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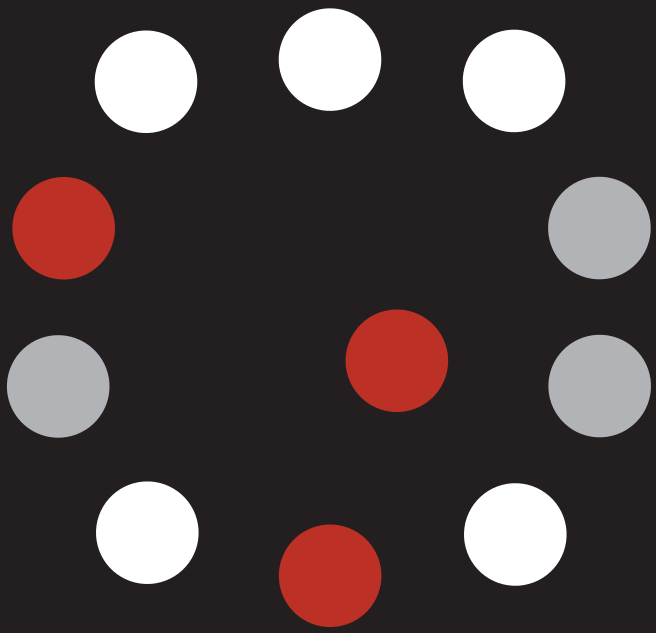
A. KARAN & G. SODHI

# PROTECTING THE HEALTH OF THE POOR

## Social Movements in the South



PROTECTING THE HEALTH OF THE POOR A. KARAN & G. SODHI

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# PROTECTING THE HEALTH OF THE POOR

## SOCIAL MOVEMENTS IN THE SOUTH

*edited by Abraar Karan and Geeta Sodhi*

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To the girls and women of the Perna tribe with whom I worked during my time in India: your courage inspires me every single day. AK

With immense gratitude to all those, in my personal and professional life as well as in the communities where I worked, who have believed in my intent and ability to contribute. GS

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# ACKNOWLEDGEMENTS

We would, first and foremost, like to acknowledge that this volume has been the product of hundreds of hours of extremely hard work, possibly thousands of emails, and several dozen Skype calls across the world – that even the effort to bring this product together was a truly global affair. There are particular people who must be specifically mentioned for their support: Dr Thomas Pogge, for bringing us all together to work on this project, serving as a guide and leader throughout the process, and for imparting to us his immense wisdom and brilliance; the CROP Secretariat team – most notably, Inge Tesdal, Jakob Horstmann, and Charlotte Lillefjære-Tertnæs, for coordinating what was an extremely complicated exchange of edited drafts, email correspondences, and general management; Torill Bull, who organized the hugely successful New Delhi workshop and conceptualized the volume from its infancy; Dr Juliana Martínez-Franzoni, for reviewing the first draft of the manuscript and providing extremely useful suggestions for its improvement, both intellectually and structurally; all of the authors, for their generous cooperation and unmatched dedication toward their intellectual contributions and the work that lies behind these chapters; the publisher, Zed Books, for bringing this work to life, so that it can be shared with thousands of others; and the poor living and surviving around the world whose stories and struggles are at the heart and soul of this volume.

## SELECTED ABBREVIATIONS AND ACRONYMS

| | |
|---|---|
| ACTIVITY | Advancing Cessation of Tobacco in Vulnerable Indian Tobacco Consuming Youth |
| AoA | Agreement on Agriculture (WTO) |
| ART | antiretroviral therapy |
| CDC | Center for Disease Control and Prevention (US) |
| CESCR | Committee on Economic, Social and Cultural Rights (UN) |
| CHP | Compulsory Health Plan (Colombia) |
| CSO | civil society organization |
| FAO | Food and Agriculture Organization of the United Nations |
| FDA | Food and Drug Administration (US) |
| FGD | focus group discussion |
| FTA | free trade agreement |
| GATT | General Agreement on Tariffs and Trade |
| GIC | General Insurance Corporation (India) |
| HAART | highly active antiretroviral therapy |
| HDI | Human Development Index (UN) |
| HIF | Health Impact Fund |
| HIV/AIDS | Human Immunodeficiency Virus Infection and Acquired Immune Deficiency Syndrome |
| HRIDAY | Health Related Information Dissemination amongst Youth (India) |
| ICDS | Integrated Child Development Services (India) |
| ICESCR | International Covenant on Economic, Social and Cultural Rights |
| IMF | International Monetary Fund |
| IMR | infant mortality rate |
| INVIMA | National Institute of Food and Drug Monitoring (*Instituto Nacional de Vigilancia de Medicamentos y Alimentos*) (Colombia) |
| IPR | intellectual property rights |
| LDCs | less/least developed countries |
| LMICs | low- and middle-income countries |
| MDGs | Millennium Development Goals |
| MMC | Malegaon Municipal Corporation (India) |

| | |
|---|---|
| MMR | maternal mortality ratio |
| MNH | maternal and newborn health |
| MSF | Médecins sans Frontières |
| NACP | National AIDS Control Programme (Uganda) |
| NAFTA | North American Free Trade Agreement |
| NFHS | National Family Health Survey (India) |
| NGO | non-governmental organization |
| NRHM | National Rural Health Mission (India) |
| NTCP | National Tobacco Control Programme (India) |
| OECD | Organisation for Economic Co-operation and Development |
| OOP | out-of-pocket |
| PEPFAR | US President's Emergency Plan for AIDS Relief |
| PPP | public–private partnership |
| R&D | research and development |
| RECOLVIH | Colombian Network of People Living with HIV (*Red Colombiana de Personas Viviendo con VIH*) |
| SAGE | Study on Global AGEing and Adult Health |
| SES | socio-economic status |
| SIC | Superintendent of Industry and Trade (*Superintendencia de Industria y Comercio*) (Colombia) |
| TASO | The AIDS Support Organization |
| TCC | tobacco cessation clinic |
| TRIPS | 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights |
| UNAIDS | Joint United Nations Programme on HIV/AIDS |
| UNASUR | Union of South American Countries |
| UNCTAD | United Nations Conference on Trade and Development |
| UNDP | United Nations Development Programme |
| UNGASS | United Nations General Assembly Special Session |
| UNICEF | United Nations Children's Fund |
| USAID | US Agency for International Development |
| VCT | voluntary counselling and testing |
| WHA | World Health Assembly |
| WHO | World Health Organization |
| WTO | World Trade Organization |

# FOREWORD

*Thomas Pogge*

This book contains a set of sophisticated essays that seek to employ intelligent academic analysis to help change the world for the better. Such work brings together four elements, memorably abbreviated as DEAR.

*Description.* Each essay describes a particular local health deficit and thereby reminds us of the staggering health inequalities that have accumulated in our world. While the vast majority of people in the richer countries, and also rich minorities in the poorer countries, live without serious health problems well into their 70s or 80s, ill health remains a persistent reality for the world's poor, who continue to die prematurely in large numbers, often as children or as a consequence of pregnancy or childbirth. While these deepest of inequalities become more pronounced, both globally and within most countries, they are also becoming less visible as the world's comfortable minority is increasingly segregating itself from the poor. The essays remind us that – despite the remarkable global health focus of the last fifteen years (featuring the Millennium Development Goals, the Bill and Melinda Gates Foundation, the Global Alliance for Vaccines and Immunization, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and the United States President's Emergency Plan for AIDS Relief) – life among the world's disadvantaged still all too often is (in Hobbes' famous phrase) 'poor, nasty, brutish, and short'.

*Explanation.* Each essay then contributes to a diagnosis of the problem in focus: why does the health deficit persist? Such explanations are complex and vary from case to case. But prominent factors in many of the essays here collected are shortfalls in local public health systems. In the poorer countries, public health systems are chronically short of resources, for four main reasons. First, they struggle against a much larger burden of disease, aggravated as it is by inadequate nutrition,

clothing, shelter and sanitation, dirty water, rampant threats from parasites and infectious diseases, climate change and its associated extreme weather events, poor education, as well as poor and often deliberately corrupted regulation of resource extraction, manufacturing, construction, traffic, tobacco, food, drugs, and the like. Second, most patients in poor countries do not have the means to purchase health insurance or to substantially contribute to their own needed medical expenses; and the public health system therefore contributes a higher proportion of national health spending. Third, poor-country public health systems receive a much smaller percentage of their country's gross domestic product (GDP) – typically around 3 per cent versus 8 per cent in the developed countries.[1] This discrepancy is in good part due to the fact that poor countries' most capable taxpayers – their own wealthy class and especially multinational corporations – have been extremely adept at dodging their tax obligations with the help of an extensive network of tax havens, secrecy jurisdictions, lawyers, bankers, accountants, and lobbyists.[2] Fourth, poor countries also have a much smaller GDP per capita than rich countries. While annual GDP per capita is around $50,000 in the more affluent countries, it is about one thirtieth of this ($1,700) in India and below $1,000 in twenty African countries.[3] Despite severe funding shortages, public health systems increasingly face first-world prices – not merely for medical equipment, but also for patented medicines (after the Trade-Related Aspects of Intellectual Property Rights, Annex 1C of the Agreement to form the World Trade Organization, forced developing countries to greatly strengthen their patent protections for new pharmaceuticals) and even for medical personnel (in order to slow the massive brain drain that siphons off doctors and nurses into the richer countries). Severely underfunded, public health systems in the poorer countries are often also beset by discrimination and corruption, withholding needed medical care from those who are most in need and legally entitled to it.

*Assessment.* Each essay also contributes to the moral assessment of the local health deficit it analyses, examining the problem through a human rights lens, for example, and then also exploring the correlative responsibilities on the part of the agents involved in creating and perpetuating the social conditions that aggravate the relevant local health deficit. It is no great insight, of course, that bad health is morally undesirable. But it is anything but trivial to work out which

health problems manifest social injustice and which constitute human rights deficits or even human rights violations. And it is even harder to allocate moral (and legal) responsibility for socially produced and socially avoidable health problems. Of special interest in this context is the distinction among the various causal pathways on which agents and institutional arrangements may be contributing to the emergence and perpetuation of health problems. Here a simple distinction is that between (actively) bringing about ill-health problems versus (passively) failing to avert or alleviate it. But this distinction is far too simple to capture everything that is morally significant about such a causal influence, especially in the case of institutional arrangements. Thus, a system of national or supranational rules can have an effect on population health by:

- requiring that certain people be excluded from specific essential nutrients or pharmaceuticals or medical procedures;
- legally authorizing such discriminatory barriers as practised by firms or private-sector medical personnel;
- failing to enforce legal restrictions against such private discriminatory practices;
- engendering excessive economic inequalities that foreseeably deprive many of the opportunity to access needed nutrients, pharmaceuticals, or medical procedures;
- avoidably failing to mitigate the adverse health effects of natural causes (such as a flood or earthquake);
- avoidably failing to address congenital health problems; or
- avoidably failing to address self-caused health problems (e.g. due to tobacco consumption).

Holding fixed the dimensions of the resulting health deficit as well as the various costs of avoiding it, the moral assessment of the relevant causal contribution to it will still vary across these diverse causal pathways.[4]

*Reform.* The final purpose of these essays is reform: to provide guidance on how crucial health deficits in the poorer countries are to be eradicated or at least curtailed. The discussion of reform builds upon the preceding elements. It builds, most directly, upon the element of *Assessment* which reveals which humanly avoidable health

deficits are morally most problematic from the standpoint of, and ought therefore to be prioritized by, some particular agent or class of agents (who may, of course, also be confronted with other moral claims on their attention and resources). *Assessment* in turn depends heavily on *Explanation*, which identifies the causal factors involved in the creation and perpetuation of a health deficit as well as the nature of the contributions these factors are making. And *Explanation* obviously depends on an accurate and comprehensive *Description* of the health deficit in question. *Reform* also has a more direct link to *Explanation* in that it calls for careful planning that involves a broad analysis of how the reformed conduct or policies or institutional arrangements would affect the health deficit under consideration as well as other morally significant parameters. One such parameter, discussed in many of the here-assembled essays, is the agency and empowerment of the people whose avoidable health problems are in focus. Any reform should ideally be informed by their understandings, needs, preferences, and values, should treat and establish them as equals in their communities, and vis-à-vis the 'reformers', and should empower them to defend, continue, and eventually help lead the reform process. Success in such an ambitious reform project requires a detailed causal understanding (*Explanation*) that extends well beyond the way things are into an analysis of how things would be if specific reform steps were successfully implemented.

We can learn a great deal from these essays – about health deficits and opportunities in the developing countries as well as, more generally, about how to think well about how to change the world for the better. For sure, such change is badly needed.

## Notes

1 See World Bank at http://data.worldbank.org/indicator/SH.XPD.PUBL.ZS

2 See T. Pogge and K. Mehta (2016) *Global Tax Fairness*, Oxford: Oxford University Press.

3 Country data as provided by the United Nations, the International Monetary Fund, and the World Bank are collated by Wikipedia at https://en.wikipedia.org/wiki/List_of_countries_by_GDP_%28nominal%29_per_capita

4 For a fuller discussion, see my (2004) 'Relational conceptions of justice: Responsibilities for health outcomes', in S. Anand, F. Peter, and A. Sen (eds) *Public Health, Ethics, and Equity*, Oxford: Clarendon Press, pp. 135–61.

# INTRODUCTION

*Abraar Karan and Geeta Sodhi*

> [H]ealth deprivation is really the most central aspect of poverty. (Amartya Sen, Nobel Laureate)

> The poorest parts of the world are by and large the places in which one can best view the worst of medicine and not because doctors in these countries have different ideas about what constitutes modern medicine. It's the system and its limitations that are to blame. (Dr Paul Farmer, founder of Partners in Health)

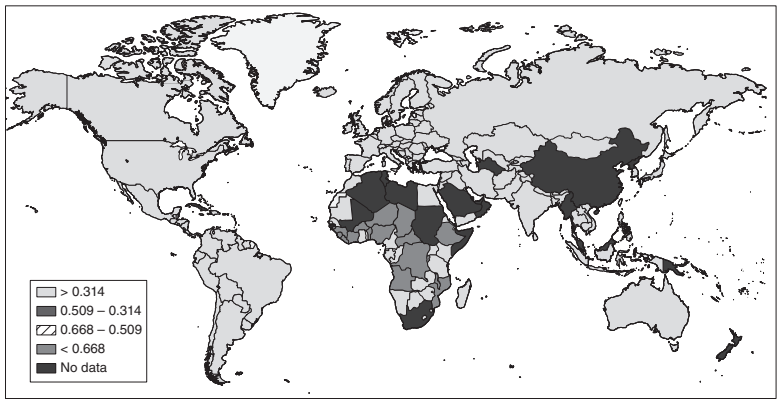
The right to health was first enshrined as a fundamental human right in the constitution of the World Health Organization (WHO) in 1946. Although international conventions have repeatedly upheld it for almost seventy years, no consensus has been reached about what 'health' means, what entitlements are guaranteed, and who has the duty of safeguarding access. Some protest that the conceptualization of health as a human right is irredeemably flawed: no government could ban a virus from spreading, or legislate a diseased human body to cure itself. If 'health' is interpreted as 'health care', however, then governments could ensure that their citizens have access to adequate medical information, effective prevention programmes, and safe treatments. But what minimum standards would these programmes have to meet? Does the right to health imply that health care must be comfortably affordable? And what responsibilities for protecting this right fall upon governments, corporations, and individuals themselves?

This volume brings together experts from around the world, including academics and in-the-field actors, who vigorously uphold the right to health as a universal human right and who consider poverty to be the greatest obstruction to this right. Poverty is distinguished by a low purchasing power, which restricts access to fee-for-service healthcare systems. It is linked to low education status and literacy levels, which impede the ability and capacity of the poor to access health care. Societal factors, such as the lower status of women

globally, can further hinder access for impoverished subpopulations. For the poor, barriers to health are posed by microeconomic realities at the household level, the larger sociocultural context that influences decision-making behaviours, political and economic environments at a national level, and variable geopolitical conditions.

The economic and social dimensions of development converge on health. If poverty is understood and recognized in terms of *deprivation*, not simply in terms of *economics*, then poor health can even be an effective metric of poverty. However, health is difficult to quantify. In 1990, the United Nations formulated the Human Development Index (HDI) to measure the 'development' of countries with reference to health (life expectancy at birth), education (actual and expected years of schooling), and living standards (gross national income per capita). It continued to use the HDI in the *Human Development Report* 2011 (UNDP, 2012). The findings are reproduced in Figure I.1, but this blunt tool does not reveal that there are many countries in 'developed regions' with a low HDI (for example Haiti), or that there is significant internal variation of development, income distribution, and human rights fulfilment within countries. To allow for development and inequality levels to be tracked both within and across countries, the United Nations developed a new index, the Inequality-Adjusted HDI (IHDI), in 2010 (Figure I.2). The striking results revealed that internal inequality often exists alongside a staggering lack of development within specific regions. The United States, for example, has an HDI of

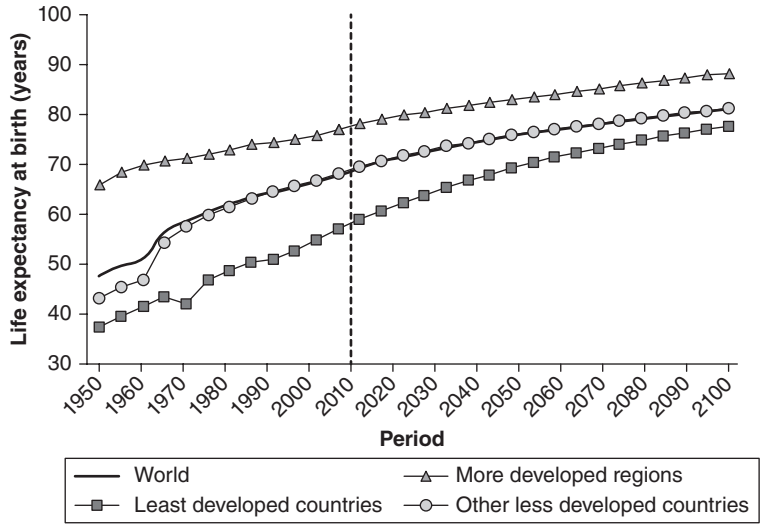

**I.1** HDI values around the world, 2011 (*source*: UNDP (undated))



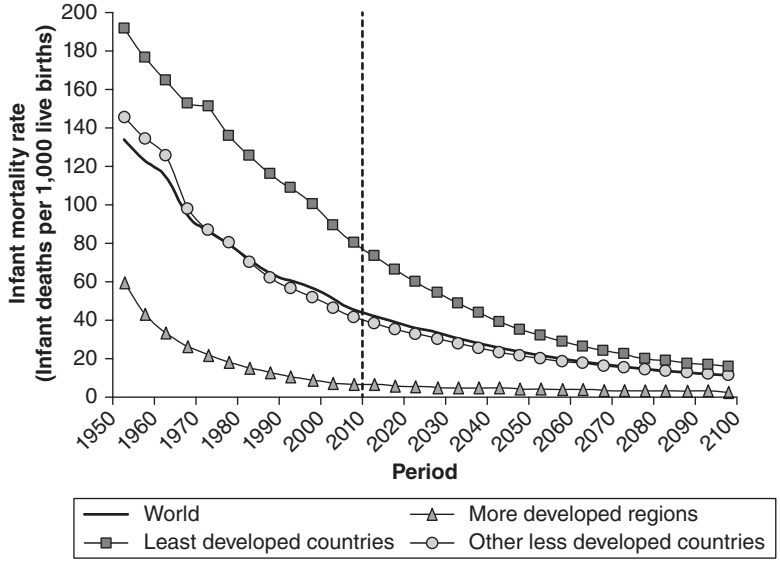

**I.2** IHDI values around the world, 2011 (*source*: UNDP (undated))

0.955 and an IHDI of 0.755, indicating a discrepancy between overall and internal levels of development.

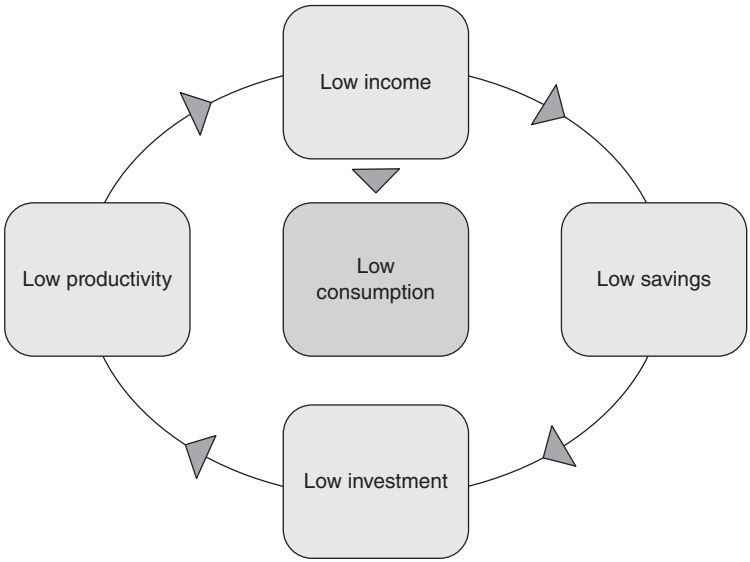
These indices acknowledge that health is at the core of development. Most health indicators show that people in low HDI countries are significantly worse off than their high HDI counterparts. In low HDI countries, life expectancy is much lower (Figure I.3) and the infant mortality rate is much higher (Figure I.4). In fact, according to the United Nations *World Mortality Report* 2011 (DESA, 2012b) and WHO (2012), conditions that have been eradicated or are rarely fatal in high HDI countries, such as pneumonia and diarrheal diseases, remain major causes of death in low HDI countries (Table I.1). Wealthier countries tend to make long-term investments in preventative care and routine check-ups, and often have insurance and social welfare schemes to protect their citizens from succumbing to medical catastrophe. In contrast, as a result of their limited resources, the poor often see a physician once their disease is too advanced for treatment, or once it is only treatable via expensive interventions (Sachs, 2006). Moreover, the fee-for-service systems prevalent in many of the low HDI settings result in poorer patients spending significant amounts of their own money on catastrophic care. Because ill health makes individuals less productive, it can further lower income and accelerate poverty cycles (Figure I.5). From the individual to the national levels, poverty infringes on the right to health, which in turn causes poverty – and the cycle continues.




**I.3** Life expectancy at birth by development group, 1950–2100 (*source*: DESA (2012b))




**I.4** Infant mortality rate by development group, 1950–2100 (*source*: DESA (2012b))




**1.5** Vicious cycle of poverty (*source*: World Bank (2004))

## Responsibilities for the right to health

The drastic inequity in major health indicators does not point to variations in medical care alone, but to the interlinked social, political, and economic dimensions of poverty, global health agendas and trade or foreign policy priorities, and the political economy and investments in public health by national governments.

Even as initiatives such as the Oslo Ministerial Declaration reiterate that global health is an important foreign policy issue, the global governance systems remain inadequate in addressing difficulties emanating from conflicts between global health agendas and foreign and trade policy priorities. Tobacco control is a case in point, with efforts and investments in combatting the tobacco pandemic challenged by trade and foreign policy priorities. Global health, in its nascent stage, is essentially a concept waiting to evolve into a discipline. Also, for global health to be fully realized, effective governance systems and structures need to be put in place. The lack of these systems and structures results in the more powerful states continuing to forfeit trade agreements and thus contributing to poor health amongst the already deprived/less privileged nations. An unfettered tobacco industry and the tobacco pandemic is the result of this reality.

TABLE I.1 Leading causes of death contributing to the difference in life expectancy at birth ('survival gap') between selected regions and the longest-lived populations, 2005–10

| Rank | Cause of death | Survival gap (yrs) | Rank | Cause of death | Survival gap (yrs) | Rank | Cause of death | Survival gap (yrs) | Rank | Cause of death | Survival gap (yrs) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Africa** | | | **Developing Oceania** | | | **Asia** | | | **Latin America and the Caribbean** | | |
| *Middle Africa* | | | | | | *South-central Asia* | | | *Caribbean* | | |
| 1 | Pneumonia | 4.7 | 1 | Heart diseases | 4.3 | 1 | Heart diseases | 2.7 | 1 | Heart diseases | 1.9 |
| 2 | Perinatal conditions | 4.1 | 2 | Perinatal conditions | 1.8 | 2 | Perinatal conditions | 2.6 | 2 | Perinatal conditions | 1.4 |
| 3 | Heart diseases | 3.4 | 3 | Pneumonia | 1.8 | 3 | Diarrhoeal disease | 2.4 | 3 | HIV/AIDS | 1.0 |
| 4 | Diarrhoeal disease | 3.1 | 4 | Stroke | 1.6 | 4 | COPD | 2.0 | 4 | Stroke | 0.9 |
| 5 | HIV/AIDS | 2.8 | 5 | COPD | 0.8 | 5 | Pneumonia | 1.7 | 5 | Pneumonia | 0.9 |
| *Southern Africa* | | | | | | *South-eastern Asia* | | | *South America* | | |
| 1 | HIV/AIDS | 14.2 | | | | 1 | Heart diseases | 2.4 | 1 | Heart diseases | 1.7 |
| 2 | Pneumonia | 2.8 | | | | 2 | Stroke | 1.6 | 2 | Perinatal conditions | 1.0 |
| 3 | Heart diseases | 2.2 | | | | 3 | Pneumonia | 1.5 | 3 | Homicides | 0.8 |
| 4 | Perinatal conditions | 2.0 | | | | 4 | Perinatal conditions | 1.3 | 4 | Stroke | 0.6 |
| 5 | Diarrhoeal disease | 1.9 | | | | 5 | Tuberculosis | 0.9 | 5 | Pneumonia | 0.6 |
| *Western Africa* | | | | | | *Western Asia* | | | *Central America* | | |
| 1 | Perinatal conditions | 3.7 | | | | 1 | Heart diseases | 4.5 | 1 | Diabetes | 1.5 |
| 2 | Pneumonia | 3.7 | | | | 2 | Stroke | 1.6 | 2 | Heart diseases | 1.1 |
| 3 | HIV/AIDS | 3.3 | | | | 3 | Perinatal conditions | 1.3 | 3 | Perinatal conditions | 0.8 |
| 4 | Heart diseases | 3.2 | | | | 4 | COPD | 0.5 | 4 | Homicides | 0.6 |
| 5 | Diarrhoeal disease | 2.7 | | | | 5 | Pneumonia | 0.4 | 5 | Nutritional deficiencies | 0.4 |

| *Eastern Africa* | | |
|---|---|---|
| 1 | HIV/AIDS | 5.3 |
| 2 | Perinatal conditions | 3.2 |
| 3 | Pneumonia | 3.0 |
| 4 | Heart diseases | 2.9 |
| 5 | Diarrhoeal disease | 2.2 |
| *Northern Africa* | | |
| 1 | Heart diseases | 4.3 |
| 2 | Perinatal conditions | 1.7 |
| 3 | Stroke | 1.4 |
| 4 | Pneumonia | 1.1 |
| 5 | Diarrhoeal disease | 0.6 |

| *Eastern Asia* | | |
|---|---|---|
| 1 | Stroke | 2.4 |
| 2 | COPD | 1.8 |
| 3 | Perinatal conditions | 0.8 |
| 4 | Heart diseases | 0.7 |
| 5 | Cancers | 0.4 |

**More developed regions**

| *More developed regions, excl. Eastern Europe* | | |
|---|---|---|
| 1 | Heart diseases | 0.9 |
| 2 | COPD | 0.2 |
| 3 | Perinatal conditions | 0.1 |
| 4 | Road traffic accidents | 0.1 |
| 5 | Homicides | 0.1 |

| *Eastern Europe* | | |
|---|---|---|
| 1 | Heart diseases | 5.9 |
| 2 | Stroke | 2.4 |
| 3 | HIV/AIDS | 0.6 |
| 4 | Road traffic accidents | 0.3 |
| 5 | Perinatal conditions | 0.3 |

*Source:* DESA (2012a)

These issues, which are shaped by the changing priorities and funding levels of the healthcare sector under each governmental administration, are determined by politics rather than by recognition of health as a right. National-level political economies shape the broad framework of national health policies and the details of their formulation, approval, and implementation. They also determine what role, if any, civil society can play in shaping health policy and facilitating access to health care for all. Although many international declarations and covenants, whether binding or informal, have recognized health as a human right, the countries that are governed by them interpret their obligations and duties to ensure the right to health in a wide variety of ways.

Depending on the political situation, national healthcare systems can prevent the need for catastrophic spending (defined as 10 per cent of a household budget) on health care. In many high HDI countries in which social welfare and high taxation are economically and socially feasible, such as Scandinavia, Spain, and the United Kingdom, single-payer healthcare models have been adopted, typically on the assumption that health is a human right for which the government is responsible. In many low HDI countries, as well as in some high HDI countries, the collection of tax revenue is greatly hindered by mass participation in an informal workforce. The resulting revenue shortfalls, sometimes coupled with the government's failure to recognize health as a human right, lead to inadequate government spending on welfare programmes. This in turn causes the poor to be left to fund their own health care and fall prey to loan sharks and/or suffer extreme poverty (Ir et al., 2012). This healthcare deficit can be filled by international organizations, non-governmental organizations (NGOs), civil society organizations (CSOs), etc., but their roles are subject to fluctuations in national-level politics.

In many countries, social and cultural barriers to health care can be as devastating as the economic costs. The best-known example may be the HIV/AIDS epidemic in sub-Saharan Africa: access to services often requires financial resources for treatment (although there are some free clinics), as well as social support to overcome the stigma (Matovu and Makumbi, 2007). The result is a hidden epidemic of HIV-positive men and women who are never diagnosed, greatly complicating the already difficult challenges of HIV/AIDS prevention and treatment. Uganda began to overcome this only through a prolonged high-publicity campaign led by national political leaders, and a programme

of free testing and treatment, exemplifying how national politics can lessen both social and economic impediments to health care. The health of the global poor can also be influenced by deeply held beliefs and cultural mores that are inconsistent with the Western treatment paradigm, which can complicate treatment and intervention strategies that are devised by actors unfamiliar with the populations whom they are hoping to help. Thus a strong partnership between local parties and international aid groups is a must when addressing complex global issues, and this union needs to collectively strategize a home-grown solution that utilizes external resources.

Still, it is important to remember that international and national bodies are far from the only actors involved in health rights; the private sector, and civil society itself, have a large influence in the health of the nation as well. While national governments are normally responsible for development concerns, such as clean water, sanitation systems, transportation infrastructure, and access to primary care in rural areas, many of these spheres are heavily affected by the actions of public and private entities. In many countries, the world has witnessed an aggressive private sector acting against the collective interest of citizens. For example, large pharmaceutical giants can leverage patent law to control the cost of pharmaceutical drugs, while healthcare technology companies can do the same with novel therapeutic inventions, which essentially guarantees the exclusion of the poor from accessing high-quality medicine. Moreover, instances of public–private collusion, such as may have been the case in several global responses to pandemic infections, further highlights the reality that health care is dictated by market forces. These forces exacerbate systemic problems and ensure that the poor, who are particularly vulnerable to exploitation, remain sick, fee-paying customers in a profit-seeking healthcare industry in both low and high HDI countries.

This volume makes an urgently needed contribution to the health and poverty discourse by exploring the complex relationship between poverty and poor health. The need for this resource became clear during the conference 'Building Consensus on Global Poverty: New Delhi Launch for Academics Stand Against Poverty' (New Delhi, 2011), which was organized by the Comparative Research Programme on Poverty (CROP), Academics Stand against Poverty (ASAP), the Research and Information System for Developing Countries (RIS), Incentives for Global Health (IGH), and the Developing Countries

Research Centre at the University of Delhi. The conference was wide-ranging, but this volume goes far beyond its scope by creating the potential for synergistic engagement amongst scholars, activists, and social entrepreneurs. To empower fundamental, international change, it presents success stories, viewpoints, and experiences to demonstrate that the responsibility for ensuring the poor's right to health belongs not only to politicians, but to everyone.

Said another way: this volume is an urgent call for action.

## About the book

This collection brings together voices from those regions of the world in which the poor are concentrated (Latin America, Asia, and Africa), and from disciplines including medicine, law, and business, to address issues affecting health care for the poor. By dividing these issues into 'legal', 'political', 'interventional', and 'multifaceted' responses to specific health issues, the organization of this volume draws connections between issues and actions in different parts of the world. We would like to acknowledge that inequality is by no means present in only these regions: as mentioned earlier, the United States is a country with great internal inequality, although it has a high HDI. However, we wanted this volume to be a means by which inequality is highlighted in those regions of the world in which it is most heavily concentrated.

Part One of the volume, 'Legal Movements', offers perspectives on the nature of right-to-health legislation. In Chapter 1, Luz Marina Bernal (legal adviser, IFARMA Foundation, Colombia) traces how Colombians mobilized in a successful class-action lawsuit against a pharmaceutical giant, arguing that its exorbitant, patent-protected price infringed their right to health. The movement was primarily driven by civil society, exemplifying the potential that people have when organizing efficiently and utilizing the legal mechanisms by which to counter policies that are inconsistent with a protection of the population's well-being. In Chapter 2, Dr Kwadwo Appiagyei-Atua (senior lecturer, Faculty of Law, University of Ghana) contends in a health-rights-based critique of international law that the poor's right to health has been sacrificed to further the intellectual property rights of multinational pharmaceutical corporations. Together, these chapters express the need to empower citizens to take an active role in legislation that impacts on their collective right to health.

In Part Two, 'Political Movements', leading experts reveal how

political trends can produce or increase healthcare-related poverty among the poor. In Chapter 3, Dr Germán Velásquez (former head of the WHO's Drug Action Programme) presents evidence to support the possibility that the WHO may have exhibited collusive behaviour in a government–private sector scheme to grow pharmaceutical profits, further marginalizing the health of the poor, by means of the imagined swine flu (Influenza A(H1N1)) pandemic.

In Chapter 4, Dr T. V. Sekher (associate professor, Institute for Population Sciences, Mumbai), Kaushalendra Kumar (research scholar, International Institute for Population Sciences), and V. P. Shijith (research officer, International Institute for Population Sciences) discuss the interrelated issues of catastrophic health expenses, health insurance coverage, and poverty in India. They make a case for national governments to provide social security to protect people against catastrophic expenditures on health care, in the absence of a global system that will protect people from the consequences of prohibitive unaffordable healthcare costs by ensuring that the costs of essential medicines are not too high. Political economy informing national-level decisions regarding social security for the poor is a reality that needs to be reckoned with, argue the authors, while advocating with national governments to honour the 'Health for All' commitment.

In Chapter 5, Dr Francisco Rossi Buenaventura (director, IFARMA Foundation, Colombia) and Luis Guillermo Restrepo Vélez (president, National College of Pharmacists, Colombia) take another perspective on affordability, seeking an alternative model of pharmaceutical innovation and income that could delink the sale price of medicines from the cost of research and development. These chapters prove that the policies of global, political, multilateral organizations can be deleterious to those whom they are supposed to benefit, and the authors call for civil societies to question these authorities and to hold them accountable.

The negative consequences of the legal and political forces explored in all of these chapters can be overcome by means of interventional approaches. In Part Three, such 'Interventional Approaches' are presented in chapters by Arora, and Sodhi and Sahu, as models for improving specific health metrics among traditionally marginalized groups in low HDI settings.

The model that Dr Monika Arora (director, Health Promotion and Tobacco Control Division, Public Health Foundation of India) presents in Chapter 6 highlights the role of youth empowerment in

a prevention and cessation intervention programme, and argues for the engagement of youth as agents of change in any public health strategy to dismantle the vicious cycle of tobacco use linked to poverty. The chapter describes a community-based movement that addresses the tobacco industry's proliferation: a consequence of the lack of a global supra-structure that should have been protecting and ensuring health for all. The community-based local movement, while coming to the rescue of poor people in the absence of adequate governance systems and structures for global health, achieves but limited success.

Then, in Chapter 7, Dr Geeta Sodhi (director, Swaasthya, India) and Dr Skylab Sahu (assistant professor, Department of Political Science, Delhi University) discuss the concrete results from a programme developed by Swaasthya, a Delhi-based NGO, to improve maternal and newborn health among an impoverished urban population in India. The chapter is set in the city of Malegaon, in a context showcasing a lack of political will. The people's movement fills the gaps left by the public health system in ensuring quality health services for the poor. India, while priding itself on being a world-class healthcare industry, has a public health system that is largely unaccountable and which continues to ignore the concerns of its poor. The authors describe the strategies underlying an effective community-led movement to ensure high-quality maternal and newborn health care for the community's poor populations.

The final part of the volume, Part Four, 'Multifaceted Movements', covers ideas that bridge aspects of these legal and political movements, and interventional approaches. In Chapter 8, Dr Camilo Pérez-Bustillo (research professor, Graduate Programme in Human Rights and Faculty of Law, Autonomous University of Mexico City) compares the grass-roots, bottom-up struggles of indigenous groups in Latin America to secure basic health and human rights with the parallel struggles of ethnic minorities in the United States towards the same ends. He focuses on forced migration, demonstrating the critical role that social movements (both literal and figurative) have had on community health, and he calls for extreme poverty to be recognized as a crime in the legal system. In Chapter 9, Abraar Karan (MD candidate, David Geffen School of Medicine, University of California-Los Angeles) also considers social movements as an agent of change. He enumerates the structural problems of a top-down approach, focusing on the disastrous

consequences of allowing geopolitical forces to shape the provision of international aid to Uganda for HIV/AIDS without reference to the sociocultural and contextual realities of recipients. By considering poverty from a rights-based perspective, these chapters advocate for social movements to be used in conjunction with medical treatment to improving health access for the poor.

As a whole, these contributions expose systemic limitations from the perspective of those whose right to health remains unfulfilled. Stated simply, poor people face barriers to recovery that wealthy people do not. Ultimately, this volume is more than a series of essays; it is a plea for people around the world to come together and set a comprehensive agenda to fight against poverty and to protect the health of the poor. Current efforts at the global, national, and local levels are heartening, but more must be done to dismantle the oppressive institutions that exploit people who are already suffering from, or are vulnerable to, disease. The time to act is now.

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PART ONE

# LEGAL MOVEMENTS

# 1 | REQUESTING A COMPULSORY LICENCE FOR KALETRA, AN HIV/AIDS ANTIRETROVIRAL DRUG, IN COLOMBIA

*Luz Marina Umbasía Bernal*

## Introduction

The patent system is built on the premise that patents incentivize innovation by offering a limited twenty-year monopoly to patentees. As a result, private industries are able to demand as high a price for their patented products as they see fit and new medicines can be prohibitively expensive. This can have devastating effects on individuals, who may become bankrupt or have to forgo treatment because of the excessive expense of new medications that are under patent (and thus cannot be produced in a cheaper, generic form). But what happens when the costs are artificially inflated to the extent that a government cannot afford a treatment that it is legally bound to provide its citizens?

In Colombia, where the government is obliged to provide free treatment to citizens with HIV/AIDS, patients are being forced to seek access to their right to health through the courts. The national health policies have encouraged abuses of the patent system, of which the opportunistic pricing of the important drug Kaletra (lopinavir/ritonavir) is representative. Abbott Laboratories, which produces and markets Kaletra in Colombia, abused the patent system to create a monopoly and secure significantly higher prices for the drug than in surrounding countries. Until 2008, it cost the state US$4,440 per patient per year in Colombia. That price has been lowered to $1,067 as a result of public pressure, but generic versions would cost only $396 (70 per cent less) if they could be sold in Colombia (FMC, 2008).

The pricing of Kaletra in Colombia is representative of the abuse of patent law to create monopolies and thereby restrict competition in the pharmaceutical sector, which was detailed in a European Commission report of July 2009, and which is worsening in developing countries – particularly in Latin America (Correa, 2010). Taking Colombia's

experience as a case study, this chapter explores how the increase in patent protection in developing countries has constructed barriers that have pushed up prices and stifled competition, thereby restricting access to the medications and forcing governments not merely to fall short of national health policy goals, but to be in breach of national health policy – that is, to fail to uphold their constitutional obligations. This chapter also outlines advocacy strategy of civil society organizations (CSOs) and contextualizes their efforts to request a compulsory licence for Kaletra in Colombia.

After providing an overview of Colombia's national healthcare system, which is currently in crisis and undergoing reform, this chapter will present a brief introduction to the way in which patents determine access to medicine. It will then explore the effects of Kaletra's soaring costs on the Colombian health system and the subsequent governmental response, with a particular focus on the process of administrative and legal actions leading Colombian civil society ultimately to making a request for a compulsory licence. Finally, the chapter will conclude with a discussion of developing countries' flexibility vis-à-vis the 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), including the influence of drug patents extended by TRIPS, as well as resistance to this influence in the form of political will for, and social concern over, the defence of right to health and life.

## Analysis of the Colombian health system

In Colombia, the health system is universal and is regulated by the Ministry of Health and Social Protection (*Ministerio de Salud y Protección Social*, or MPS) under constitutional mandate. The system is decentralized, with mandatory public enrolment comprising a contribution scheme that includes formal workers and their families. There is also the so-called Subsidized Plan for the poor and vulnerable. Moreover, there are also special regimes for particular groups (such as army, police, teacher, and Colombian Oil Company, or ECOPETROL, health systems) and a public network to address health problems among the uninsured (under the 1993 Social Security Act, or Law No. 100 of 1993).

The system is operated by the Benefit Plans Administrators (BPA), public and private health-promoting entities, and administrators of the Subsidized Plan, who act as intermediaries and managers of state

resources provided by the annual premium (known as a unit capitation payment, or UCP). The central component of the social security system in Colombia is the Compulsory Health Plan (CHP), which includes integrated services for treatment and disease prevention, as well as workers' compensation for medical and maternity leave (under Law No. 100 of 1993).

Economic factors have contributed to a steady dismantling of the system at the operational and implementation levels, and has caused a crisis in the healthcare sector. The government did not regulate the cost of medicines and, as a result, high drug prices contributed to the ongoing crisis in the financing of the Colombian health system. The price of Kaletra provides a case in point: in addition to monopolistic pricing, the entities responsible for delivering the drug to patients have created barriers to access, such as increasing the paperwork needed to obtain it.

In the case of people living with HIV/AIDS, the government was not fulfilling its legally mandated obligation to provide free treatment, forcing patients to go to court to claim guardianship of the fundamental right to health and access to services that are not included in the CHP. As a result of legal action, Kaletra was included in the CHP in 2004. Nevertheless, the Colombian price remains higher than elsewhere in the South American Andean region and continues to impose a financial burden on the Colombian health system.

## Patents and the violation of the right to health

National authorities have traditionally granted patents as an instrument of industrial policy to advance national development and only to a lesser extent as a right of the inventor. It has been argued that higher standards of intellectual property can lead to technology transfer (that is, the importation of technological capacity) because foreign firms would be encouraged to invest in developing countries and to install their technologies. However, there is also a counterargument that those foreign firms that have obtained patents in developing countries are able to make inroads and profits in these countries without having to produce the patented products there, because they can import the products and sell them at monopoly prices (Khor, 2005).

