stringent laws and regulations. These factors make developing countries very attractive research destinations. Although research has contributed additional resources in many developing countries, in some instances they have also diverted scarce financial, human, infrastructure and equipment resources from health service delivery to research initiatives.

Despite international biomedical ethics principles focused on and unanimously affirming the fundamental need to protect human research participants, some developed country research interests have skirted the edges of international biomedical ethics guidance principles developed since the Nuremberg Code in 1947<sup>1</sup>. It is critical that developing countries permitting externally funded research have a policy *and* the statutory authority to protect, failing which these countries will be unable to enforce their interests and those of research study participants.

Research initiatives and technological innovations offered by wealthier countries are often very attractive to developing countries. In the context of an often extreme disparity in financial, human, facilities and equipment resources, many developing countries opt for the benefits of research and innovation. Only later do they become aware of the long-term consequences and sometimes substantial costs (financial and other) to research study participants and local partners. Where these hidden costs are considered, generally they are only addressed in informal agreements with no force of law.

Without adequate legislation and enforcement powers, an under-resourced country lacks the ability to negotiate and protect its interests and balance wealthier countries' initiatives and innovations against the developing country's health needs. The fact that a wealthier country usually has greater access to information throughout a research study or initiative (for instance, owning any data generated by the research) further complicates the issues.

Where hidden costs are considered they are often only addressed in informal agreements with no force of law. Without adequate legislation or internationally viable contracts and enforcement powers, an under-resourced country will lack the ability to negotiate and protect its interests, and balancing wealthier countries' resources, initiatives and innovations against the developing country's interests. These issues are complicated by the extent to which asymmetric information governs research studies and technological innovations from their inception to completion.

Health Partners works with developing country health ministries, institutions and professionals to create practical short-, medium- and long-term solutions to problems arising from externally-funded biomedical research initiatives. Services we offer include:

- Assessing benefits and costs inherent in accepting externally funded research, including the range of positive and negative impacts on health service delivery
- Determining what bearing, if any, taking part in research studies will have on the capacity of a government or ministry to deliver health services and meet targets in terms of a country's Poverty Reduction Strategy Paper or other agreements with the World Bank or International Monetary Fund and participation in the Highly Indebted Poor Countries Initiative
- Addressing, where applicable, the extent to which national health priorities, including debt relief targets, are defined in a Poverty Reduction Strategy Paper and whether research studies contribute to or drain resources required to meet these targets
- Addressing, where applicable, the extent to which the developing country is in a realistic position to meet Millennium Development Goal targets, and whether research studies contribute to or drain resources required to meet these targets
- Transferring essential knowledge about international biomedical ethical guidance principles
- Creating an awareness of wealthy, developed country laws governing research sponsors in developing countries to ensure compliance by sponsors with their home countries' legal requirements while conducting research elsewhere
- Developing skills and expertise required by the developing country to negotiate with sponsors that have superior resources for the protection of the interests of research study participants and the country
- Working with the health ministry and any other relevant government institution to establish terms of reference recommended in international biomedical ethics guidance principles for the development of effective developing country research ethics committees  
Working with the relevant health ministry to draft viable policies and accompanying legislation to enable the developing country to ensure the full force of law is behind its policies
- Developing underlying legal instruments to establish the parameters of research, defining required protection mechanisms for research study participants and ensuring that the interests of the developing country government are protected
- Working with the health ministry to enable it to take appropriate action for the protection of its interests and those of research study participants where an externally sponsored biomedical research study is acting outside

permissible parameters.

Biomedical research initiatives undertaken by Health Partners include:

- Establishing the rights of developing country governments to address externally funded research
- Developing comprehensive biomedical ethics policies to protect the developing country's interests and those of research study participants while creating an attractive well-regulated environment for developed country research sponsors
- Developing comprehensive enabling legislation, with secondary regulations, to ensure the full protection of the country's interests and people
- Creating relevant legal instruments establishing parameters of research, defining protections for research study participants and ensuring that the interests of the developing country government are protected.

As an example, Health Partners worked with the **Malawi** Ministry of Health and other stakeholders to develop a biomedical research and ethics policy, which forms a chapter in the Malawi National Health Bill.

The paramount goal of Health Partners is to work closely with all relevant stakeholders to meet the interests defined by the government and ministry of health to ensure policies and the statutory authority, with relevant underlying legal instruments, to protect the health interests of the country.

\* References: Ethical and policy issues in research involving human participants (2001) United States National Bioethics Advisory Commission guidance; Ethical and policy issues in international research: clinical trials in developing countries (2001) United States National Bioethics Advisory Commission guidance; Nuffield Council on bioethics report on The ethics of research related to health care in developing countries (2002); Nuffield Council on bioethics follow up discussion paper on The ethics of research related to health care in developing countries (March 2005).