There are several ways in which a strong intellectual property rights (IPR) regime can hinder developing countries' access to technology. Obstacles to technology transfer make it difficult for developing countries and their home-grown firms to upgrade infrastructure to the

extent necessary if they are to compete successfully with foreign firms. Such obstacles thus impede competition (Khor, 2005). Patents, which grant exclusive rights to market a product for twenty years, provide a significant barrier of this type. They can also create barriers to access: monopolies not only install artificial barriers to other firms entering the market, but the exclusive right to market a given product also leads to the potential abuse of this dominant position in the form of high prices (Khor, 2005).

Human rights are those promises that we, as a global society, should collectively employ to protect the existence of every individual. They are often expressed and guaranteed by law, embodied by examples such as the right to health, the right to privacy, the right to property, the right to life, etc. A state interferes with a human right if it limits the exercise of that right, encroaches on the right, or fails to fulfil a positive duty associated with the right. Article 4 of the 1966 International Covenant on Economic, Social and Cultural Rights (ICESCR) adopts the approach of examining, first, a limitation to a right, and then possible justification for such limitation. The state must guarantee the economic accessibility of medicines as part of its fulfilment of Article 4, which sets standards for evaluating accessibility, with average household income as one among several factors. By allowing monopolistic pricing, patents interfere with the right of access to medicine, especially in developing countries: unfortunately, governments in developing countries often lack the resources to pay for drugs priced artificially high (Hestermeyer, 2006).

### Kaletra: A study of the costs of the patented drug

According to an analysis of the HIV situation in the Andean subregion over the period 2003–05, the Benefit Plan in Colombia covers highly active antiretroviral therapy (HAART) – that is, first-line antiretrovirals – but the drug supply is irregular, especially for the poor (Kusunoki Fuero and Nagles Peláez, 2007). Regulatory and institutional barriers, such as delays in the timely delivery of medicines and extended administrative procedures associated with drug delivery, limit access to care for high-cost diseases. As a result, patients must seek recourse through the legal system to access care and treatment.

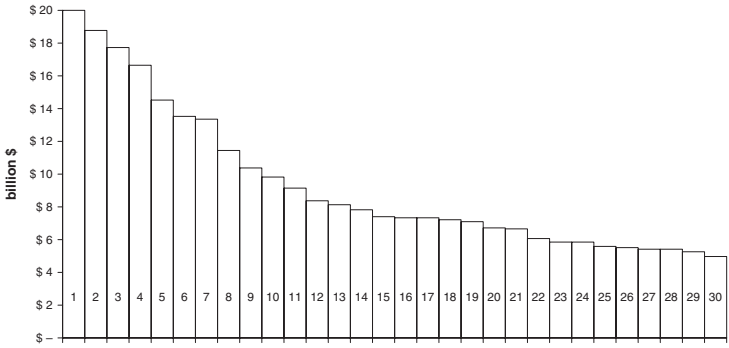
The patent protection provided by intellectual property law constitutes a barrier to access to essential medicines. In Colombia, Kaletra, an antiretroviral treatment for HIV/AIDS produced by

Abbott Laboratories, provides a representative case. The drug is patented, which provides Abbott with a monopoly on the marketing of this medicine. The exorbitantly expensive drug is the only form of lopinavir/ritonavir that exists in Colombia.

The cost of antiretroviral drugs in Colombia is the highest in the so-called Andean subregion, a group comprising Venezuela, Ecuador, Peru, and Bolivia (Trout et al., 2007). Several reasons for this discrepancy exist. The first explanation relates to the way in which the national health system is structured. There are more than 100 buyers for antiretrovirals, who either buy these drugs directly or through intermediaries. This restricts their ability to achieve enough purchasing power to take advantage of economies of scale. Additionally, unlike many Latin American countries, Colombia has no national price referencing system that buyers might use when negotiating with pharmaceutical companies. In short, Colombia lacks a single purchaser; instead, health maintenance organizations (*entidades promotoras de salud*, or EPSs), healthcare providers (*instituciones prestadoras de servicios*, or IPSs), and local health authorities form a fragmented group of intermediates. The high number of buyers increases transaction costs, and expands the opportunities for corruption among monopolies and oligopolies (that is, it raises the risk of anti-competitive practices). Information asymmetries give vendors a stronger negotiating position than that of buyers. Such monopolies or oligopolies exist because of the patent protection and data exclusivity measures provided under the current IPR regime in Colombia (Garavito and Ruiz, 2008). Figure 1.1 provides a comparison of high-cost drugs in Colombia in 2006.

In an analysis conducted by IFARMA–Health Action International on the specific impact of the lopinavir/ritonavir patent, it was found that the drug accounts for the largest expenditure in the Andean region. This product was patented in Colombia, Chile, and Ecuador; however, Abbott decided not to seek patents in Peru, Bolivia, and Venezuela. The countries used in the comparison in Table 1.1 – Colombia, Chile, and Peru – were chosen for their complete dataset (2004–06).

By 2008, Kaletra prices in Colombia had increased to $3,443 through institutional channels and $3,296.16 through commercial channels; in Peru, the price of the lopinavir/ritonavir generic was only $396 (see Figure 1.2). This analysis reveals that the price of the drug tends to rise (that is, in Colombia) or remain relatively stable (that is, in Chile) when the medicine is under patent. In contrast, the only country in the




1 Lopinavir + Ritonavir 167mg (tab)
2 Imatinib Tabletas 100mg (tab) – Glivec
3 Eritropoyetina Sln Iny 2000 UI
4 Interferón Beta 1B 8.000.000 UI
5 Infliximab 100mgs (amp)
6 Ciclosporina 100 mg. (tab)
7 Somatropina Rec Hum Slniny Genotropin 16ui(amp)
8 Rituximab Slniny 500mg/50ml (amp)
9 Imatinib Tabletas 400mg (tab) – Glivec
10 Zoledronico Acido Vial 4mg (amp)
11 Interferón Beta 1A 12.000.000 Ui 44 mcg tratamientos
12 Indinavir 400 mg. (tab)
13 Etarnecept Slniny 25mg (amp)
14 Vigabatrin 500mg (tab)
15 Nelfinavir 250 mg.
16 Ritonavir 100mg.
17 Lamivudina + Zidovudina Tabletas 450mg – Generico
18 Abac + Zidov + Lamiv tab300+300+150(fco)
19 Ciproterona Acetato 50 mg. (tab)
20 Valganciclovir 450mgs tabs
21 Docetaxel 80 mg/vial (vial)
22 Factor Antihemofilico Viii Solucion Inyectable 500UI (amp)
23 Paclitaxel 100mg – Sol. Esteril
24 Micofenolato 500mg (tab)
25 Somatropina Slniny 24ui Saizen (amp)
26 Interferon Alfa 2A Pegasys Vial 1ml 180 mg(amp)
27 Toxina Botulinica 100 U.I.
28 Gemcitabina Slniny 1g (amp)
29 Calcitriol 0.25 mcg (tab)
30 Trastuzumab Ampollas 440mg/50ml (amp)

**1.1** Expensive drugs in Colombia, 2006 (*source*: Fundación Ifarma (2006))

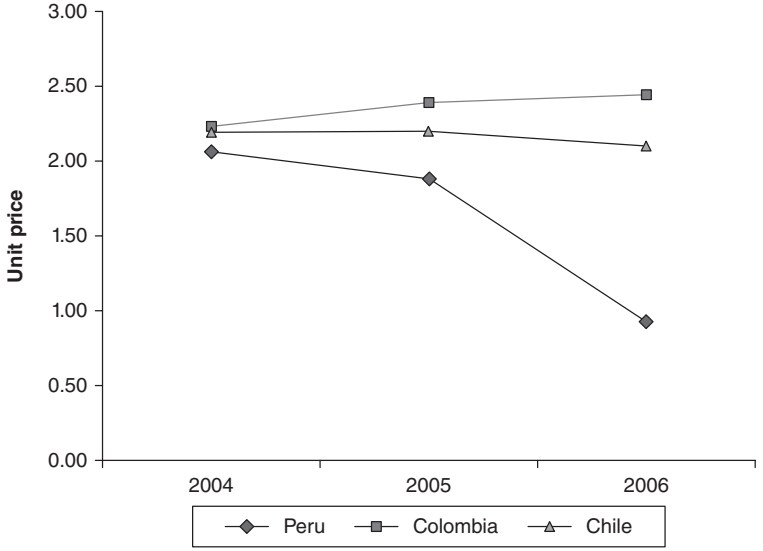
TABLE 1.1 Comparison of the history of the price of patented lopinavir/ritonavir vs lopinavir/ritonavir without a patent

| Country | Patent protection | 2004 price (US$) | 2005 price (US$) | 2006 price (US$) |
|---|---|---|---|---|
| Peru | No | 2.06 | 1.88 | 0.928 |
| Colombia | Yes | 2.231 | 2.388 | 2.44 |
| Chile | Yes | 2.189 | 2.2 | 2.1 |

*Source:* IFARMA–AIS (2007)

region that benefits from competition for this medicine is Peru: without a patent on the drug, the price has reduced significantly over time.

Later, Kaletra was put on the list of drugs controlled by the state. Following the government's use of references for price (based on prices in neighbouring countries), the current Colombian market price stands at about $1,000 per patient per year. However, it is still possible to acquire the generic drug, which is the cheaper version of the original, from another producer.




**1.2** Evolution of the price of lopinavir/ritonavir in countries in which the drug is patented (Colombia and Chile) versus a country without a patent on the drug (Peru) (*source*: IFARMA–AIS (2007))

## Compulsory licences

The compulsory licence request made by Colombian CSOs resulted in a reduction in the high price for Kaletra, making the drug more accessible in Colombia. These high prices had been possible because of the passive and permissive actions of the state, whose behaviour ultimately favours the interests of the patent owner. Even though the price has since been reduced, at time of writing lower-priced generics are not yet available on the market. If there were generics on the market, they could generate enormous savings for a health system currently in crisis, enabling it to expand access to medicine, and thereby to reduce HIV/AIDS-related morbidity and mortality – a scenario that would be possible if there were a *compulsory licence* for Kaletra.

The international framework for the request of a compulsory licence in this context comprises:

- TRIPS;
- Decision No. 486 of the Andean Community Establishing the Common Industrial Property Regime;

- the World Trade Organization (WTO) 2001 Doha Declaration on TRIPS;
- the 2001 Declaration of Commitment on HIV/AIDS, 'Global Crisis, Global Action', of the United Nations General Assembly Special Session (UNGASS); and
- the WHO, UNAIDS, and UNICEF initiative 'Towards Universal Access'.

From a legal perspective, national mechanisms used in response to the HIV/AIDS epidemic have included:

- the 1991 Constitution of Colombia;
- the Social Security Act (Law No. 100 of 1993);
- Decree No. 1543 of 12 June of 1997 to provide for the Rules for the Management of HIV, AIDS, and STDs [sexually transmitted diseases];
- the National Policy on Sexual and Reproductive Health, which conducts specific actions for the issue of HIV/AIDS, including the programme management model against HIV/AIDS;
- the National Public Health Plan;
- Law No. 972 of 15 July 2005 providing for Rules to Improve Care for People Affected by Catastrophic Illnesses, particularly HIV/AIDS;
- the new evidence-based guidelines of care for people living with HIV/AIDS;
- the National Strategic Plan for HIV/AIDS, 2004–07; and
- the recent National Strategic Plan, 2008–2015.

A licence is a mechanism provided by the patent holder or imposed by the state to generate competition in different markets (Maybarduk, 2008). A compulsory licence requires the owner of a patent or copyright licence to forgo its rights of exclusion in exchange for a payment set either by law or by some other form of arbitration. In essence, an individual or company granted a compulsory licence can market the product in question without seeking the patent holder's consent, as long as it pays the patent holder a set fee.

In Colombia, any group interested in obtaining a licence must pay a royalty determined by the Superintendent of Industry and Trade (*Superintendencia de Industria y Comercio*, or SIC) according to Decision No. 486 (and related regulations). There is also an implied condition: no entity can sell any medicine, including lopinavir/ritonavir, without

approval of the National Institute of Food and Drug Monitoring (*Instituto Nacional de Vigilancia de Medicamentos y Alimentos*, or INVIMA). This is the body responsible for implementing the Ministry of Social Welfare's policies on health monitoring and drug quality control.

Compulsory licensing is a mechanism used worldwide. Unfortunately, in Colombia, the government denied the compulsory licence for Kaletra without even exploring the extent to which its action affected the public interest. The decision also contravenes the current constitutional trend towards defending the human right to access to health care and improvement of quality of life. Moreover, the government's stance violates the right to public health within a social security system. Colombia's social security system and, as a result, the public's right to health has been challenged by the monopoly-driven high costs of medicines: a direct result of the construction of a strong IPR regime.

In 2001, the WTO announced:

> Each member [of TRIPS] has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency. (2001 Doha Declaration, Article 5(c))

Andean Community rules also provide for compulsory licensing as a means to remedy anti-competitive practices. The legal framework that applies to this case in Colombia is Decision No. 486 of the Andean Community – specifically Article 65 – and Resolution No. 17585, under which the SIC is declared the competent officer to grant licences when prompted by public interest.

The United States and the European Union (itself for certain sectors and its member states in relation to certain pharmaceutical drugs) have been active in non-voluntary licensing. In the United States, compulsory licensing focuses on military and nuclear energy, while in the case of the European Union, it is more commonly used in the computer industry (Maybarduk, 2008). There have, however, been several instances in the United States in which a compulsory

licence has been used in the pharmaceutical sector. Moreover, in several other countries, including Canada, this legal mechanism has been used in a systematic manner (as part of economic policy) to aid the further development of the national pharmaceutical industry (Weissman, 2007). In Canada, for example, until the 1990s, the granting of compulsory licences for pharmaceutical products was part of a strategy of technology transfer and industrial development for the generic drug industry (Rimmington, 2009).

The case of the United States is also particularly significant. The American government has pursued a contradictory practice whereby it uses disparate policies domestically and internationally, fostering competition in the domestic market, while simultaneously restricting competition abroad. In January 2008, for example, the Court of Appeals for the Federal Circuit lifted the ban against Merck's use of a patent belonging to Innogenetics and ordered the issuance of a compulsory licence to Merck. Two months later, in March 2008, Roche agreed to court-imposed conditions so that it could sell Mircera, a drug that was deemed to violate several patents held by Amgen. Amgen was opposed to Roche's marketing of Mircera, meaning that the judge had to grant the licence in spite of opposition. The licence granted to Roche had five conditions attached, including a royalty payment of 22.5 per cent to Amgen.

It is worth noting that Merck and Roche both benefited from the granting of these compulsory licences – and yet, when the Thai government issued compulsory licences against their own patented products (efavirenz, or Stocrin, in November 2006; erlotinib, or Tacerva, in January 2008), both companies reacted very strongly. In short, the position of these companies with respect to compulsory licensing varied radically, with each acting in each case according to its own interests: in the United States, Merck and Roche promoted and profited from compulsory licensing; in Thailand, they expressed their total dissatisfaction with the compulsory licence and demanded that the Office of the United States Trade Representative (USTR) take action against the state.

The US Supreme Court granted the 'well-recognized remedy' of compulsory licences in antitrust actions as early as 1952, in *United States v. Besser Mfg Co.*, 343 US 444, 1952. The following examples show how the US government has used the compulsory licence to its advantage to increase competition since then.

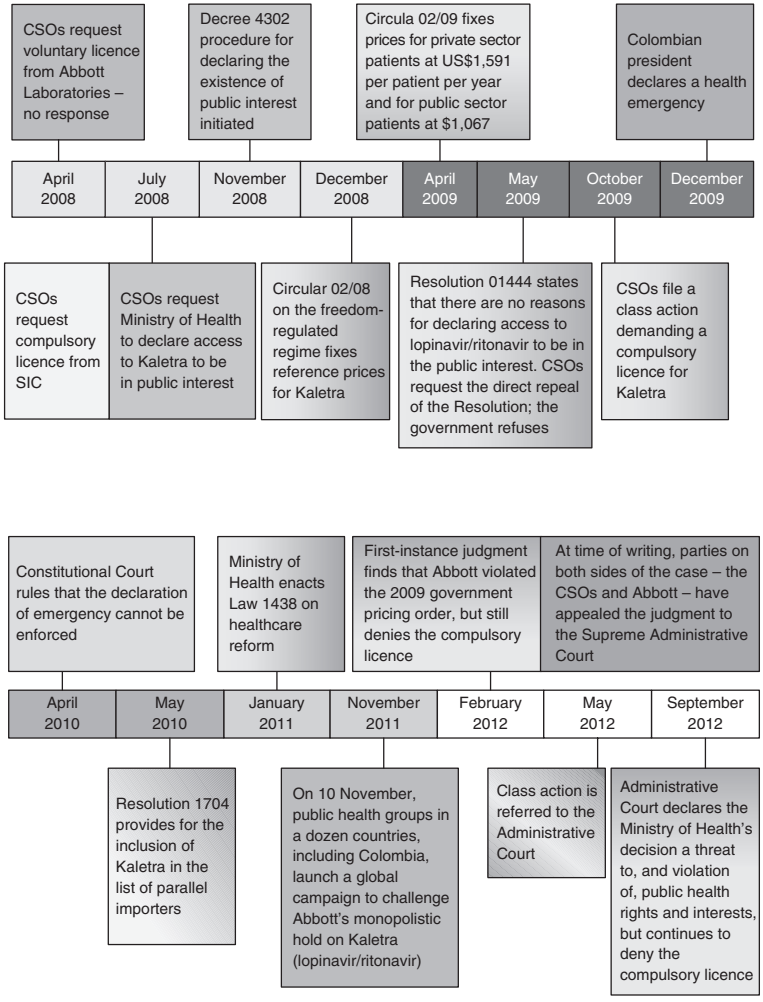
- In 2001, Secretary Tommy Thompson of the Department of Health and Human Services (DHHS), threatened to use section 1498 of Title 28 of the federal US Code (28 USC 1498) to authorize the importation of generic ciprofloxacin in order to prepare for a possible anthrax attack (Love, 2007).
- At the US Congress hearing in November 2005, Secretary Michael Levitt of the DHHS testified in the House of Representatives that he was then requiring Tamiflu's patent holders (Roche and Gilead) to consider developing US-based manufacturing facilities for this product. In this way, the US government sought to ensure greater access to Tamiflu if it were to be confronted with a bird flu pandemic (Press Trust of India, 2011).

The following examples show how the Brazilian government has also used the compulsory licence to its advantage to increase competition.

- Brazil granted its first compulsory licence for drugs in 2007. There were 75,000 Brazilians with HIV/AIDS taking the antiretroviral efavirenz. The brand-named drug by Merck and BMS, efavirenz, cost $1.59 per person per day, but there were generic versions with prices of about $0.45 per person per day. The competition between generic firms led to a decrease in the price of generic efavirenz to $0.25 per day. On 4 May 2007, Brazil issued a compulsory licence by means of a decree signed by the Minister of Health and then President Lula (Love, 2007).
- In addition, several years ago, Brazil used compulsory licensing as a negotiating tool with the pharmaceutical companies. In 2001, Brazil announced that it was considering compulsory licences for efavirenz and nelfinavir; in the following months, Merck offered discounts for both. In 2003, Brazil threatened licences for lopinavir, efavirenz, and nelfinavir, and discounts were again obtained. In 2005, the possibility that a licence would be used resulted in discounts of 46 per cent for Kaletra, 50 per cent for Viread, and 65 per cent for imatinib, a treatment made by Novartis for leukaemia (Love, 2007).

*Requesting a compulsory licence for Kaletra in Colombia* Under TRIPS Article 31(b), a compulsory licence cannot be implemented until users have spent a reasonable period of time seeking a voluntary licence with reasonable terms and conditions. In Colombia, there are approximately 12,000 persons living with HIV/AIDS.

The timeline of major events leading to the compulsory licence request (see also Figure 1.3) includes the following events. In April 2008, the Bureau of Organizations Working on HIV/AIDS and the Colombian Network of People Living with HIV (*Red Colombiana de Personas Viviendo con VIH*, or RECOLVIH) requested an open licence from Abbot Laboratories for lopinavir/ritonavir (Kaletra) for reasons of public interest. At the time, the request received no response.




**1.3** Timeline of request for compulsory licensing of Kaletra in Colombia

In July 2008, because of the lack of response from Abbott, requests were made to the government through an administrative channel: a collection of CSOs – including IFARMA, the Health Mission, the Bureau of Organizations Working on HIV/AIDS, RECOLVIH, Essential Action (providing technical support), and several organizations from the international civil society community – submitted an application for a compulsory licence for Kaletra to the patent office (that is, the SIC). They asked that the Ministry of Health declare access to the drug a matter of public interest.

In November 2008, the Ministry of Commerce issued Decree No. 4302. The decree, in accordance with Article 65 of Decision No. 486 of the Andean Community, established the procedure for declaring an issue a matter of public interest.

In accordance with the law, the Ministry of Health formed a technical committee that produced Resolution No. 01444 (MPS, 2009). The Resolution brought an end to the administrative proceedings regarding Kaletra, since it ruled that there were no reasons for declaring access to lopinavir/ritonavir a matter of public interest. As a result, the patent office refused to issue a compulsory licence.

In May 2009, the CSOs requested the direct repeal of Resolution No. 01444. The government replied in depth, denying the request and confirming its original position. As a corrective measure to the high price of the medicine, the government instead took the decision to control the drug's price and established a reference price according to neighbouring countries in the region. The government continues to monitor the price of the drug today.

As a response to the Ministry of Health, in order to prevent potential consequential damage and the violation of human rights and collective interests, several CSOs chose to continue the issue in court. On October 2009, CSOs in Colombia filed a class action lawsuit (in Spanish, *acción popular*) that claimed that the collective right to access to healthcare services, as well as administrative morality, was threatened by the government's refusal to grant a compulsory licence.

Originating in Roman law, class actions are considered the procedural means *par excellence* for the protection of collective rights and interests. It is a legal concept that has been developed in a variety of countries, including the United States, England and Wales, and Germany. In Colombia, it was initially implemented under the Civil

Code as a mechanism for protecting public property and preventing damages to property.

Class actions are also designed to ensure protection of administrative morality. They present a mechanism by which people can enforce the protection of the public interest, and they represent a tool for preventing and/or repairing resulting damage. In this case, the class action filed by the CSOs demanded that the judge order:

- the SIC to grant an open compulsory licence – for the lifetime of patents granted to Abbott Laboratories – to produce, manufacture, import, export, distribute, offer for settlement, sell, buy, or use the medicine called Kaletra (lopinavir/ritonavir);
- Abbott Laboratories to suspend any administrative or judicial action the purpose of which was to defend the patent; and
- INVIMA to allow any laboratory with the appropriate manufacturing capacity to produce quality drugs to register the active ingredient, lopinavir/ritonavir.

Meanwhile, in December 2009, the Colombian president declared a health emergency – but, in April 2010, the Constitutional Court ruled that the declaration could not be enforced.

In January 2011, Law No. 1438 implemented a health system reform that sought to reverse the serious economic crisis affecting public health.

Efforts have also been made to promote the cause through social media, such as the 'Campaign for Access to Kaletra' (Public Citizen, 2011a). Civil society organizations requesting the licence in question have produced educational materials – notably a video clip that shows the various communication pieces published in an attempt to raise awareness (Morales, 2008).

The Positive Communication Foundation (*Comunicación Positiva*) has also held press conferences, forums, and presentations on the subject in public places, aiming to promote the 'Campaign for the Right to Health not Patents' (Morales, 2010).

Further, a six-part radio series has chronicled the full history of the struggle of CSOs in Colombia in pursuing the licence to an essential drug for the treatment of HIV. Some podcasts were also produced in order to facilitate dissemination by other organizations (Morales, 2008).

Another advocacy action has been the Global Kaletra Campaign. This is a worldwide campaign aiming to expand access to vital HIV treatment. On 10 November 2011, public health groups in a dozen countries, including Colombia, launched a global campaign to challenge Abbott Laboratories' monopolistic hold on Kaletra (lopinavir/ritonavir). The goal was to spur competition by generic drug makers and thereby lower the medicine's price; the permissions sought were also to allow the use of the drug's components in new, more effective, combination treatments. This campaign represents an unprecedented global effort to challenge the pharmaceutical industry's political power and to improve access to lifesaving medicines (Public Citizen, 2011b).

On 29 February 2012, a decision by Bogotá's Administrative Court found that Abbott had violated a government pricing order in 2009. The Court consequently directed the Ministry of Health to initiate procedures for sanctions against Abbott (potentially including financial penalties). The Court stated that Abbott had abused its dominant market position by pricing an essential medicine 350 per cent higher in Colombia than in neighbouring countries (about $3,500 compared to about $1,000). This threatened the sustainability of Colombia's health system and violated 'public administrative morality'. According to the Court, 'mercantile utility and patent ownership' do not justify 'disobeying the national policy of price control for HIV/AIDS medicines'. Its ruling nonetheless called for the continuation of Kaletra on a parallel importation list to ensure its availability at the international reference price.

At time of writing, parties on both sides of the case – the health groups and Abbott – have appealed the Administrative Court's judgment to the Supreme Administrative Court. In the meantime, in September 2012, the Administrative Court declared that the Ministry of Health's failure to adopt the necessary measures to regulate Kaletra's price represented a threat and violation of the rights and interests of public health. The Court ordered the Ministry of Health to implement the policies necessary to regulate the price of Kaletra and also instructed the Ministry to grant more favourable conditions for the financial sustainability of the health system – but the compulsory licence was again denied.

## Analysis

The correct response of the administration would surely have been to act within its duties to protect the interests of the community (in accordance with Article 2 of Chapter 1 of Colombia's Administrative

Code) and to oversee compliance with the purposes of the state, which in this specific case are directly linked to the right to life and to health. The *common good*, as established in Article 333 of the Constitution of Colombia for the exercise of economic activity, is negatively affected by expedition of the demanded act (Resolution No. 01444).

Article 3 of Chapter 1 of Colombia's Administrative Code lays out the guiding principles for actions aimed at fulfilling the duties of the state, providing that administrative proceedings must be 'conducted according to the principles of economy, speed, efficiency, impartiality, publicity and contradiction'. These requirements were not taken into account.

The evolution of the price of Kaletra in Colombia, according to the data reported in Resolution No. 01444 (MPS, 2009), is outlined next (see Table 1.2).

TABLE 1.2 Kaletra (institutional channel) vs generic lopinavir/ritonavir in 2008

| | US$ per patient per year | Total annual expenditure (US$) |
|---|---|---|
| Kaletra | 3,443 | 18,629,047 |
| Lopinavir/ritonavir | 470 | 2,551,630 |
| Price difference | – | 16,077,417 |

*Note: n* = 5,429 patients

TABLE 1.3 Kaletra (trade channel) vs generic lopinavir/ritonavir

| | US$ per patient per year | Total annual expenditure (US$) |
|---|---|---|
| Kaletra | 3,296 | 17,893,984 |
| Lopinavir/ritonavir | 470 | 2,551,630 |
| Price difference | – | 15,342,354 |

*Note: n* = 5,429 patients

TABLE 1.4 Kaletra with 'regulated freedom' sale price vs generic lopinavir/ritonavir

| | US$ per patient per year | Total annual expenditure (US$) |
|---|---|---|
| Kaletra | 1,000 | 5,429,000 |
| Lopinavir/ritonavir | 470 | 2,551,630 |
| Price difference | – | 2,877,370 |

*Note: n* = 5,429 patients

In 2012, the reference price for Kaletra was $1,000. According to official data, sales in 2011 were reported as $11,364,763.38. If it had bought lopinavir/ritonavir through the generic drug market, the Colombian health system would have saved more than 50 per cent of this amount. These figures derive from the data reported in Resolution No. 01444.

By refusing to issue a declaration of general public interest in access to competitive conditions, the administration subjected the general public to the economic interest of a private business party. The medication was granted the status of 'regulated freedom' and there was no reduction in the price of the product, which confirms the state's *in*efficiency.

In this case, the health authority's decision to deny the compulsory licence also runs contrary to its mandated principles. Urgency of state action is required when a situation involves state obligations to guarantee the rights of its inhabitants to health, dignity, life, and rights. This obligation has been established by Colombia's Constitution, and ratified by Colombia in a series of international treaties related to the ICESCR and TRIPS.

On the other hand, the right of petition has not been thoroughly fulfilled. The Constitutional Court has established in this regard that:

> the essential nucleus of the right of petition resides in the prompt and timely resolution of the question, given that the possibility to recur to the authority will be useless if said authority does not resolve or reserves for itself the decision made … The response should comply with the following requirements: 1. Timeliness. 2. It should be resolved in a manner that is thorough, clear, precise and congruent with the request. 3. It should be made known to the petitioner. If these requirements are not met, a violation is incurred of the fundamental Constitutional right to petition. (Corte Constitucional Colombia Exp T-478409 M.P, 1 November 2001, *per* Manuel José Cepeda Espinosa)

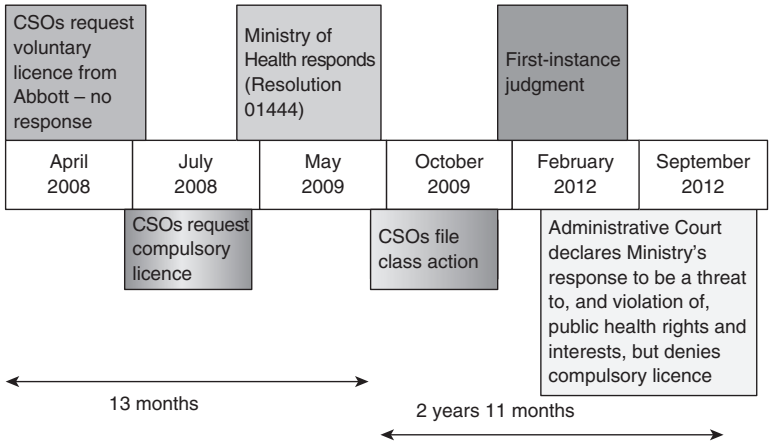
In accordance with Resolution No. 4966 of 2009, partially amending Decree No. 4302, the Colombian state has a maximum of three months in which to resolve an application to the Ministry. With this in mind, note the response time frame established from 7 April 2008 to 14 May 2009 (in the official gazette), but notified by electronic mail on 22 May

2009 (Figure 1.4). After a significantly longer time than expected, the price of Kaletra remains high.

Article 4 of Law No. 972 of 2005, by which standards are adopted to improve care for people living with HIV/AIDS, addresses the importance of regulating costs in the health system. The rules indicate that the government may use mechanisms that guarantee access and establish a centralized system for negotiation of medication prices in order to reduce costs.

Law No. 972 of 2005 also warns that a drug's inclusion in the CHP does not exonerate the government from the duty to obtain reasonable prices. Despite not having the direct duty to pay for treatments included in the CHP, the Law affirms that the strong financial standing of the health system is an indispensable prerequisite for the effective provision of the health service and the fulfilment of a fundamental right to health. The government's decision to deny the licence request therefore does not adequately respect Law No. 972, which addresses issues related to public policies regarding high-cost diseases such as HIV/AIDS.

In conjunction with Decision No. 486 of the Andean Community, the Doha Declaration of 2001, the UNGASS on HIV/AIDS, and the 'Towards Universal Access' initiative, TRIPS addresses a balance




**1.4** Timeline of the request for a compulsory licence

between property rights and public, social, and general interests. If a medicine costs the Colombian system more than it costs those in neighbouring countries, the provisions of TRIPS may be used in actions pertaining to the public interest, given that the impact achieved would be directly related to the financial optimization of the health system. This link between medical provision and the public interest must be continuously emphasized.

An example is the India Patents Act 1970, as amended in 2005, establishing strict requirements for the determination of inventive activity. Patents are not automatically issued for different forms of the same molecules, such as salts, esters, or polymorphs. Furthermore, case-by-case decisions are made to establish the level of inventive activity in an effort to prevent the evergreening of molecules.

In strictly legal terms, the concession of compulsory licences, together with patent requirements, is one of the few spheres in which state sovereignty remains important in economic matters related to the management of IPR (Seuba, 2009).

On the other hand, when a medication is in the CHP, universal access for the entire population is understood in principle. But when medications in the CHP pertain to the treatment of a high-cost disease, as does Kaletra, it may gravely affect the financial stability of a system that must guarantee a fundamental right to health. For that reason, the same law that guarantees access to a given medication imposes an obligation on the executive authority to seek better prices. The law also allows the executive to apply the provisions of IPR frameworks to the context in question.

The law facilitates state intervention to uphold the concepts of reasonability and proportionality in private business enterprises with broad public interest. Access to certain goods and services for all persons – in particular for those with lower incomes – is an inherent implication of this law.

The promotion of local productive capacity in developing countries is important. To encourage the use of a technological base to expand knowledge, it is important to apply strict standards in the granting of a patent; discretion at this stage could obviate the political pressure involved in the concession of compulsory licences. The increase in number of patents for products that are not truly new inventions affects access, especially given the difficulty in applying the compulsory licence option in developing countries.

The administrative action assigned a 'regulated free market' regime to the medication, resulting in a reduction of the high price set for the Colombian market (in comparison to the price set by the same company in other countries).

With a compulsory licence, Colombia could import high-quality generic forms of lopinavir/ritonavir at low costs; alternatively, the national pharmaceutical industry could be stimulated to develop the medication and enter the market. Public Citizen, a non-profit organization based in Washington, DC, leads the charge against undemocratic trade agreements that advance the interests of mega-corporations at the expense of citizens worldwide. It is an important actor in global access to medications and specifically recommends the use of open licences.

Public law exists that stipulates certain values, principles, and individual/collective rights that may not be left in pure theoretical terms. These regulations have been established not only to protect the lives of all persons through the provision of essential goods, services, and rights, but also to assure compliance with the social duties of the state and of private parties.

Unnecessary patents not only block access to medications, but also affect the production options of these medications in the developing countries. The increase in patents for medicines that are not truly new inventions affects access and, despite the existence of the compulsory licence option, these licences cannot be obtained or applied in developing countries.

## Conclusions

Kaletra prices have fallen around 70 per cent in Colombia owing to the efforts led by CSOs (such as IFARMA, Mission Health, the Bureau of Organizations working on HIV/AIDS, RECOLVIH, Essential Action, and Public Citizen) to obtain a compulsory licence for the drug, the impact of which is evident in the measures taken by the National Commission on Drug Prices and Medical Devices (*Comisión Nacional de Precios de Medicamentos y Dispositivos Médicos*) in Colombia to set a reference price (Comisión Nacional de Precios de Medicamentos y Dispositivos Médicos, 2009).

The lack of 'universal access' in Colombia is a function of the cost of antiretroviral medications. A licence will create competition against Kaletra by means of the introduction of generics into the market,

fostering a drastic and immediate change in the drug price. This effect will then be reflected in the total health expenditure.

Colombia has the duty to issue compulsory licences for reasons of public interest. In the case of Colombian people living with HIV/AIDS, irregularities in the delivery of drugs represent one such public interest. The effects on individuals' overall health of these treatment disruptions and the high cost of Kaletra are the principal factors that triggered this request ultimately to promote competition by allowing more companies in the market.

Compulsory licences foster access by creating competition in a monopoly market. A compulsory licence would mean potential savings somewhere between $5,754,000 and $32,280,834 (taking into account data supplied by the Colombian Ministry of Health). However, Resolution No. 01444 violated the state's duties, suggesting that the issue is also an administrative problem.

In September 2012, the Administrative Court declared that the Ministry of Health's failure to regulate Kaletra's price represented a threat to, and violation of, public health rights and interests. The Court ordered the Ministry to implement the policies necessary to regulate the price of Kaletra and to establish more favourable conditions for the financial sustainability of the health system – yet a compulsory licence was denied.

Nonetheless, the movement has yielded the following achievements:

- the Ministry of Health's actions have been declared a threat to, and violation of, public health rights and interests;
- there has been a reduction of 70 per cent or more in the price in Colombia of a key HIV drug;
- parallel imports have been adopted in Colombia;
- a policy of price ceilings has been imposed;
- broad national discussion on price, access to medicines, and patents has been instigated; and
- price control laws have been issued, the Court ruling in 2013 setting the price at $648 per patient per year.

Even if it is possible to issue a compulsory licence for lopinavir/ritonavir, applicants will expect the government to use this flexibility in the interest of public health.

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# 2 | IMPACT OF THE WORLD TRADE ORGANIZATION'S AGREEMENTS ON AGRICULTURE AND ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS ON THE HEALTH OF CITIZENS IN THE DEVELOPING WORLD: A POVERTY-PRODUCTION-BASED CRITIQUE

*Kwadwo Appiagyei-Atua*

> Globalization has brought an increased flow of money, goods, services, people and ideas. Yet, gaps are widening, both within and between countries – in life expectancy, in wealth, and in access to life-saving technology. Those left behind, and experiencing poverty and ill health, feel disempowered, marginalized and excluded. (Pillay, 2008)

## Introduction

The World Trade Organization (WTO) was founded in 1995 as the authority over global trade governance, superseding the General Agreement on Tariffs and Trade (GATT) of 1947 (Crowley, 2003). The goal was to create a stable and predictable trading system with fair and transparent rules for all participants, with a remit greatly expanded from goods to include, for instance, the trade in agricultural products and intellectual property (Crowley, 2003). However, despite admirable aims on the global stage, the WTO's policies have caused endemic poverty at the individual level.

This kind of poverty is difficult to analyse. The standard model, known as the 'poverty reduction approach', follows the neoliberal economic model of development and considers 'neutral' factors (such as malnutrition) without identifying responsible actors (Appiagyei-Atua, 2008), and thus tackles the superficial symptoms of poverty. In response to its inadequacy, a new structuralist and contextualist model, called the poverty *production* approach, has been developed. By identifying the specific actors and/or policies that create poverty and

holding them accountable, it addresses the root causes of poverty. This 'actors and actions' model, which represents a paradigm shift, involves identifying the origin, context, and effects of poverty-producing forces, as well as ways of counteracting them.

This chapter adopts the poverty production approach to understanding how WTO policies have become root causes of poverty, focusing on agriculture and intellectual property (especially pharmaceutical patents). It analyses the WTO's mandate and functions, arguing that fulfilling its objectives for agriculture and intellectual property has transformed it into a poverty-producing machine acting in contravention of international human rights agreements. By considering poverty production a human rights issue and focusing on its victims, the chapter concludes with recommendations not simply for helping the victims out of poverty, but also for enabling them to access their rights to health and food, amongst other things, and for contributing to development in general.

## From the GATT to the WTO

The WTO was established through the Uruguay Round negotiations that took place between 1986 and 1994.The Agreements setting up the WTO were signed at the Marrakesh ministerial meeting held in April 1994. Article III of the WTO Agreement outlines the functions of the WTO, which includes facilitating the implementation, administration, and operation of the WTO Agreement, as well as multilateral trade agreements (MTAs) and plurilateral trade agreements (PTAs). The WTO is also to provide a forum for negotiations among its members concerning their multilateral trade relations. The Organization is also empowered to administer the Understanding on Rules and Procedures Governing the Settlement of Disputes (Annex 2 to the WTO Agreement) and the Trade Policy Review Mechanism (Annex 3). Finally, with a view to achieving greater coherence in global economic policymaking, the WTO is mandated to 'cooperate, as appropriate, with the International Monetary Fund and with the International Bank for Reconstruction and Development and its affiliated agencies' (Article III(5) of the Agreement).

## The WTO and poverty production under the Agreement on Agriculture (AoA)

The Agreement on Agriculture (AoA) is one of the two main sectoral agreements in the Uruguay Round that provides the specific rules

regarding the liberalization of agricultural products.[1] The AoA was created to curb agricultural subsidies and import barriers, including non-tariff barriers (inherent in the 1947 GATT), with the goal of correcting market distortions in the agricultural sector.

The AoA is defined by three main areas aimed at promoting trade liberalization: market access;[2] domestic support;[3] and export competition.[4] The long-term objective of the Agreement is to establish 'a fair and market-oriented agricultural trading system' (Preamble, paragraph 2), whereby a reform process shall be initiated through the negotiation and the establishment of strengthened and more operationally effective GATT rules and disciplines. In seeking to achieve this goal, paragraph 6 of the Preamble provides that commitments made by states parties should aim at promoting equity among them:

> having regard to non-trade concerns, including food security and the need to protect the environment … and taking into account the possible negative effects of the implementation of the reform programme on least-developed and net food-importing developing countries.

Thus, on the face of it, the WTO, by means of the AoA, could take into account and incorporate human rights and environmental concerns into its modus operandi. Yet these very objectives have been defeated in practice, bringing untold hardships on farmers in developing countries. Among the negative consequences occasioned by a rigid application of the AoA rules have been environmental degradation, food insecurity, land-grabbing, and changes in the cultural lifestyle (particularly the eating habits) of local farmers. These consequences have culminated in producing poverty and have impacted negatively on the right to health of people in developing countries.

The major factors responsible for these developments are the application of the concept of 'comparative advantage' by that WTO, and the incapacity of the AoA to deal with the issue of the export subsidies and tariff barriers aimed at liberalizing trade in agriculture that are applied by developed countries.

## Theory of comparative advantage

An issue plaguing the WTO and which is held responsible for the health plight of citizens of developing countries is the application of the

principle of comparative advantage on which the WTO thrives as its underlying economic model. The principle, in theory, provides that:

> [E]ach country should produce what it can do best, and trade that good with the products other countries are able to produce best. With the profit from exports, countries can buy goods that they cannot reasonably produce themselves. This increases trade and promotes the economic performance of all Member States, which eventually raises the standard of living, and ensures full employment and the growth of real income. Following this economic theory, all countries participating in the international trading system will be better off. (Zagel, 2005: 9)

Yet, in practice, the principle does not work in this way. For example, emphasis on the production of cash crops for export has encouraged the development of homogenization in agriculture and a substitution of poly-cropping with mono-cropping (de Schutter, 2009a: 34).

Protection for plants and species, and their resistance to specific diseases, drought, or variations in temperature, is achieved through the coexistence of different types of plant with different traits. Poly-cropping makes this possible. However, the application of monocultural production techniques, with the goal of maximizing the production of a few crops, has had devastating impacts on environmental sustainability and food security, and has ultimately resulted in deepening poverty for many developing countries. Mono-cropping has led to loss of crop genetic diversity as farmers have abandoned their local varieties for genetically uniform varieties that produce higher yields under certain conditions (de Schutter, 2009b: 2). The result is an increase in outbreaks of pests and disease, the depletion of soil fertility, and the exposure of vulnerable crops to weather-related events. Yet reaction to these negative environmental consequences has been a massive application of harmful agrochemicals, which has often exacerbated the problem by destroying the pests' natural enemies, and by enabling pests and pathogens to develop pesticide resistance (Gonzalez, 2004: 421–2).

The end result has been severe damage to food crops and an increase in the vulnerability of the world's food supply. Another effect is a high increase in food prices. Another FAO study, conducted in 2001 on the impact of AoA on fourteen developing countries, revealed that the:

> AoA's liberalization policy significantly increased food importation in these countries, with many registering sudden increases in the value of their food imports in the years following their accession to the AoA. The food import bill more than doubled in countries that are significant food producers and exporters such as Brazil and India and increased 50–100% in countries like Bangladesh, Pakistan and Thailand. In fact, many agricultural exporting countries in the 70's and 80's [*sic*] like the Philippines have been transformed into net food importers as a result of import liberalization under AoA … This has led to displacement of small farmers and food-insecure groups, further exacerbating hunger and food insecurity among rural households. (Glipo, 2003: 6)

Another negative impact of the WTO policies is changing patterns in nutrition and food habits in developing countries. But, more dramatically, as noted by Yelpaala (2012: 73), there has been a cultural shift that has resulted in the redistribution of the global disease burden.

The monopolization of agricultural trade by transnational agribusiness also places farmers in developing countries at an enormous competitive disadvantage, and threatens to perpetuate poverty and hunger (Gonzalez, 2004: 425). The conclusion is obvious: absolute poverty has increased in sub-Saharan Africa and relative poverty has increased in the majority of countries.

### Export subsidies and trade barriers

Developed countries have used subsidies to make their farmers' products cheaper on the world market than those from developing countries, resulting in 'dumping'[5] in developing countries. At the same time, tariff barriers are placed on goods that farmers in developing countries would wish to export to markets in the developed countries. Under the AoA, these trade-distorting measures are supposed to be eliminated. However, ambiguities and exceptions have dogged the process, and these have been exploited by the developed countries to maintain tariffs and subsidies. The net effect is that subsidy levels in industrialized countries actually went up after the coming into effect of the AoA. Gonzalez (2004) puts the figures at $308 billion in 1986–88 and $318 billion in 2002. In this way, the AoA has legitimized and 'institutionalized the double standard in the agricultural sector:

protectionism in wealthy countries; liberalized trade in poor countries' (Gonzalez, 2004: 425). One analysis gives a graphic representation of the level of injustice done to farmers of developing countries: according to that report, the level of daily subsidy of a cow in Europe and the United States is about $2.70, while the daily income of a small and marginal farmer in the developing world is less than half of this amount (Glipo, 2003: 5).

The solution to this predicament, however, does not simply lie in the elimination of agricultural subsidies and reduction of tariffs. The impact of such an exercise in reducing the inequities in the global trading system would be minimal: not enough to promote food security and ecological sustainability in the long term.

The major stumbling block is the monopolization of agricultural markets by a few multinational corporations, which are in charge of supplying inputs (seeds, pesticides, fertilizers), and those that purchase their agricultural output (and which use their market power to dictate agricultural commodity prices) (Gonzalez, 2004: 425 *ff*). Globalization has also affected the distribution of innovative technology in agriculture, with seed and food production concentrated in the hands of global agrobusiness multinational enterprises (Yelpaala, 2012). Application of these measures has resulted in poverty production for many farmers from developing countries.

As Olivier de Schutter (2009b: 3), UN Special Rapporteur on the right to food, notes:

> *[T]he top 10 seed companies have 67 percent of the global proprietary seed market; the world's largest seed company alone, Monsanto, accounts for 23 percent of that market; and the top three companies (Monsanto, DuPont and Syngenta) account for 47 percent of the market, including 65 percent of the maize seed market and over half of the proprietary soybean seed market.* This means that these companies reap a disproportionate portion of the final value of the crop, and that the dependency of farmers on the inputs they provide may not be sustainable unless antitrust legislation is not used more proactively to tackle such concentration. (Emphasis original)

## Poverty and health

According to the United Nations' Committee on Economic, Social and Cultural Rights (CESCR, 2001: para. 7), poverty is 'usually

understood more broadly as the lack of basic capabilities to live in dignity. This definition recognizes poverty's broader features, such as hunger, poor education, discrimination, vulnerability and social exclusion.' In support, Amartya Sen (1999: 87) contends that 'poverty must be seen as the deprivation of basic capabilities rather than merely a lowness of incomes, which is the standard criterion of identification of poverty'.

Poverty comes about through denial of rights, since rights are needed to help an individual, or a group of people, to meet their needs, to participate in development, and to protect the gains of development. Thus, when these rights are respected, protected, and fulfilled, they provide the key to moving people out of poverty and making them contributors to, instead of victims of, development. It is in agreement with this view that the CESCR (2001: para. 1) has noted that 'poverty constitutes a denial of human rights'.

Poverty, in turn, has its negative repercussions on health, as confirmed by Muennig and colleagues (2010), who concluded that, of all of the health factors measured, poverty had the greatest negative impact on health.[6] Poverty was determined to take away 8.2 years of health, meaning that poor people have 8.2 fewer years in which they are healthy than those who live at above 200 per cent of the federal poverty level (FPL).[7] Globally, there is a stark relationship between poverty and poor health: in the least developed countries (LDCs), life expectancy is 49 years, and one out of every ten children die before their first birthday. In developed countries, on the other hand, the average life span is 77 years, while the infant mortality rate is six per 1,000 live births (WHO and World Bank, 2001: 4). It is in the context of this unfortunate phenomenon that Kofi Annan (2001) noted that '[t]he biggest enemy of health in the developing world is poverty'.

Also, the then Organization of African Unity (OAU), in its 1987 Declaration of Health as Foundation for Development, underlined that 'agricultural and other efforts at production (macro or microeconomic) are frustrated by the inadequate health status of many populations in Africa, the vicious cycle of ignorance, poverty and disease persists [and that] poor health is delaying economic "take off"'. Thus, in sum, poverty induces health problems. It forces people to live in poor and unhealthy environments, with deprived sanitation, indecent housing or homelessness, and lack of access to potable water, among others. Poverty, in turn, causes hunger, or induces the poor to adopt poor eating

habits or unhealthy diets, etc. Poverty also perpetuates or worsens the health conditions of the poor, or leads to their early death, because of inability to afford health care. Ill-health, in turn, fosters poverty, because it disables the weak and sick from engaging in productive labour. Moreover, changes in eating habits lead to the development of new diseases.

When a poor person becomes ill or injured, the entire household can become trapped in a downward spiral of lost income and high healthcare costs. The cascading effects may also include diverting time from generating an income or from schooling to care for the sick. Illness in the family may also force the sale of assets. More prone to disease, and with limited access to health care and social insurance, poor people are more vulnerable to this downward spiral.[8] More than a third – 3.5 million – of all child deaths annually and 11 per cent of the total disease burden worldwide are estimated to be the result of maternal and child undernutrition, which are directly related to, or induced by, poverty.

Yet, after causing poverty in many a developing country, the producers of poverty and its attendant diseases have placed insurmountable obstacles in the way of the poor, the sick, and the marginalized to prevent them from accessing affordable medicine and health care as a result of the introduction of the 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[9]

## The WTO and poverty production under TRIPS

During the final stages of the Uruguay Rounds, the United States, after it had been lobbied and prodded by the pharmaceutical giants, adopted the position that the absence of a strong intellectual property rights (IPR) regime in developing countries was a barrier to trade that needed to be countered. It was estimated that this cost industrialized countries about $200 billion in lost royalties every year. Thus TRIPS was introduced, with the goal of harmonizing developing countries' IPR laws with those of the Western world, so as to suit the trading interests of multinational corporations – particularly those in the pharmaceutical and software sectors. The United States was supported by the European Union, Canada, Switzerland, and Japan, among others, which played a hegemonic role in the negotiations (Adusei, 2010; Yelpaala, 2012).

The WTO's TRIPS establishes patentability for product and process inventions in 'all fields of technology, provided that they are

new, involve an inventive step and are capable of industrial application' (TRIPS Article 27(1)). These products and processes are then qualified as private property rights under TRIPS (Preamble, paragraph 4). Yelpaala (2012: 64) laments that, under this trade regime, a state's right to trade was tied to the protection of intellectual property – that is, the public interest of states has been subjugated to the protection of foreign private IPR.

However, some flexibilities were introduced to allow for a supposedly smooth transition for developing countries and LDCs to regulate their local patent laws so that they fall in line with the international standards. Developing countries were permitted to delay the application of most provisions of TRIPS for five years following its entry into force – that is, until 1 January 2000 (TRIPS Article 65(2) and (3)). Least developed countries, on the other hand, were given to 1 January 2006 (TRIPS Article 66(1)).

In spite of this, Adusei (2010: 62) argues that:

> [T]he grant of product patents gives the owner exclusive rights over the composition of the drug itself regardless of how it is produced, and the process patents give the owner exclusive rights over the scientific method of producing the drug. Further, the enjoyment of patent rights is without discrimination as to whether the products are imported or manufactured locally. Moreover, TRIPS requires each signatory country to provide an effective enforcement mechanism for patents. To cap it all, the grant of patents is backed by a dispute settlement mechanism that can hold states liable for any infringement.

Under this arrangement, the end-users of drugs patented and manufactured by the big pharmaceutical companies are forced to pay expensive prices, and governments eventually become 'toll collectors' for these companies, while their citizens remain impoverished and die from diseases such as HIV/AIDS, malaria, and tuberculosis (Adusei, 2010; Bhagwati, 2004). Thus, for example, absent patent protection, in India, 150 mg of the anti-fungal drug flucanozole (used in HIV patients to prevent or treat fungal infections) costs $55 – yet in countries such as the Philippines and Indonesia, where the same drug is patented, it costs $697 and $703, respectively (Sykes, 2002). Thus, when the European Union drafted a free trade agreement

(FTA) with India, UN Special Rapporteur on the right to health, Mr Anand Grover, had cause to warn that the draft FTA 'could prevent millions of people from gaining access to necessary, life-saving and life-prolonging medicines', owing to the fact that India is currently the largest supplier of generic medicines to the developing world (PTI, 2010).

In 2003, the World Health Organization (WHO) declared poor access to antiretroviral medicines an international health emergency. The Organization spearheaded an initiative with the so-called three by five target: provision of treatment to 3 million people in poor countries by the end of 2005 (WHO and UNAIDS, 2006). Around the same time, the Clinton Foundation brokered agreements with 'big pharma', as well as some leading medical technology companies, to launch two major price-reduction agreements. The agreements resulted in the reduction of the costs of testing for and treating HIV/AIDS from $3,600 to around $250 per patient per year in poor countries (Schoofs, 2003). Although the goal of 3 million people – out of an estimated need for therapy among 9.7 million people – was not reached until the end of 2007, 'three by five' played an important role in catalysing concerted action to expand treatment access in poor countries. There are therefore important lessons to be learned from this experience.[10]

Attempts by countries such as South Africa, Brazil, and India to counter TRIPS resulted in legal action, or the threat of legal action, or sanctions against them. For example, following the enactment of the Medicines and Related Substances Control Act of 1997 by South Africa, a number of pharmaceutical companies initiated legal action against the country (Nash, 2000).

When the 'grace period' for developing countries and LDCs under TRIPS was near exhausted, the reality began to sink in: that they had made a bad deal under TRIPS. Consequently, some intellectual efforts have been exerted in an attempt to resolve the inequities inherent in TRIPS (Correa, 2002). However, in the view of Yelpaala (2012: 67–68), this goes not go deep enough: 'These studies are mostly concerned with content and textualism rather than structure and contextualism. Little attention is devoted to the structural and systemic problems which seem to be foundational in the problems posed by TRIPS.'

This suggested 'contextualist' and 'structuralist' approach is worth analysing in considering the imbalances inherent in TRIPS and as identified by the UN Conference on Trade and Development

(UNCTAD), which notes, for example, that an overwhelming 84 per cent of the patents in developing countries are owned by mainly multinational corporations of five developed market economies, as opposed to less than 1 per cent by nationals of developing countries (DESA/UNCTAD/WIPO, 1974; Oddi, 1987).

Apart from the intellectual effort, some political pressure has also been brought to bear on the WTO's Council for TRIPS to change the rules to suit the interests of developing countries. Some fifty developing countries from Africa, Asia, Latin America, and the Caribbean put forward a joint statement to the Council, in anticipation of the Doha Ministerial Conference, asking it to take steps to ensure that 'the TRIPS Agreement does not in any way undermine the legitimate right of WTO Members to formulate their own public health policies and implement them by adopting measures to protect public health' (Oh, 2001).

The Doha Conference recognized the severity and reality of the public health problems within the developing countries. However, in its 2001 Declaration, it sought only to provide solutions within the flexibilities inherent in TRIPS, as long as their use was consistent with that agreement. Neither did the 2001 Doha Declaration resolve the issue of the right of developing countries lacking the capacity to manufacture generic drugs to grant a compulsory licence to others to do same for them. The ministers deferred resolution on this matter to a later date.

## Post-TRIPS

Thus, in the post-TRIPS era,[11] it has seemed as though the attempts made to respond to the concerns of developing countries – particularly by organizations such as WHO, UNCTAD, the United Nations Development Programme (UNDP), and the World Intellectual Property Organization (WIPO) – have been but piecemeal (Adusei, 2010). For example, the resolutions passed by these organizations to support developing countries are not binding on WTO. In the end, patent regulatory and institutional lapses still persist in sub-Saharan Africa in particular (Adusei, 2010).

What is worse, the 'TRIPS-plus' obligations that developing countries in general have had to assume through bilateral and regional agreements made with developed countries are even more onerous than those to which they bound themselves under TRIPS proper (Adusei,

2010). Such relatively high IPR standards limit the fragile flexibilities provided under TRIPS and the Doha Declaration, as well as the terms of trade of sub-Saharan African countries as primary consumers of pharmaceutical products and processes. It is therefore contended that such TRIPS-plus agreements violate the spirit of TRIPS (UNCTAD/ICTSD, 2005).

## Relationship between rights and trade: How the WTO got it wrong

The Uruguay Round negotiations took place amidst an ambience of growing recognition in the international community of a linkage between rights and development, largely influenced by the sustainable development movement after the two concepts (human rights and development) had gone their separate ways, even being seen as being inimical to one another other (Ksentini, 1994).

The International Monetary Fund (IMF) and World Bank followed this pattern. At their inception, although supposed to be guided by human rights issues, both asserted themselves as strictly economic-focused institutions, the mandates of which did not extend to incorporating human rights and environmental concerns into their activities and projects. As noted by Peter Uvin (2002: 1), they 'did not consider human rights issues as part of their professional domain: they neither weighed the implications of their own work on human rights outcomes, nor sought explicitly to affect human rights through their work', which tendency continued until well into the 1990s. The IMF and World Bank may be excused for the initial position that they held, considering the historical context into which they were born.

Within the UN system, however, one may point to the various development debates in which the United Nations recognized the limited place given to human rights. In the late 1980s and into the 1990s, the intellectual and operational gap between rights and development began to narrow and ultimately merge. Reference can be made to the work of Amartya Sen (1999), Martha Nussbaum (1999) of the feminist/gender school of the time – particularly the gender and development (GAD) movement – and others, who all focused on the need to empower human beings through respect for their rights to enable them to contribute more effectively to development. The UNDP, among other UN agencies, introduced its Human Development Reports to highlight the need to promote human development as the basis for

attaining economic development. In its 1996 report, it categorized various aspects of growth that, in its observation, were unsustainable. Touching on 'voiceless growth', for example, the report defined it as a type of growth:

> in which growth in the economy has not been accompanied by an extension of democracy or empowerment. Political repression and authoritarian controls have silenced alternative voices and stifled demands for greater social and economic participation. Policy makers once debated whether they should choose economic growth or extensive participation, assuming that these were mutually exclusive. That debate is dead. People do not want one or the other – they want both. But too many people are still denied even the most basic forms of democracy, and many of the world's people are in the grip of repressive regimes. Voiceless growth can also be growth that gives women only a minor role in an economy's management and direction. As Human Development Report 1995 showed, human development, if not engendered, is endangered. (UNDP, 1996: 2–3)

Thus the Uruguay Rounds presented a perfect opportunity for states to allow such developments to influence the negations and the agreements that ultimately emerged out of them. Yet the WTO rather preferred to stick to the 'watertight compartment' position originally adopted by the IMF and the World Bank: that it is a trade, not a human rights, organization and therefore not the appropriate forum for addressing human rights concerns (CESCR, 2004: para. 20). The rationale for this position, although weak, lame, and unsustainable, has yet not been critically challenged from a human rights and international law perspective. The result has been flagrant violation of the rights of citizens in developing countries as the WTO seeks to implement most of its agreements.

The subsequent impact of TRIPS and TRIP-plus on the rights of the victims is well captured by bodies such as the former Sub-Commission on the Promotion and Protection of Human Rights (2000: para. 6), which noted the 'apparent conflicts between the intellectual property rights regime embodied in the TRIPS Agreement, on the one hand, and international human rights law, on the other'. Yet the WTO is under international obligation not to drag the world back into the 1950s, for

we now live in an era of human rights consciousness and human rights are supposed to be mainstreamed into every aspect of human lives, including trade (Bobbio, 1996; Epp, 1998).

Not only are the terms of the WTO agreement not human-rights-friendly, but they are fundamentally opposed to certain rights of citizens in developing countries, including the right to work, the right to life, the right to food, the right to water, the right to a healthy environment, and the fundamental right of a state to trade, all of which culminate in an impact on the right to health. These rights and others have a 'direct and immediate bearing upon the eradication of poverty' (CESCR, 2001: para. 1). It is apparent that the WTO violates rights in three principal ways:

- by disallowing its own introduction of rules linking human rights to development;
- by imposing the same limitation on member states; and
- by directly violating certain rights, including those noted above and elsewhere in this chapter – particularly the right to health.

## Right to health

Article 12(1) of the International Covenant on Economic, Social and Cultural Rights (ICESCR) explicitly recognises 'the right of everyone to the enjoyment of the highest attainable standard of physical and mental health'. The right to health is considered to be one of the fundamental rights that links with almost every other right, including those elaborated earlier. In its General Comment on the right to health, the CESCR (2000: para. 1) noted the all-encompassing nature of this right, confirming that '[h]ealth is a fundamental human right indispensable for the exercise of other human rights' and that '[e]very human being is entitled to the enjoyment of the highest attainable standard of health conducive to living a life in dignity'.

The Committee interpreted the right to health as an inclusive right extending not only to timely and appropriate health care, but also to the underlying determinants of health, such as access to safe and potable water, and to adequate sanitation, an adequate supply of safe food, nutrition, and housing, and healthy occupational and environmental conditions (CESCR, 2000: para. 11). In this way, the Committee confirms the insidious role of poverty in denying people access to such determinants and ultimately impacting on their health.

In this regard, it is pertinent to refer to the Committee's General Comment on the right to food to properly situate the role and place of food in the equation:

> [T]he right to adequate food is indivisibly linked to the inherent dignity of the human person and is indispensable for the fulfilment of other human rights enshrined in the International Bill of Human Rights. It is also inseparable from social justice, requiring the adoption of appropriate economic, environmental and social policies, at both the national and international levels, oriented to the eradication of poverty and the fulfilment of all human rights for all. (CESCR, 1999: para. 4)

Furthermore, the Committee noted in its General Comment on the right to health (CESCR, 2000: para. 39) that:

> To comply with their international obligations in relation to article 12, States parties have to respect the enjoyment of the right to health in other countries, and to prevent third parties from violating the right in other countries, if they are able to influence these third parties by way of legal or political means, in accordance with the Charter of the United Nations and applicable international law.

Further, the General Comment provides that:

> States parties should ensure that the right to health is given due attention in international agreements and, to that end, should consider the development of further legal instruments. In relation to the conclusion of other international agreements, States parties should take steps to ensure that these instruments do not adversely impact upon the right to health. (CESCR, 2000: para. 39)

In this respect, when drafting, adopting, and signing treaties such as the WTO Agreement itself, and related ones such as the AoA and TRIPS, the obligation of international actors to ensure that these treaties are in conformity with the ICESCR should be taken into account and respected. Yet the opposite is the case in a number of instances.

More directly, the Committee notes:

> [C]oordinated efforts for the realization of the right to health should be maintained to enhance the interaction among all the actors concerned, including the various components of civil society. In conformity with articles 22 and 23 of the Covenant, WHO, The International Labour Organization, the United Nations Development Programme, UNICEF [the United Nations Children's Fund], the United Nations Population Fund, the World Bank, regional development banks, the International Monetary Fund, the World Trade Organization and other relevant bodies within the United Nations system, should cooperate effectively with States parties, building on their respective expertise, in relation to the implementation of the right to health at the national level, with due respect to their individual mandates … The adoption of a human rights-based approach by United Nations specialized agencies, programmes and bodies will greatly facilitate implementation of the right to health. (CESCR, 2000: para. 39)

This segment of the General Comment on the right to health firmly indicts the WTO and requires it to align its activities and practices with international law, affirming that the Agreement establishing the WTO – the *raison d'être* of improving trade – is not an end in itself; rather, the aim of improvement in trade should be to serve the goal of human development. Inherent in these objectives is the requirement that the WTO applies human rights principles, or at least establishes the proper relationship between human rights and trade. Among some key rights that can be inferred from the Preamble to the WTO Agreement are the right to food, right to health, right to work, right to development, and right to a healthy environment. Also, for example, paragraph 1 of the Preamble notes that, in performing its functions, the WTO should focus trade and economic relations on, among other things:

> *raising standards of living, ensuring full employment and a large and steadily growing volume of real income* and effective demand, and expanding the production of, and trade in, goods and services, while allowing for the *optimal use of the world's resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment*. (Emphasis added)

The WTO therefore cannot dissociate itself from applying human rights principles in seeking to promote world trade.

In this way, then, the WTO can be seen to be violating international law by producing poverty, and thereby violating the 'right to not be poor' of sick people, farmers, etc., which can be inferred from the various international human rights instruments – in particular, the International Bill of Rights.[12]

### The WTO and the environment

Another contention is that sustainable development is also reflected in the Preamble to the WTO Agreement (although this has not impacted much on the operations of the WTO), which came into force about six months after the 1992 UN Convention on Biological Diversity (CBD).[13] Incidentally, the WTO has provisions that seek to trump the CBD so that a country that adopts policies to protect the environment in good faith may end up violating TRIPS. This is because, among other things, TRIPS is intended to grant private property rights over products and processes in order to provide monopoly control to those who claim to have 'invented' new plants, animals, or micro-organisms, or uses thereof (GAIA and GRAIN, 1999). Further to this, it is estimated that, each year, up to 30 million hectares of farmland are lost to environmental degradation, conversion to industrial use, and urbanization, partly or largely attributed to implementation of the AoA (OHCHR, 2010). Yet sustainable development and protection and preservation of the environment are also considered cornerstone policies of the UN Charter, as reflected, for example, in the CBD.

The CBD, among other things, affirms the sovereign rights of a country over its natural resources as a way of strengthening its capacity to conserve and use biological diversity on a long-term basis. Article 3 of the Convention stipulates that:

> States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.

Also, paragraph 20 of the Preamble to the CBD provides that the conservation and sustainable use of biological diversity are of critical importance for meeting the food, health, and other needs of the growing

world population, for which purpose access to, and sharing of, both genetic resources and technologies are essential.

Yet these noble attempts to protect the biological diversity of the world are being challenged by TRIPS, which seeks to take away the sovereign rights of states over their natural resources, and convert them into private rights for individuals and corporations.

How, then, can this be seen as aligning with Article 22 of the CBD, which stipulates that, where the exercise of rights and obligations provided for in any existing international agreement 'would cause a serious damage or threat to biological diversity', those rights and obligations shall not be affected? This Article provides strong grounds to question and invalidate portions of TRIPS and the AoA, because there is ample evidence to show the devastating and irreparable harm that these agreements are causing to biodiversity, in developing countries in particular.

### The WTO and the United Nations

Although the WTO is not a UN agency, its Agreement establishes some links with the United Nations. Parallels can be seen, for example, between the phrase 'raising standards of living, ensuring full employment *and a large and steadily growing volume of real income* and effective demand' (emphasis added), which appears in paragraph 1 of the Preamble to the WTO Agreement, and the Preamble to the UN Charter, in which the United Nations expresses its determination:

> to establish conditions under which justice and respect for the obligations arising from treaties and other sources of international law can be maintained, and to promote social progress and better standards of life in larger freedom, and for these ends to employ international machinery for the promotion of the economic and social advancement of all peoples.

More directly, the phrase in the WTO Preamble mirrors Article 55(a) of the UN Charter, which makes reference to the fact that 'the United Nations shall promote *higher standards of living, full employment, and conditions of economic and social progress and development*' (emphasis added). This can be interpreted as meaning that the WTO rules are subordinate to the principles of the UN Charter (FIDH, 1999).

In fact, Article 103 of the latter explicitly states that: 'In the event of a conflict between the obligations of the Members of the United Nations under the present Charter and their obligations under any other international agreement, their obligations under the present Charter shall prevail.' Furthermore, under the UN Global Compact, its specialized agencies and other worldwide intergovernmental organizations, such as the WTO, agree to integrate universally recognized human rights into their law and practice (Weiler, 2001; Yelpaala, 2004).

### The WTO and international law: The contradictions

It can be argued that the treacherous process through which the WTO came into being provides a basis for its invalidation under the Vienna Convention on the Law of Treaties (VCLT).[14] As noted by several scholars and writers, the WTO Agreement and TRIPS, in particular, were drafted under coercive and repressive conditions dictated by the United States and other Western countries. Gathii (2002: 294), for example, writes that, '[d]uring the Uruguay Round, the United States unilaterally pressured developing countries opposed to its negotiating position, such as Brazil, Thailand, and India. Therefore, the Agreement was negotiated "within a coercive bargaining context"'.

Adusei (2010: 60) also notes that:

> First, there are glimpses of coercion by the West to procure the consent of less developed countries to cede their autonomy on IP matters. This coercion is evidenced by threats of retaliatory sanctions under the US Trade Act and a possible forfeiture of GATT/WTO status … In addition, developed countries used their superior bargaining power to ensure compliance by less developed countries.

Consider, then, Article 9 VCLT, which provides that 'the adoption of the text of a treaty takes place by the consent of all the States participating in its drawing up except as provided in paragraph 2'. Thus *consent* is crucial to ensuring the recognition of a state as a party to a treaty. Where this consent is lacking, the treaty will be deemed to be invalid, as expressed in Article 51: '[T]he expression of a State's consent to be bound by a treaty which has been procured by the coercion of its representative through acts or threats directed against

him shall be without any legal effect.' Furthermore, Article 52 VCLT stipulates that 'a treaty is void if its conclusion has been procured by the threat or use of force in violation of the principles of international law embodied in the Charter of the United Nations'. Moreover, the actions of the United States and its allies also violate Article 2(4) of the UN Charter, which provides that: 'All Members shall refrain in their international relations from the threat or use of force against the territorial integrity or political independence of any state, or in any other manner inconsistent with the Purposes of the United Nations.'

It is also noteworthy that the WTO's Uruguay Round of negotiations did not meaningfully involve countries from sub-Saharan Africa. What is worse, those few that participated were constrained by insufficient access to information that was freely available to Western negotiators (Gervais, 2007: 10). In addition, it has been argued that the LDCs were ignorant of the extensive nature of the obligations that they adopted (Yu, 2006: 375). The result, according to Adusei (2010), is that LDCs embraced high Western standards of IPR protection as part of their domestic laws without a proper appreciation of the ramifications of such acceptance. Had there been no coercion, marginalization, lack of information, etc., developing countries would not have raised so strong a voice to argue against TRIPS and ask for changes.

These phenomena also offend the VCLT and provide a solid basis on which to invalidate a treaty, because they may be interpreted as constituting fraud or error. Article 49 VCLT states that 'if a State has been induced to conclude a treaty by the fraudulent conduct of another negotiating State, the State may invoke the fraud as invalidating its consent to be bound by the treaty'. Furthermore, Article 48 provides that:

> [A] State may invoke an error in a treaty as invalidating its consent to be bound by the treaty if the error relates to a fact or situation which was assumed by that State to exist at the time when the treaty was concluded and formed an essential basis of its consent to be bound by the treaty.

## Conclusion and recommendations

This chapter has examined the manner in which goods are produced, trade is regulated, and wealth is distributed under the WTO, the

successor to the GATT, and how this impacts on poverty and the health of citizens of the developing world.

It has revealed that WTO policies have engendered large-scale poverty and relegated millions to the fringes of society, fighting for survival in insanitary conditions, bereft of food and access to potable water. What is worse, changes in eating habits occasioned by AoA conditionalities have led to the development of new diseases. Yet the producers of poverty and its attendant diseases have placed insurmountable obstacles in the way of the access of the poor and the sick to affordable medicine and health care by means of the introduction of TRIPS. The TRIPS Council, for instance, has usurped the functions of some international organizations such as WIPO originally invested with the mandate controlling intellectual property in a manner that will evenly benefit citizens of the developing and developed worlds.

At the same time, the WTO has adopted a watertight compartment policy that sidelines human rights from its operations and activities, claiming that they lead to trade distortions and that the organization itself is not a human rights, but a trade-oriented, body. Consequently, the WTO has acted in violation of the UN Charter, the Vienna VCLT, the CBD, and the other major human rights treaties.

The very rights that are violated hold the key to turning around the fate of the millions who have been condemned to poverty, ill-health and indignity, and marginalization. To end these violations, rights should be used as a tool of empowerment to turn victims of poverty into actors who should fully participate in ending poverty and contributing to development at large, by recognizing their right to health and food, among other things. The goal is not simply to help the victims out of poverty, but also to enable them to contribute to development. Therefore globalization needs to be reoriented towards human rights, rule of law, and sustainable development – and away from the financial enrichment of a few.

## Notes

1 The other is the Agreement on Textiles.

2 See AoA, Pt III, Arts 4 and 5. This covers the process of 'tariffication', which involves the elimination of non-tariff barriers, such as import bans, import quotas, or quantitative restrictions on imports, and their conversion into tariffs.

3 AoA, Pt IV, Arts 6 and 7, deal with government support to farmers, to identify those mechanisms that result in trade distortion and how these can be eliminated.

4 AoA, Pt V, Arts 8–11, touch on the elimination of export subsidies to avoid trade distortion.

5 'Dumping' is the importation of a product at an export price below its 'normal value' (that is, usually the price of the product in the domestic market of the exporting country), which imports cause injury to a domestic industry in the territory of an importing contracting party. See, e.g., Art. VI of the WTO Agreement.

6 The other factors at which they looked included smoking, obesity, lack of health insurance, and binge drinking, all of which had a less significant impact on health outcomes than living in poverty.

7 This is a standard measure of health burden, used by the WHO.

8 Derived from comments provided by Dr Gijs Walraven during workshop proceedings in Delhi, India.

9 Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco, on 15 April 1994.

10 Information originally derived from comments made by Dr Walraven during the Delhi workshop.

11 This represents the fourth juridical phase in the attempt to internationalize patent rules.

12 See, e.g., ICESR Art. 11 and Art. 25 of the Universal Declaration of Human Rights (UDHR).

13 The Convention was opened for signature on 5 June 1992 at the UN Conference on Environment and Development in Rio de Janeiro, Brazil, and came into force on 29 December 1993.

14 Adopted on 22 May 1969 and entered into force on 27 January 1980.

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PART TWO

# POLITICAL MOVEMENTS

# 3 | MANAGING AN A(H1N1) PANDEMIC: PUBLIC HEALTH OR HEALTHY BUSINESS?

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## Introduction

Journalists are frequently criticized for the sensationalist reporting of natural disasters or epidemic outbreaks. Surprisingly, the public discussion of the 2009 pandemic of swine flu, influenza A(H1N1),[2] was characterized by responsible coverage in media outlets, but melodramatic statements from international organizations and national health ministries. Especially in the aftermath of the inappropriate response of the World Health Organization (WHO), journalists asked questions that the experts could not answer: was there ever a high risk of a pandemic, and if so, of what magnitude? Could it be possible that billions of dollars were wasted on a drug that had not been proven effective against A(H1N1) owing to a series of escalating mistakes, or were WHO's actions part of a calculated financial scheme? Five years later, those journalists' concerns have been vindicated by means of independent evaluations by entities including the European Council (Cassel, 2010) and the French Parliament (Assemblée Nationale, 2010).

The story begins in 2000, when the company Roche considered withdrawing the antiretroviral oseltamivir INN (marketed as Tamiflu) from the market because of low sales. When bird flu, influenza A(H5N1), broke out in 2005, developed countries amassed vast stocks at WHO's recommendation. Because of the scale of the overestimate – it caused 300 deaths, not 150 million – there seems to have been an incentive for WHO to cover its tracks. Although oseltamivir had not yet undergone human trials for A(H1N1) in 2009, hundreds of millions more doses were purchased at the urging of WHO advisers, some of whom stood to benefit financially from the hundreds of billions of dollars of sales.

The mishandling of the response to A(H1N1) has been disastrous for WHO, and the discrepancy between the quantity and shelf life of the pharmaceuticals acquired by developed and developing nations is representative of the way in which developing countries are penalized

in regards to access to antiretrovirals. This chapter explores how oseltamivir was transformed from an unpopular drug to one that came to represent international corruption, flawed and potentially dangerous public health policies, and wasteful spending. It then analyses the motivations of decision makers at the international, national, and corporate levels, and concludes by exploring the lasting ramifications of the response to A(H5N1) and A(H1N1).

## Stockpiling oseltamivir: The case of A(H5N1)

In the case of avian influenza H5N1, when the threat arose in 2005, there was stockpiling of the medicine oseltamivir, which had unproven effectiveness for an illness that had not even yet propagated. This decision was unprecedented in the history of medicine. These medicines were to be kept in stock for about 20–50 per cent of the population in several developed countries, including Canada, the United States, Japan, the United Kingdom, and France (see Table 3.1). However, given that oseltamivir's shelf life is only between five and seven years, these stocks have most likely already been destroyed at the time of writing.

If we look at the history of public health through the twentieth century, we will see that there have been hundreds of variants of influenza viruses. Apart from A(H1N1), which is of swine origin, how many have actually caused human infections? The answer is: only four. During the height of the threat of the avian influenza, A(H5N1), leading scientists informed the media that the virus was highly pathogenic. In August 2005, the chief of cabinet of the WHO Director General's office announced in a press release that 150 million people in the world could die as a result of this possible pandemic. In October of the same year, only two months later, WHO said that the number was more likely to be roughly 20 million people. In January 2006, it was announced that it could be approximately between 2 million and 7.4 million (Dawn, 2001). In October 2010, WHO reported a total of just 331 deaths (over the course of nine years), with most concentrated in Indonesia and Vietnam (WHO GIP, 2011).[3] Most common illnesses have a higher mortality rate than that of A(H5N1).

With such a disparity in expected and observed outcomes, it must be asked how the original estimates for number of deaths were calculated. When WHO predicted that between 2 million and 7.4 million people would die, the answer that epidemiologists presented was that this calculation was made based on historical experience (WHO, 2005a).

TABLE 3.1 Comparison of international oseltamivir/zanamavir stockpiling trends, 2008

| Country (population) | Size and composition of stockpile | Uses | Comment |
|---|---|---|---|
| Canada (33 m) | ~25% of population is covered<br>50.7 m doses of oseltamivir and 5 m doses of zanamivir, plus other federal and private stockpiles (~80 m total) | Early treatment; rapid containment; outbreak control; post-exposure prophylaxis in phases 4/5 | Private stockpiles may be present for pre-exposure prophylaxis |
| United States (304 m) | 25% of population (Goal 35%)<br>Almost all oseltamivir | Early treatment; rapid containment (prophylaxis to be covered by private stockpiling) | Endorses private stockpiling; has well-established shelf-life extension programme |
| United Kingdom (61 m) | 25% of population; recent commitment to increase to 50% population (32.8 m)<br>Two-thirds oseltamivir<br>One third zanamivir | Early treatment; enough for severe pandemic and small amount for pre-exposure prophylaxis | Post-exposure prophylaxis in households under consideration; looking at alternatives for expiring stock |
| France (62 m) | 50% of population; may share with other EU countries<br>240 m doses of oseltamivir<br>90 m doses of zanamivir | Early treatment; pre-exposure prophylaxis in phase 4/5 | Stock began to expire in 2008; looking at shelf-life extension |
| Japan (127 m) | 23% of population (target 45%); may share with Thailand and other Asian countries<br>240 m doses of oseltamivir<br>90 m doses of zanamivir | Large yearly treatment | Has a shelf-life extension programme |

*Source*: Public Health Agency of Canada (2008)

According to the recorded historical experiences, we can see that, in the Spanish flu (H1N1) epidemic of 1918–20, approximately 40 million people had died globally. For the Asian flu of 1957–58, 2 million people had died. During the more recent outbreak of Hong Kong flu H3N2 in 1968–69, 1 million people had died. The basis of the WHO mortality estimate for the H5N1 strain of 2–7.4 million people, given the historical figures, is still unclear.

The drug oseltamivir (registered as Tamiflu) was developed by the American company Gilead Sciences,[4] which gave an exclusive licence to Swiss company Roche in 1996 for the period of validity of

the patent (that is, twenty years).[5] In 2000, several years before the threat of pandemic, Roche considered the possibility of withdrawing this medicine from the market on the grounds of its low sales volumes worldwide. The threat of the financial losses from oseltamivir have therefore been considered by many to be the driving force behind the creation of what may have been a faux pandemic. In general terms, oseltamivir is effectively a more sophisticated version of aspirin, serving solely to attack flu-like symptoms and to diminish them.

On 27 October 1999, the US Food and Drug Administration (FDA) issued the first approval of the treatment for type A and B influenza without any complications.

On 20 November 2000, the FDA extended the prophylaxis indications, precisely one year after talks began about the possible epidemic and pandemic risk of avian influenza. However, the question was: how could the indications be extended without any opportunity of carrying out clinical trials to test whether this medicine could prevent the infection and spread of the disease?

In 2004, WHO recommended the stockpiling of oseltamivir (WHO, 2004). In France, for example, a stock for 50 per cent of the population was made: a situation that had never before been seen in relation to other diseases. Stockpiling also occurred in many developing countries following WHO recommendations.

Unfortunately, the oseltamivir stockpiling especially penalized developing countries. Developed countries received a large supply of raw materials that have a shelf life of ten or fifteen years more than the finished product, which has only five years of validity. Most of the developing countries received that finished product, which five-year life span, in good storing conditions, could be extended by a maximum of one or two years. Thus developing nations were to have a much shorter window of protection from a possible pandemic than developed nations, which could utilize the raw materials to produce effective drugs.

On the constitution of a stock (stockpiling), the US Center for Disease Control and Prevention (CDC) in Atlanta, GA, published a study suggesting that, despite the steep initial outlay, governments would save money by stockpiling the antiviral drug oseltamivir as a hedge against a future influenza pandemic (Balicer et al., 2005).

The study, based on mathematical modelling, argued that since there was a flu pandemic at least once every eighty years, governments could save more than US$3.50 for every $1 that they invested in the drug.

In August 2005, WHO announced that it had received 3 million doses of oseltamivir from Roche in order to constitute a stock, and the recommendation of establishing stocks later appeared in the form of a WHO manual and guide (WHO, 2005b).

Yet it appears that Roche may have been involved in a commercial strategy more than a public health intervention. After Roche supplied the 3 million doses, the WHO director general was thankful for the donation, implying that it had started the stockpiling purely out of public health necessity (WHO, 2005b). The next morning, at a meeting of the ministries of health of the member states of the European Union, the importance of having a stock was ratified,[6] following WHO's example.

In this context, a lot of questions emerge: why have a stock of oseltamivir instead of a stock for antiretroviral drugs? Why not prepare the world for HIV/AIDS in the same way as for pandemic influenza A (H1N1)? Why and how was the efficacy of existing drugs announced before knowing the results of human clinical trials? Clearly, there was no time for developing those clinical trials and the drugs were distributed without a clear indication of their safety or efficacy. When the stockpiling started, there was very little reference to possible resistance; today, there would have been serious resistance (Baz et al., 2009). All of these questions indicate that this medicine should not have been massively distributed as it was (Moscana, 2009). No reference was made by national or international health authorities to these problems or the implications of resistance in a case of massive use.

In Japan, there had even been several cases of suicide among young people aged 14–25 who were under treatment with oseltamivir: side effects that were known at the time of mass distribution, but were not well publicized.[7]

The FDA, WHO, and Roche made various comments after stockpiling had occurred. The FDA clearly affirmed that it did not consider any aspect related to preparedness in relation to avian pandemic or A(H1N1) (US FDA, 2014).

On the other hand, WHO asserted that 'evidence suggests that some antiviral drugs, notably Oseltamivir, can reduce the duration of viral replication and improve prospects of survival' (WHO, 2014). Several WHO documents even referred to oseltamivir as the one and only effective medicine against the possible avian pandemic. Yet this fervent support of oseltamivir is dubious, given that most authorities

would argue that there are other medicines, such as zanamivir, as well as cheaper alternative such as alcohol-based solutions and masks, which could also be effective. The WHO statement itself was also somewhat premature given that transmission among humans had not yet developed. It was known that there was some effectiveness of the medicine in common seasonal flu, but for this new type of influenza, although there was some sensitivity in the in vitro experience, medical trials had not yet been carried out.

Nevertheless, Roche's website called the medicine 'one of the most important medicines currently available to fight both seasonal and pandemic influenza' (Roche, 2007).

### New pandemic, old response: Looking at A(H1N1)

The estimated number of deaths attributable to common seasonal flu every year is approximately 500,000 cases per year (Laporte, 2009). Reports cited 18,449 deaths as being caused by A(H1N1) (WHO, 2010). As reported by the media and scientific literature, the most serious concern was that the severity and mortality of the disease was not considered in the decision for the announcement of 'phase 6' – the final phase in which a disease outbreak has reached global proportions – of the pandemic (Walsh, 2009).

A study published in *The Lancet* has estimated the death toll from the 2009 A(H1N1) pandemic to be fifteen times higher than originally reported by WHO (Dawood et al., 2012). While 18,449 deaths from the flu virus were confirmed in 2009, the authors suggest that as many as 500,000 may have died. Nonetheless, this falls several magnitudes short of the estimated death toll of 2–4 million that WHO had originally stated prior to the several billion dollar's worth of sales of vaccines (*BBC News*, 2010).

After explaining the statistical model used to count possible deaths in developing countries, *The Lancet* article concludes that it will be necessary to improve the global response to possible future pandemics, and to develop the capacity to produce enough influenza vaccines for the African continent and Southeast Asia (Dawood et al., 2012). In some countries of the North, more than 90 per cent of the vaccine stock was not used and had to be destroyed.

The greatest peculiarity with oseltamivir is that there was no proven efficacy for its use in the H1N1 pandemic, but yet WHO recommended its use regardless. This may have been the Organization's attempt

to justify the relevance of the A(H5N1) stockpiling, which it had recommended with little actual usage years earlier.

In September 2010, WHO Director General Margaret Chen announced the end of the A(H1N1) pandemic. Alongside her announcement, the publication of statistics also came to an end. The halt in reporting of statistics is another unusual response, particularly when it would have been useful to continue monitoring the disappearance of the virus to ensure that the pandemic was completely over.

However, during the time that the pandemic was considered active, WHO had established an operations room in Geneva, with people working shifts to check surveillance on death and harm from the virus 24 hours a day. There were live broadcasts around the world on a case-by-case basis. What was the justification for this quick communication? Given that the Organization knew that death rates were actually turning out to be much lower than expected, it is likely that it wanted to over-report to create the sensation that the pandemic was real and more prevalent than it actually was. Deaths caused by high-mortality diseases are usually reported by WHO once a year.

### Pushing vaccines for H1N1: Faulty calculations

Following the same logic in the management of the pandemic, let us analyse how some European governments – of highly sophisticated countries that could afford all of the necessary planning – calculated the required number of vaccines in order to face the pandemic in their country (see Table 3.2).

Germany, with 82 million inhabitants, bought 50 million vaccines. Belgium, with 10 million inhabitants, bought 12.6 million doses. France is a very interesting case, since, with only 60 million inhabitants, it purchased 94 million doses of the vaccine. Lastly, Switzerland and Holland bought doses twice the size of their populations (Velasquez, 2010).

In the case of France, the French Parliament carried out an investigation about the management of the pandemic. This enquiry questioned the Ministry of Health about the purchase of the 94 million vaccines (*L'Express*, 2009), and the justification given was that the population would possibly have needed a second dose. Still, the amount purchased seems arbitrary: more than enough to provide every citizen with a single dose, yet not nearly enough to provide each with a second dose. When the pandemic ended, the official information from

TABLE 3.2 Government purchases of vaccines for H1N1

| Country | Population | No. vaccines purchased |
|---|---|---|
| Germany | 82 m | 50 m |
| Belgium | 10 m | 12.6 m |
| Spain | 47 m | 37 m |
| France | 60 m | 94 m |
| Italy | 60 m | 48 m |
| Netherlands | 16 m | 34 m |
| Switzerland | 7 m | 13 m |

*Sources*: Various

the French Ministry of Health indicated that only 6 million people had received the vaccine.

In the beginning, it was announced that excess doses from developed countries would be donated to poor countries, but some countries from the Global South indicated no intention of receiving this gift, because influenza was not a dire health risk given the high temperatures (30–35°C in most African countries), which mean that the likelihood of developing influenza is much lower than it is in the North.

In relation to oseltamivir, as mentioned earlier, there had been no human clinical trials to justify prophylaxis in the case of the A(H1N1) pandemic. Scientists informed the media that the virus had a high mutation capacity and suggested that the mutation could become much worse. However, they did not mention that this influenza could self-extinguish, as had other types of avian influenza before – most notably, the Holland H7N7 Dutch flu outbreak in 2003 (*Bio Report*, 2006) and A(H1N1), which apparently diminished its intensity and practically disappeared.

There has been an incredible waste in terms of stockpiling. In the United States, for instance, 40 million vaccines against swine influenza, worth about $260 million, were incinerated (O'Callaghan, 2010).[8] Only 6 per cent of the vaccines purchased by the French government for H1N1 were actually used; the remaining doses have to be destroyed. It is difficult to understand the public health rationale for the massive purchases of A(H1N1) vaccines by the governments of the North.

As reported by Deborah Cohen and Philip Carter in the *British Medical Journal* (Cohen and Carter, 2010), some of the experts

advising WHO on the pandemic had declarable financial ties with drug companies that were producing antivirals and influenza vaccines. According to Cohen and Carter (2010), the WHO guidance on the use of antivirals in a pandemic was authored by an influenza expert who, at the same time, was receiving payments from Roche, the manufacturer of oseltamivir (Tamiflu), for consultancy work and lecturing.

## Conclusions

There was confusion and a complex mix of interests of different, and sometimes opposite, actors. The first group of actors – WHO and the national health authorities – legitimately intended to protect the population using clear public health values and perspectives, notwithstanding the fact that some mistakes were made. Nonetheless, it is quite suspect that several of the WHO advisers on the pandemic management had financial ties to Roche and Gilead, which monetarily gained significantly from the oseltamivir sales. Moreover, because stocks of oseltamivir were already stockpiled from the A(H5N1) pandemic scare of 2005, it was strategic for WHO to promote it as the primary drug of choice for A(H1N1), so that the existing stocks would be of use, reducing the criticism of WHO for advising stockpiling in that earlier instance.

The second group – the governments and political leaders, who perhaps did not have public health concerns as their priority – may have been more interested in protecting or promoting themselves from a political point of view. In a situation in which the public is alarmed by the possibility of a pandemic, governments have almost no choice but to react with precautionary measures, such as stockpiling vaccines. Given that the public has historically distrusted European governments when it comes to health matters – the AIDS-contaminated blood scandal that killed several hundred people in France being a noteworthy example (Dorfman, 1991) – it is unsurprising that European governments acted quickly to obtain oseltamivir stocks.

The third group of actors – the pharmaceutical (and para-pharmaceutical) industries – were obviously led by their own commercial interests. Oseltamivir is produced by Swiss pharmaceutical company Roche and developed by Gilead Sciences, both of which are likely to have benefited to the tune of billions from the global sales of the drug. Given that several members of the WHO advisory committees have associations with Roche, it is likely that they financially benefited as well.

According to the Council of Europe report entitled *The Handling of the H1N1 Pandemic: More Transparency Needed*, relations and interactions between these three groups were not always clear at the national and international levels, complicating the management of the A(H1N1) pandemic (Flynn, 2010).

In conclusion, there were both positives and negatives in relation to the pandemic response. On the positive side, a process of sanitary education was put in place on a worldwide level and at an unprecedented scale. In a matter of hours, the world was alerted to the potential risk of a pandemic of lethal proportions and in the event that the flu actually did begin to spread, at least people would be aware.

The global response was also demonstrative of the fact that, in cases of global risk, there are available resources that nations are willing to use for the protection of their citizens. A market valued at $400 billion[9] was created for the vaccine in a matter of days.

On the negative side, the concept of vaccination itself was put at risk. The most important therapeutic tool in public health is our ability to prevent a disease and we do not yet know the consequence of this lapse. Messages were improperly spread, and this double-edged communication between the media and the scientific community resulted in a mixed public response. In France and Spain, many health workers themselves refused the vaccine (Cannet, 2009), as documented by many popular journals, with even hospital workers quoted as saying 'I will not take the vaccine' (Wyderko, 2009). These messages pose a potentially harmful influence on future public opinion regarding vaccination and related public health responses.

Finally, WHO, the ministries of health in several countries, and some scientific communities were implicated in poor decision making in the face of a public health crisis (Flynn, 2010), resulting in a significant loss of credibility. There remains an unanswered question about how their authority was affected and how this loss of credibility is going to influence their ability to address similar problems in the future.

## Notes

1 We would like to recognize our editor, Abraar Karan, for his significant contribution to this chapter.

2 According to the World Health Organization (WHO, 2009), a pandemic alert 'phase 5' is characterized by human-to-human spread of the virus into at least two countries in one WHO region. Pandemic 'phase 6' (the highest stage) is characterized by community-level outbreaks in at least one other country in a different WHO region. The H1N1 pandemic

was first described by WHO in April 2009; on 10 August 2010, WHO Director-General Margaret Chan announced the end of the H1N1 pandemic.

3 Indonesia reported 146 and Vietnam, 59 (WHO GIP, 2011).

4 One of the main shareholders of this pharmaceutical company, as revealed in several media news at that time, was Donald Rumsfeld, who acted as general manager until 2001, when he was appointed US Secretary of Defense. The English press mentioned that when the United States decided to constitute a stock of oseltamivir, Mr Rumsfeld had to abandon the room of the Secretaries Council owing to the possible conflict of interests that his presence in the meeting could represent.

5 From the filing date of the patent application.

6 In relation to the national antiviral stockpile in thirty European countries that are members of the European Influenza Surveillance Scheme (EISS). All countries except Ukraine had a stockpile of the neuraminidase inhibitor (NAI) oseltamivir (Meijer et al., 2007).

7 'In March 2007 the Japanese authorities advised against prescribing oseltamivir (Tamiflu, Roche) to adolescents aged 10–19 years. This unusually severe measure resulted from the separate suicides of two 14 year-olds who jumped to their deaths while taking oseltamivir; 52 other deaths (14 in children or adolescents) have been associated with the same drug. So far, similar action has not followed in Europe. When a regulatory authority warns doctors not to prescribe a drug but decides not to retract its marketing authorisation prescribers and patients are entitled to be concerned and a little confused.' (Maxwell, 2007)

8 'Yet in addition to the roughly 40 million doses that have already expired, the AP reports that another 30 million will likely go unused and eventually expire — meaning that a total of 43% of the swine flu vaccine supply will be wasted.' (O'Callaghan, 2010)

9 'Vaccine makers could produce 4.9 billion pandemic flu shots per year in the best-case scenario' (Margaret Chan, WHO Director General, quoted by Reuters, 21 July 2009); 'Wealthier countries such as the U.S. and Britain will pay just under $10 per dose [of the H1N1 flu vaccine] ... Developing countries will pay a lower price [circa $400 billion for Big Pharma] (Business Week, July 2009).' (Chossudovsky, 2009)

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# 4 | CATASTROPHIC HEALTH EXPENDITURE, HEALTH INSURANCE COVERAGE, AND POOR PEOPLE IN INDIA: NEW EVIDENCE ON HEALTHCARE COSTS LEADING TO IMPOVERISHMENT

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Every year, around 150 million people face financial catastrophe and about 100 million suffer poverty as a result of out-of-pocket (OOP) payments for health care. More than 90 per cent of them reside in low-income countries (Xu et al., 2007). India, along with Bangladesh and Vietnam, has some of the highest burdens of OOP payments for health care in Asia (van Doorslaer et al., 2007). Each year, 5 per cent of Indian households experience catastrophic health expenditure (Shahrawat and Rao, 2011), meaning that health care consumes at least 10 per cent of the household budget and cannibalizes resources for basic human needs such as food (Hubbard et al., 1995; Wagstaff and van Doorslaer, 2003). Most studies of catastrophic health expenditures are insensitive to the payment mechanisms, but households may be forced to exhaust savings, sell assets, and go into debt (Russell, 2004; Sauerborn et al., 1996; Wilkes et al., 1998). Because the poor have fewer resources on which to draw, the incidence and intensity of catastrophic health expenditure is concentrated among them: it makes the poor even poorer, rather than drawing the affluent into poverty (Wagstaff and van Doorslaer, 2003). Because many Indians have no alternative to private health care, which is unaffordable, unreliable, and impoverishing (Shiva et al. 2011), access to health care is a major producer of poverty and creator of inequity in India (Gumber and Arora, 2006).

Several factors are driving increasing numbers of Indians into healthcare-related poverty. First, as a developing nation, India has a very high level of private healthcare spending (the majority of which is OOP) compared to government spending (Berman et al., 2010), which puts an undue financial burden on poor households (Shahrawat

and Rao, 2011). Second, the real cost of health care is increasing: the average expenditure per hospital admission tripled between 1986 and 2004, in both government and private hospitals, and in both rural and urban areas (Shiva et al., 2011). Third, privatization continues, following from the liberalization policies from 1991. Most significantly, there is a lack of mechanisms to finance health care. The most robust solution would be a social security system, which is urgently needed, but improbable in the short term (Mahal et al., 2010). Protecting the poor from catastrophic OOP expenditure by means of health insurance is crucial, especially in such a highly privatized system, but there are economic, practical, and cultural significant barriers to its uptake. For instance, existing health insurance coverage is insufficient, varies greatly between rural and urban areas, is limited to a small proportion of people in the organized sector (IIPS/WHO/WHO RO, 2006), and normally covers only in-patient hospital care even though medicine is normally a greater expense (Shahrawat and Rao, 2011). Thus most schemes fail to protect the poor from high OOP payments.

This chapter addresses the nature and magnitude of health insurance coverage in India, which is expected to grow rapidly in coming years. It estimates the proportion of the household budget allocated to health care in different socio-economic groups and it explores coping mechanisms of the households to meet healthcare costs. By doing so, it examines the impoverishment effects on households of catastrophic health expenditure. Finally, it revisits the situation of health insurance in India and its potential for meeting the economic burden of health care.

## Data

We used the household data collected in the *Study on Global AGEing and Adult Health (SAGE), India*, undertaken by the International Institute for Population Sciences (IIPS) during 2007–08 and sponsored by the World Health Organization (WHO) (WHO/IIPS, 2011; Kowal et al., 2012). This is a nationally representative sample survey covering 9,626 households (completed interviews) from six states of India: Assam; Karnataka; Maharashtra; Rajasthan; Uttar Pradesh; and West Bengal. In a way, these six states represent the geographical, economic, and demographic variations in India.

A sample size of 10,000 households at national level was targeted and the number was allocated to the six states according to their population

size. The national-level estimates were computed by pooling the data of all six states. The study used two-stage sampling in rural areas and three-stage sampling in urban areas. The primary sampling units (PSUs) in rural areas were villages, while in urban areas, the PSUs were city wards. From each city ward, two census enumeration blocks (CEBs) were selected. The last level of selection was households. The households selected were distributed among rural and urban areas in proportion to the distribution of the state's population. The survey comprises 2,494 (26.9 per cent) urban and 7,132 (73.2 per cent) rural households. The module gives weekly, monthly, and yearly household consumption expenditure, including food, non-food, and health payments.

For the purpose of analysis, all household expenditures were converted into monthly consumption expenditure. Each household has been asked about the coping strategy adopted to meet unforeseen health payments.

In this chapter, we have considered the monthly consumption expenditure to be a direct measure of the economic well-being of households.

## Definitions

*Household consumption expenditure* comprises both monetary and in-kind payments for all goods and services, and the money value of the consumption of home-made products.

*Health expenditure* implies the OOP health payments made by households for the health services received by any household member. Out-of-pocket health payments include doctor's consultation fees, purchases of medication/traditional medication, and hospital bills, but expenditure on ambulance/transportation and special nutrition are excluded. Any reimbursement (from insurance, employer, government, etc.) is deducted to find out the net OOP payments.

*Food expenditure* is the amount paid on all foodstuffs by the household, excluding expenditure on alcoholic beverages, tobacco, and food consumption outside the home.

*Non-subsistence spending* constitutes the expenditure aggregate of the household's health and non-food items. Household capacity to pay is defined as a household's non-subsistence spending.

*Catastrophic spending* on health occurs when a household is forced to reduce its basic expenses over a certain period of time in order to

cope with healthcare expenses for its members. In this study, when the health expenditure of the household is more than the non-subsistence spending, then it is considered to be catastrophic health spending.

## Findings

*Health expenditure* The OOP health expenditure and different dimensions of health expenditure across groups of sample households are presented in Table 4.1. Mean household expenditure was INR6,671, out of which INR852 was being incurred as OOP expenditure on health, which amounts to an average of 10 per cent of the total household expenditure and 22 per cent of the non-subsistence spending. Almost 24 per cent of the households spend either equal to or more than their capacity to pay (non-subsistence spending) on healthcare services; consequently, they have to forgo their basic subsistence consumption. Almost a third (31 per cent) of the total households are living below the poverty line. According to this survey, 35 per cent of the poorest households incurred catastrophic health expenditure.

Mean monthly consumption expenditure of the households incurring catastrophic health expenditure is INR5,724 compared to INR6,968 for those households without catastrophic health expenditure. However, households with catastrophic health expenditure incurred six times more OOP health expenditure than those households without. The households with catastrophic health expenditure, on average, spend 29 per cent of household consumption expenditure and 60 per cent of non-subsistence expenditure, respectively, for OOP health payment. As a result of this spending, it was found that 24 per cent of these households became impoverished. Out-of-pocket health payments accounted for 28 per cent of the non-subsistence expenditure among the poorest households, compared with only 15 per cent among the richest households.

The impoverishment effect of catastrophic health expenditure is 8 per cent among uninsured households, with INR823 monthly OOP health payments, while it is only 1 per cent for households with at least one member insured, at a monthly OOP health expenditure of INR1,240. The share of OOP health payments of non-subsistence spending was 22 per cent for uninsured households and only 12 per cent for those insured households with three or more insured members. According to this survey, only 21 per cent of urban households were living below the poverty line, compared with 34 per cent in rural

TABLE 4.1 Household consumption expenditure, poor households, healthcare payments, and their effects, by household characteristics, India, 2007

| | Mean household monthly consumption expenditure (INR) | Percentage poor | Impoverishment because of OOP health payments (%) | Percentage incurring catastrophic health expenditure | Mean OOP monthly health payments (INR) | Mean OOP health payment as percentage of household expenditure | Mean OOP health payment as percentage of household's non-subsistence expenditure |
|---|---|---|---|---|---|---|---|
| *Age of head of household* | | | | | | | |
| 18–35 | 5,103 | 38.9 | 8.5 | 25.4 | 671 | 9.0 | 23.6 |
| 36–50 | 5,989 | 30.4 | 6.5 | 20.4 | 758 | 8.9 | 18.9 |
| 51–65 | 7,387 | 27.8 | 7.0 | 25.3 | 932 | 9.9 | 22.2 |
| 66+ | 7,787 | 29.8 | 8.2 | 27.4 | 1,059 | 10.7 | 24.4 |
| *Education level of main income earner* | | | | | | | |
| Illiterate | 4,533 | 44.6 | 10.0 | 32.0 | 626 | 10.9 | 26.8 |
| Less than primary and primary school completed | 5,157 | 36.5 | 8.4 | 23.6 | 673 | 9.6 | 21.3 |
| Secondary school completed | 6,504 | 27.6 | 7.2 | 23.6 | 974 | 10.6 | 21.4 |
| High school completed | 8,213 | 19.6 | 4.8 | 19.3 | 1,019 | 10.0 | 18.7 |
| College and above | 12,739 | 7.9 | 1.7 | 13.0 | 1,350 | 9.3 | 14.4 |
| *Household members aged 50+* | | | | | | | |
| None | 5,595 | 21.3 | 7.2 | 33.2 | 715 | 9.1 | 19.8 |
| One | 5,924 | 24.3 | 6.7 | 34.0 | 693 | 10.0 | 21.9 |
| Two | 8,346 | 26.8 | 7.7 | 25.5 | 1,148 | 11.6 | 23.4 |
| Three or more | 11,663 | 19.3 | 8.0 | 16.8 | 1,306 | 10.5 | 19.6 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| *Catastrophic health expenditure* | | | | | | | |
| No | 6,968 | 29.7 | 1.9 | — | 369 | 4.4 | 9.7 |
| Yes | 5,724 | 34.6 | 24.1 | — | 2,370 | 28.6 | 59.7 |
| *Place of residence* | | | | | | | |
| Urban | 8,447 | 21.3 | 4.5 | 16.5 | 894 | 8.6 | 16.7 |
| Rural | 6,020 | 34.4 | 8.2 | 26.5 | 829 | 10.8 | 23.3 |
| *Household members insured* | | | | | | | |
| None | 6,349 | 32.3 | 7.5 | 24.5 | 823 | 10.2 | 22.0 |
| One | 10,380 | 7.6 | 0.9 | 14.8 | 1,240 | 10.3 | 16.1 |
| Two | 11,424 | 12.6 | 6.4 | 17.4 | 983 | 10.0 | 16.6 |
| Three or more | 13,484 | 6.4 | 1.5 | 10.6 | 1,301 | 7.9 | 12.4 |
| *Household size* | | | | | | | |
| Single member | 2,810 | 51.4 | 4.6 | 28.3 | 147 | 8.6 | 22.0 |
| 2–5 members | 5,460 | 30.6 | 6.5 | 21.3 | 633 | 9.4 | 19.8 |
| 6–10 members | 7,054 | 32.0 | 7.9 | 26.9 | 914 | 11.0 | 23.7 |
| 11+ members | 12,080 | 21.5 | 9.0 | 23.6 | 2,011 | 11.0 | 21.8 |
| *Wealth quintiles* | | | | | | | |
| Poorest | 2,817 | 61.8 | 10.4 | 33.4 | 417 | 10.4 | 27.6 |
| Poor | 4,340 | 39.4 | 8.8 | 27.4 | 585 | 10.5 | 24.0 |
| Middle | 6,833 | 23.3 | 8.2 | 23.5 | 687 | 10.1 | 21.1 |
| Rich | 7,141 | 14.4 | 6.3 | 18.9 | 1,131 | 10.2 | 18.6 |
| Richest | 13,536 | 4.2 | 1.6 | 13.1 | 1,497 | 9.6 | 14.7 |
| India (Pooled) | 6,671 | 30.8 | 7.2 | 23.9 | 852 | 10.2 | 21.6 |

*Source*: WHO/IIPS (2011)

areas. The impoverishment effect resulting from catastrophic health payments is 8 per cent in rural areas and 5 per cent in urban areas. The economic status of the households measured in terms of wealth quintiles shows a positive association with the OOP health payments and negative association with the catastrophic health payments. Only 13 per cent of households belonging to the highest wealth quintile incurred catastrophic health expenditure, compared to 33 per cent of households from the lowest wealth quintile.

*Sources of healthcare financing* Households resort to many strategies to meet their OOP health expenditure. These range from current income (74 per cent) as the major source of finance, followed by savings (26 per cent), borrowings from family or friends (20 per cent), and selling of household items (8 per cent). Twelve per cent of households sold their assets in order to finance catastrophic health expenditure, compared with only 6 per cent of households without catastrophic health expenditure, while 34 per cent of households borrowed from family or friends to finance catastrophic health expenditure, compared with only 14 per cent of households without catastrophic health expenditure (see Table 4.2). The percentage of households borrowing from family and/or friends consistently declined, from 25 per cent among the poorest to 9.5 per cent for the richest households. Even among households with one or two insured members, only 10 per cent paid health expenditure from the insurance.

Households headed by elderly persons (aged 66 or over) are 1.27 times more likely (CI = 1.025–1.565) to incur catastrophic health expenditure than those households headed by a person of aged 18–35. Households in which the main earner completed high school have a lower chance (OR = 0.78, CI = 0.655–0.926) of incurring catastrophic health expenditure than those households in which the main income earner is illiterate. Rural households are 1.65 times more likely (CI = 1.431–1.890) to incur catastrophic health expenditure than their urban counterparts. The odds ratio of incurring catastrophic health expenditure decreases from 0.77 (CI=0.667–0.880) for the poor households to 0.33 (CI=0.268–0.396) for the richest households (see Table 4.3).

Households incurring catastrophic health expenditure are 12.67 times (CI = 10.351–15.513) more likely to be impoverished than those households without catastrophic health expenditure. Rural households

TABLE 4.2 Sources of healthcare financing by household characteristics, India, 2007 (%)

| | Current income | Savings | Insurance | Selling of household assets | Borrow from family/ friends | Borrow from others | Other sources |
|---|---|---|---|---|---|---|---|
| *Age of head of household* | | | | | | | |
| 18–35 | 73.9 | 25.7 | 0.7 | 6.5 | 25.6 | 5.1 | 8.3 |
| 36–50 | 75.0 | 23.0 | 1.5 | 7.1 | 18.9 | 6.6 | 9.2 |
| 51–65 | 73.2 | 28.1 | 1.4 | 8.8 | 18.6 | 6.3 | 9.7 |
| 66+ | 71.9 | 28.2 | 1.7 | 8.7 | 17.4 | 5.5 | 12.1 |
| *Education level of main income earner* | | | | | | | |
| Illiterate | 67.7 | 23.7 | 0.6 | 9.2 | 25.4 | 5.5 | 12.1 |
| Less than primary and primary school completed | 72.5 | 23.6 | 1.2 | 8.1 | 19.0 | 6.8 | 10.5 |
| Secondary school completed | 75.1 | 26.2 | 1.1 | 7.6 | 17.5 | 6.0 | 9.5 |
| High school completed | 76.2 | 28.4 | 1.3 | 8.7 | 17.6 | 5.0 | 8.1 |
| College and above | 86.0 | 29.4 | 3.9 | 4.8 | 10.5 | 7.8 | 7.0 |
| *Household members aged 50+* | | | | | | | |
| None | 72.2 | 24.3 | 1.5 | 7.2 | 21.5 | 5.9 | 9.0 |
| One | 74.2 | 24.2 | 0.9 | 7.1 | 18.5 | 5.1 | 9.8 |
| Two | 74.3 | 28.4 | 1.7 | 9.3 | 19.2 | 7.5 | 10.5 |
| Three or more | 74.1 | 37.8 | 2.9 | 8.6 | 16.8 | 6.7 | 10.5 |
| *Catastrophic health expenditure* | | | | | | | |
| No | 77.0 | 23.6 | 1.4 | 6.2 | 13.7 | 5.7 | 9.3 |
| Yes | 65.4 | 31.5 | 1.4 | 11.8 | 33.7 | 7.2 | 11.0 |

TABLE 4.2 (*continued*)

| | Current income (%) | Savings (%) | Insurance (%) | Selling of household assets (%) | Borrow from family/ friends (%) | Borrow from others (%) | Other sources (%) |
|---|---|---|---|---|---|---|---|
| *Place of residence* | | | | | | | |
| Urban | 85.3 | 20.8 | 2.2 | 5.7 | 17.6 | 5.6 | 6.3 |
| Rural | 69.3 | 27.8 | 1.1 | 8.6 | 20.3 | 6.3 | 11.0 |
| *Household members insured* | | | | | | | |
| None | 72.9 | 25.6 | 0.6 | 7.7 | 19.8 | 5.7 | 9.5 |
| One | 83.1 | 29.5 | 10.4 | 8.0 | 17.4 | 9.5 | 13.5 |
| Two | 76.0 | 35.0 | 10.1 | 16.3 | 22.4 | 12.9 | 16.4 |
| Three or more | 85.5 | 28.6 | 14.3 | 6.0 | 13.8 | 12.7 | 10.4 |
| *Household size* | | | | | | | |
| Single member | 56.9 | 16.2 | 1.1 | 1.3 | 32.7 | 3.8 | 14.1 |
| 2–5 members | 73.7 | 23.4 | 1.5 | 7.6 | 19.2 | 5.7 | 10.0 |
| 6–10 members | 73.8 | 27.3 | 1.3 | 7.9 | 19.8 | 6.3 | 9.4 |
| 11+ members | 74.8 | 34.8 | 1.3 | 9.8 | 18.6 | 7.9 | 9.5 |
| *Wealth quintiles* | | | | | | | |
| Poorest | 69.2 | 20.9 | 0.2 | 8.7 | 25.0 | 3.4 | 9.0 |
| Poor | 70.3 | 26.3 | 0.3 | 6.2 | 22.7 | 4.8 | 10.0 |
| Middle | 70.2 | 23.7 | 1.3 | 9.5 | 20.8 | 7.6 | 10.9 |
| Rich | 75.0 | 24.9 | 2.6 | 10.0 | 19.8 | 7.9 | 11.9 |
| Richest | 82.5 | 33.4 | 2.8 | 5.7 | 9.5 | 7.8 | 7.5 |
| India (Pooled) | 73.6 | 25.9 | 1.4 | 7.8 | 19.6 | 6.1 | 9.8 |

*Note*: Row sum will not be equal to 100, because some households may be financing healthcare costs from more than one source.

*Source*: WHO/IIPS (2011)

TABLE 4.3 Odds ratio of incurring catastrophic health expenditure and impoverishment resulting from OOP health payments by household characteristics, India, 2007

| | Catastrophic health expenditure | | Impoverishment | |
|---|---|---|---|---|
| | Odds ratio (OR) | 95% confidence interval (CI) | Odds ratio (OR) | 95% confidence interval (CI) |
| *Age of head of household* | | | | |
| 18–35 | 1.00 | | 1.00 | |
| 36–50 | 0.84** | 0.724–0.978 | 0.90 | 0.692–1.166 |
| 51–65 | 1.00 | 0.833–1.194 | 1.01 | 0.732–1.404 |
| 66+ | 1.27** | 1.025–1.565 | 1.13 | 0.768–1.648 |
| *Education level of main income earner* | | | | |
| Illiterate | 1.00 | | 1.00 | |
| Less than primary and primary school completed | 0.91 | 0.802–1.041 | 1.03 | 0.825–1.278 |
| Secondary school completed | 0.94 | 0.807–1.095 | 0.88 | 0.671–1.146 |
| High school completed | 0.78** | 0.655–0.926 | 0.84 | 0.611–1.157 |
| College and above | 0.74** | 0.588–0.935 | 0.63* | 0.374–1.063 |
| *Household members aged 50+* | | | | |
| None | 1.00 | | 1.00 | |
| One | 1.15* | 0.994–1.338 | 0.76** | 0.577–0.993 |
| Two | 1.15 | 0.947–1.399 | 0.87 | 0.614–1.243 |
| Three or more | 0.95 | 0.662–1.367 | 0.98 | 0.517–1.866 |
| *Catastrophic health expenditure* | | | | |
| No | | | 1.00 | |
| Yes | | | 12.67*** | 10.351–15.513 |
| *Place of residence* | | | | |
| Urban | 1.00 | | 1.00 | |
| Rural | 1.65*** | 1.431–1.890 | 1.45** | 1.089–1.917 |
| *Household members insured* | | | | |
| None | 1.00 | | 1.00 | |
| One | 0.94 | 0.678–1.298 | 0.23** | 0.071–0.733 |
| Two | 1.16 | 0.756–1.774 | 1.15 | 0.521–2.530 |
| Three or more | 0.85 | 0.572–1.259 | 0.64 | 0.249–1.632 |

TABLE 4.3 (*continued*)

| | Catastrophic health expenditure | | Impoverishment | |
|---|---|---|---|---|
| | Odds ratio (OR) | 95% confidence interval (CI) | Odds ratio (OR) | 95% confidence interval (CI) |
| *Household size* | | | | |
| Single member | 1.00 | | 1.00 | |
| 2–5 members | 1.19 | 0.791–1.804 | 2.02 | 0.835–4.888 |
| 6–10 members | 1.58** | 1.046–2.397 | 2.04 | 0.841–4.960 |
| 11+ members | 1.54* | 0.977–2.417 | 3.52*** | 1.387–8.960 |
| *Wealth quintiles* | | | | |
| Poorest | 1.00 | | 1.00 | |
| Poor | 0.77*** | 0.667–0.880 | 0.95 | 0.752–1.191 |
| Middle | 0.61*** | 0.512–0.719 | 1.02 | 0.772–1.351 |
| Rich | 0.50*** | 0.424–0.587 | 0.64*** | 0.472–0.858 |
| Richest | 0.33*** | 0.268–0.396 | 0.27*** | 0.176–0.430 |

* $p < 0.00$
** $p < 0.05$
*** $p < 0.01$

*Source*: WHO/IIPS (2011)

are 1.45 times (CI = 1.089–1.917) more likely to be impoverished than urban households. Households with one insured member are less likely (OR = 0.23, CI = 0.071–0.733) to be impoverished than those households without any insured members. Households belonging to the rich (OR = 0.64, CI = 0.472–0.858) and richest (OR = 0.27, CI = 0.176–0.430) wealth quintiles are less likely to be impoverished than the poorest households.

*Health insurance coverage in India* Health insurance is one of the measures of social security by which members of the community are assured the benefit of medical care when they fall sick. The health insurance movement has a history spanning a century and a half. Its origins are largely found in the Industrial Revolution and developments in the field of medicine.

The entry of many private insurance companies into the sector will surely have an impact on the cost of health care, equity in the financing

of care, its quality, and its cost-effectiveness (Mahal, 2002). However, many believe that community-based health insurance, rather than market-mediated or government-provided insurance, is an appropriate way of reaching the poor (Ahuja, 2004). The choice between public health financing or private insurance is hardly available in India, however, because of the government's limited ability to marshal sufficient resources to finance health spending.

Since the independence of India, the healthcare system has been expanded and modernized to some extent, with the availability of modern healthcare facilities and better training of medical personnel (Ellis et al., 2000). At the same time, the healthcare sector in India is still mainly focused in urban areas only, even though the majority of the people are living in rural areas. The paradox is that around 73 per cent of rural people get 20 per cent of the healthcare facilities, while around 27 per cent of urban people get the remaining 80 per cent of the facilities. Infrastructure, human resource, and quality-related inequities in the availability, utilization, and affordability of health care are a matter of concern. Government health facilities are perceived as not functioning well and as being of poor quality. Because of this, the majority of people when they are ill seek outpatient care from the private sector.

As regards health insurance coverage in India, only 11 per cent of the country's population has access to insurance policies (Shahrawat and Rao, 2011). The majority of curative healthcare spending is met by households only. Some studies reveal that around 69 per cent of health spending is financed as OOP expenses. As a consequence of the liberalization and privatization of the healthcare system, healthcare expenses have also increased. Since 1994–95, health expenditures have grown at 14 per cent and this growth is higher for inpatient care (Government of India, 2005). These financial burdens arise mainly because consumers are either not insured at all, or are insured inadequately for their healthcare expenses.

Health insurance is not a familiar concept among the people of India, so neither is its coverage adequate. However, there is some evidence that health insurance coverage is gradually increasing (Shijith, 2011). This may be as a result of high healthcare costs, the entry of private players into the insurance sector, the government's universal health insurance policy, and the community-based health insurance schemes in some states (see Table 4.4). Health insurance, as we know it today,

TABLE 4.4 Community health insurance (CHI) schemes in India

| **NAME** Location(s), Year established | Target population | Type | Remarks |
|---|---|---|---|
| **ACCORD** Gudalur, Nilgiri, Tamil Nadu, 1992 | Scheduled tribes of Gudalur Taluk who are members of Adivasi Munnetra Sangam (AMS), the tribal union (*n* = 13,070 individuals) | Type I | Linked with New India Assurance Company |
| **BAIF** Uruli Kanchan, Pune, Maharashtra, 2001 | Poor women members of the community banking scheme and living in the 22 villages around Uruli Kanchan town (*n* = 1,500 women) | Type III | Linked with United India Insurance Company |
| **BULDHANA** Urban Cooperative and Credit Society, Buldhana, Maharashtra, 1986 | Farmers living in Buldhana district (*n* = 175,000) | Type III | Linked with United India Insurance Company |
| **DHAN** Foundation Kadamalai Block, Theni District, Tamil Nadu, 2000 | Poor women members of the community banking scheme and living in the villages of Mayiladumparia Block (*n* = 190,499) | Type II | No linkages; operates the scheme itself |
| **Karuna Trust** T Narsipur Block, Mysore District, Karnataka, 2002 | Total population of T Narsipur Block and Bailhongal Block, with a focus on the scheduled tribe and scheduled caste population (*n* = 634,581 individuals) | Type III | Linkage with National Insurance Company |
| **MGIMS Hospital** Wardha, Maharashtra, 1981 | Small farmers and landless labourers living in the 40 villages around Kasturba Hospital (*n* = 30,000 individuals) | Type I | No linkages; operates the scheme itself |
| **Navasarjan Trust** Pathan district, Gujarat, 1999 (discontinued in 2000) | Select scheduled caste individuals in two blocks of Pathan district, North Gujarat (*n* = n/a) | Type III | Linkage with New India Assurance Company |
| **RAHA** Raigarh, Ambikapur, Jashpur and Korba districts of Chhattisgarh, 1980 | Poor people living in the catchment area of the 92 rural health centres and hostel students (*n* = 92,000 individuals) | Type I | Has its own providers |

| | | | |
|---|---|---|---|
| **SEWA**<br>11 districts of Gujarat, 1992 | 534,674 SEWA Union women members (urban and rural), plus their husbands, living in 11 districts<br>(*n* = 1,067,348 individuals) | Type III | Linkage with National Insurance Company |
| **Students' Health Home**<br>Kolkata, West Bengal, 1952 | Full-time students in West Bengal state, from class 5 to university level<br>(*n* = 5.6 million students) | Type I | Has its own health facilities |
| **Voluntary Health Services Centre**<br>Chennai, Tamil Nadu, 1972 | Total population of the catchment area of 14 mini health centres in the suburbs of Chennai<br>(*n* = 104,247 individuals in town blocks) | Type I | Has its own hospital and health centre |
| **Yeshasvini Trust**<br>Bangalore, Karnataka, 2003 | Members of the cooperative societies in Karnataka<br>(*n* = 25 lakhs) | Type II | No linkages; operates the scheme itself |

*Note*: In India, there appear to be three basic designs of community health insurance scheme, depending on who is the insurer. In *Type I*, the hospital plays the dual role of providing health care and running the insurance programme. In *Type II*, the voluntary organization is the insurer, while purchasing care from independent providers. In *Type III*, the voluntary organization plays the role of an agent, purchasing care from providers and insurance from insurance companies.

*Source*: Devadasan et al. (2004)

was introduced only in 1912 when the first Insurance Act was passed (Devadasan et al., 2004). The current version of the Insurance Act was introduced in 1938. Since then, there was little change until 1972, when the insurance industry was nationalized and 107 private insurance companies were brought under the umbrella of the General Insurance Corporation (GIC). Private and foreign entrepreneurs were allowed to enter the market with the passing into law of the Insurance Regulatory and Development Act (IRDA) in 1999 (Rao, 2004). In the aftermath of the new economic policies (liberalization and globalization), some of the major national and international private insurance companies entered the insurance industry. But only a few companies are working in the field of health insurance.

The main reasons for inadequate health insurance coverage in India are low levels of awareness about health insurance among people and the high cost of private health insurance, which is unaffordable for the majority of people. Before the IRDA, government insurance companies

such as LIC and GIC were the major players in the health insurance sector. In 1986, GIC's 'Mediclaim' policy became the first health insurance policy available to the general public in India. Mediclaim is a reimbursement-based insurance for hospitalization and does not cover outpatient treatment. Since the premium is on higher side, it remained limited to rich and middle class segments.

Low expenditure on health care in India has led to vast inequities in the distribution of healthcare services between the different strata of society (Narayanan, 2008). Owing to low health insurance coverage and the cost of curative healthcare services, the vast majority of the health spending is financed by OOP payment in India (Shahrawat and Rao, 2011). India spends around 6 per cent of its gross domestic product (GDP) on meeting healthcare needs, through both private and public sectors. Of these expenditures, 75 per cent is private OOP costs spent by households. The health insurance constitutes a small proportion of total financing. It is estimated that less than 10 per cent of the total financing in the health sector is through various types of insurance (Bhat and Reuben, 2001).

The financial burden of healthcare expenditure in India is enormous and is growing day by day. Almost all segments of the Indian community face some direct or indirect OOP expenses for utilization of the healthcare services. The heaviest burden is borne by the people engaged in non-formal rural and urban activities. Bhat and Saha (2004) found that new economic policy, such as liberalization and globalization, the rapid growth of medical technology, and a rising middle class have led to a huge increase in private medical care expenditures in India. Mavalankar and Bhat (2000) argued that, with the proliferation of various healthcare technologies and a general price rise, the cost of health care has also become very expensive and unaffordable to large segment of population. Liberalization of the Indian economy and important legislation such as the IRDA Act, allowing private health insurance players into the Indian market has had considerable impact.

According to Bhat and Reuben (2001: 3):

> Health insurance can be broadly defined as financial mechanisms that exist to provide protection to individuals and households from the costs of health care incurred as a result of unexpected illness or injury. Under this mechanism insurer agrees to compensate or agrees to guarantee the insured person against loss by specified

> contingent event and provide financial coverage. Against this protection the insured party pays a premium and the insurer provides required services or pays the agreed sum spent on hospitalization in case of illness of insured person.

Health insurance can be defined in a very narrow sense, whereby an individual or group purchases health coverage in advance by paying a fee called a 'premium'. But it can also be defined broadly, by including all financing arrangements whereby consumers can avoid or reduce their expenditures at the time of use of services (Mavalankar and Bhat, 2000).

Health insurance is very well established in many countries, but in India it is a new concept (except for the insurance provided to organized sector employees). Health insurance needs to be given higher priority in India, because of the rising cost of health care and the financial burden it places on households. One of the important points that does need to be understood is that health insurance per se is simply a financing mechanism, and does not in any way ensure that health services are delivered efficiently and effectively (Ahuja, 2004). Similar questions were raised by Bhat and Saha (2004), who argued that expanding insurance services without considering whether medical services are available or sufficient may not serve any purpose; the cost and quality of these services is equally important. Another important issue in this context is: who will regulate the practices of insurance providers? Government in India may be seen to be trying to divert attention from an inefficient healthcare delivery system by emphasizing health insurance as a solution. Indeed, Rao (2004: 3835) points out that:

> High priority accorded to health insurance in these days could have some reasons: (1) push of the private, including the corporate and for profit sector, which is unable to maximize returns due to lack of effective demand; (2) enhance FDI by promoting India as a health destination for foreign clientele; (3) pull of the private insurance companies and third party administrators to deepen the insurance market through financial incentives such as tax exemptions and subsidies for premiums; and (4) protect the poor from impoverishment due to high medical costs.

A mushrooming of private healthcare facilities, the increasing cost of healthcare services, the financial burden of healthcare costs among poor and marginalized people, and a changing epidemiological pattern of diseases all influence the attitude of the people and government. The government and people have therefore started exploring various health financing options such as health insurance (Mavalankar and Bhat, 2000). The limitations of health insurance in India can partly be attributed to the lack of standardization of healthcare provision and to the absence of data on which insurance companies can base their health insurance products (Ahuja, 2004). The increasing competition among these companies has, however, started to make its mark on the insurance sector in the form of a wider range of product offerings, aggressive marketing, and the provision of better customer care.

According to two nationwide demographic surveys, the *National Family Health Survey (NFHS-3)* (IIPS/Macro International, 2007) and the *District Level Household and Facility Survey (DLHS-3)* (IIPS, 2010), only 5 per cent of the households in India are covered under any type of health insurance. However, 2009–10 data on health insurance revealed that, from 2007–08 onwards, the number of health insurance policies and the number of covered members were on the rise. In 2008–09, the number of policies was 45,75,725; it had increased to 68,84,687 (serviced by third-party administrators, or TPAs) only a year later, in 2009–10. Higher coverage of health insurance is reported in urban areas. The coverage in rural areas is still very low, as is evident from both the DLHS-3 (3.2 per cent) and NFHS-3 (2.2 per cent).

According to the DLHS-3, among the insured, central or state government health schemes are the most subscribed (39.2 per cent), followed by the employee state insurance (ESI) scheme (17 per cent). This clearly points out the dominance of public mandatory schemes and employer-based schemes, even after the entry of private players into the health insurance market. Among households belonging to the lowest three wealth quintiles, however, less than 3 per cent were covered by any health scheme or health insurance (Shijith, 2011).

Table 4.5 shows the distribution of health insurance coverage of household members by characteristics of the households. Only 6 per cent of households had at least one insured member in 2007. Disaggregation of the households by number of insured members shows that about 3 per cent of households have only one insured member and nearly 2 per cent of households have at least three insured

TABLE 4.5 Number of household members covered under health insurance by household characteristics, India, 2007 (%)

| | No insurance | One person insured | Two persons insured | Three or more persons insured |
|---|---|---|---|---|
| *Age of head of household* | | | | |
| 18–35 | 96.1 | 2.3 | 0.9 | 0.8 |
| 36–50 | 94.4 | 3.0 | 1.2 | 1.4 |
| 51–65 | 93.1 | 2.8 | 1.7 | 2.4 |
| 66+ | 93.2 | 2.6 | 1.6 | 2.6 |
| *Education level of main income earner* | | | | |
| Illiterate | 97.6 | 1.2 | 0.6 | 0.7 |
| Less than primary and primary school completed | 96.0 | 1.8 | 1.0 | 1.2 |
| Secondary school completed | 95.1 | 2.1 | 1.8 | 1.0 |
| High school completed | 92.0 | 4.8 | 1.2 | 2.0 |
| College and above | 81.2 | 7.0 | 4.0 | 7.9 |
| *Household members aged 50+* | | | | |
| None | 95.6 | 2.4 | 0.9 | 1.1 |
| One | 93.9 | 3.2 | 1.3 | 1.6 |
| Two | 92.7 | 2.7 | 1.8 | 2.8 |
| Three or more | 91.3 | 2.4 | 3.0 | 3.3 |
| *Catastrophic health expenditure* | | | | |
| No | 93.3 | 3.1 | 1.5 | 2.2 |
| Yes | 96.6 | 1.7 | 1.0 | 0.7 |
| *Place of residence* | | | | |
| Urban | 90.1 | 3.7 | 2.0 | 4.2 |
| Rural | 95.5 | 2.4 | 1.1 | 1.0 |
| *Household size* | | | | |
| Single member | 96.9 | 3.2 | 0.0 | 0.0 |
| 2–5 members | 93.1 | 3.2 | 1.5 | 2.2 |
| 6–10 members | 94.8 | 2.4 | 1.3 | 1.5 |
| 11+ members | 95.4 | 1.8 | 1.4 | 1.4 |
| *Wealth quintiles* | | | | |
| Poorest | 99.1 | 0.5 | 0.2 | 0.2 |
| Poor | 98.3 | 0.9 | 0.5 | 0.4 |

TABLE 4.5 (*continued*)

| | No insurance | One person insured | Two persons insured | Three or more persons insured |
|---|---|---|---|---|
| Middle | 96.5 | 1.9 | 1.2 | 0.5 |
| Rich | 90.4 | 5.3 | 2.0 | 2.4 |
| Richest | 85.1 | 5.8 | 3.3 | 5.8 |
| India (Pooled) | 94.0 | 2.8 | 1.4 | 1.8 |

*Source*: WHO/IIPS (2011)

members. Only 2.5 per cent among households with an illiterate main income earner have at least one insured member, whereas it is 19 per cent among those households with a main income earner educated to college level or above. Only 3 per cent of households incurring catastrophic health expenditure have at least one insured member, compared to 7 per cent of those households that did not experience catastrophic health expenditure. There is considerable rural–urban difference in health insurance coverage: 10 per cent of households in urban areas have health insurance coverage, compared to only 4 per cent in rural areas. Most importantly, only 1 per cent among the poorest households has health coverage, compared with 15 per cent of the richest households. The private health insurance policies can be afforded only by the economically better-off households. However, recent experiments in community health insurance schemes for poor families are encouraging.

## Discussion and conclusions

Healthcare payments are pushing many Indian households into poverty year after year. It was found that a third of poor households incurred catastrophic health expenditure, and that the impoverishment effect of catastrophic health payments is 8 per cent among uninsured households, while it is only 1 per cent for households with at least one insured member. Twenty-six per cent of sample households borrowed from family or friends and others, while 8 per cent sold their assets to meet healthcare expenses. Rural households are more likely to experience catastrophic health spending than their urban counterparts. Only 6 per cent of Indian households have health insurance coverage, with considerable rural–urban differentials. Most importantly, only 1

per cent among the poorest households has health coverage, indicating that most health insurance policies existing today are affordable only to economically better-off households.

Who is responsible for providing health insurance cover to the people? Those with health problems will definitely spend money to save their lives, even if it results in their financial disaster. In this context, health insurance has emerged as an alternative financing tool with which to meet the healthcare needs of the people. However, this alternative financing has not yet reached vast sections of the people in India. How can India achieve universal health insurance coverage without an adequate number of healthcare facilities and resources? This is even more critical since a large proportion of India's population is poor and a significant number of households gets pushed into the poverty trap every year by catastrophic health expenditure. Some community health insurance schemes targeting poor families in different states are, however, showing encouraging trends. The governmental agencies therefore need to play a more active role in facilitating and ensuring health insurance coverage for the people of India – particularly its poor.

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# 5 | CRISIS OF THE GLOBAL INNOVATION MODEL FOR MEDICINES: A CIVIL SOCIETY ORGANIZATIONS' PERSPECTIVE

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## Introduction

The global model of fostering innovation in medicines is in deep crisis. In developed countries, it has long been argued that there is a direct correlation between intellectual property protection for pharmaceuticals and pharmaceutical innovation: the more protection, the more innovation. However, the model has become market-oriented, based on intellectual property rights (IPR), and controlled by multinational pharmaceutical companies. As a result, intellectual property protection has enjoyed an unprecedented expansion in recent decades, while innovation has stagnated. Stated another way, the use of intellectual property protection as a tool for promoting pharmaceutical innovation has so profoundly failed to fulfil the needs of society that it has become counterproductive.

Developing countries in particular suffer from being forced to enter a comprehensive, global, market-based system that is driven by IPR protection to increase the already-exorbitant costs of medication. Because they cannot benefit from the costly innovations that they help to finance, the global model of innovation has become an obstacle to innovation and access to medicines in these countries. As pharmaceutical innovation is transformed from a national issue into an international catastrophe controlled by global industry, developing countries are victims of both edges of the sword: (a) they are charged extortionate costs for medicines for chronic diseases, which (b) fund innovation programmes that neglect the specific health problems that they face.

Health is a fundamental human right and access to life-saving medicines is a concrete expression of that right. In this chapter, we address two ways in which the right to health is being eroded:

- the lack of access to essential medicines resulting from exorbitant prices that place them beyond the means of patients and healthcare providers; and
- the non-availability of effective medicines as a result of the lack of innovation (Hogerzeil and Mirza, 2011; Love, 2007).

First, the chapter offers the perspective of the authors' own countries on poverty and its relation to health, disease, and access to medicines. Next, we discuss the current IPR-focused model of innovation and its impact on the South. Then, we demonstrate why we believe this model to be in crisis. Finally, we present potential remedies that are being discussed globally and call for fundamental change to remove intellectual property protection from healthcare innovation.

The chapter represents the view of Alliance, a consortium of civil society organizations (CSOs), not that of the authors' governments or local industries. Because our main focus is to defend the public interest by bringing the voice of citizens (as interpreted by participating organizations) to all situations, we strive for scientific and technical rigour, but do not take an academic point of view. Our presence has been controversial in the World Health Assembly (WHA), governmental consultation meetings in Latin America, the Pan American Health Organization conference on regulatory harmonization (PANDRH), and consultations with CSOs on HIV/AIDS. Yet, in many of these participation spaces, multinational pharmaceutical companies themselves act as CSOs. For instance, they finance patients' organizations (composed of patients suffering from chronic, orphan, and rare diseases) that claim to represent civil society, but are instead a lobbying strategy to debilitate our arguments and to obtain additional influence (Alves et al., 2010; IAPO, 2010). Such obstacles underscore the importance of our mission to offer the perspective of CSOs in low- and middle-income countries on the model of innovation, the crisis, the costs incurred by the Global South, and viable alternatives.

## Poverty, health, and access to medicines

For our organizations and the Alliance, the fundamental societal problem to solve in developing countries is poverty. For the purpose of this chapter, 'poverty' is understood as inequality and exclusion. Given

that we are moving towards democratic market societies, 'poverty' in this context can be described as the exclusion of the needs of citizens produced by market responses (ECLAC, 2009).

Today, the international community recognizes the strong relationship between poverty and health. Three of the eight Millennium Development Goals (MDGs) call for specific health improvements by 2015: reducing child mortality; reducing maternal mortality; and slowing the spread of HIV/AIDS, malaria, and tuberculosis. Following the publication of multiple World Health Organization (WHO) global health reports demonstrating links between health and economic development, several global public–private partnerships (PPPs) were established as part of the Global Fund to Fight AIDS, Tuberculosis and Malaria in 2002 (WHO, 2002).

While increasing resources for health is necessary, it is not sufficient to improve the well-being of the poor and to meet the MDGs for public health. The majority of health spending disproportionately benefits the wealthy. This is evident from the increasing inequality with respect to health globally, and particularly in Latin America (United Nations, 2010).

According to a WHO study conducted in 2011, at least a third of the global population suffers from lack of regular access to essential medicines (Hogerzeil and Mirza, 2011). The case of HIV/AIDS is emblematic. In 2008, WHO, UNAIDS, and the United Nations Children's Fund (UNICEF) estimated that, out of 9 million people needing treatment, only 3 million were receiving it, the vast majority of whom were situated in sub-Saharan Africa (Velásquez, 2008). Today, there is substantial evidence that demonstrates the efficacy of antiretrovirals for the treatment of HIV/AIDS; yet, after thirty years, these medicines are still not available for all those in need.

It is interesting to note that, during the negotiations of some free trade agreements (FTAs), rich countries argued that citizens in developing nations were unfairly benefiting from innovations in medicines without sharing the costs of innovation, while citizens in developed countries paid higher prices owing to the stringent IPR regimes in their nations (Drahos and Braithwaite, 2002). After the FTAs are implemented, however, developing countries certainly 'contribute' to the costs of research and development (R&D) of new medicines, because they must incorporate stronger intellectual property measures in their legislation, and these measures often result in

high-cost medicines that are unaffordable for most patients and healthcare providers (Rossi Buenaventura, 2007).

This lack of access occurs at the same time as the developed world is facing an overuse of drugs: an increase in consumption of medicines and an increase in consequent side effects. It is similar to the coexistence of nutritional deprivation and obesity, of poverty and opulence (Farmamundi and Solanes, 2013).

On the other hand, there is no incentive to invest in research for the diseases of poor people. Developing countries not only face the frustration derived from lack of access; we also face the frustration that results from lack of innovation for diseases prevalent among our populations (Trouiller et al., 2002). This is the case for 'type III diseases', such as malaria, tuberculosis, Leishmaniasis, schistomiasis, and Chagas disease, which disproportionately affect developing countries (WHA, 2008) and for which there are no incentives to dedicate resources for R&D. The proportion of innovations developed to address the medical needs of the poor in low-income countries is always minimal compared to the total number of innovations brought to markets throughout the world as a whole (Trouiller et al., 2002).

Yet the poor in developing countries also suffer from diabetes, cardiovascular diseases, and cancer. For these diseases, there are new innovations entering to the market that are beyond the means of individuals, families, and health systems in developing countries. This form of exclusion is striking, especially in light of the fact that, too often, there are health services and medicines exclusively available to the elite, particularly in middle-income countries. Latin America is the most unequal continent and disparities there have reached frightening proportions (ECLAC, 2009).

In many cases, mortality is much more related to poverty, exclusion, inequality, and lack of health services. Lack of access to medicines, even if they are low-cost, is only an additional element of the vicious circle of poverty, disease, and premature death.

We have learned that access to medicines is a national issue and that countries are using different mechanisms to face this complex situation. As each of our countries tries to find ways in which to guarantee their citizens the right to health, the following section will show how large pharmaceutical industries are using myriad techniques to shape the system in a way that protects their own interests.

## Global system of innovation

Following the establishment of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1994, members of the World Trade Organization (WTO) were required to provide minimum standards for IPR protection. All developing countries were forced to join this global system of innovation.

The vast majority of these nations did not previously grant patents for drugs, as was the case in some developed countries (UNCTAD/ICTSD, 2005).

The process of accession to the WTO differs from accession processes to other international entities. It is not like an invitation from an intellectual property agency such as the World Intellectual Property Organization (WIPO), or from an entity that promotes industrial innovation, such as the United Nations Conference on Trade and Development (UNCTAD). And certainly it is not an invitation aimed at helping countries to fight against poverty. Instead, an interested government must enter a process of bilateral and multilateral negotiations with the WTO. The applicant government must abide by certain terms to which both it and other WTO members agree.

The cost of *not* acceding to the WTO is exclusion from the global market. The majority of developing countries compete for market access for agricultural commodities in which there is ample competition. According to the 2005 Human Development Report, rich countries typically apply minimum trade tariffs to other developed countries, while maintaining very high tariffs for poor countries (UNDP, 2005). The application of different tariff schemes provide developed countries with a level of political influence and control over the countries of the periphery.

One of the well-known schemes that imposes pressure on developing countries to incorporate, enhance, and enforce IPR for pharmaceuticals (and for copyrights) is the 'Special 301 Report' of the United States Trade Representative (see, for example, USTR, 2010). This report requires the USTR annually to create 'watch lists' and 'priority watch lists' of foreign countries that do not provide adequate and effective protection to US intellectual property. If the country fails to alter its patent system in a way that the USTR deems inappropriate, that country can become subject to sanctions. For example, the USTR characterized Thailand's efforts to expand access to high-cost treatments for HIV, heart disease, and cancer as 'a weakening of respect for patents' and

elevated the country to the priority watch list in 2007: the year in which Thailand granted several compulsory licences (USTR, 2007).

Historically, governments in developed countries have used IPR regimes to better their economic interests, modifying the regimes as their perception of these interests evolve.

In times of colonialism, imperial countries employed an economic model that favoured the monopoly of strategic products. It was precisely in opposition to these monopolies that some colonized countries established more flexible systems that favoured the development of local industries.

Between 1790 and 1836, the United States issued patents only to its own citizens, since it was a net importer of technology. After 1836, foreign companies were allowed to obtain patents in the country, but they faced fees that were ten times the rate for US citizens. It was only after 1861 that the US government treated foreign patent applicants on a (almost wholly) non-discriminatory basis (Commission on Intellectual Property Rights, 2002).

In the global trade negotiations that led to the WTO, developed countries submitted proposals that promoted the monopoly power of their industries. Today, we are repeating history in the form of international agreements of forced compliance, such as TRIPS and bilateral trade agreements (BTAs) (Khor, 2007).

It is important to note that, prior to TRIPS, a number of countries applied exceptions for patents for some sectors of industry. These often included medicines and foods, because they were considered essential goods. The 1994 Agreement eliminated this option, because it obliged WTO countries to grant patents in all fields of technology (CIPIH, 2008).

Intellectual property protection confers different degrees and different time frames of exclusivity in the market. 'Exclusivity' means that a patent holder can prevent others from using the invention (making, selling, importing) without its authorization. This protection allows the patent holder to fix and modify the price of the product in order to maximize profits. After the implementation of TRIPS, all countries paid similar prices for pharmaceutical innovations (although there are reports that, often, poor countries pay higher prices than those in developed countries), yet not everyone benefits equally – certainly not poor countries (UNCTAD/ICTSD, 2005). Big pharma invests enormous amounts of resources (especially in

lobbying efforts) to shape a global patent protection scheme that favours its own interests.

The agenda to globalize and enforce intellectual property rights globally (Drahos and Braithwaite, 2002) developed at a time when the Reagan Administration implemented legislation in the United States to reform relations between universities and enterprises: the Drug Price Competition and Patent Term Restoration Act of 1984 (known as the 'Hatch-Waxman Act'). This legislation allowed universities to license the results of their research to for-profit pharmaceutical companies – that is, publically funded knowledge became 'privatized'. As a result, the pharmaceutical industry experienced an unprecedented soar in profits and growth during the last quarter of the twentieth century (Angell, 2004).

During this time, the term 'blockbuster drugs' emerged, referring to products that generated annual sales of at least US$1 billion (Goozner, 2004). The success of these drugs encouraged pharmaceutical companies to invest significant resources on their marketing and development.

To maximize profits, the pharmaceutical industry altered its business model. Companies focused primarily on increasing the value of their stocks and expanding their portfolio of patented products. They engaged in a number of mergers, concentrating the power of the industry in the hands of a few large firms.

The implications of these mergers and acquisitions, although successful for the value of stocks and for profits, included a reduced scope and diversification of research lines, dried pipelines, and resources concentrated only on potential blockbuster drugs (LaMattina, 2011).

In parallel, the companies pursued aggressive lobbying strategies and patent litigation efforts. Expanding exclusivity in the market became a primary focus, given the consequent skyrocket in sales and profits (CIPIH, 2008). Combined with the concentration of marketing efforts and resources in blockbuster drugs, the practices of pharmaceutical companies have created an environment in which the variety of therapeutically efficacious drugs is limited, generic manufacturers face significant risk, and the price of medicines is maintained at an exorbitantly high level.

As a result, expenditures on drugs in developed and developing countries are concentrated in new and costly medicines, *regardless of safety or efficacy* (Farmamundi and Solanes, 2013; HCAAM, 2008).

Nowadays, this innovation model is well entrenched. Actors face serious difficulties when trying to modify these practices. In industry, those that propose alternatives are fast replaced. Close ties between politicians and industry, combined with the effectiveness of pharmaceutical lobbyists, discourage new policies. And even patients' organizations mitigate their own opposition, since they rely on funding and discounts from pharmaceutical companies, and experience significant marketing pressure (Alves et al., 2010).

This is precisely the situation that led the Intergovernmental Working Group on Public Health, Innovation, and Intellectual Property (IGWG) to establish the World Health Assembly *Global Strategy and Plan of Action on Innovation, Intellectual Property and Access to Medicines* (WHA, 2008; see also Velásquez, 2011).

## Crisis of the innovation model

We have described the global architecture of pharmaceutical innovation and the role of intellectual property. Now, we want to argue that this intellectual-property-based model of innovation is facing a deep crisis. The crisis, from the perspective of developing countries, is expressed in the absence of research and innovation that address the health problems of their citizens – that is, in the neglected diseases. From a global perspective, it is evident that our society as a whole faces a crisis of the innovation model: a crisis of costs, transparency, results, and, above all, a crisis of relevance.

*Crisis of costs* In the September 2011 issue of the *The Lancet Oncology*, experts including healthcare professionals, policymakers, and cancer survivors examined the prospects for cancer management in high-income countries. Their conclusions were certainly overwhelming: according to the article, developed countries are unable to finance the cost of treatments and innovation of new drugs for the disease (Sullivan et al., 2011).

Almost four years ago, the European Parliament, with the support of some non-governmental organizations (NGOs) – notably Health Action International (HAI) Europe – convened a meeting in Brussels headed 'Can We Afford the Current Model of Medical Innovation?' At that meeting, while all welcomed the progress made in investment in neglected diseases, the participants asserted that the rising costs of innovation were creating an untenable situation not simply for the

developing world, but also for the countries of the European Union (HAI, 2010).

Expenditures on medicines constitute an increased share of general expenditures on health in developed countries. A decade ago, no industrialized country spent more than 10 per cent of its health budget on medicines; today, Germany spends 15.2 per cent, Spain, 22.8 per cent, Finland, 16.3 per cent, France, 16.6 per cent, Italy, 20.1 per cent, and the United States, 12.48 per cent (Velásquez, 2011). In successive annual reports from the social security system in France, a constant growth in health expenditures was registered, mostly attributable to medicines. The September 2008 report attributes the increase in expenditures to the 'structure effect', a phenomenon that implies that there is a higher concentration of prescriptions and expenditures on the newest and the most expensive medicines (HCAAM, 2008). One can conclude that, at least for members of the Organisation for Economic Co-operation and Development (OECD), the model of innovation is creating an unsustainable growth in expenditures.

Certainly, the global market is concentrated in the OECD countries. By 2011, nine countries accounted for 85 per cent of the global consumption in medicines, almost half of which was in North America (IMS Health, 2011) (see Table 5.1).

Table 5.2 presents the distribution of expenditures on medicines by main countries in each region. It includes growth rates between January 2010 and January 2013.

Given the outstanding difference among growth in OECD and developing countries, the term 'emerging markets' is used for those

TABLE 5.1 Sales of medicines per region, 2011

| Region | Sales (US$bn) | % |
|---|---|---|
| North America | 244.6 | 47.31 |
| Europe (top five) | 107.3 | 20.75 |
| Japan (including hospitals) | 86.8 | 16.79 |
| Australia/New Zealand | 9.5 | 1.84 |
| China (hospital) | 32.8 | 6.34 |
| Latin America (top four) | 36 | 6.96 |
| Total | 517 | |

*Source*: IMS Health (2011)

TABLE 5.2 Sales of medicines through retail pharmacies and growth rates per region/country, 2010–13

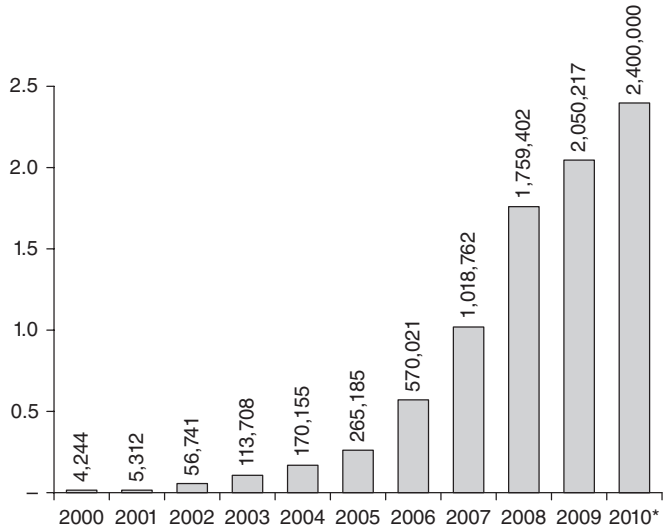
| | 2010–11 | | 2011–12 | | 2012–13 | |
|---|---|---|---|---|---|---|
| Region/country | US$bn | Growth (%) | US$bn | Growth (%) | US$bn | Growth (%) |
| North America | 244.6 | 3 | 253 | −3 | 257.7 | 0 |
| United States | 225.2 | 3 | 234.8 | −3 | 238.7 | 0 |
| Canada | 19.4 | 2 | 19.3 | −3 | 19 | −1 |
| | | | | | | |
| Europe (top five) | 107.3 | 3 | 103 | −7 | 104.6 | 0 |
| Germany | 36 | 8 | 38 | −4 | 38.5 | 4 |
| France | 27.8 | 1 | 26.2 | −9 | 26.5 | −3 |
| Italy | 15.7 | 1 | 14.1 | −10 | 14.5 | −1 |
| Spain | 14.2 | 0 | 12.7 | −14 | 12.1 | −4 |
| United Kingdom | 13.6 | 2 | 13 | −3 | 14 | −1 |
| | | | | | | |
| Japan (including hospitals) | 86.8 | 1 | 96.2 | −5 | 87.4 | 2 |
| Australia/New Zealand | 9.5 | 5 | 12.7 | −2 | 11.3 | −2 |
| China (hospitals) | 32.8 | 22 | 52.3 | 20 | 56.2 | 14 |
| | | | | | | |
| Latin America (top four) | 36 | | 43.2 | 4 | 43.8 | 15 |
| Brazil | 17.9 | 20 | 22 | −2 | 22.7 | 15 |
| Mexico | 7.9 | 3 | 9.6 | 4 | 8.9 | 4 |
| Venezuela | 6.2 | 32 | 7.9 | 21 | 6.4 | 24 |
| Argentina | 4.1 | 26 | 6.7 | 10 | 5.8 | 22 |

*Source*: IMS Health (2011)

whose growth is above 10 per cent (IMS Health, 2011). From the perspective of developing countries, the pharmaceutical industry's business model will have worrisome implications for these emerging markets. Since the business model creates an imperative to increase sales annually, companies will expand their lobbying efforts and marketing resources in emerging markets. A prospective analysis forecasts an increase in consumption of drugs in the emerging markets and a decline in the United States (IMS Institute for Healthcare Informatics, 2011).

The particular case of Colombia is illustrative. The Colombian General System of Social Security in Health (*Sistema General de Seguridad Social en Salud*) has an essential medicines list that includes around 660 active principles, selected following the recommendations of WHO and of evidence-based medicine. Nevertheless, if a physician writes a prescription for a drug that is not on the list, patients can use a legal mechanism to obtain it. This mechanism was made available following the global movement promoting health as a human right. A similar mechanism can be found in other Latin American countries, including Brazil, Uruguay, Argentina, and Bolivia, where terms for it include *Amparo Constitucional*, *tutela*, and *recurso de amparo*, among others. In all of these countries, there has been a growing tendency to use the legal mechanism to access newer, more exclusive, and more expensive medicines.

Annual expenditures on these medicines in Colombia have grown from around COP4.2 billion (US$2.3 million) in 2000 to COP2.4 trillion (US$1.2 billion) in 2010, as is shown in Figure 5.1. Most of the top twenty medicines responsible for this increase in sales are new and expensive; a form of IPR protection, including patents, data exclusivity, or trade marks, covers the majority of them (FMC, 2010).




**5.1** Annual spending on medicines not on the essential medicines list, Colombia 2000–10 (in millions of Colombian pesos) (*source*: https://bournepartners.wordpress.com)

Typically, we have attributed barriers to access of medicines to patents. However, recent assessments have shown that data exclusivity protection can also contribute to the high cost of drugs. In the few countries that have implemented data exclusivity protection measures, the impact on the pharmaceutical market has been severe (Shaffer and Brenner, 2009).

In the same way, people tend to ignore the weight of trade marks, which are a class of intellectual property that have a significant impact on access. A study conducted by IFARMA in Colombia showed that, in a sample of fifty essential drugs of high consumption, pioneer brand medicines cost twenty-two times more than their generic equivalent on average and secondary brands cost six times more (Vásquez Serrano, 2010). Given that these drastic price differences are not attributable to quality differences, as is common in luxury goods markets, there is no justification. From a health perspective, these price differences are unacceptable, especially in contexts of poverty.

*Crisis of transparency* There are two aspects that make the pharmaceutical industry and this intellectual-property-based innovation model one of the least transparent. First, there is an absence of public data on the real costs of R&D and other activities as a result of the pharmaceutical companies' strong resistance to providing this information and, instead, the publication of data that fails to reflect real costs. Second, pharmaceutical companies have been increasingly manipulating data from clinical trials to advance marketing goals.

In the last ten years, estimations of the cost of introducing successful products to market have been the subject of intense debate. The well-known study by DiMasi and his group at Tufts University estimated the cost of innovation at about $800 million in 2000 (Goozner, 2004), rising to $1.2 billion in 2003 (DiMasi, 2003) and to about $1.5 billion in 2010 (DiMasi, 2010), or (according to Andreas Seiter of the World Bank) $2 billion in 2006 (Seiter, 2010). Both of these calculations are remarkably close to those suggested by big pharma.

These high costs have been used to justify the high price of new drugs and price increases for newer innovations. Understanding that intellectual property is an arrangement between society and those who specialize in innovation, and that the arrangement should be beneficial for both parties, such costs show a huge imbalance in favour of rich societies. For societies with high levels of poverty, it is a significant

burden that compounds distressing scenarios of poverty and inequality (CIPIH, 2008).

It must be noted, then, that these figures have been the subject of controversy. Many academics have disputed them on the grounds that such calculations exaggerate costs to justify high prices and enable maximization of profits. A recent publication in the London School of Economics journal *Bio Societies* challenges these calculations, estimating that the cost of drug development could range from as little as $13 million to as much as $234 million, averaging about $43 million (Light and Warburton, 2011).

In a systematic review, authors considered that despite three decades of research in this area, no published estimate of the cost of developing a drug could be considered acceptable (Morgan et al., 2011). In most of the studies, there is a lack of a reasonable audit and disclosure of – at the very least – the drugs that the authors used for their estimations. Certainly, an important part of the debate rests on the way in which big pharma has managed to keep its figures secret. Like few other industries in the world, the pharmaceutical industry has achieved data industrial secrecy; it is not required to report its data to authorities or public information systems.

But this manipulation of data is not restricted to the economic and financial aspects. There is a growing global concern over the handling of information from clinical studies – namely, safety and efficacy data. Each year, we are surprised by new scandals about dangerous products, the adverse effects of which were minimized, or even hidden. Less publicized, but equally distressing, is the fact that there is a strong tendency to disclose only favourable results for products and to silence negative ones. In some cases, this bias has led to lawsuits against scientists who questioned the way in which the results were presented. The behaviour is so widespread that there have been global initiatives to establish an international clinical trials registry platform (Reveiz et al., 2010; WHO ICTRP, 2004).

This particular issue has been used as the storyline of several popular films: *The Constant Gardener*, directed by Fernando Meirelles; *The Fugitive*, starring Harrison Ford; *Michael Clayton*, starring George Clooney; *Limitless*, starring Robert De Niro; and *I am Legend*, starring Will Smith. From a more academic perspective, there are a lot of publications compiling the most representative examples of this manipulation of data from clinical trials. Table 5.3 provides a selection

TABLE 5.3 Cases of manipulation of data from clinical trials

| Year | Product | Laboratory | Case |
|---|---|---|---|
| 1980 | Benoxaprofeno | Ely Lilly | The publication of safety risks prompted the company to issue a lawsuit threat against the researchers. |
| 1987 | Levotiroxine | Boots | Boots managed to block the publication of results from a clinical trial until journalistic research findings revealed that the company had exerted pressure on the researchers. |
| 1996 | Deferiprona | Apotex | The publication of severe side effects prompted the company to fire and issue a lawsuit against the researcher. |
| 2002 | Rofecoxib | Merck | In the studies CLASS and VIGOR, an important risk of cardiovascular effects was hidden. An independent publication claimed scientific fraud and the author was sued. Two years later, the product was retired from the global market. |
| 2004 | Paroxetine | Glaxo | A publication in the *Canadian Medical Association Journal* (CMAJ) revealed that trials showing no advantages of the product (compared to the placebo) had been silenced. |
| 2004 | Gabapentine | Pfizer and Warner-Lambert | Between 1994 and 2000, Pfizer engaged in illegal off-label promotion of the drug. In 2003, total sales reached more than €2.2 million; 90% of these sales had been prescribed for unapproved indications. Pfizer pleaded guilty and received a fine of US$400 million. |

*Source*: Cañas (2011)

of these cases based on a systematic review conducted by Martin Cañas of the Medical Federation of Buenos Aires (Femeba).

The manipulation of data from clinical trials can be seen to be getting worse, in light of growing evidence of bias in the publication and the management of results. This bias is also apparent in the preparation of reports for scientific journals, some of which have included ghost authors. The relocation of clinical trials from universities and public hospitals into clinical research organizations in which researchers are

less independent also raises doubts about the integrity and reliability of the data (Cañas, 2011).

These practices have sullied the reputation of medical journals to such an extent that thirteen of the most recognized journals signed a unified declaration in 2001 obliging researchers to declare conflicts of interest and sponsors. The declaration also required researchers to register all clinical trials, and to assume responsibility for trials, data, and timely publication (Angell, 2004).

From our perspective, we also consider the fact that this industry is more oriented towards marketing than towards R&D as an expression of the crisis of transparency. Figures from the balance sheets of major laboratories show much higher marketing expenses compared to research expenditures (see Table 5.4).

*Crisis of results* During the negotiations of FTAs, one of the arguments presented by the developed countries is that there is a direct relationship between intellectual property protection and innovation. But there was an impasse in innovation during the last decade of the last century despite a dramatic increase in intellectual property protection.

The 1994 TRIPS greatly increased the number of countries granting patents to pharmaceuticals and, in subsequent years, as a result of FTAs, protection has been increasingly broadened and enforced.

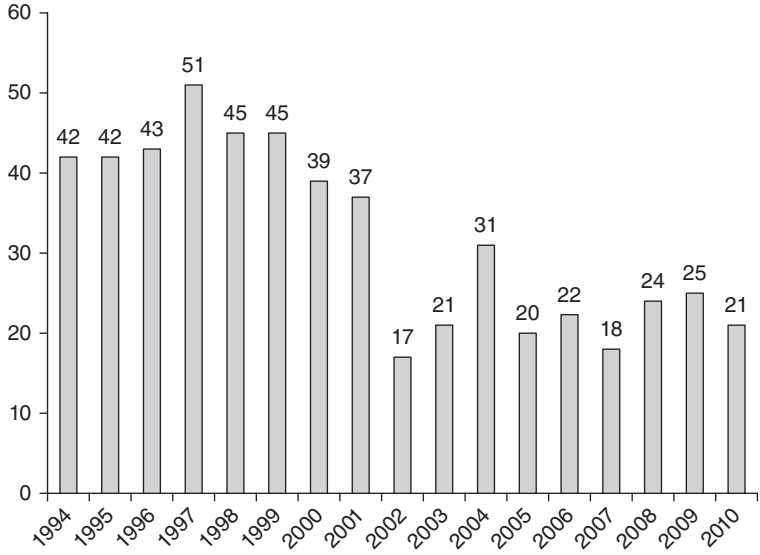
TABLE 5.4 Investment in marketing vs investment in R&D of nine major pharmaceutical laboratories in 2002

| Firm | % of income for marketing | % of income for R&D |
|---|---|---|
| Merck | 13 | 5 |
| Pfizer | 35 | 15 |
| Bristol-Myers Squibb | 27 | 12 |
| Abbott | 23 | 10 |
| Wyeth | 37 | 13 |
| Pharmacia | 44 | 16 |
| Eli Lilly | 30 | 19 |
| Schering Plough | 36 | 13 |
| Allergan | 42 | 15 |

*Source*: AIS LAC (2002)

However, Figure 5.2 shows that the number of new chemical entities has declined since the mid-1990s. According to the US Federal Trade Commission (US FTC, 2003) and the European Commission's Directorate General Competition (DG COMP, 2009), the proliferation of patents and the increasing amount of litigation have led to a complex network system in which research has become a risky activity. Perhaps the intellectual property protection has exceeded a limit after which, far from being a stimulus to innovation, it has become an obstacle. The 2009 report of DG COMP's pharmaceuticals sector enquiry also concluded that excessive focus on litigation is hampering generic competition and weakening innovation (DG COMP, 2009).

The particular case of antibiotics is very illustrative. The number of newer and more potent antibiotics has declined over the past couple decades as a consequence of reductions in investments in this critical therapeutic group. Antibiotics are usually taken over short periods; thus it can be seen as more advantageous to invest in products for chronic diseases that are consumed over a longer period of time. Moreover, many new antibiotics have been developed for infections that are resistant to older antibiotics. These newer drugs are used sparingly to




**5.2** Decline of number of new chemical entities of pharmaceutical use, 1994–2010 (*source*: US FDA, 2010)

preserve their effectiveness; thus the sales of these products will be limited, regardless of the size of investments in marketing. In this case, then, a model exclusively based on intellectual property is not a good incentive for R&D (So et al., 2011).

*Crisis of relevance* Even more worrying than the decline in the number of new chemical entities is the fact that the therapeutic value of some innovative products is inflated by marketing campaigns and that they do not actually solve health problems in society.

The top products sold in the world are statins, products whose therapeutic relevance is poor (Greving et al., 2011). Products for sexual performance, initially presented as remedies for erectile dysfunction, fall into one of the fastest-growing groups of the business. Novel antidepressants have increased their sales and indications, despite huge doubts about their efficacy. In other words, we have more 'blockbuster' drugs, but fewer effective responses to health needs.

In 2002, in the United States, the National Institute for Health Care Management (NIHCM) evaluated new medicines that had been introduced during the 1990s. Almost 60 per cent were active principles already in the market, with only minor modifications, very little innovative value, and very little therapeutic gain (Chokley, 2002).

In France in 2002, the prestigious newspaper, *Prescrire*, published an evaluation of commercialized medicines spanning 1981–2001: just 3.1 per cent represented an authentic therapeutic innovation; the rest of the products were effectively 'me too' products (*Prescrire*, 2002). This is commonly the case, because companies face much lower risk when they invest in the modification of successful products than when they invest in truly innovative products, despite claims about commitments to health and innovation (Angell, 2004).

## Technology transfer and local innovation

One of the many promises made to developing countries by the developed world and never fulfilled has been the promise of technology transfer, and to help with the promotion of local research groups and industries.

A study conducted in Argentina, Brazil, Colombia, India, and South Africa, sponsored by the International Development Research Centre of Canada, showed that, between 2004 and 2008, the majority of patents were granted to foreign multinationals, except in India, where

most of patents filed and granted were for local industries (Correa, 2011). The exception in the case of India is certainly not a consequence of intellectual property protection. India was one of the few countries that used the transition period term under TRIPS to grant patents to medicines until 2005. But India also implemented aggressive industrial promotion policies in the previous century that helped to generate the industry that it has today. These policies were intended to promote local development and to improve export revenues; they were not specifically aimed at fulfilling local health needs. Thus the drug needs of the population of India are still large and access is still unequal.

Another promise of TRIPS and IPR regimes relates to the dissemination of the information that leads to inventions: through patent information systems, it is said, the scientific community can learn about the scientific and technological advances made by research groups. However, in recent years, examinations of databases in several developing countries have demonstrated that information is not transparent and is not intended to facilitate the dissemination of research results. Instead, key information remains secret, to encourage litigation. Finding which products are covered by one or more patents can be both very difficult and expensive (Correa, 2011): the Global Fund to Fight AIDS, Tuberculosis and Malaria, for example, uses a significant portion of its resources to determine whether patents protect a product that it seeks to purchase.

## Civil society's perspective on alternatives

What makes this expensive and inefficient model capable of being maintained and expanded? There are two factors: the enormous power of the pharmaceutical industry – that is, the monster; and the great weakness of governments and intergovernmental spaces. Market democracies, especially those located in OECD countries, are becoming increasingly the expression of corporate interests, since corporate lobbyists have a strong influence on policymaking processes. Sometimes, this influence is denounced and scandals come to light, but most of the time, it remains hidden in the process (Chomsky, 2011).

Building democratic societies that serve primarily the needs of the majority has not been easy, especially in developing countries, and there is certainly still a long way to go. That task – which, by nature, is the responsibility of governments – has failed. The UN agencies, which were established to avoid a third world war, have become forums for

debate, analysis, and the development of programmes and strategies to make societies more just, more equal, more egalitarian, and more democratic. Yet, since they are governmental organizations and governments seem to have an increased tendency to respond to interest groups, the United Nations has fallen short as well. Governments and the United Nations spend too much time, effort, and money responding to those who support them. There seems therefore to be an important role here for NGOs.

What do we want? We want a model of innovation without intellectual property – no more, no less. We want a model that is capable of delinking innovation and the price of medicines. Proposals to improve the current model, such as patent pools, transfer certificates, or prizes to neglected diseases, are insufficient.

There are a few research initiatives that focus on developing cheap, very simple interventions, with important gains in public health, such as trace elements supplementation (for example zinc for the treatment of diarrhoea, or magnesium for hypertension). Even so, there is negligible interest in developing these forms of drugs because of the poor business prospects that they offer. For example, some meetings were organized with industrial parties to discuss the use of magnesium in hypertension, but the discussion was abandoned, since there was no business perspective: there was only a limited opportunity to develop and market a 'product', and to 'create' a market.

Within the Banco del Sur (South Bank) of the Union of South American Nations (UNASUR), the Alliance of NGOs for access to medicines has proposed the creation of a prize for innovation in medicines for certain diseases – that is, neglected diseases (Banco del Sur, 2008). This would also allow us to benefit from innovation as we continue our battle against the strengthening of intellectual property protection for medicines. The proposal is currently under analysis in the Bank. We are optimistic about the outcome of this proposal, because the Bank is an entity that considers social investment a priority for the regional ambitions of UNASUR.

It is needless to say that there was once a time when innovation arose from research groups whose motivation was science, knowledge, and solidarity with human suffering. Their results were the subject of open debate and always remained in the public domain. Today, innovation decisions are no longer to be in the hands of scientists, researchers, and universities; instead, corporations, chief executive officers (CEOs),

and the value of stocks determine the fate of millions in the world. It does not seem that these populations are faring well: not from the perspective of society, humanity, or the species, nor according to long-term analyses. But from the perspective of market fundamentalism, this is irrelevant.

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PART THREE

# INTERVENTIONAL APPROACHES

# 6 | ADVANCING TOBACCO USE PREVENTION AND CESSATION AMONG SOCIO-ECONOMICALLY DISADVANTAGED YOUNG PERSONS IN INDIA

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## Introduction

Tobacco use is an emerging threat to the health of young persons in India, and young persons (10–24-year-olds) constitute 28 per cent of India's population. This is a bigger problem for those growing up in a disadvantaged urban setting, where the prevalence of tobacco use is especially high. Of those living below the poverty line in India, more than 40 per cent are children and adolescents. To effectively tackle tobacco use among disadvantaged populations, Project ACTIVITY (Advancing Cessation of Tobacco in Vulnerable Indian Tobacco-Consuming Youth) – a community-based, group randomized trial to prevent the onset of tobacco use and to promote tobacco cessation among young people (age 10–19) residing in low socio-economic communities in Delhi – was conducted during 2007–11. This chapter describes the results of the study, which employed qualitative methods to highlight the role of youth empowerment in a tobacco-use prevention and cessation intervention among socio-economically disadvantaged communities.

In this study, fourteen slum communities were matched and randomized to intervention (seven communities) and control (seven communities) groups. The two-year intervention was designed to target intrapersonal and socio-environmental risk factors to prevent the onset of tobacco use and to promote tobacco cessation, using four intervention strategies: training workshops; community-based cessation camps; interactive activities; and policy enforcement. Peer leaders, adult community leaders, and non-governmental organization (NGO) personnel were identified and trained to facilitate the intervention. Thirty-five focus group discussions (FGDs) with young persons (504

individuals) and parents (forty-one individuals), and in-depth interviews with adult leaders (seven individuals) were conducted using separate FGD and interview guides, respectively, at the end of the intervention.

The study revealed that most of the participants were aware of different components of the two-year intervention implemented in their communities. All felt that they had gained knowledge about the harmful consequences of tobacco use, the provisions of the Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act 2003 (the Tobacco Control Law), and myths related to tobacco use and quitting. Young persons participated in intervention activities, such as leadership training, rallies, street plays, and tobacco cessation camps. Some youth participants reported that their family and community members successfully reduced their own tobacco use following the intervention. Moreover, the sale of tobacco products to minors by tobacco vendors in their community also diminished. Adult community members supported youth participation and created tobacco-free zones. Parents and adult leaders reported that they benefited from this programme, which brought about change in both their own and community members' perceptions towards tobacco use, and that they looked forward to similar interventions.

The chapter concludes that engaging young persons as change agents to prevent tobacco use and to promote tobacco cessation in socio-economically disadvantaged communities may be an effective public health strategy to counter the vicious cycle of tobacco use and poverty.

## Background

Globally, poverty is both a cause and an effect of tobacco use. Dealing with the tobacco burden is especially important in resource-poor, low- and middle-income countries (LMICs), where 80 per cent of the world's smokers and the majority of smokeless tobacco users reside and where tobacco-related deaths, as well as illness, are highest (WHO, 2011). A major reason for high tobacco burden in LMICs is the shift in focus of the tobacco giants from developed to developing countries, targeting vulnerable women and children, who are still largely non-users (Gilmore et al., 2015). Across the globe, prevalence of tobacco use is highest among the poor (WHO, 2004). This has major implications, threatening the achievement of the United Nations'

Millennium Development Goals (MDGs) of eradicating extreme poverty and hunger, as well as supporting development, in LMICs.

Tobacco use by the poor has immediate short-term, as well as long-term, adverse economic effects. As an immediate consequence, increased spending on tobacco products by the poor diverts financial resources from other basic necessities, such as food, shelter, education, and health care (WHO, 2004). Thus tobacco affects not only the user, but also the entire family and, more importantly, the children. It has been estimated that, in India, household expenditure on tobacco ranges from 0.54 per cent to 6.3 per cent in rural, and 0.5 per cent to 7.24 per cent in urban, households (John, 2008), with spending reported to be much higher in China (17 per cent) and Mexico (9–22 per cent) (Gong et al., 1995; Vazquez-Segovia et al., 2002). In the long term, continued tobacco use causes the poor to succumb early to adverse health effects, such as cancers, cardiovascular disease, and respiratory diseases. This leads to additional healthcare costs for both the patient and the government, and represents an additional financial burden in the form of loss of income and absenteeism, leading to yet further impoverishment (WHO, 2004). Tobacco consumption impoverishes about 15 million people in India, and estimates indicate that direct expenditure on tobacco would increase rural and urban poverty rates by 1.5 per cent and 0.72 per cent, respectively (John et al., 2011).

Low socio-economic status (SES) is a strong determinant of tobacco use among adolescents. According to a World Health Organization (WHO) report, low parental income and education are independently associated with higher adolescent smoking rates (WHO, 2010). The report also suggests that disadvantaged adolescents are more likely to have parents who use tobacco and to have a permissible attitude towards tobacco use, peers who use tobacco, easy access to tobacco products, exposure to targeted advertising, and lack of supportive tobacco-free environments, all of which are conducive to tobacco uptake in this group. Furthermore, less advantaged adolescents are more likely to continue tobacco use into adulthood as compared to those that are better off. The less-advantaged group experiences higher stress levels as a result of unemployment and poverty, and thus perceives tobacco use to be a stress-reliever (Haustein, 2006).

India, which is the world's second largest consumer and third largest producer of tobacco products in the world (WHO, 2015),

also has the highest number of adolescents in the world (UNICEF, 2012a). Of those living below the poverty line in India, more than 40 per cent are children and adolescents (UNICEF, 2012b). Moreover, 60–80 per cent of the children in India live in low-resource settings (PLAN, 2005). Adolescence is the age at which experimentation with tobacco most commonly begins (US CDC, 2001). However, in low SES communities in India, the age of initiation has been reported to be as low as 6 years old (Arora et al., 2010a). Consistent with the global fact that tobacco use is higher in the poor, a previous study conducted by the authors with students in sixth and eighth grades in thirty-two schools in Delhi and Chennai demonstrated that the prevalence rate for ever having used any tobacco product was 18.9 per cent for government school students (representative of low SES), as compared with 12.2 per cent for private school students (representative of high SES) (Mathur et al., 2008). A recent publication by the authors suggests that the prevalence of ever having used and current use of tobacco among adolescents (10–19 years old) staying in low SES communities, including communities participating in the study reported in this chapter, is 8 per cent and 4.88 per cent, respectively (Arora et al., 2010b). Data from a biochemical validation study of these respondents suggest that the actual prevalence of current tobacco use is almost double that of the current self-reported estimate (Dhavan et al., 2011). Poor students experience greater psychosocial risk for tobacco use as compared to those of high SES (Mathur et al., 2008). Another study conducted in Mumbai with 400 street children engaged in petty jobs observed that the average income of these children was INR29 (that is, less than US$1) per day and that a variety of tobacco products were consumed by these children: most commonly, *gutkha* (a mixture of tobacco, areca nut, catechu, and flavouring substances), which was consumed by about 46 per cent of the children (Path Canada, 2002). This was followed by *beedi* (a local hand-rolled cigarette), cigarettes, and other products in that order. The study also suggested that, among these children, the highest expenditure was on *gutkha* (more than INR6 per day) and that the spending increased with increasing income up to INR200 per day.

As observed in the developed countries, several individual, as well as socio-environmental, factors have been shown to be associated with tobacco use among young persons in the Indian context (Perry, 1999; Reddy et al., 2006; Stigler et al., 2006). Intrapersonal factors, such as

social susceptibility to tobacco use, advocacy skills, and self-efficacy, and socio-environmental factors, such as the perceived prevalence of tobacco use, exposure to tobacco advertising, and a lack of support for tobacco-control-related public policies, were found to be consistently associated with tobacco use among children and adolescents (Stigler et al., 2006). Also, other factors, such as tobacco use by peers and parents, the social acceptability of tobacco use by adults, and the easy availability and accessibility of myriad varieties of tobacco products, are important to address for prevention and control of youth tobacco use. Children and adolescents belonging to the low SES group are exposed to a pro-tobacco environment in their homes and neighbourhoods, and this group also lack the necessary skills with which to resist peer pressure as compared to the better-off, all of which are important contributors to tobacco use among this group (Mishra et al., 2005).

Because poverty and tobacco use are closely associated with each other, strategies to deal with these also need to be linked. Community mobilization is a promising concept, with the potential to contribute to both poverty alleviation and tobacco control programmes (Dongier et al., 2003; Forster et al., 1998). Such community involvement gives control of decisions and resources to local community groups. Well-designed programmes with a major community involvement component are inclusive of the poor and the vulnerable groups, build positive social capital, and give representation and a voice to the poor in community, as well as government entities, and thus such programmes are more responsive to the needs of the poor (Dongier et al., 2003). Such a process has been employed in the National Rural Employment Programme (NREP) in West Bengal, India, where public participation through the local governing bodies called *panchayats* have resulted in the decentralization of implementation authority from the central and state governments, granted instead to those better acquainted with local needs (John, 1992). Hence the projects have been more responsive to local needs and received wide public support. Focusing further on the community, the United Nations Population Fund (UNFP) recommends empowering the young persons in the communities by providing them with education, opportunities, and resources for enhancing the overall health of the communities (UNFP, 2003). Youth empowerment is now employed as a frontline strategy in tobacco control (Altman and Feighery, 2004). Peer-led health activism has been employed elsewhere in a school-based tobacco prevention intervention in India, where the

intervention was able to reduce the prevalence of tobacco use by 17 per cent in the intervention group, as compared to a 68 per cent increase in the control group (Perry et al., 2009).

Offering help to quit through treatment facilities for tobacco dependence is an important measure recommended by the WHO for tobacco control (WHO, 2008). Behavioural counselling alone is recommended as an effective treatment for tobacco dependence among adolescents. A number of clinical trials conducted with pharmaceutical aids, such as nicotine patches and Bupropion, have shown limited success among young people in the form of low quit rates, low sustained abstinence at three and six months, and rapid relapse after stopping drug therapy (Colby and Gwaltney, 2007). Pharmacological treatments for tobacco cessation are expensive for the poor population in India. A pack of ten Bupropion tablets can cost anywhere between Rs60 and Rs400 (depending on the brand), and the complete course lasts for between seven and twelve weeks (meaning a total cost for the full Bupropion course of Rs540–9,660). A pack of ten nicotine gums (Nicorette) can cost around Rs50 and the complete course lasts for about four to six weeks (making total cost for a full nicotine gum course of Rs980–1,120, assuming that the person starts with ten gums a day and reduces by two gums a day each week).

Currently, there are only nineteen tobacco cessation clinics (TCCs) in India, located in tertiary care hospitals that cater to twenty-nine districts out of the forty-two included within the National Tobacco Control Programme (NTCP), launched in 2007. The majority of these TCCs are linked to psychiatric clinics. The taboo associated with mental illness leads to hesitation among the patients, especially children and adolescents, to seek treatment in these TCCs, which hesitation is complemented by lack of knowledge about cessation services and lack of access to these hospitals, especially among the poor. Because of the stigma attached to visiting the TCCs, it is necessary that community-based innovative programmes for the prevention and cessation of tobacco use are developed and tested in India. These interventions engaging with children and adolescents are innovative, with trained and converted adolescents acting as agents of behavioural change in the community. Moreover, the number of TCCs is inadequate to reach the 275 million tobacco users in the country; thus efforts beyond the government's initiative on tobacco cessation need to be tested and scaled up.

Evidence suggests that there are large numbers of poor children and adolescents in low-resource settings in India who are highly vulnerable to tobacco use. Hence targeted interventions are deemed to be necessary for this group before experimentation with tobacco begins. There is a need for low-cost, community-based tobacco-use interventions for socio-economically disadvantaged young persons living in low-income communities in India.

Based on their previous experience of developing settings-based interventions for the prevention and control of tobacco use (Perry et al., 2008, 2009; Stigler et al., 2007), the authors, in collaboration with University of Texas, embarked upon Project ACTIVITY in fourteen low SES communities of Delhi, India, to address the prevention and cessation of tobacco use among young persons belonging to these communities (Arora et al., 2010b). This chapter describes how Project ACTIVITY changed community norms by means of improving knowledge and positively altering perceptions of community members, and hence changing their tobacco use behaviour, particularly among those belonging to the poorer section of the society, who experience higher exposure to market forces perpetuated by the tobacco industry. In doing so, this chapter focuses on youth empowerment and leadership as key strategies for mobilising the community and influencing community norms. Also, this study tested for the first time the use of technology-based strategies such as mobile health (m-health) for tobacco-use prevention and cessation in low SES Indian settings.

## Materials and methods

*Study design* Project ACTIVITY is a community-based, group randomized trial, designed to test the efficacy of an intervention that aims to prevent the onset of tobacco use and to promote tobacco cessation among young persons (aged 10–19) residing in low SES communities in Delhi. Fourteen slum communities were matched and randomized to intervention (seven communities) and control (seven communities) groups. Communities in the intervention condition received a community-based, multi-component intervention implemented across two years (2009–11). Communities in the control group received free eye and dental care services as a token of participation in the study.

A qualitative study was conducted post-intervention (in 2011) to assess the perspectives of young persons, parents, and adult leaders through FGDs and in-depth interviews in the seven intervention

communities. Repeated surveys of participants before (2009), during (2010), and after (2010) the intervention were conducted to evaluate the efficacy of Project ACTIVITY, and the results from these surveys are under review for publication elsewhere. Ethical clearances for the study were obtained from the Independent Ethics Committee (IEC), Mumbai, India, and the Institutional Review Board (IRB), University of Texas Health Science Centre, at Houston, TX. Project ACTIVITY was funded by Fogarty International Center (FIC) and the National Institutes of Health (NIH), Award #R01TW007933.

*Study setting* Communities were recruited systematically from a list of forty-four registered resettlement colonies and Jhuggi Jhopri (JJ) clusters/slums (1,079) obtained from the Municipal Corporation of Delhi (Arora et al., 2010a). The eligibility criteria for the study included:

- a resettlement colony with a neighbouring JJ cluster;
- residence within a radius of 25 kilometres from the research office;
- more than 500 households in each of the resettlement colony and the JJ cluster;
- no demolition during the study period; and
- the presence of a known NGO working in the community and willing to participate.

The local NGOs provided a channel for establishing connectivity with people residing in the community. Before randomization, the communities were matched based on similar demographic profiles (such as ethnicity, religion, language, occupation of adults, number of households, population per block, school-attending/non-school-attending children living with family, etc.).

*Participants* Thirty-five FGDs were conducted with 504 young persons (including boys and girls, aged 9–21) and forty-one parents (including men and women, aged 35–50) in all of the intervention communities. Twenty-eight FGDs were conducted with young persons in four groups based on age and gender (that is, 9–14-year-old boys, 9–14-year-old girls, 15–21-year-old boys, 15–21-year-old girls), and seven adult FGDs were conducted separately by gender. Each group comprised between eight and ten participants (both literate and illiterate, and

tobacco users and non-users). In-depth interviews were also conducted with seven adult community leaders (including men and women, aged 35–70) residing in each of these intervention communities. The purpose of conducting the discussions with different groups was to reach as many groups of young persons and adults as possible, and to obtain the wider perspective on the issue, so as to be able to triangulate emerging findings and confirm impact as reported.

*Data collection and analyses* The FGDs were conducted with the use of two separate FGD guides, one for parents and one for young persons. The guidelines comprised a list of semistructured questions in Hindi. Parents and young persons were asked to share their awareness level of the tobacco-related programme run by Health Related Information Dissemination amongst Youth (HRIDAY) in their communities and their participation in different activities as part of Project ACTIVITY. They were also asked about any new information on the health consequences of tobacco and various provisions of the Tobacco Control Law. There were some questions on any changes in their own, their families', and their communities' views towards tobacco use and tobacco cessation in the last two years. In addition, there were some questions such as 'Did you notice any change in yourselves, your family members and in your community with regard to tobacco use practices?', and 'Were strategies employed like rallies, street plays, peer leadership effective, useful and empowering?' Participants were also asked to share their opinions on the need to run such programmes in the community.

In-depth interviews were conducted with community adult leaders using an interview guide. Adult community leaders were asked to share their opinions on tobacco use among adults and children in their communities. They were asked about any initiative to enforce provisions of the Tobacco Control Law within the community. Their opinion was also explored on quitting tobacco – that is, the ideal age at which to quit, and the support and type of support needed for quitting. Some questions were asked such as 'In your opinion, if a tobacco user decides to quit tobacco, whom would he/she approach?', and 'What kind of information would he/she need?' The FGDs and interview guides were translated and conveyed in the local language of the participants (that is, Hindi). The discussions were conducted at a scheduled time and place, at the convenience of the participants and within the community.

Triangulation of data from youth and parent FGDs and interviews with adult leaders was employed to increase the credibility and validity of results (Bryman, 2012). The confidentiality of responses during FGDs and interviews was assured. A moderator, assisted by a notetaker, conducted the FGDs and interviews. Each FGD and interview lasted for about 35–40 minutes, was audio-taped, and was later transcribed and translated into English to ensure reliability of the data. NVivo software was used to develop the coding scheme, and the data were coded and organised under finalised themes congruent with the purpose of the study (Morse and Richards, 2002).

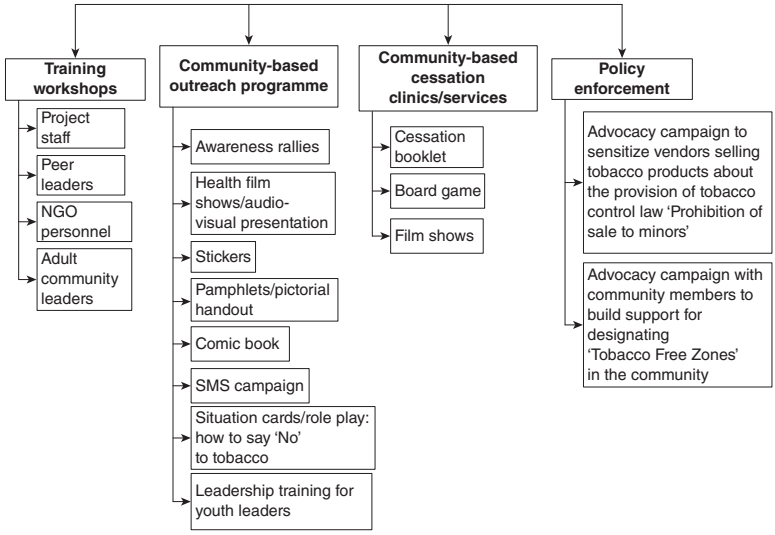
*Project ACTIVITY intervention* The two-year intervention embraced multiple comprehensive, community-based, cost-effective strategies to promote awareness and skills around the prevention and cessation of tobacco use among young persons (Jarvis and Wardle, 2006; Milton et al., 2004; Perry et al., 2008; Sussman, 2002). The intervention model was based on social cognitive theory (Bandura, 1986). Intervention strategies were employed to influence intrapersonal and socio-environmental risk factors to prevent the onset of tobacco use and to promote tobacco cessation (Arora et al., 2010a). These strategies are described in Figure 6.1.

Project ACTIVITY intervention material consisted of a colourful and pictorial booklet on tobacco cessation, activity manuals for adult leaders, peer leaders, and NGO personnel, a pictorial comic book for children, pictorial situation cards, interactive board games, and colourful handouts, developed to sensitize community members to various aspects of tobacco.

*Strategies and implementation* The four intervention strategies included:

- training workshops for project staff, partner NGOs, youth peer leaders, and adult community leaders;
- community-based interactive activities and outreach programmes;
- community-based cessation camps; and
- enforcement of the key provisions of the Tobacco Control Law in India.

Peer leaders, adult community leaders, and NGO personnel were identified and trained to facilitate the intervention programme, and




**6.1** Project ACTIVITY intervention strategies

served as intervention implementers and important change agents in the community. In the first year, the intervention included six interactive activities, which made use of films, street plays, rallies, and role play. The second year of intervention was implemented with the help of a support group, comprising adult leaders and young people already motivated to become leaders and agents of change in their communities, focused on the issue of tobacco-use prevention and cessation, as well as the enforcement of the tobacco control laws through leadership education.

The peer leaders were provided six weeks' extensive training to enhance their leadership capacity and to motivate them to work collectively, with trust and cooperation, towards change in their respective communities. The first week was dedicated to group building followed by group visioning, and then community mapping to learn about tobacco-use norms, tobacco vendors' familiarity with the Tobacco Control Law, and barriers to adhering with some of its provisions. The programme devoted extensive sessions of advocacy skill building among the youth leaders to help them to communicate effectively, and also trained them to engage community members individually and in groups to understand the norms and motivations for tobacco-use prevention and cessation.

Multiple community-based interactive activities and tobacco cessation camps, an SMS text campaign, and outreach programmes were organized in the second year of the study. Repeated sessions for each activity were carried out at different strategic locations in the communities to reach the maximum number of children and young persons enrolled in the study. Community-based cessation camps were organized to provide access to group counselling services and face-to-face counselling for tobacco cessation. All activities were life-skills-based to build skills among young persons so that they could effectively prevent and reduce tobacco use among their peers both now and in the future.

*Process measures* To assess the fidelity of the implementation of intervention components, feedback from youth leaders and adult leaders was collected. In the first year of intervention implementation, feedback forms for all activities were completed by peer leaders, adult leaders, and project staff at the end of each session of the activity. In the second year, FGDs and interviews were conducted with peer leaders and adults to collect their feedback after each session. Attendance records for each session were also maintained.

## Results

The results from the FGDs and key informant interviews with parents, adult community leaders, and youth leaders are presented in this section, grouped under the themes that emerged from these discussions.

*Awareness about tobacco and its multiple adverse impacts* The majority of parents felt that they learned many new things related to tobacco because of the intervention. During the discussions, it was revealed that the children who were involved in the intervention did share the information with their parents and family members. Parents reported hearing new information, such as about the ill-effects of tobacco use (of which they were not aware) from their children. One of the parents said: 'I used to smoke one to three cigarettes but my children opposed this habit by saying that it can cause throat problem[s] and cancer.' Parents could recall having seen pictures of cancer victims during different programme activities, which they felt were threatening and were effective in motivating tobacco users to quit. One parent shared: 'There were two to three users in our

street but [they] quit tobacco use completely when they saw these pictures.'

Youth participants in all of the groups shared that they received new information from the intervention. They also talked about the harmful health effects of tobacco. One of the boys shared: 'We watched a film through which we came to know about the harmful effects of tobacco.' They also mentioned that use of tobacco leads to various illnesses, such as hair loss, cataracts, weakness of limbs, brain damage, throat cancer, etc., and also learned how they could help their tobacco-using friends to quit. The majority of boys aged 9–14 also mentioned that '[t]obacco use not only causes wastage of money, but it also leads to illnesses such as throat cancer'. They also came to know about the harmful effects of tobacco on the environment, and how it may deteriorate the social status and the economic position of a person. One of the girls aged 9–14 shared: 'Tobacco use is nothing but wastage of money.'

The girls aged 9–14 also reported receiving information about the various types of tobacco (smoking, chewing) such as *gutkha*, cigarette, *beedi*, and *hookah*, and also about snuffing, which involves *naswar* and other tobacco products. Some of the participants mentioned alternatives for tobacco. One of the participants suggested that, '[w]henever there is urge for using tobacco, *elaichi* [cardamom] should be used'.

Community youth (aged 15–21) and their parents both reported becoming aware about the Tobacco Control Law. They shared information around issues such as the prohibition of tobacco sales to minors and the prohibition of smoking in public, but they conveyed that enforcement of smoke-free law still needs to be sufficiently strengthened in their communities. One of the parents reported:

> If we ask children to go and buy gutkha for us, they refuse as a result of intervention and inform us that it is a punishable offence, so we have also stopped sending our children to buy tobacco for us.

One of the adult leaders who owned a shop shared: 'I do not give tobacco products to minors, I explain [to] them that it is illegal and their parents also understand and cooperate now.'

The majority of parents and youth participants shared that the intervention helped in changing certain perceptions related to tobacco use. One of the young persons shared:

> Earlier people used to take tobacco to get relief from tooth ache, and used to smoke to get relief from gastric problem but after getting information that tobacco use is addictive and may cause life threatening diseases, they think before consuming it.

In most of the cases, immediate family members, such as a father or brother, made an attempt to quit tobacco use during the intervention. In certain cases, young persons too reported quitting. Some girls aged 15–21 shared: 'A sudden change in the perception of tobacco users was difficult to achieve but small changes in practices were observed such as decrease in the number of cigarettes used by an individual in a day.'

Many of the adult leaders also shared that the intervention was able to clear some of the myths regarding tobacco use. As one participant shared: 'Earlier we thought that tobacco use can ease dental pain and abdominal discomfort. Now we tell our family members and others, if there is pain in their teeth, they should go to the doctor and people listen to us.'

*Effective community mobilization strategies* The majority of parents shared that their children and community members were involved in the 'tobacco control programme' organized by the research group. They were aware of all of the activities of the intervention, such as health-focused films, rallies, cessation camps, and interaction with tobacco vendors. They shared that the rallies and films were very effective in disseminating information related to the harmful effects of tobacco use. They appreciated the intervention effort and expressed the need to organize such interactive sessions at regular intervals. Very few participants were aware about the messages sent to them via text on their mobile phones, however, informing them about the harmful effects of tobacco use and ways in which they could prevent its uptake among young persons. Most of the parents were not sure about the duration of the intervention; according to them, it varied from six months to more than two years.

For adult leaders, rally seemed to be a favourite medium with which to spread awareness: 'People come out and listen to slogans raised by youth, it really made an impact.' They were also aware of the street plays, but most could not watch the performance. Tobacco cessation camps were appreciated by all, although some participants

expressed their concern about the timings and duration of the camps: 'Tobacco cessation camps should be organized on a holiday and in the evening.'

Girls aged 9–14 mentioned that they organized camps and played the game 'card jodo' (a join-the-cards board game), which was a skill-building exercise to learn about the harmful consequences of tobacco use, about tobacco cessation, and about the Tobacco Control Law. Most of the youth leaders shared their experiences of working as support group. One of the girls mentioned:

> My father used to smoke beedi extensively and I was scared talking to him about this habit however, after the intervention, without any hesitation, I could tell him about the ill-effects of the tobacco, due to which he has reduced his beedi consumption.

The majority of youth leaders reported that they were very enthusiastic about being members of support groups.

They also added that they completed a survey of shopkeepers selling tobacco products and made them understand some provisions of the Tobacco Control Law. Most of the selected youth leaders attended the six-week-long leadership training and were highly appreciative of *saathi dal neta* training (training for peer leaders), finding it very useful and effective: 'We learnt to talk about tobacco with confidence from the programme.' Boards with advertisements of the ban on sale of tobacco products to minors were distributed among shopkeepers. As quoted by one girl: 'We distributed boards which had information that selling tobacco to children below 18 years is an offence.' They further conveyed that they interacted with the tobacco vendors, distributed the warning boards, and persuaded them to display these. Inculcation of a sense of ownership by these youth and other community members for the programme was evident, with the youth participants often referring to the programme initiatives as initiatives taken *by* them, for example, '*We* distributed boards …' and '*We* created tobacco-free zones …' (emphasis added). Adults too displayed ownership: '*We* used to tell tobacco users …'

The majority of the youth leaders reported that they shared the information with their family and friends. They often went home and passed the information to their parents by talking to them or by showing them the materials given. One of the girls aged 15–21 mentioned: 'The

pictures given in the book were very effective in making a mark in the minds of people about the problems caused due to tobacco use.'

Youth participants across groups and communities participated in intervention activities, such as leadership training, rallies, street plays, and tobacco cessation camps. Boys aged 9–14 participated enthusiastically in the rally, street play, and camp, in which people were informed about the ill effects of tobacco and laws on tobacco control. One parent conveyed that children played a very important role in dissemination of the information: 'They have spread the information in whole community through innovative health messaging used as a part of the programme.' The peer-to-peer learning approach among young persons was widely appreciated and contributed to community mobilization for tobacco control. Some members of the community considered tobacco-cessation camps to be a very important and effective feature of the intervention. One youth mentioned: 'People approached us even after the tobacco cessation camp to know about ways to quit tobacco.' They shared that the intervention was effective for illiterate people as well, because their children shared the information and showed them pictures of cancer victims, which were very effective.

Boys added that, with the knowledge received through the intervention, they felt capable of, and confident in, approaching a person and persuading him or her to quit tobacco use, saying that they could now easily justify their action. The intervention made them more informed and aware of the burden of tobacco, tobacco control laws, and strategies to quit tobacco use. But, at the same time, girls mentioned that there were also instances in which, even after repeatedly giving information, individuals were not interested in quitting.

Some parents actively participated in intervention implementation. Other parents encouraged their children to participate in the intervention. Initially, there were some inhibitions among community members related to the participation of girls in the intervention, but they themselves later took the initiative and supported their children and project staff whenever they needed support.

Many of the adult leaders agreed that increase in tobacco use was a cause of concern and a major issue in their communities, and thus they supported intervention through active participation in ensuring effective implementation of tobacco control policies.

Some girls talked about playing board games and creating tobacco-free zones: 'We have created tobacco free zone[s] and performed street

plays during the rally.' They were also aware of the SMS campaign and shared that, '[d]uring the programme, SMS was sent regarding tobacco control and we enquired by going door to door to check whether community people received SMS or not'. Tobacco-free zones were created with the help of adult community members and peer leaders. Some adult community members, including the women and girls, monitored the designated area to check for tobacco use. An adult leader reported: 'We used to request tobacco users not to use tobacco products in the areas designated tobacco free zones in our community.'

*Changing behaviours of community members* During the discussions, most of the parents shared that many of their fellow community members quit tobacco use after the implementation of intervention activities. Most of them claimed that they knew friends, or children, or family members who had given up tobacco use (*gutkha*, cigarettes, or *beedi*) as a result of this intervention. Change in community norms and practices around tobacco use were also reported by parents and families. As one of the parents reported: 'Shopkeepers used to sell cigarettes to children earlier but since the time [the] programme started, things have changed for better.' Another participant commented: 'After the rally which was organized during the programme, the nearby shopkeeper stopped selling gutkha to children.' During the discussions, one parent shared: 'Now, if you sit and observe near our lane, you will not be able to find even one person who smokes in front of small children.' Additionally, a mother mentioned: 'My husband used to smoke two bundles of beedi in a day, but now he has quit completely.'

## Discussion

Overall, Project ACTIVITY's intervention strategies appear to have changed community norms about tobacco use, improved youth, parent, and community member's knowledge about the negative health effects of tobacco, positively altered the perceptions of community members, and increased youth exposure to non-tobacco-using role models, and hence potentially changed tobacco use behaviour. Evaluation of Project ACTIVITY through student surveys complements the findings of the current study and suggests that, in the resettlement colonies, any tobacco use significantly decreased in the intervention group over the study duration, while it increased in the control

group; the increase in knowledge about tobacco control policies and the harmful effects of tobacco was also significantly higher in the intervention group compared with the control group (data yet to be published). The effective implementation of tobacco control policies in these communities, by means of the project's activities, may help to sustain this behaviour change over time. The most important feature that was highlighted as emerging from the study is how potent youth engagement and empowerment for tobacco control initiatives can be in this community context, and how this can be a useful strategy to secure parental and adult leader support.

Previous research from developed countries shows that community participation in health-related programmes was restricted to voluntary and advisory work for the community members; however, the scenario has changed over the years, with emerging local councils and groups consisting of active community membership, including young people, who are involved in the decision-making process and its implementation (Holden et al., 2004). Such community ownership and involvement in the project's activities were also observed in our intervention. Traditionally, females in India, especially in rural and low SES settings, have not been granted an equal status as compared to males when it comes to household decisions, because the male is usually the breadwinner for the household (Prakash, 2003). Support for the participation of girls in the intervention activities over time suggests that the intervention was effective in achieving change from initial inhibition to parental support and active participation. Usually, there exists a normative vacuum and lack of communication between children and their parents in Indian society when it comes to issues such as substance abuse. Yet research shows that intergenerational communication plays an important role in promoting healthy behaviours (Rajiv and Rimal, 2003). This strategy was successfully utilized in this intervention, wherein the young persons were able to communicate the harmful effects of tobacco and provisions of the Tobacco Control Law with the adults and persuade them to change their tobacco-use behaviours.

Community-based models are not only effective in empowering youth, but also go beyond that by creating an enabling environment by positively changing community norms and the enforcement of policies (Dongier et al., 2003). Most importantly, with their efforts, the young persons appear to have been able to persuade their close

affiliates to make an attempt to quit. Congruent with pre-existing literature, this represents a change in the community norms wherein the children and young adults are now accepted as agents of behaviour change. Through peer leadership, these young people have been actively engaged as agents of change in tobacco control interventions and advocacy efforts in developed, as well as developing, countries over the past few years (Arora et al., 2010a; Perry et al., 2009; US CDC, 2010). Adult support and reaction to youth advocacy efforts are considered critical to the success and sustainability of such efforts (Ribisl et al., 2004). In the current study, the young people were able to gain support among the adult community members and to establish tobacco-free zones in their communities, as well as garner participation in the multiple activities of the intervention, which appears to be a major reason why the intervention was effective in bringing about changes in community environment. Community ownership, which is recognized as a key element for sustainability of the programme, and environmental and behavioural change (Werner, 2002) were at the core of the intervention.

By means of the SMS text campaign, the intervention utilized the potential of 'm-health' as an innovative and contemporary public health strategy to advance tobacco control knowledge in the community through mobile phone connections. In developed countries such as Norway, the United Kingdom, and the United States, sending mobile-based text messages for smoking cessation has been shown to be between two and six times more effective as a cessation tool than traditional cessation methods (WHO, 2012). Although 86 per cent of parents recruited in this study owned a mobile phone, very few participants in our study were aware of the SMS sent to them, because of limited knowledge of the phones' messaging function. This suggests that technology-based solutions such as 'm-health' need to be adapted carefully for use in low SES settings, even in urban areas, in developing countries such as India. This could be done by adapting the text messages and converting these into pictorial or voice messages, to account for illiterate and mobile-novice populations.

*Sustainability* This community-based intervention programme was successful in changing the community norms regarding tobacco use by means of NGO's community outreach efforts and by positioning tobacco control as a development activity. A multi-component,

evidence-based intervention led by trained peer leaders led to ownership of the issue, and these trained and committed personnel are expected to sustain the momentum of tobacco control. Three factors – innovation, leadership education, and self-help group approaches – are key to scaling up such intervention programmes for poor and disadvantaged groups. In the past, sustained advocacy efforts by HRIDAY with the Government of India, backed by robust research evidence from a school-based tobacco use prevention intervention, Project MYTRI (Mobilising Youth for Tobacco Related Initiatives in India), resulted in convincing the Ministry of Health and Family Welfare to incorporate school health programmes on tobacco control into the NTCP (Arora et al., 2011). By demonstrating the effectiveness of the Project ACTIVITY intervention, the authors aim to develop an evidence base with which to advocate for scaling up this community-based programme to complement the NTCP. This proposed scaling-up exercise will further ensure that a sustainable campaign for demand reduction is initiated at national level for supporting effective tobacco control in the country.

*Limitations* Because of the prolonged nature of the intervention (two years), peer and community leaders developed a strong rapport with the research staff. Because tobacco use among young people is still associated with a cultural taboo in the Indian context, it is possible that the respondents provided socially desirable responses: an issue described as problematic respondent behaviour inherent in qualitative research (Collins et al., 2005). This qualitative assessment of effectiveness will further be corroborated with analysis of the quantitative surveys conducted as a part of the end-line evaluation.

## Conclusion

The use of tobacco is deeply rooted in Indian society and the behaviour is reinforced by its acceptability as a social norm. Tobacco use, being both a cause and an effect of poverty, leads to diversion of scarce economic resources, leading to further impoverishment of users belonging to the low socio-economic strata of society. This vulnerable group experiences higher pro-tobacco risk factors, both intrapersonal (such as lack of knowledge, skills, self-efficacy) and socio-environmental (for example exposure to tobacco advertising, peer and parent tobacco use, easy access, etc.), as compared to those

with higher educational levels and SES. The tobacco industry therefore continues to exploit the health and well-being of this low SES group, particularly its young members. Interventions involving community mobilization by engaging young people as change agents to prevent tobacco use and promote tobacco cessation in low SES communities in India appears to be feasible and potentially efficacious. This may be a crucial public health strategy to effectively counter the vicious cycle of tobacco use and poverty that persists globally today. Film screenings, street plays, pictorial booklets, rallies, and tobacco cessation camps appear to be appropriate and favoured strategies with which to mobilize communities, and positively influence community norms and health-promoting behaviours. The knowledge and skills gained by the participants through such interventions enable them to take control of their own health, to create health-promoting environments and policies, and also to alter the pervading social norms. Such strategies can counter the tobacco industry forces and therefore improve the health of the poor.

This was the first community-based, multi-component intervention in India targeting youth tobacco use in low SES settings in Delhi – that is, among the group most vulnerable to tobacco use, and its related health and economic effects. The results of this study, along with a subsequent quantitative evaluation, will overcome barriers resulting from a lack of research evidence to support the upscaling of the Project ACTIVITY interventions to low SES settings elsewhere in India and other LMICs.

Evidence available from the developed country settings suggests that technology-based strategies such as m-health are effective in tobacco cessation. Considering the tremendous potential of such strategies to be able to reach a large population quickly, with high availability of mobile phones, we tested an SMS-based mobile phone campaign for the prevention and control of tobacco use in this low SES setting. However, a low level of awareness about the SMS sent highlights the need to be careful when using such strategies in a low SES setting. Further research should test the use of alternative delivery methods, such as the use of pictorial messages or voice messages, instead of text messages in Indian low SES settings.

This study was also limited to urban low SES settings. Further research is required to develop and test strategies for the prevention and control of tobacco use among young people and communities

in rural settings. Further research should also focus on tobacco cessation among young people (particularly belonging to low SES) to address issues such as availability, accessibility, and affordability of cessation services, including socio-economic aspects of tobacco cessation.

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# 7 | ADDRESSING THE VULNERABILITY OF URBAN POOR WOMEN TO NEGATIVE MATERNAL AND NEWBORN HEALTH OUTCOMES

*Geeta Sodhi and Skylab Sahu*

## Introduction

In 2013, 289,000 mothers died from complications during childbirth and 6.3 million children died before their fifth birthday (One International, undated). The vast majority of maternal and neonatal deaths occur in the world's poorest countries. The less developed countries account for as many as 98 per cent of all reported neonatal deaths (Zupan, 2005). Maternal mortality is unacceptably high, with some 800 women dying from pregnancy- or childbirth-related complications around the world every day. Almost all of these deaths occur in low-resource settings and most could have been prevented. Of maternal deaths globally, 99 per cent occur in developing countries. More than half of these deaths occur in sub-Saharan Africa and almost a third occur in South Asia.

The maternal mortality ratio (MMR) in developing countries in 2013 was 230 per 100,000 births, compared with a ratio of 16 per 100,000 in developed countries (WHO, 2014). There are large disparities between countries: a few have extremely high MMRs of 1,000 or more per 100,000 live births. There are also large disparities within countries: between people with high and low incomes, and between those living in rural and urban areas (WHO, 2014). The high number of maternal deaths in some areas of the world reflects inequities in access to health services, and highlights the gap between rich and poor.

Neonatal mortality rates – that is, the number of deaths predicted within twenty-eight days from birth per 1,000 live births – are becoming increasingly significant as mortality generally improves among those aged under 5, yet the proportion of those deaths that occur during the neonatal period increases. With that increase occurring in every region and across almost all countries, systematic action is required

among governments and their partners to extend effective care to women and babies. Over the last two decades, improvement in neonatal mortality has been slower than improvements in mortality among those aged under 5 in almost all regions. Globally, neonatal mortality declined only 28 per cent between 1990 and 2010, from 32 deaths per 1,000 live births to 23 (an average of 1.7 per cent a year), compared with an improvement of 2.2 per cent per year for mortality among the under-5s and 2.3 per cent per year for maternal mortality (You et al., 2011).

Maternal and neonatal deaths are major health concerns in India. A high number of women in India die each year as a result of complications during pregnancy and childbirth. The World Health Organization (WHO) estimates that, of 529,000 annual maternal deaths, 136,000 (that is, 25.7 per cent) and almost 30 per cent of neonatal deaths occur in India alone. The global neonatal mortality rate (NMR) is 23 per cent – yet India has a rate of 32 per cent, worse even than many of its immediate neighbours: Nepal has an NMR of 28 per cent; Bangladesh, 27 per cent; Bhutan, 26 per cent; and Sri Lanka, 10 per cent (You et al., 2011).

Even within India, there are variations in MMRs and NMRs between rural and urban areas, as well as between highly and less developed states. In states such as Kerala and Tamil Nadu, the MMR (in 2011–13) is 61 and 79, respectively, whereas in states such as Madhya Pradesh and Uttar Pradesh, the respective MMR is 221 and 285 (Office of the Registrar General and Census Commissioner India, 2013). Similarly, the NMR is highest in less-developed Chhatisgarh and Orissa, at 51.1 and 45.4 respectively, while it is lowest in Kerala and Tamil Nadu, at 11.5 and 19.1 respectively (IIPS and Macro International, 2007). Similar differences also emerge in healthcare coverage: the percentage of women who had three or more antenatal care visits in Bihar, for example, is an abysmally low 17 per cent compared with more than 90 per cent in the more highly developed states Kerala, Goa, and Tamil Nadu.

The direct causes of neonatal deaths include prematurity, low birth weight, neonatal infections, birth asphyxia, and birth trauma; the direct causes of maternal deaths include postpartum haemorrhage, anaemia, obstructed labour, hypertensive disorders, postpartum sepsis, and unsafe abortions (Government of India Planning Commission, 2003). There are, however, several underlying factors that contribute

to neonatal and maternal mortality, including limited access to safe abortion services, a lack of skilled birth attendants, low antenatal or postnatal care coverage, inadequate referrals, compromised access to services for those without transport, and low availability of client-centred, high-quality services.

Effective maternal health services are still not within reach of the majority of the Indian population. In 2007, it was reported that while more than 75 per cent of women who had a live birth in the preceding five years (2000–05) reported receiving antenatal care, the quality of that care was far from satisfactory (IIPS and Macro International, 2007). Few of these women received a complete package of antenatal care services: most of these women started antenatal care only after their first trimester and only about half reported an adequate number of antenatal check-ups. Moreover, only a little over a third (36 per cent) reported receiving information about possible complications during pregnancy (IIPS and Macro International, 2007).

The Indian government has been taking steps to improve maternal and newborn health. Through its National Rural Health Mission (NRHM), the government reaches out to pregnant women in underserved areas in an attempt to ensure that they receive three essential antenatal check-ups and are made aware of the importance of a hospital or health centre delivery. In an attempt to improve newborn health, the government took steps such as launching an immunization project, operationalizing newborn care facilities in districts identified as weak, promoting a policy of breastfeeding exclusively to the age of 6 months, developing the role of community-based midwives (known as *dai*), and implementing *dai* training to provide key messages for newborn health in 166 districts (WHO, 2005). Non-governmental organizations (NGOs) have been supplementing these governmental efforts, either taking the initiative or following the government's lead in their attempts to improve maternal and newborn health.

This chapter analyses the efforts of, and the outcomes emanating from, an initiative on maternal and newborn health (MNH) undertaken by Swaasthya, an Indian NGO, in the urban slum areas of Malegaon, a small city in Maharashtra, one of the western states of India. Swaasthya set up and implemented its MNH initiative in collaboration with the Programme for Appropriate Technology in Health (PATH), its lead partner for Malegaon, under Sure Start, an initiative intended to catalyse sustainable improvements in maternal and newborn health.

Swaasthya was supported by the Bill and Melinda Gates Foundation, and implemented by PATH in selected districts within Uttar Pradesh and urban sites within Maharashtra.

## Background

*Swaasthya* Swaasthya is an India-based NGO focusing on health matters. It undertakes intervention research to develop innovative and evidence-based community programmes that are replicable, as well as sustainable. Since its inception, Swaasthya has been implementing health programmes in the slums of Delhi.

Swaasthya follows an enabling and empowering process wherein the community is provided with new knowledge and is supported in taking well-informed decisions. The planning model adopted is bottom-up rather than top-down – that is, Swaasthya engages with the community across all stages of programme development and implementation, so that communities own the problem as well as its solution.

With regards to its MNH initiative, the organization worked in Malegaon, an urban poor slum area with high numbers of maternal and neonatal mortality cases. The organization took several innovative measures in the area, including empowering the people to participate in a community-based accountability mechanism to ensure a better quality of health care. The Swaasthya programme also focuses on how governments can successfully collaborate with national and international organizations to improve maternal and newborn health.

*Vulnerable populations* The problems relating to maternal and newborn health are more acute for hard-to-reach communities, such as urban slums, in which the majority of the people are poor and vulnerable, as well as among religious minorities. Slums in India, as elsewhere, are usually inhabited by the very poor or socially disadvantaged (Sud, 2007). Urban poverty is characterized by food insecurity, extremely poor living conditions, and a lack of job security; thus the urban poor are vulnerable in multiple ways. Their dependence on the informal sector makes their income highly insecure. Events such as serious illness typically lead to financial shock for the household. The environmental conditions in which they live, and the lack of access to water, sanitation, and safe drinking water, increase their physical vulnerability (World Bank Human Development Unit, South Asia Region, 2004).

Health conditions among the urban poor are similar to, or worse than, those of the rural population and far worse than urban averages. Often, the aggregate data for urban populations mask the realities of the urban poor. For instance, the rural average for mortality rates among the under-5s is 103.7 per 1,000, compared to the urban average of 63.1, but averages among the urban *poor* are 101.3 – that is, almost as high as the rural averages. Likewise, the infant mortality rates (IMRs) for rural, urban, and the urban poor are 73.3, 47, and 66 per 1,000, respectively.

Similar patterns are seen with regard to access to health services. Home deliveries comprise 68.9 per cent of the total in rural populations, as opposed to 30.6 per cent in urban populations and 54.1 per cent among the urban poor. Complete immunization by the age of 23 months in urban populations is 57.6 per cent, as compared to 38.6 per cent for rural populations and 42.9 per cent among the urban poor. The patterns hold for health behaviours as well. For example, figures for the initiation of breastfeeding among the rural population stand at 21.5 per cent compared to 28.9 per cent for the urban population and 17.9 per cent among the urban poor (analysis of NFHS 3 (2005–06): Agarwal, 2007). Also, the primary health infrastructure in urban slums is inadequate, with only one urban family welfare centre or health post per 1,500,000 residents (Srivastav and Agarwal, 2006).

Religious minorities are yet another vulnerable population subgroup. Various studies conducted during the past decade have shown that Muslims have been increasingly socially and economically marginalized. As a result, Muslims are the furthest behind in terms of education and employment. A review of monthly consumption patterns shows that the percentage of Muslims in the bottom 20 per cent is far higher than that of those in the top 20 per cent, in both rural and urban areas (Sachar et al., 2006). The participation of Muslims in regular salaried jobs – especially in the government, or large public and private sector enterprises – is much lower than that of workers from other socio-religious communities. Instead, Muslims have higher than average reliance on self-employment, home-based work, and are concentrated in self-employed manufacturing and trade activities. Given the informal nature of their work participation, they tend to be more vulnerable than other workers (Sachar et al., 2006).

A large number of Indian Muslims inhabit slums and thus are likely to have extremely poor health outcomes (Huda, 2007). In such

populations, the different sets of vulnerability factors combine not only to produce poor health indices, but also to bar the success of routine large-scale health programmes. Interventions are required at the local level, developed and implemented with community participation: 'Local populations have a genuine role in crafting and improving health care provision in their neighbourhoods and these programmes have a far greater chance of success' (Urban Health Resource Centre, 2007: ix). In order to address the health concerns of vulnerable populations effectively, health programmes have to adopt a rights-based approach: 'Transparent partnerships with standard protocols, based on the rights and entitlements of all citizens would prove very effective in improving health of the urban poor' (Urban Health Resource Centre, 2007: ix). The focus then has to be on capacity building within the community, so that the community itself can demand accountability from service providers and negotiate for better services: 'Improving efficiency of the system through decentralization and convergence between different departments, NGOs and ULBs [urban local bodies], is yet another critical strategy for improving health of urban poor' (Urban Health Resource Centre, 2007: ix).

*Malegaon* The city of Malegaon is often called the 'city of slums'. Forty per cent of the Malegaon population live in slums and almost all slum residents are Muslim. The Muslim community in Malegaon historically grew from waves of migration, particularly from northern India. Famine in 1862 forced Muslim weavers in the Varanasi area to move to Malegaon, as did the political upheavals in Hyderabad in the late 1940s and 1950s. Communal riots, especially from the 1960s onwards, have undoubtedly contributed to swelling numbers of Muslim migrants to Malegaon (Philipose, 2006).

The slums of Malegaon are lacking in basic amenities such as drinking water and toilet facilities. It is not surprising then that Malegaon has poor health indicators such as a high population density, a high birth rate, a high death rate, and high maternal mortality rates.

Women in this community remain particularly vulnerable to poor health outcomes as a result of factors such as low literacy levels, a lack of decision-making power, their young age at marriage, high fertility rates, and the overall low priority accorded within the family to their health. These sociocultural factors combine with limited access to health care to result in high maternal and infant mortality.

## Situational analysis of Malegaon

To assess the basis for setting up a collaborative MNH initiative in the most vulnerable slums of Malegaon, Swaasthya carried out a community-based situation review and analysis, aiming to understand the knowledge levels and practices in the community and among the care providers with regard to maternal and newborn health. It was a way of gauging needs, defining key issues, and identifying assets within the defined community. A defined set of MNH issues was explored to expose prevailing practices and influential factors. For this purpose, the study used focus group discussions and in-depth interviews with community members and healthcare providers as its techniques.

*Key findings*

- *Socio-economic status (SES)* People in Malegaon live in abject poverty, with an average monthly income of INR1,200–1,500 per month, to support an average family size of between ten and twelve members.
- *Health infrastructure and services* Malegaon has a total of three referral hospitals and nine urban health posts, run by the Malegaon Municipal Corporation (MMC). Each urban health post has a staff strength of one medical officer, four auxiliary nurse midwives, one public health nurse, and ten link workers (for community outreach). In addition, there are several charitable hospitals and dispensaries.
- Women from many areas have to travel quite a distance to access facilities. Road access and public (or other) transport is poor in many areas, yet is necessary to reach facilities, especially during deliveries or during the rainy season.
- Community reports frequently cite medicine stocks running out, equipment failures, and a lack of availability of care providers and/or beds.
- It was also said that care providers within the public health service were abusive, with behaviours ranging from taunts and threats, to physical abuse.
- Community members were unaware of their health entitlements and the government's health programmes and policies.
- *Dai* (that is, traditional community-based birth attendants, mostly without any formal training) were perceived as being caring towards women, and also as being able to provide a comprehensive package

of services and care. The community seems to pay no attention to whether or not a *dai* has received any formal training.

- *Antenatal care* Prevalent myths and misconceptions compromise pregnant women's consumption of nutritive foods. For example, it is believed that consumption of hot foods, including fish, eggs, and meat, can also cause bleeding and miscarriage.
- The community seemed to lack a proper understanding about, and therefore did not ensure, rest and a proper diet for pregnant women. Pregnant women did not take iron or folic acid supplements through either their pregnancy or postnatal periods.
- Pregnant women were registered for antenatal care mostly only during the third trimester.
- Only three out of ten women reported going to the hospital during pregnancy.
- *Delivery* Deliveries most commonly took place at home, facilitated by untrained *dai* in unclean settings.
- Women's control over their decisions regarding place of delivery was limited.
- *Postnatal and newborn care* For the first few days, newborns were given a range of foods, including honey, arandi oil, goat's milk, and onion juice.
- Breastfeeding was initiated only by the second or third day of life.
- First milk (that is, colostrum) was discarded.
- Postnatal care was marked by no rest or proper diet for the new mother.

The intervention programme was therefore developed on the basis of these findings. A set of behavioural change communication messages was developed, to be packaged as contextually sensitive and appropriate tools.

### Maternal and newborn health initiative in Malegaon

Swaasthya set up and implemented the MNH initiative in Malegaon in a population base of 50,000 from February 2007 to August 2011. The organization implemented the programme in partnership with the MMC.

The project population was divided into two slum clusters, situated around two different urban health posts within the city. The project population was identified in consultation with MMC officials based

on the inadequate coverage of, and poor health indicators within, the public health service.

The MMC, established in 1998, was a relatively new corporation with inadequate healthcare facilities, as well as an inadequate skill set with which to tackle some of the grave health problems in the city. This led to the need to mobilize the community with regard to maternal and newborn health, as well as the need to develop and build the skills with which to tackle the problems related to service delivery and quality of care at the facility level; it also raised a concern about outreach in one of the most closed and conservative community structures in the state.

The project in this city thus not only aimed to build the capacity of the MMC to improve upon poor maternal and newborn health indicators, but also addressed questions related to outreach.

### Objectives of Swaasthya's MNH initiative in Malegaon

The goal of the MNH initiative was to substantially enhance maternal and newborn health by means of effective community action among urban poor families dwelling in the slums of Malegaon. Its objectives were expressed as follows.

> *Objective 1* To significantly increase individual, household and community action that directly and indirectly improves maternal and newborn health.
>
> *Objective 2* To enhance systems and institutional capabilities for sustained improvement in maternal and newborn care and health status.

Towards these objectives, Swaasthya adapted and replicated the implementation strategies, processes, and tools that had proved successful in its MCH programme in Delhi slums. The integration of such prior experience and learning was ensured at all stages – that is, throughout all of conceptualization, formative research, programme planning, capacity building, implementation, monitoring, and documentation.

### Key elements of the MNH initiative

*Linkages with the MMC* Links with the MMC were developed to emphasize and ensure its commitment to enhancing maternal and

newborn health in Malegaon. Interactions were held with public health service functionaries at different levels at Malegaon and firm commitments were sought. The aim of these links were to:

- try to reduce the number of maternal and newborn deaths in the community;
- enhance understanding about quality-of-care norms among urban health post staff, community members, programme managers, and community-based care providers;
- ensure the quality of the public health services provided by the MMC; and
- ensure the continuity of Swaasthya-led activities beyond the conclusion of the MNH initiative in Malegaon.

*Behaviour change communication (BCC)* Communication strategies aiming to change behaviours were used in different forms and among different sets of beneficiaries. Interpersonal communication – both one-on-one and in small groups – formed the backbone of this component of the programme. These communicators actively engaged in developing and field testing communication tools.

The behavioural change communication component focused on:

- building community awareness of maternal health entitlements, programmes, and policies to increase uptake and demand for quality maternal and newborn public health services; and
- expanding the knowledge base at individual, household, and community levels on maternal and newborn health issues.

A set of clearly articulated key messages was developed on relevant topics such as comprehensive antenatal services, comprehensive antenatal care, the danger signs during pregnancy, preparing for delivery, the danger signs during delivery, the danger signs after delivery, comprehensive postnatal services, comprehensive postnatal care, comprehensive newborn care, and danger signs for the newborn. These key messages were incorporated into interpersonal communication tools that were developed using a participatory approach, thus ensuring that they were contextually appropriate.

The tools were used by trained, community-based, interpersonal communicators during behavioural change communication sessions,

conducted as semi-structured discussions in small groups at the following intervention levels:

- small, unorganized (unstable) groups of women in different streets within the target area, which intervention helped to build community-level awareness of, and support for, maternal and newborn health issues;
- organized (stable) groups comprising pregnant women, lactating women, and key persons in their immediate environments, such as mothers in law, which sessions ensured peer support in addressing some of the sociocultural barriers, facilitated by means of establishing linkages at community level with the local government Integrated Child Development Services (ICDS) programme; and
- home-based sessions offering individual antenatal and postnatal care to women and their family members during home visits, which interventions helped to enhance household-level support.

*Referral services* A system was set up for referring community members to appropriate public health services. The purpose of this component of the programme was to facilitate access to services and thus to convert demand into service seeking. As a part of this referral service, service seekers were provided with information about appropriate service delivery points, along with details such as location, timing, distance, fee structure, and other relevant information relating to the service. In addition, service seekers were also provided with referral tokens, which were subsequently collected from service delivery points to track service utilization.

*Capacity building among government functionaries* Functionaries of the health department as well as the ICDS were included under this component. Swaasthya's approach included a mix of structured training workshops, on-the-job training, and handholding sessions. The training comprised:

- technical modules on maternal and newborn health;
- skills-building modules focusing on interpersonal communication skills, the conducting of behavioural change communication sessions, providing referrals, counselling skills, and supervisory skills; and
- perspective-building modules centred on quality of care.

*Community-based accountability mechanisms regarding quality of care* A mechanism was established under the programme to review the quality of services provided under the public health service. It brought together the service providers (the system itself), service seekers (the community), and facilitators (Swaasthya workers), providing a platform from which the community could raise issues and concerns related to health services, prompting responses from the service providers, and facilitating their seeking of solutions collectively.

Towards setting up of this forum, exercises to build perspectives among care providers on issues of quality of care, gender, clients' rights, and ethical considerations were undertaken. Thereafter, Swaasthya developed a set of client satisfaction norms based on discussions with the community and service providers. These were also displayed at service delivery points, so that community members could refer to them, helping to shape their expectations of the public health service. Subsequently, a mechanism, in the form of exit polls, was set up to monitor the adherence of the public health service to these defined norms, the findings of which were reported through the quality-of-care mechanism.

The quality-of-care meeting continues to observe discussions by all representatives once every three months. The meetings also include a social audit of maternal and newborn deaths, along with feedback from the community about the kind of services being delivered at the urban health posts and the community's satisfaction with these services.

*Community-based network groups* 'Cluster groups' – that is, community-based social mobilization networks comprising community members – were formed to collectively facilitate and support women's access to health care. Leaders of these groups represented the community's interests at the quality-of-care meetings (see above). Cluster groups were formed with a vision of sustaining, convening, and leading quality-of-care discussions beyond the duration of the MNH initiative.

## Results

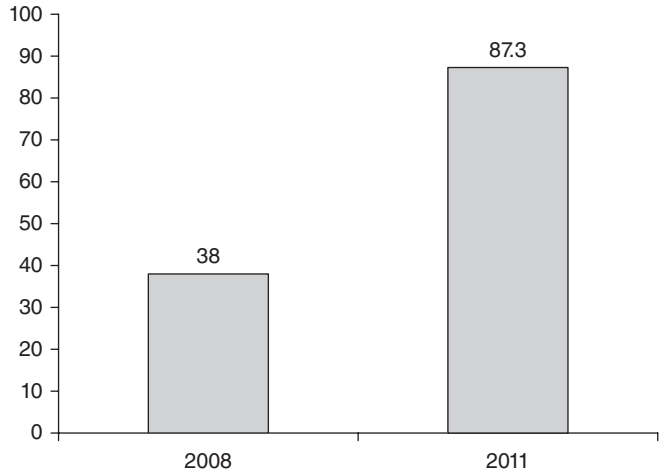
Between February 2007 and August 2011, Swaasthya reached out to 50,000 people across two urban health posts. As a result of strong strategies and their effective implementation, the MNH initiative was able to influence the community positively, to build capacities among members of the public health service, and strengthen the service overall.

The programme changed behaviours and practices at individual, household, and community levels. Members of the implementation team, all of whom were from the community, experienced change in their own attitudes and thus in their practices related to health. There was also a positive effect on the health providers within the public health service.

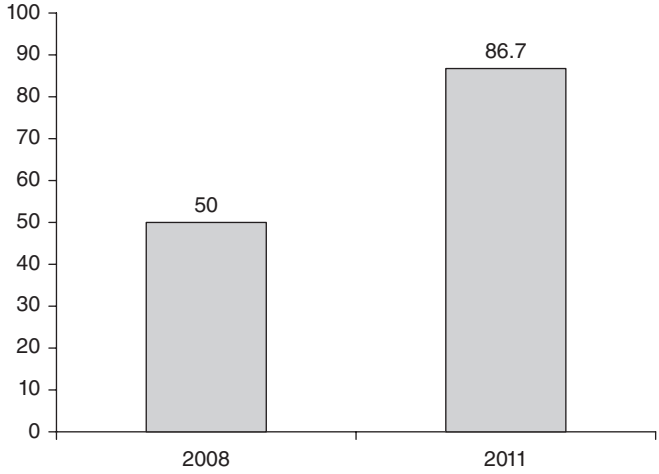
These changes can all be evidenced with quantitative and qualitative data analysis.

*Community effects* We analysed quantitative data to assess the effects of the MNH initiative on practices related to maternal and newborn health. A comparison of yearly averages for a set of four indicators between 2008 and 2011 is presented in Figures 7.1–7.4. There was an increase in the percentage of women registered within the first twelve weeks of pregnancy: from 38 per cent in 2008 to nearly 88 per cent in 2011 (Figure 7.1). Data were not available for 2008 for women reporting for antenatal check-ups, but a more than threefold increase was seen between 2009 and 2011, at 27 per cent and 96 per cent respectively.

There was a significant increase in the number of institutional deliveries as well. The percentage of postnatal women reporting recent



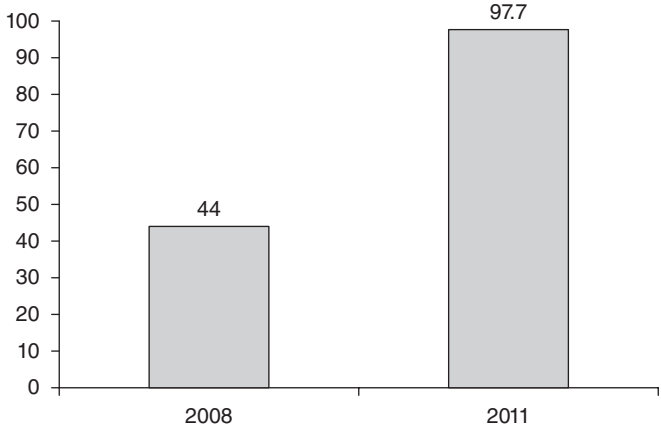

**7.1** Pregnant women registering for antenatal care within first twelve weeks of pregnancy, %



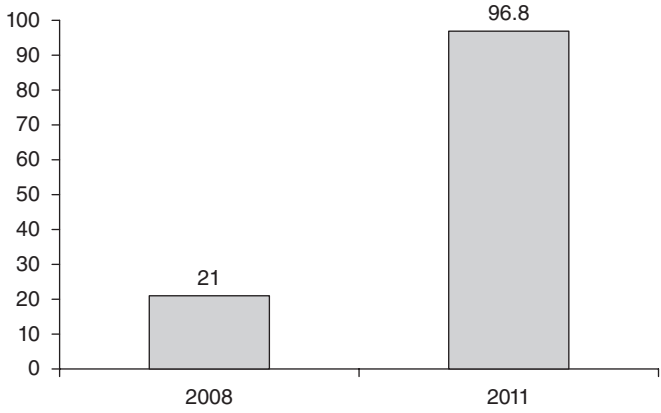

**7.2** Postnatal women reporting recent delivery at an institution, %

delivery at an institution increased from 50 per cent in 2008 to 87 per cent in 2011 (Figure 7.2).

Indicators related to newborn health also showed strong positive trends. The percentage of newborns weighed within 24 hours of birth increased from 44 per cent in 2008 to 98 per cent in 2011 (Figure 7.3).




**7.3** Newborns weighed within 24 hours of birth, %




**7.4** Breastfeeding initiated within one hour of birth, %

Finally, data show that, in 2011, nearly all newborns (97 per cent) were reported to have been breastfed within the first hour of life in contrast to a meagre 21 per cent in 2008 (Figure 7.4).

Qualitative data, in the form of narrations by women from the target community, provide further evidence in support of these changes. The story of 'Shabeena' (name changed) shows the kind of change that community women experienced as a result of the MNH initiative:

> Shabeena, when approached by a field worker during home visits, narrated her past experience. When first contacted, she had a history of 5 earlier pregnancies and deaths of three children. She was ignorant about antenatal care package and also the benefits of institutional delivery.
>
> The field worker gave her the required information on the benefits of the antenatal care package and consequences of home delivery. The mother-in-law and husband were also told about the above information who then agreed for a check-up as well as for institutional delivery. The woman delivered her fourth baby at one of the government hospitals. The baby weighed 3.7 kgs at birth and survived to grow up as a healthy child.
>
> Her previous ignorance had cost her the lives of her three kids who died soon after birth. She mentioned, 'How much I regret not

> going for check-ups and for institutional delivery. But at the same time, I think how could I have done so? I lacked the information and moreover, the constant fear of going against the wishes of my in-laws prevented me from doing so'.

Muslim women residing in the slums of Malegaon do not practise any form of family planning because of religious constraints and therefore have large families. However, even though family planning was not on the agenda for this MNH initiative, Swaasthya introduced a relevant behavioural change communication package in response to requests from women in the community.

There is anecdotal evidence of change in the attitudes and practices of some of the community members towards family planning. 'Fatema' (name changed) is an example of a woman who accessed family planning services despite her Islamic context:

> Fatema, a woman residing in the slum clusters in Malegaon, was keen on using family planning measures in order to have less children. Her husband, however, did not agree to her suggestion, saying they will have the number of kids they are destined to have. She attended the sessions on family planning held under this initiative and through that was informed about various practical measures and resorted to one of those.

Leaders of community-based women's groups also emerged as informal sources of information and support for their neighbours. They now accompany pregnant women to hospitals and give them the required information on antenatal care, such as the need for early registration, and the importance of three antenatal check-ups, of institutional delivery, and of two postnatal care check-ups, and about the care of newborns.

Through this initiative, community members acquired a strong understanding of quality of care, and their right to demand accountability from the public health service for every maternal and/or newborn death. Capacities of community leaders were developed to convene discussion where a social audit of maternal and newborn deaths was conducted in the presence of the public health service representatives.

*Effects on Swaasthya's field workers* A significant change was also seen among the outreach workers employed within this initiative, who were,

as a point of policy, from the community itself. The story of 'Ayesha' provides some insight into the kind of changes that outreach workers experienced:

> Ayesha, a 24 year old woman from Numani Nagar, one of the intervention areas, worked on the initiative as an outreach worker from the start of the project. She shared her experience that reflects how her style of living was changed and how she felt empowered after she joined Swaasthya. In the past, she used to be at home but now she went out for work and she became independent. With this, there had been a marked difference in her behaviour and way of talking. Her knowledge has increased immensely. For example – 'khana khane ke baad chai nahin pite' (one should not have tea soon after a meal). This has also translated into some behaviour change with respect to more nutritious dietary intake and the consumption of milk in the household has gone up. Before she joined Swaasthya during her first pregnancy and delivery, she did not have her check-ups done but during the subsequent one, while she was working with Swaasthya, she got checkups done at Ali Akbar Hospital. She also took IFA [iron and folic acid] tablets and TT [tetanus toxoid] injection. Her delivery took place at the hospital, was a normal delivery and had healthy a newborn. She also availed benefit of JSY [*Janani Suraksha Yojana*, a safe motherhood intervention under the NRHM] (the government scheme) as she had learnt about it and the procedures involved.

*Public health service effects* One of the significant outcomes of this initiative was an enhanced and shared understanding of quality of care among community members and managers and care providers within the public health service. The public health service's commitment to quality of care also increased. A set of quality-of-care norms, developed jointly, were displayed at the various health service delivery units. Furthermore, the public health service's accountability to community members fell into place, and there were efforts by the service to institutionalize its social audits on maternal and newborn death by incorporating these into the agenda for monthly staff meetings.

As a result, there was a change reported in the way in which services were provided at the urban health posts. This was validated by the data

collected through periodic exit polls conducted with clients attending these facilities (Table 7.1).

TABLE 7.1 Results of exit polls conducted in December 2010

| Indicators reported | % |
|---|---|
| Good behaviour by doctors and auxiliary nurse midwives | 84 |
| Administration of complete antenatal care package | 96 |
| Provision of counselling services | 45 |
| Cleanliness within the facility | 100 |
| Observation of right to privacy | 50 |

**Sustainability and replicability**

Even while designing the MNH initiative, Swaasthya envisaged that the sustainability of the interventions and outcomes would be addressed by means of a set of key strategies.

- The organization hired fieldworkers from the community itself, so as to create a resource pool that would remain with the community even beyond the life of the initiative.
- Also towards achieving sustained outcomes, the focus was on strengthening public health services and building capacities among its functionaries.
- Community-based social mobilization networks were set up to ensure, collectively and in a sustained manner, the demand for, and access to, high-quality, client-sensitive health services.
- It was planned that responsibility for the various intervention elements of this initiative would be handed over to one or another of the local stakeholders for sustained implementation beyond the initiative, after building their capacities to do so:
    - the monitoring of public health services for adherence to quality-of-care norms through exit polls was to be handed over to community-based cluster groups,
    - referrals services were to be handed over to community-based cluster groups and community-based functionaries of the ICDS and health department; and
    - the quality-of-care discussion platform was to be handed to leaders of the community-based cluster groups.

The MNH initiative was able to effectively and successfully roll out these sustainability strategies. Moreover, with several achievements to its credit, it influenced several government organizations and NGOs to adapt and replicate, or even scale up, one or more of its components. The local authorities hired many of the community group members whom Swaasthya had trained. The MMC also adopted and took to scale the communication tools developed and used within the MNH initiative.

## Conclusion

In the poverty-stricken slums of Malegaon, Swaasthya's community-based intervention programme enabled communities to:

- acquire an understanding about maternal and newborn health issues, and adopt healthy practices;
- develop perspectives on quality of health care, and define acceptable standards and norms for the public health service's maternal and newborn health services; and
- set up community-based mechanisms to demand accountability from the public health service.

Through these interventions, the marginalized community's access to quality services was enhanced, and the programme was able to achieve a number of positive and desirable outcomes, including:

- an increase in the percentage of newborns breastfed within an hour of birth (from 21 per cent to 94 per cent);
- an increase in the percentage of pregnant women registering for antenatal care within their first twelve weeks of pregnancy (from 38 per cent to 87 per cent); and
- an increase in the percentage of women reporting recent delivery at an institution (from 50 per cent to 87 per cent).

The Malegaon initiative provides precious learning regarding effective healthcare programming for vulnerable, marginalized communities. It demonstrates how the inclusion of otherwise marginalized communities can be ensured. It also provides insights into useful principles that should underpin such initiatives.

To ensure optimal benefits and desirable outcomes from health services, programmes need to be designed, planned, and implemented

using a bottom-up, participatory approach whereby communities are seen not as passive recipients of services, but as actively engaged partners, with rights.

Intervention programmes or health services that rely on *either* service delivery *or* health education, each to the exclusion of the other, are not effective. For optimal results, service delivery and demand-generation activities need to be implemented in tandem.

Demand-generation interventions must also address gaps in information about the health service itself, so as to enhance access and thus convert 'demand' – that is, the felt need for services – into actual service-seeking behaviours.

To ensure the delivery of high-quality services and high levels of client satisfaction, a multipronged approach is required, as follows.

- Community-specific desirable key attributes of a high-quality health service need to be understood, defined, and adhered.
- Training programmes for care providers should not only include technical issues, but also provide orientation on quality-of-care concepts and parameters, as well as build communication skills.
- Community members also need to be oriented on quality-of-care concepts, parameters, and attributes, so that they can pressure managers and care providers to provide high-quality services.
- Community-based mechanisms need to be set up whereby clients' voices and stories of discontent with services can be heard and resolved jointly by managers, care providers, and community representatives.

The Malegaon experience is, in essence, a reiteration of the rights-based approach that places the right to health of communities and 'all people' at the centre when designing, planning, and implementing healthcare programmes. It is therefore particularly relevant in the context of protecting the health of the poor.

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PART FOUR

# MULTIFACETED MOVEMENTS

# 8 | INTERNATIONAL POVERTY LAW AND HUMAN RIGHTS FROM BELOW: LATIN AMERICAN AFFIRMATION OF THE RIGHT TO HEALTH OF INDIGENOUS PEOPLES, MIGRANTS, AND THE DISPLACED

*Camilo Pérez-Bustillo*

*Dedicated to the memory of Doña Ernestina Ascensión Rosario (1934–2007)*

## Introduction

In the notorious Dred Scott case of 1857, the US Supreme Court held that black people in the United States, whether free or slave, had 'had no rights which the white man was bound to respect', except '[rights] such as those who held power and the government might choose to grant' (*Dred Scott v. Sandford*, 60 US (19 How) 393, 407, 405 (1857)). The legal status of African American slaves in the United States of the 1850s is broadly analogous to that of the global poor within the framework of today's 'world system'. In the era of neoliberal capitalist globalization, do the poor and powerless have any rights that the rich and powerful are 'bound to respect'?

The right to health is an essential component of the internationally recognized economic, social, and cultural rights that shape the relationship between human rights norms and issues of poverty and inequality. These provisions must be understood as part of an overall shift in emphasis in United Nations' policy towards the characterization of state policies that produce and reproduce extreme poverty as the causes of serious human rights violations, within the framework of what I have referred to elsewhere as 'international poverty law' (Pérez-Bustillo, 2003, 2014). This shift is reflected in the May 2001 Statement on Poverty of the UN Committee on Economic, Social and Cultural Rights, and in the UN Guiding Principles on Extreme Poverty and Human Rights, which were approved by the General Assembly in December 2012 (United Nations, 2012).

In Latin America, entire sectors of society are systematically denied the right to health. Capitalist and liberal hegemonic notions of rights assume them to be necessarily embedded in exploitative and ecocidal market economies. But for the last twenty years they have been challenged 'from below' by the emergence of counter-hegemonic paradigms of human rights and alternative governance, including indigenous experiences of community-based autonomy. These reimagined notions of rights have arisen from popular social movements rooted in the poorest and most excluded sectors of the region, for example indigenous peoples and 'peoples in movement', such as migrants, refugees, and the displaced. They tend to be characterized by an insistence upon the equality and interdependence of all rights (civil, political, economic, social, environmental, etc.). By prioritizing the recognition of the rights of 'peoples' (communities), 'persons' (without borders, as opposed to 'nation states'), and social interests that transcend private property and the market, these alternative visions seek to undermine these systems' universalist, globalizing pretensions regarding their theoretical promises of freedom and democracy.

In this chapter, I explore the historical origins of contemporary notions of human rights, and what these reveal about where we are in the struggle for the globalization of human rights and for the construction of alternative, counter-hegemonic (or anti-systemic) paradigms of global justice and human rights. Starting with the rape and murder of the 73-year-old indigenous woman Doña Ernestina Ascensión Rosario in Mexico in 2007, I present a number of case studies from across Latin America to demonstrate that the contributions of Latin American experiences are central both to 'making' this history and to 'remaking' it, or shaping the alternatives that may determine its liberatory potential. I suggest the outlines of a re-reading of the history of human rights and of potential new directions from a Latin American perspective, drawing on the contributions of the struggle for African American rights. In doing so, I explore initial theoretical aspects of the evolving relationship between contemporary grass-roots social movements in Latin America, and the emergence of alternative, counter-hegemonic paradigms of global justice and human rights throughout the world (Santos and Rodríguez Garavito, 2005; Dussel, 2012; Rajagopal, 2003; Zibechi, 2008). In sum, my argument here is that Latin American social movements of this kind have contributed to rethinking and reshaping key aspects of hegemonic paradigms

of human rights, which are characterized by largely unexamined assumptions as to the supposedly uniquely Western, and specifically European, character and origins of contemporary human rights and international law.

My approach, which makes use of a number of theoretical frameworks, assumes that contemporary human rights norms – and their conceptual and structural characteristics and limitations – are the historical product of the struggles of social movements and their impact on evolving patterns of reflection, discourse, and practice. This includes examples such as struggles against feudalism, colonialism, imperialism, slavery, racism, and national oppression, the exploitation of workers, and the domination of women. The largely unwritten history of the 'making' (Thompson, 1963) of international human rights is the history of the ebbs and flows in a non-linear trajectory regarding the extent of recognition of the rights of those most marginalized and excluded in each historical period. Such an approach also involves a distinct rupture with epistemological assumptions of a positivist, functionalist, and determinist character that are still prevalent in many circles. It includes an insistence upon a critical understanding of legal definitions of rights in any specific historical period as minimums rather than maximums ('floors', not 'ceilings'), and thus as points of departure instead of destinations in themselves.

## Right to health in the context of hegemonic and counter-hegemonic human rights notions and practices

The theoretical implications of contemporary efforts to secure a meaningful right to health for indigenous peoples, migrants, and the displaced in Latin America and among Latino communities in the United States, and the relationship of those efforts with broader processes seeking to develop alternative paradigms and strategies of human rights advocacy and activism 'from below', must be addressed. My point of departure for these reflections is the now-lifeless broken body, but indomitable spirit, of Doña Ernestina Ascensión Rosario, a 73-year-old indigenous woman of Nahua ethnicity (a speaker of *Nahuátl*, the language of the powerful Mexica, or 'Aztec', civilization devastated by the Spanish invasion, conquest, and colonization that began in 1521), who, according to the most reliable available accounts (including her own deathbed declarations), was beaten, raped, and killed by Mexican military personnel in the Zongolica region of

Veracruz in February 2007 (Moncada Cota, 2007a, 2007b; Sieder and Sierra, 2010).

Zongolica is one of the poorest, most marginalized regions in Mexico, where – as in others such as Chiapas, Guerrero, and Oaxaca, and in fact throughout the country, as throughout Latin America – to be indigenous is, by definition, to be poor and hungry, and to live in ill health. The impoverishment of the country's indigenous peoples leads directly to their dispossession and forced migration, which is further exacerbated by the militarization of their communities by the Mexican government. This has intensified throughout the last four years in the name of the so-called wars against terrorism and against drugs, resulting in more than 100,000 civilian deaths and thousands of forced disappearances. Doña Ernestina's case highlights the complex issues regarding the right to health in the Mexican context and that of Latin America's indigenous peoples, since it arises in a region in which the stereotypical explanation for such a death would reflect the overall violations of this right that are characteristic of such communities.

These characteristics are what might lend passing plausibility to Mexican President Felipe Calderón's otherwise ill-founded assertion that Doña Ernestina's death was the result of 'neglected chronic gastritis' (Sieder and Sierra, 2010: 14)[1] and most assuredly not attributable to the troops whom she died claiming had 'forced themselves upon' her. Similarly, when the state Attorney General's office closed the case in May 2007, it concluded that the cause of death was 'parasitosis' – yet four out of the five medical opinions, examinations, exhumations, and autopsies available concur that the death was related to vaginal and anal lacerations, and cranial and other contusions resulting from a severe beating, and confirm the presence of 'abundant' seminal fluids, all of which clearly tends to substantiate Doña Ernestina's own allegations.

Eight years later (at time of writing), no one has been prosecuted for Doña Ernestina's death. Instead, two of the officials in the state medical examiner's office and at the hospital in which she was treated have been removed from their positions in apparent reprisal for their insistence on the non-official version of her murder, and the case is pending before the Inter-American Human Rights Commission, with the support of organizations such as Amnesty International. What does the 'right to health' (or to life, for that matter) mean in a context that is so thoroughly marked by issues of gender, racism, poverty, and inequality? My hypothesis, based on Doña Ernestina's case and others

of a more collective character that will follow, is that there can be no meaningful discussion of the right to health and its implications unless such vectors of dispossession and disempowerment are situated as the point of departure.

*Relevant theoretical frameworks* Theoretical frameworks developed by scholars such as Balakrishnan Rajagopal, Upendra Baxi, Boaventura de Sousa Santos, and Enrique Dussel, among others, are crucial for understanding the importance of differentiating between hegemonic and counter-hegemonic, non-Eurocentric approaches to globalization and human rights. Such approaches also lay the basis for an emphasis on the development of alternative perspectives grounded in the Global South, as part of broader efforts seeking 'global justice'. Santos and Rodríguez Garavito (2005), for example, identify struggles for global justice with the same impulses that have given rise to the emergence of what they define as 'subaltern legal cosmopolitanism' – that is, a new form of globalized, authentically universalist 'common sense', which, for Rajagopal (2003), takes the form of a reconceptualization of the history and implications of 'international law from below'. Rajagopal draws here on Baxi's (1985, 1986) long-standing emphasis on refashioning human rights from a perspective centred on the alleviation of 'human suffering' and '*rightlessness*', grounded in turn in his recognition that discourses about rights are 'always and everywhere' ultimately discourses on the state, and on the mitigation and transformation of its diverse forms of 'justified violence', which annul what he, together with Norwegian theologian Hans Egil Offerdal (2003), describes as the 'right to be human' and/or to a 'dignified life'. Dussel (2008), meanwhile, weaves together strands derived from the philosophy, theology, ethics, and politics of 'liberation', as he defines it, in the context of the age of 'globalization and exclusion' (with globalization itself understood as a form of exclusion on a global scale), the point of departure of which is Doña Ernestina's suffering 'from the perspective of the victims'. Baxi similarly emphasizes how the hegemonic, occidentalist, and Eurocentric version of the history of human rights itself reflects and reproduces the 'logic of exclusion and inclusion', which he identifies at the core of dominant discourses and practices (Rajagopal, 2003).

Indigenous peoples and 'peoples in movement' (migrants, refugees, and the displaced) represent key case studies of global exclusion. The essence of my argument here is that indigenous peoples, on the one

hand, and migrants, refugees, and the displaced (reframed here from the perspective of their integrality as 'peoples in movement'), on the other, share key characteristics as groups conceptually and structurally excluded from the contemporary global system – groups who have had their rights to dignity and equality systematically violated. My focus will be on examples drawn from the experiences of indigenous peoples in the context of Latin America and of Latino immigrant communities in the United States, where an increasing number of those forced to migrate from Latin America and those who are forcibly displaced are of indigenous origin, in settings such as Alabama, where the second largest sector of Latino immigrants is of Guatemalan indigenous Mayan origin, and where state anti-immigrant legislation was adopted in 2011 severely restricting or eliminating the access of undocumented immigrants to publicly funded education and healthcare services. Similar legislation has been adopted in states ranging from California in 1994 to Arizona, Georgia, South Carolina, Indiana, and Utah within the last few years, and reflects equivalent trends in US national policy that have been replicated in the European Union and Australia as part of the imposition of a new global paradigm following the events of 11 September 2001 ('9/11') – a paradigm that subordinates migration policy to the supposed imperatives of 'national security' and 'anti-terrorism'.

My approach here reflects Santos and Rodríguez Garavito's (2005) epistemological redefinition of the 'Global South', beyond its geographical referent, to include all forms of exploitation and suffering induced by global capitalism. Their framing of this approach has its roots in key categories of dependency and 'world systems' theory, and includes an attention that I embrace here to the nuances of 'North–South' analysis. These include the extent to which the experiences of indigenous peoples and migrants highlights the presence of a deeper 'south' located *within* semi-peripheral settings such as Mexico, which itself constitutes a 'southern' domain in the face of the hegemonic North embodied by the United States in the form of structures and processes such as the North American Free Trade Agreement (NAFTA). This also includes counter-intuitive cases in Latin America such as Costa Rica and Argentina, which, although located geographically to the south, are more prosperous in relative terms and thus have become key destinations for those migrating from poorer countries to the north (Nicaragua, Bolivia, and Paraguay).

Similar echoes of complexity are present in the insistence of the UN Development Programme (UNDP) on disaggregating Human Development Index (HDI) indicators into specific sectors (women, indigenous peoples, children, etc.) and regions. This laid the basis for comparing trends across regions, and, in cases such as Mexico (classified overall as a country of medium wealth with a medium HDI value), for detecting correlations and convergences between markedly lower HDI values in regions in which indigenous peoples are concentrated, such as Chiapas, Oaxaca, and Guerrero. Equivalent patterns can also be seen in cases such as Peru, Ecuador, and Colombia, in which racism and ethnic/cultural discrimination emerge as key causal factors that reflect the genocidal implications of convergent modes of state and market violence.

*Guerrero's Montaña region: A case study* Indicators of this kind also make it possible to discern implicit correlations at deeper levels of analysis, reflected, for example, in the fact that those municipalities with the lowest HDI values in the Mexican state of Guerrero (in which long-standing tourist destination Acapulco is situated) – which also have the highest rates of infant and maternal mortality, lowest birth weights, most stunted growth, most hunger, and highest rates of preventable childhood mortality from disease – happen too to have populations overwhelmingly (80 or 90 per cent) of indigenous origin (SIPAZ, 2012). These populations are primarily located in the region known as *La Montaña* ('The Highlands'), which includes eight of the fifty municipalities in the country with the lowest HDI values – values that are roughly equivalent to those of Gambia or Rwanda, which are among the lowest ranking in the world: 154th and 155th out of the 172 countries included in the HDI rankings, respectively (UNDP, 2011). The Highlands are also the communities of origin that expel the largest numbers and proportions of their residents into increasingly intertwined circuits of internal and external (international) migration, overwhelmingly to the northern, more prosperous regions of Mexico itself and to the United States. A leading human rights non-governmental organization (NGO) operating in the region, the Tlachinollan Human Rights Center, has described the desperate, survival-driven character of these engrained, recurrent migration patterns with a phrase that encapsulates the underlying dilemmas: *Migrar o morir* ('Migration or death') (Centro de Derechos Humanos de la Montaña, 2005).

As Kerry Kennedy (2011), head of the RFK Center for Justice and Human Rights, wrote in an open letter to her daughters published upon her return from a site visit to Guerrero ('the poorest area in the poorest state in the country'):

> To be indigenous in Guerrero is like being African-American in Mississippi 50 years ago. People barely subsist in abject poverty, and starvation is rampant. Racism has a long, wicked history and a stronghold on the present. Those who dare speak truth to power are threatened, imprisoned, tortured, disappeared, raped, and murdered with absolute impunity.
>
> Abel and his team from Tlachinollan are the civil rights leaders of our times. They arm communities with the tools of activism, track abuses, confront perpetrators, and forge ahead under constant threat of death. They are legal aid attorneys, defense bar, community organizers, environmental activists. Tlachinollan staff engages both indigenous and peasant grassroots groups, and advocates to improve access to legal representation, healthcare, housing, education, plumbing, electricity and more. Rising violence related to the Mexican government's recent efforts to combat narco-trafficking led Abel to condemn excessive militarization and denounce abuses. In turn, he and his team have endured increasing threats and violence …
>
> All of this violence, the duplicity, and the impunity take place in the context of the horrific poverty and marginalization of the indigenous people in rural Mexico. In much of the Montaña region, as in so many indigenous communities across Guerrero, access to basic services is nearly non-existent.
>
> One man I met left his home at 1 AM to walk down the mountain with his wife and two-year-old, in order to reach the closest pharmacy for dysentery medicine at 8 AM. The pharmacy was closed.
>
> One community was told the students would need to bring their own chairs and desks to school, buy a desk for the teacher, and pay the teacher's salary, even though all of this is supposed to be provided by the government. When the community managed to jump through all these hoops, instead of sending an educator, the government sent a part-time student who was also in charge of grounds-keeping.

> For these indigenous children, there are no books at all which teach the native languages, traditions, and stories, or hold up a single indigenous person as a role model. Classes are taught in Spanish, and students are often made to feel ashamed of their indigenous neighborhoods, language, and community roots. In the midst of widespread poverty, as Abel says, this treatment amounts to 'cultural genocide' …
>
> Many others talked about the federal government's granting of mining concessions on native lands that are considered sacred. These grants are given without consultation with, permission from, or plans for revenue sharing with the indigenous communities. Environmental desecration is a major concern.
>
> Still others talked about losing whole neighborhoods to migration, both within Mexico to northern agricultural fields, and to 'Tlapa York', otherwise known as Manhattan and Queens, where so many indigenous families from Guerrero have been forced to seek work. Migration widows are abandoned to fend for themselves and their children. Communities are torn asunder. In the fields, conditions are even more horrendous than in the villages left behind, as indigenous men and women become indentured servants to their employers, and families confront wage theft, child labor, and sexual assault.

The intertwined causes (and/or effects) of such migration and displacement include structural conditions of poverty, inequality, and discrimination, and preventable illnesses. Inequality and discrimination can be characterized by systematic violations of the right to a 'dignified life', which is typically framed in terms of the evolving categories of economic, social, and cultural rights. These include the right to health, which is clearly violated in contexts characterized by high rates of hunger, and maternal and child mortality. Such conditions are, in turn, often induced and/or exacerbated by neoliberal economic and free trade policies such as those promoted by every Mexican government since 1982, and by environmental devastation and the dispossession of land and resources, militarization, paramilitarism, and other forms of state terror (reflected, for example, in the so-called wars against terror and drugs), which tend to be intertwined with the multiple forms of systemic violence inherent in the capitalist mode of production. All of this together poses virtually insurmountable obstacles to compliance

with Article 28 of the Universal Declaration of Human Rights, one of its most sweeping provisions, which demands the construction of a 'social and international order in which the rights and freedoms set forth in the Declaration *can be realized*' (emphasis added).

Under such adverse conditions, the free exercise of the rights 'to migrate', '*not* to migrate', and 'not to be arbitrarily or forcibly displaced', which together lay the basis for the universal right to free human mobility derived from Articles 13 and 14 of the Universal Declaration of Human Rights, is impossible, in a manner analogous to Amartya Sen's (1998) insistence that poverty itself is fundamentally a lack of control over one's own circumstances, and thus ultimately a violation of an individual and collective right to self-determination. My approach to the 'right to health' in this chapter is, in large part, centred on the genocidal implications precipitated by its violations in the context of indigenous peoples, as highlighted by Abel Barrera's statement in the extract above.

*Indigenous peoples in Guatemala* The same kinds of recurrent patterns as relate to infant and maternal mortality, hunger, etc. that are evident in the Highlands of Guerrero are present in HDI data for Guatemala's primarily Mayan indigenous majority, with equivalent correlations between indigenous status, poverty, and ill health manufactured by deprivation (Escobar, 2009–10). Given the prevailing levels of impoverishment among Guatemala's indigenous majority (in comparison with Mexico, where indigenous peoples constitute a minority in the country as a whole, despite being a majority in the poorest regions, such as Chiapas, Guerrero, and Oaxaca), 49 per cent of the country's population is malnourished, according to data made available in 2007 by the Guatemalan government (which is prone, of course, to underreporting), while the malnutrition rate among the country's indigenous majority is a staggering 69 per cent – the highest in Latin America and the sixth highest in the world (higher, as of that date, than the prevailing continental rates in Africa and Asia). Similar rates prevail for incidences of rickets.

The foreseeable results of this routinized holocaust include data indicating that 53 per cent of the deaths of children aged under 5 are attributable to causes related to malnutrition (Pérez-Bustillo, 2007). All of this has led to intermittent 'waves' of infant deaths in recent years resulting from acute malnutrition in regions of Guatemala such

as Chiquimula, mostly inhabited by the Ch'orti indigenous people (whose HDI value, at 0.367, is very close to that of the poorest communities in the Highlands of Guerrero, and falls between those of Sudan and Afghanistan), and Alta Verapaz, in the community of San Juan Chamelco, as well as others elsewhere, such as Camotàn and Jocotàn.

*Indigenous communities in Northern Mexico (Tarahumara moutains, Chihuahua)* As of January 2012, a similar wave of deaths and hospitalizations resulting from hunger was raging in the long-marginalized Rarámuri indigenous communities located high in the Tarahumara mountains of the northern state of Chihuahua in Mexico. In one community alone (the municipality of Creel), thirty children under the age of 5 had been hospitalized for malnutrition compared to four a year previously, while at the same time over 50 per cent of Chihuahua's territory in those regions most afflicted by hunger has been ceded to mining operations exploited by transnationals such as Canada's Blackfire Exploration Ltd, which devastate the local ecology and do not return any discernible benefits to the communities affected.

The theoretical approaches highlighted in this chapter (that is, those of Rajaghopal, Baxi, Santos, and Dussel) include attention to the impact of recognizing substantive human rights claims within constitutional frameworks (as in South Africa, India, Venezuela, Bolivia, Ecuador, Colombia, Brazil, and Mexico, to varying degrees), as well as to the central contributions of counter-hegemonic social movements to more radical processes emphasizing the reconceptualization and redefinition of traditional notions of sovereignty, and those relating to hegemonic configurations of the nation state and state power, citizenship, identity, territory, democracy, and participation. The latter include efforts to redress health-related rights in the context of the Permanent People's Tribunal and other tribunals of conscience, emerging models of alternative health provided through autonomous structures in indigenous communities that reject funding and interference from the national government, such as those of the Zapatistas in Mexico and their equivalents in contemporary Bolivia and Ecuador, and community-based efforts to resist denials of such rights promoted by anti-immigrant laws such as those of Arizona and Alabama in the United States.

*Origins and prospects* The overall trend towards increasing inequities on a global scale – which has led Dussel (2008) to characterize this historical period as the age of 'globalization and exclusion', and others, such as Luigi Ferrajoli (2004), to define it as that of 'global social apartheid' – and its implications can best be grasped 'from the perspective of its victims' (Dussel, 2008). More specifically, it is imperative to ground our critique as to the origins and possible trajectory of the global system within those groups most affected by its polarities. This insistence on approaching issues of human rights 'from below' is closely related to that suggested by Rajagopal (2003) in relation to international law, and by Santos and Rodríguez Garavito (2005) in relation to the overall relationship between law and processes of globalization. This perspective is rooted in the critical insight suggested by thinkers such as Amartya Sen, Thomas Pogge, and Pierre Sané, and by social movements such as Mexico's Zapatistas, that the essence of poverty is in fact the absence of meaningful human rights. (The Zapatistas similarly suggested, for example, that it is Mexico's widespread poverty and inequality that makes its democracy dysfunctional.)

This also necessarily implies that poverty can be effectively addressed and overcome only if it is approached from a perspective that understands it to be a violation of such rights. There is an increasingly significant trend in recent jurisprudence from the Inter-American and European human rights systems, and from constitutional courts in South Africa and India, among others, which seeks to ground human rights claims closely connected to conditions of poverty, such as those regarding economic, social, and cultural rights, in an underlying right to a dignified life (as is already suggested in Article 23 of the Universal Declaration of Human Rights).

Willem van Genugten and I have suggested elsewhere that the systematic denial of justiciable and enforceable rights to the poor (for example in terms of the economic, social, and cultural rights that shape their conditions of life in relation to education, work, health, housing, land, participation, discrimination, etc.) should be understood as a 'poverty of rights' (Pérez-Bustillo and van Genugten, 2001) and 'inequality of rights' (Pérez-Bustillo, 2007) that is characteristic of excluded and marginalized sectors throughout the world, and which, according to Upendra Baxi (1986) and Hans Egil Offerdal (2003), results in the denial of their 'right to be human' as such. This approach builds on Hannah Arendt's (1951) insistence in her seminal critique

of the limits of the Universal Declaration on Human Rights that the fundamental human right from which all others flow is the 'right to have rights', which Arendt argued is disturbingly absent from the Declaration (and much of the contemporary normative machinery of international law and international human rights) because of its emphasis on the protection of the rights of those with recognized membership of national communities and thus its failure to recognize the rights of the stateless.

All of this includes a recognition of how initially hesitant advances at one moment can be completed at a much higher level of complexity later, as the result of the pressure of vigorous social movements. A key example is the adoption of the Declaration of the Rights of Man and the Citizen in 1789 in the context of the early stages of the French Revolution, which, despite its classical liberal rhetoric of 'liberty, equality, and fraternity', denied all three of these dimensions of human freedom to millions of African slaves within the French colonial empire, to women, and to men who were not property owners. The Declaration's failure to address the issue of slavery was not remedied until the rebellion of slaves in Haiti, led by Toussaint Louverture in 1791, compelled the French National Assembly to finally abolish it in 1794 (Blackburn, 1988; James, 1963). Despite such initial advances in France, and then in the United Kingdom (and only much later in the United States and Brazil), the first enforceable international convention against slavery and the slave trade was not adopted until 1926. Similarly, the Nazi genocide was completely 'legal' during the period in which it was carried out and the first international convention against genocide was not adopted until 1948.

Debates in the international community regarding the rights of indigenous peoples thus highlight the extent to which the world system and hegemonic versions of international law and human rights discourses and practices are characterized by inequalities of rights. This is particularly so given the fact that the history of efforts to secure international recognition of the rights of indigenous peoples is completely intertwined with the origins of international law (and what we have now come to understand as 'human rights'). The recent adoption of the UN Declaration on the subject is, in this sense, simply the latest stage in a continuing and still incomplete process of recognition of such rights, which in fact existed before the so-called international community itself. These efforts began with early scholars

such as Bartolomé de Las Casas, Francisco de Vitoria, Francisco Suárez, and Hugo Grotius in the sixteenth and seventeenth centuries, who laid the foundations of what has come to be known as the 'Salamanca school', which developed the first systematic approach to what we currently define as 'international law' and thereby engendered its most precocious stepchild, 'international human rights' (Dussel, 2008). The still widely unacknowledged origins of these rights lie in Las Casas' arduous efforts to explore, document, and ultimately critique the theological, legal, and ethical bases for the Spanish conquest of the New World (Gutiérrez, 1995).

Las Casas' work drew in large part upon the widespread resistance of indigenous peoples to these processes, and insisted upon the legality and legitimacy of their assertions of self-defence, sovereignty, and armed rebellion (Gutiérrez, 1995). The echoes of their defiance continue to resonate today. The new UN Declaration would not exist if there had not been a notable resurgence in demands for the recognition of the rights of indigenous peoples as a result of widespread controversy regarding the implications of the observance in 1992 of 500 years since the European conquest of the Americas, the awarding of that year's Nobel Peace Prize to Guatemalan human rights activist Rigoberta Menchú, Mexico's Zapatista rebellion in 1994, and analogous movements in countries such as Ecuador and Bolivia (culminating in the election in the latter in 2005 of its first indigenous president, Evo Morales). The significance and limits of the new UN Declaration can be fully understood only in this context.

Contemporary debates in the international community tend to reflect the imperatives of 'state logic' and 'market logic' (Falk, 2000), which continue to be dominant in such contexts. These logics are centred on the defence of the interests of existing nation states as the most privileged subjects of international law, understood as the framework for governing relations among states, as distinct, for example, from an international system structured around the 'rights of peoples' (the 1976 Universal Declaration of the Rights of Peoples or Declaration of Algiers) – also evident in the African Charter on Human and People's Rights, adopted in Banjul in 1981, which is the basis of the African regional human rights system. But, according to Falk (2000), this dominant statist logic is in turn subordinated to the imperatives of transnational capital, as reflected, for example, in the neoliberal economic policies imposed by the International Monetary

Fund (IMF), the World Trade Organization (WTO), the World Bank, and free trade agreements (FTAs).

Indigenous peoples fall somewhere along the edges of the traditional understanding of 'self-determination' in hegemonic versions of international law. The prevailing, somewhat Orwellian, understanding is that all peoples are theoretically equal, but not all have an equal right to self-determination. The new UN Declaration on the Rights of Indigenous Peoples (adopted finally by the UN General Assembly in September 2007) is the latest effort to somehow square this troublesome circle, at least in the context of indigenous and tribal peoples. It specifically recognizes the right of indigenous peoples to self-determination (Article 3), which has already been universally accorded to all 'peoples' by Article 1(2) of the 1945 UN Charter, and Article 1 of each of the 1976 International Covenants on Civil and Political and on Economic, Social, and Cultural Rights. Deep divisions regarding such issues and their implications were reflected in the complex, multilayered process leading up to the approval of the 2007 Declaration, which included thirteen years of deliberation regarding its specific contents and the failure ultimately to adopt it, as had been expected, after its initial approval in an earlier version by the new UN Human Rights Council in 2006.

The amendments that made the Declaration's final approval possible in somewhat diluted form included most notably an insistence, in language added to the initial draft of Article 46(1), on disavowing any exercise of indigenous people's right to self-determination under Article 3 that 'would dismember or impair totally or in part, the territorial integrity or political unity of sovereign and independent states' (an implicit allusion to the implications in the indigenous rights context of cases such as Kosovo, Tibet, and the Basque region). The standard for assessing whether military activities conducted on the lands or territories of indigenous peoples are justified was also diluted from an original requirement that the state at issue demonstrate a '*significant threat to* relevant public interest' by striking the first (italicized) part of the phrase, so that now simply demonstrating a 'relevant public interest' is enough. And yet, because the rest of this Article continues to insist on free agreement or a request by the indigenous peoples involved in such situations, Colombia, a state in which traditional indigenous authorities insist upon the right to bar all armed groups from operating on their territories, felt obliged to abstain in the final vote.

Article 3 of the Declaration on the Rights of Indigenous Peoples specifically contributes a much-needed bridge between civil and political rights, on the one hand, and economic, social, and cultural rights, on the other, by adding that 'by virtue of that right they freely determine their political status and freely pursue their economic, social, and cultural rights'. These words reaffirm in essence that the rights of self-determination held by indigenous peoples have both the civil and political dimensions traditionally associated with this concept and the equally important additional dimensions related to the full and equal enjoyment of economic, social, and cultural rights. This in turn means that violations of the economic, social, and cultural rights of indigenous peoples have both an intrinsic significance in and of themselves, in relation to each other (in terms of rights in specific dimensions such as education, work, health, housing, etc., and their interdependence), and an additional significance because they reflect, and serve as indicators of, the extent to which the underlying right to self-determination is being respected. The Declaration is particularly notable from the perspective of poverty research because more than half of its Articles (that is, Articles 1, 2, 7–8, 10, 17–24, 26–29, 31–32, and 38–44) focus on those economic and social dimensions of indigenous rights that have a direct relationship with issues of poverty.

## Overall landscape

Aspects of these Latin American movements are analogous to Thompson's (1963: 9) approach in his epic history of the English working class, which he summarized as 'a study in an active process, which owes as much to agency as to conditioning', to Du Bois' (1935) classic *Black Reconstruction in America*, and to James' (1963) *Black Jacobins*. Common features on which I seek to draw in this chapter include: Thompson's (1963: 9) insistence on the creativity and resilience of resistance movements characterized by people who 'were told that they had no rights' (in convergence with Baxi's notion of 'rightlessness'), but who insisted 'that they were born free'; Du Bois' revolutionary affirmation of the centrality of African American traditions and values of democratic struggle to US history, civilization, and democracy (Levering Lewis, 1995); and James' (1963) equally momentous recentring of the history of the French Revolution, and of the origins of contemporary notions of human rights, from the

perspective of Haitian resistance and rebellion against slavery and colonialism (Dubois, 2004; Nesbitt, 2008).

These three advocate a reconceptualization centred on the contributions of counter-hegemonic thinkers and activists such as Las Casas, of the indigenous people's resistance movements to which he gave voice in the sixteenth century, of their contemporary successors (for example Mexico's Zapatistas), and of the Haitian Revolution between 1791 and 1804 (as explored in James, 1963). Together, the traditions of critical reflection and struggle founded by Las Casas and by the Haitian Revolution and their contemporary equivalents – from the Zapatistas to Brazil's *Movimento dos Trabalhadores Rurais Sem Terra* (MST), or 'movement of the landless', plus the region's human rights movements for justice and against impunity – provide the basis for articulating and advancing alternative, counter-hegemonic paradigms of rights and governance from below with global implications.

Such movements have also vigorously questioned and sought to undermine the primacy given in this context to nation states as the most privileged subjects of rights, and as themselves 'rights givers' to structures of representative, rather than participatory, democracy and to individual, rather than collective or group, rights of a civil or political character. The tendency from a hegemonic perspective is to prioritize the latter – particularly those associated with interests related to liberty and property within a market framework, rather than those of an economic, social, or cultural character, associated with imperatives of equality. These efforts have included ongoing activism and advocacy regarding such issues at the grass-roots level by means of direct organizing and the construction of alternative spaces of power, and also in many instances by means of influential voices to varying degrees 'inside', or at the gate of, state structures of power and influence, and their equivalents in transnational normative spaces such as the United Nations.

Significant components of the international and regional human rights agendas associated with such visions have been enacted into law and policy in many key states to varying degrees, at least in formalistic terms, with many inconsistencies and gaps in actual implementation throughout the last twenty years. Much of this has been accomplished at least in part through processes of legal and constitutional transformation in the context of 'transitions to democracy' (often including truth commissions and/or trials of key human rights violators)

in the aftermath of US-backed authoritarian regimes (Eckstein and Wickham-Crowley, 2003; Roht-Arriaza, 2005).

Such approaches are also reflected in processes involving the direct incorporation ('constitutionalization') of international human rights standards into constitutional texts on a scale unprecedented elsewhere in the world. This makes it possible to enforce these standards in domestic courts and, where necessary, through recourse to the Inter-American Human Rights Court of the Organization of American States (the judgments of which, by contrast, are not recognized as binding by either the United States or Canada), and in some cases have succeeded in translating such achievements into broader instruments of international law or policy in key normative spaces with significant potential impact beyond their country of origin. A key example is how Mexico's Zapatista rebellion in 1994 became the decisive spark for unprecedented (albeit only partially successful) efforts to reform Mexico's own constitution, federal and state laws, and overall state policy to finally recognize the cultural and linguistic dimensions of the existence and rights of the country's indigenous peoples. Moreover, it also ultimately promoted the adoption of the UN's Declaration on the Rights of Indigenous Peoples by the General Assembly in September 2007 and the intensification of an equivalent process within the Organization of American States.

The critical, highly contradictory, factor in this context was the way in which the Zapatista uprising itself and its implications served to 'name and shame' the Mexican state into becoming the leading rhetorical champion of the Declaration within the United Nations. Most of the heavy lifting in this complex process was ironically undertaken by leading Zapatista advisers from Mexico and indigenous advocates from elsewhere in Latin America. Here, as with the Mexican state's similar rhetorical championing in the United Nations of the rights of migrants and of its version of market-friendly environmentalism as host of the Sixteenth Conference of State Parties (COP) in December 2010, there is a vast, largely unnavigable gulf between its supposedly respectable standing regarding such issues in the 'international community' and its actual policies and practices on a daily basis with respect to its own people – practices that include the systematic violation of the rights of indigenous peoples and migrants, both Mexican and in transit through the country's territory from Central America and elsewhere, as especially notable patterns.

All of this coincides and must be contrasted dramatically, for example, with the Mexican state's continuing militarization of Chiapas and every other region characterized by indigenous unrest. It should also be contrasted with the unleashing of a US-backed counter-insurgency process, which has included reliance upon paramilitary forces responsible for massacres such as that of Acteal in December 1997 (which left forty-five dead, thirty-six of them women and children), reminiscent of similar instances of state savagery in Guatemala, Peru, and Colombia. It was only, relatively speaking, a small step from this precipice to Mexico's current free fall as the latest example of generalized state terror (or 'Colombianization') in the region (in the name of the 'war against drugs'), with the encouragement of persistent mechanisms of US domination, such as the Security and Prosperity Accord of North America (the national security complement to NAFTA), the Mérida Initiative (Mexico's version of Plan Colombia, explicitly modelled after its predecessor), and Mexico's leading role with its Central American neighbours to the south in the Meso-American Project (formerly the Plan Puebla Panamá) (Carlsen, 2007).

Despite such dialectical complexities, it is nonetheless crucial to recognize that the advances in UN recognition of indigenous rights symbolized by the adoption of the 2007 Declaration would not have been achieved without the impetus and leadership provided by the Zapatista rebellion and its effects. This case exemplifies the direct impact that a counter-hegemonic movement can have 'against the grain', from the 'outside' and 'from below' in relation to hegemonic structures and processes from above and the transformation of their normative content. Given the highly contested character of issues regarding indigenous and minority rights to self-determination and autonomy in the contemporary international arena, my argument here is that the Zapatista rebellion's contribution to reshaping the terrain as to such issues is equivalent to that of the Haitian Revolution and its impact, leading to the abolition of slavery in Paris in 1794.

Similarly, Latin American social movements elsewhere, which were indispensable factors in shaping the conditions that made possible a shift away from the most rapacious variants of neoliberal policies in the region (such as indigenous movements in Ecuador and Bolivia, movements of the landless in Brazil, and urban popular movements in Venezuela and Argentina), have also made significant contributions to the 'refoundation' of several of these states through extensive

constitutional reform processes (foreshadowed previously in Colombia in 1991 and Nicaragua in 1987). The two most far-reaching examples are the new constitutions of the 'refounded states' of Bolivia in 2009 and Ecuador in 2008. Both of these include the redefinition and institutional restructuring of their respective states as 'plurinational' and 'pluricultural' in character, which thereby at least rhetorically go beyond the limits of liberal multiculturalism (see Van Cott, 2000; cf. Santos, 2010), which is generally associated with much more limited discursive affirmations of cultural diversity and pluralism (as in Mexico's 1992 and 2001 constitutional reforms, which fell well short of the demands of the Zapatista movement based upon the 1996 San Andrés Accords, a key part of the still-stalled peace process between the Mexican state and the Zapatistas).

Enrique Dussel's (2008) conceptualization of a Latin American 'political spring' stresses the relationship between advances of this kind at the level of state power in terms of electoral victories by centre-left political forces (which he highlights to varying degrees in contexts such as Bolivia, Venezuela, Ecuador, Brazil, Argentina, and Uruguay, between 1998 and 2006, joined later by El Salvador in 2009, offset by notable defeats for such forces in 2006 in Mexico and Peru, and a right-wing military coup in Honduras in 2009) and their origins in counter-hegemonic social movements. Examples of the latter within the same period include those led by indigenous sectors in Bolivia and Ecuador, by urban popular and human rights movements and other allies in the cases of Venezuela and Argentina, and by former left insurgent movements transformed into political parties or into significant sectors of governing centre-left political parties or coalitions in Nicaragua, El Salvador, Uruguay, and Brazil. The specific landscape varies greatly in each case, and is also highly contested in terms of the extent to which this overall trend has actually contributed to the region's ultimate liberation from US domination and that of its domestic allies in each country (Barrett et al., 2008; Stahler-Sholk et al., 2008). The electoral advances cited are also key in terms of providing spaces and opportunities for formal political, constitutional, and legal ruptures with the 'internal colonialism' (Casanova, 2006; Lander, 2006) or racist neocolonialism characteristic of Latin American states post-independence. Peruvian scholar Aníbal Quijano (2000) is particularly persuasive regarding the deeply rooted structural dimensions of the colonialist paradigm in

the region, which he describes in terms of the 'coloniality of power' in Latin American states and societies.

## Conclusions

The alternative approaches and experiences highlighted in this chapter by means of a necessarily limited range of representative examples provide an emerging normative basis for Amartya Sen's (1998) suggestion that poverty, as reflected in conditions that violate the right to health, must be understood as the deprivation of an individual's and a community's ability to control his or her or its own circumstances. This in turn, once translated into the language of rights, would imply that the conditions of poverty that undermine and violate the right to health take their most concrete form as violations of individual and/or collective rights to self-determination in both a literal and metaphorical sense. This leads us then to a further understanding of poverty as a deprivation of rights to full and equal citizenship, which is drawn in part from, and enriched by, Brazilian educator Paulo Freire's notion of an inextricable link between education and citizenship, with education itself reconceived as a vehicle for self-determination in the most intimate sense – that of making history your own, and that of your community, and ultimately that of giving history a human face, in which the global poor would be finally recognized as equal subjects, with 'the right to have rights' (Arendt, 1951).

Contemporary efforts to develop counter-hegemonic paradigms of global justice and human rights, including the right to health, must include legacies, fruits, and lessons rooted in the contributions and limitations of previous struggles to dignify economic, social, and cultural rights overall, and they must seek to fashion a weave capable of drawing together the disparate strands of the demands for a non-colonialist international order yet unmet since the 1955 Bandung Conference (which was a step towards the Non-Aligned Movement, the UN Conference on Trade and Development, or UNCTAD, the G77, etc.). These include the recognition of the 'right to development' and 'sustainable development', and respect for the 'rights of Mother Earth', as serious alternative paradigms rather than as panaceas, together with the construction of alternative institutional structures on a global scale equivalent to those being developed in the Latin American region within the context of the Bolivarian Alliance for the Peoples of Our Americas (*Alianza Bolivariana para los Pueblos de*

*Nuestra América*, or ALBA), the Southern Common Market (*Mercado Común del Sur*, or Mercosur), the Union of South American Nations (*Unión de Naciones Suramericanas*, or UNASUR), and the recently established Conference of Latin American and Caribbean States, and initiatives such as the creation of a Bank of the South and of an alternative Latin American currency, the African-Latin American Summits, and the April 2010 Global People's Summit on Climate Change and the Rights of Mother Earth in Cochabamba, convened by the Bolivian government. To varying degrees, all of these efforts are derived from critiques of the depredations of neoliberalism first launched by the Zapatistas and of the international financial institutions, such as those at Seattle, Porto Alegre, Genoa, Cancún, and elsewhere, and lay the basis for the construction, *from below*, of a new global 'social and international order in which the rights and freedoms' recognized by the international community 'can be fully realized' (as articulated by Article 28 of the Universal Declaration of Human Rights).

The time has come to convene an 'International Poor People's Tribunal' building on the spirit and contributions of the Russell Tribunal, its primary successor, the Permanent People's Tribunal based at the Lelio Basso Foundation in Rome, and related counter-hegemonic experiences of alternative justice in the context of tribunals of conscience and truth commissions, the mandate of which should be centred on the characterization of poverty as a grave violation of human rights that ought to trigger levels of scrutiny, and ultimately punishment and reparations akin to that applied to crimes against humanity, within the overall framework of international criminal law.

But the ethical force – the 'army of ideas' necessary to bring this about, as Puerto Rican revolutionary pro-independence activist, poet, and philosopher Clemente Soto Vélez (1991: 118) once characterized it – can come only from among the victims of the global system of domination themselves and those of us who cast our lot with them, because, as Ernst Bloch (1996: xxix) argued:

> [L]iberation and dignity are not automatically born of the same act; rather they refer to each other reciprocally – with economic priority we find humanistic primacy. There can be no true installation of human rights without the end of exploitation, no true end of exploitation without the installation of human rights.

Mexico's Zapatistas have come to symbolize the essence of such an approach, both as a movement that prefigured the critique of neoliberal globalization that has since become generalized in the 'global justice' movement, and more particularly because of their rigorously ethical wedding of critical theory and humane praxis. Much of this is reflected in their approach, for example, to issues regarding the relationship between 'reason' and 'force' in the context of globalized struggle that confronts such movements:

> If you cannot have both reason and force, always choose reason, and let the enemy have force. In many battles force may obtain victory, but in the struggle as a whole only reason will triumph in the end. Those who are powerful will never be able to wrest reason from their force, but we will always be capable of deriving force from our reason. (Marcos, EZLN Subcommander, 1997)

## Note

1 See also http://www2.womenslinkworldwide.org/wlw/sitio/caso-interna.php?idcaso=139&idi=en

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# 9 | SOCIOPOLITICS OF HIV IN UGANDA: PROPOSING A SOCIO-BEHAVIOURAL MOVEMENT IN RESPONSE TO DONOR POLITICS AND THE ECONOMIC CRISIS

*Abraar Karan*

When HIV/AIDS first broke out in Uganda in 1979, scientists were forbidden from speaking its name. The authors of the 1985 *Lancet* article describing the first rural outbreak had to call it 'Slim', a colloquial term referring to wasting (Serwadda et al., 1985). The veil was thin, but the combination of denialism and homophobia was so powerful that Ugandan authorities would not have allowed the publication had the authors used 'HIV/AIDS' (Kinsman, 2010: 55). When the article was published, 20 per cent of Ugandans had already been infected with 'Slim'; within the next ten years, Uganda's HIV/AIDS prevalence rate was transformed from the highest in the region to the only rate in significant decline.

This celebrated victory was achieved by means of a complex, sustained, multifaceted campaign that responded to specific social and cultural concerns. Both from the ground up and the top down, profound change was realized on a vast scale across the socio-economic spectrum, from community-level, national, and international actors. However, donors effectively froze funding levels in 2009. The effects were devastating and quickly resulted in a reversal of many of these astonishing advances. This chapter asks how, in the context of diminishing donor support, Uganda can revive the internal mobilization and societal behaviour change that allowed the 'Pearl of Africa' to first curtail HIV in the early 1990s.

After offering an overview of the consequences of the plummeting funding for the treatment of HIV/AIDS patients in Uganda, this chapter situates the crumbling infrastructure within the complex socio-political history of AIDS prevention and treatment programmes in Uganda, from what may be the earliest emergence of the disease to the present (see Figure 9.1). It traces the development of sweeping

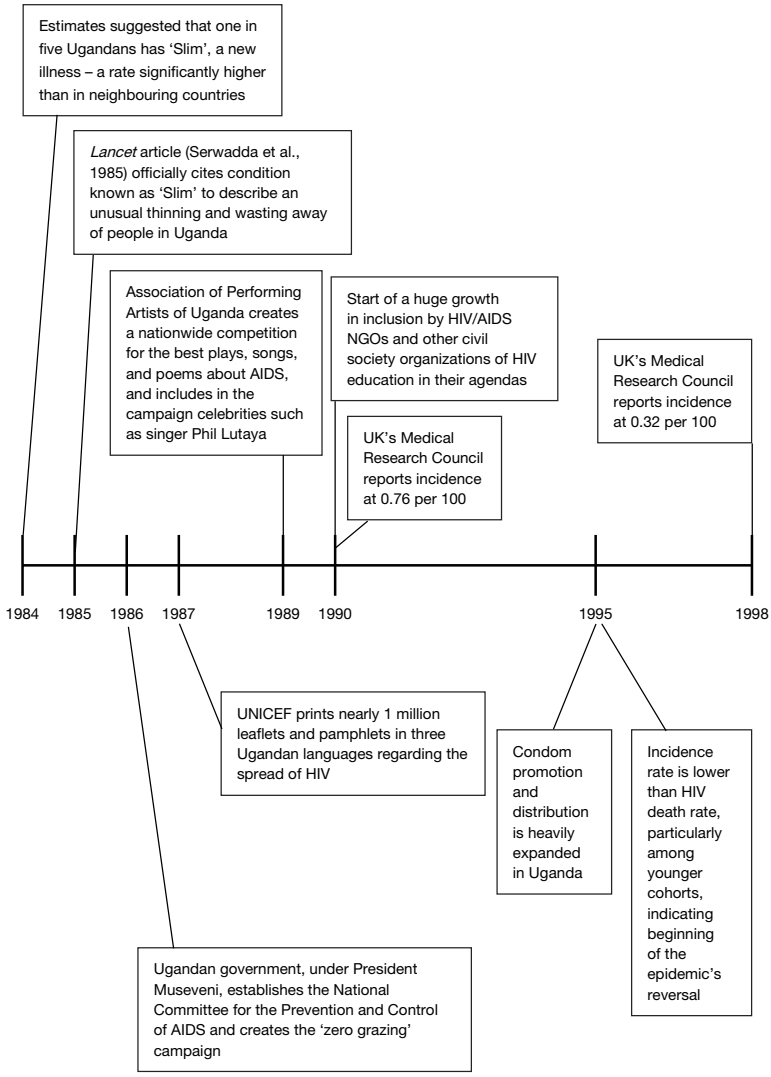
ideological shifts that enabled the successful turnaround of AIDS prevention and treatment, from fighting an initial cultural and religious backlash against condoms to profoundly modifying sexual choices at the individual level. After reviewing the culturally specific myths, misconceptions, and challenges facing treatment strategies, from antiretroviral therapy (ART) to voluntary counselling and testing (VCT), the chapter concludes that a social-behavioural movement is the best strategy for continuing Uganda's success against HIV/AIDS in the future despite disadvantageous donor politics.

## Introduction

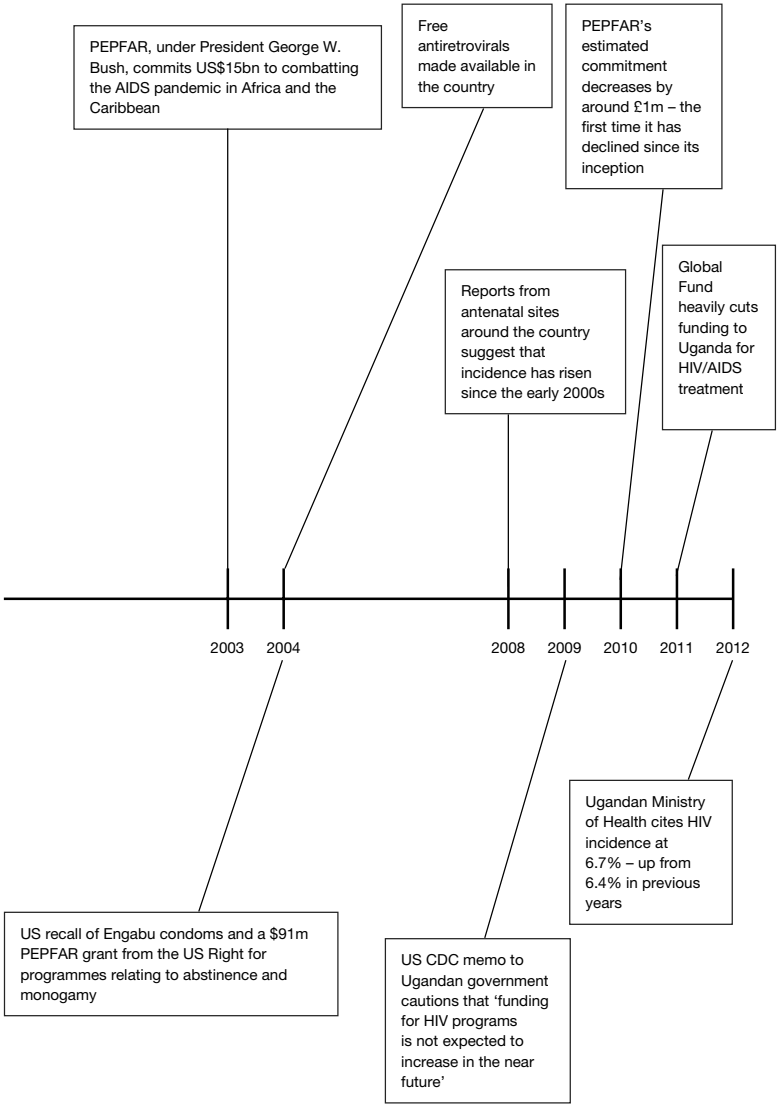
In October 2009, a memo from the US Center for Disease Control and Prevention (CDC) to the Ugandan government cautioned that 'funding for HIV programmes is not expected to increase in the near future' and that, as a result, 'PEPFAR [the US President's Emergency Plan for AIDS Relief] Uganda [could not] continue to support scale-up of antiretroviral treatment without a plan from the Government of Uganda on how these patients [would] be sustained' (US CDC, 2009). These warnings were issued in light of an economic crisis and shifting donor interests, and they held true: by fiscal year 2009, PEPFAR funding to Uganda had relatively flatlined, with an increase of just US$2 million as compared to increases of past years of around $50 million (see Figure 9.2); in 2010, PEPFAR's estimated commitment actually *decreased* by about $1 million (PEPFAR, 2010b).

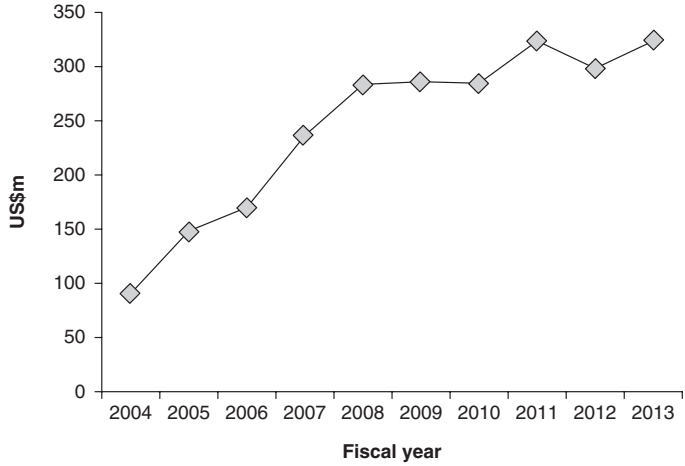
Unfortunately, this financial reduction had already been felt on the ground in Uganda. In early 2010, Dr Peter Mugyenyi, head of the Joint Clinical Research Centre (JCRC), lamented that, 'every day, we have to turn away patients who need treatment ... [and] tell them "There is a [funding] freeze"' (Stockman, 2010). Furthermore, the medical coordinator of the Mulago branch of The AIDS Support Organization (TASO), Uganda's largest indigenous non-governmental organization (NGO) for AIDS care, said that there had been a fourfold increase in the number of new patients approaching the Kampala clinic, most of whom had been turned away from smaller clinics that had lost funding (interview with the author, July 2010). She explained that people used to be convinced that there would always be drugs with which to treat the disease; now, they were telling each other, 'If you get the disease, you will die.'

This scenario has haunting similarities to that in the 1980s, when an HIV-positive blood test was essentially a death sentence. In a study




**9.1** Timeline of relevant events relating to the HIV/AIDS epidemic in Uganda, 1984–2012


PEPFAR, under President George W. Bush, commits US$15bn to combatting the AIDS pandemic in Africa and the Caribbean
Free antiretrovirals made available in the country
PEPFAR's estimated commitment decreases by around £1m – the first time it has declined since its inception
Reports from antenatal sites around the country suggest that incidence has risen since the early 2000s
Global Fund heavily cuts funding to Uganda for HIV/AIDS treatment
2003
2004
2008
2009
2010
2011
2012
US recall of Engabu condoms and a $91m PEPFAR grant from the US Right for programmes relating to abstinence and monogamy
US CDC memo to Ugandan government cautions that 'funding for HIV programs is not expected to increase in the near future'
Ugandan Ministry of Health cites HIV incidence at 6.7% – up from 6.4% in previous years




**9.2** Uganda PEPFAR investment

formally examining the effects of the donor aid flatlining in Uganda between 2009 and 2010, it was found that, of 1,309 eligible patients who made visits to a clinic sponsored by PEPFAR and the Global Fund, only 819 were started on treatment (Geng et al., 2010). There was a 50 per cent decrease in ART initiation for those presenting between February and March 2010, and newly initiated patients were largely covered by the Family Treatment Fund (FTF), a small private foundation that was also quickly reaching capacity. Most clinics lacked insulating bodies such as the FTF and thus the actual rate of enrolment is likely to have been even lower. Along with the economic downturn, the 'political winds ha[d] changed', said Sharonann Lynch, a senior health policy adviser at Médecins sans Frontières (MSF) (McNeil, 2010). She expressed the belief that 'world leaders feel the heat is off' and that 'they're fatigued'. Furthermore, in a meeting with African leaders in August 2010, President Obama asserted that the global community was 'never going to have enough money to simply treat people who are constantly getting infected' (Rukmundo and Lirri, 2010). With the launch of his $63 billion Global Health Initiative, which refocused the United States' global health concerns from HIV to child and maternal health, the waiting lists among those in Uganda and other PEPFAR recipient countries could only grow longer (McNeil, 2010; PEPFAR, 2010a).

In mid-2010, US Global AIDS Coordinator Dr Eric Goosby said that he was 'worried we'll be in a "Kampala situation" in other

countries soon' (McNeil, 2010). A December 2011 MSF report noted that Uganda had been denied Global Fund grants in its last two rounds and that the Clinton HIV/AIDS Initiative that supported paediatric treatment was expected to end its funding in 2012 (MSF, 2011). In March 2012, the Ugandan Ministry of Health announced the results of the Ugandan AIDS Indicator Survey, reporting that the incidence rate had slightly risen from around 6.4 per cent in preceding years to 6.7 per cent (Masaba, 2012). As of 2013, according to Joint United Nations Programme on HIV/AIDS (UNAIDS), the number of people living with HIV/AIDS was at 7.4 per cent, accounting for roughly 1.6 million people. While PEPFAR funding did eventually increase in 2011, it once again fell in 2012 and remains subject to a dangerously tenuous international political environment (see Figure 9.2).

As the global struggle against AIDS slowly worsens with regard to funding and support for treatment programmes, Uganda's future is therefore likely to depend on its ability to recreate the past.

## Uganda's early successes: Behaviour change before the availability of antiretroviral therapy

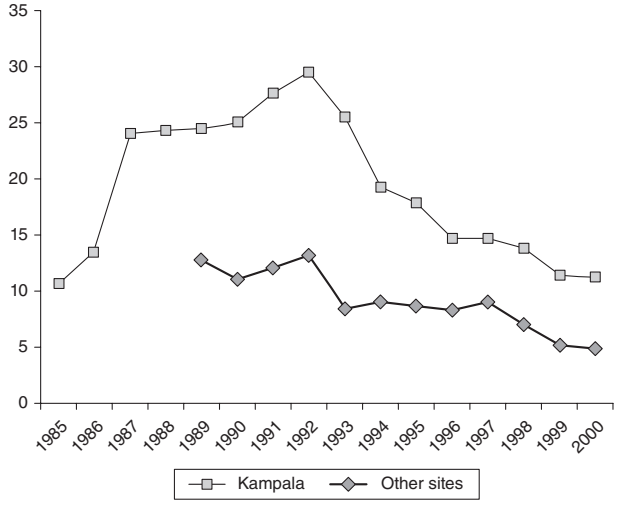
*Politics of perception: Initial shaping of the epidemic* Kasensero, a small fishing village roughly 8 kilometres north of the Uganda–Tanzania border, is thought to be the epicentre of the first population-wide outbreak of HIV in the world (Kinsman, 2010: 45). The war with Tanzania brought with it a migration of illness, delivered in the form of rape by soldiers of the Tanzanian People's Defence Forces in 1979. The first days of the outbreak were marked by confusion and myth, and the word 'witchcraft' was thrown around frequently (Kinsman, 2010: 46). As is evident in the *Lancet* article about 'Slim' in 1985 (Serwadda et al., 1985), the notion of AIDS denialism in Uganda was present from the beginning of the epidemic. A paper by Carl Saxinger and colleagues (1985) published in the journal *Science* suggested that the HTLV-III virus was actually harmless and that it was not a marker for AIDS, further denying the evidence that AIDS was present in Uganda. Absent any acknowledgement of AIDS in the early 1980s, Ugandan society was unable to respond to the threat. The shaping of the disease was thus a key aspect of people's reactions and behaviours.

From the start, the illness was made a product of its environment and people took ownership of it: they gave it a name ('Slim'); they gave it a cause ('witchcraft'); and they posited certain unquestionable

'facts' ('Slim was not AIDS because AIDS was a homosexual, white man's disease') (Kinsman, 2010: 55). The reaction to this outbreak carried a distinctly sociocultural element that shaped the initial (lack of) response, and was rooted in the way in which Ugandans perceived illness and health. Ultimately, the sociocultural element of Ugandan society was a critical component of how successfully the country was able to manage the HIV epidemic. As will be elaborated, Uganda's eventual success in the early 1990s, as well as the decline of that response since, has much to do with the politics of perception and culture, and the way in which this perception will evolve is a factor that will determine the outcome of the AIDS epidemic.

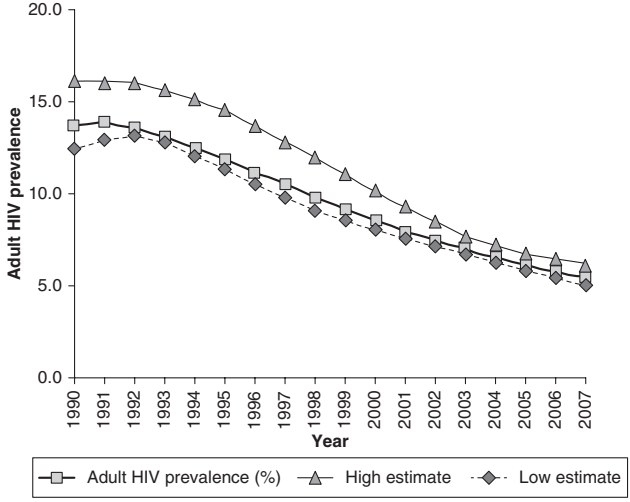
The prevalence rate in Uganda in the 1980s was much higher than in other surrounding countries, either in fact or reported as such because of better monitoring. In 1984, it was estimated that one in five Ugandans was infected with the virus (Kinsman, 2010: 57); over the next decade, Uganda was the only country to experience substantial declines in those prevalence rates – albeit that the exact numbers differ according to various sources (see Figures 9.3 and 9.4).

What was it about Uganda's response to the AIDS pandemic that allowed it to curtail the disease so drastically? Until 1998, when




**9.3** Median HIV prevalence among pregnant women in Uganda (*source*: Adapted from USAID (2002))

*Note:* Interpolated for one-year gaps in site data




**9.4** Estimated percentage adult HIV (15–49) prevalence, 1990–2007 (*source*: Adapted from UNAIDS/WHO (2008))

UNAIDS's Drug Access Initiative was established in Uganda, there was virtually no population-wide access to ART (Kinsman, 2010: 113). Furthermore, condom use was not expansively promoted until 1995, at which point prevalence had already began to significantly decline. The Ugandan people's perceptions of HIV and their subsequent personal choices regarding sexual behaviour during the years prior to 1995 have been exalted as one of Africa's AIDS triumphs. Uganda's campaign, as compared to those of any neighbouring countries, has been lauded for its 'intensity, depth, breadth, and extensiveness' (Slutkin et al., 2006: 358). A significant national movement to educate, warn, and inspire Ugandan citizens, effected by means of determined action taken by both civil society and President Yoweri Museveni's government, has been credited with the historical reversal of the epidemic. In retrospect, then, Uganda can be described as having had the 'strongest planned and best supported national AIDS program, with the largest national and international staffing and most intensive, broadly inclusive, decentralized and community based public education program in Africa' (Slutkin et al., 2006: 358).

*Museveni's march: Starting off on the right foot* When Yoweri Museveni came to power, bringing an end to the Ugandan civil war, he was

extremely active in pursuing answers to the questions of what AIDS was, what impact it was having on the population, and what was to be done about it (Kinsman, 2010: 59). He was described as being both serious and pragmatic about HIV from the start. An encounter with Museveni, in which he was shown pamphlets urging readers to 'Love Carefully', resulted in outright rejection: the president pointed out that most people could not read, let alone read English, which rendered the pamphlets pointless (Kinsman, 2010: 59). In an era of AIDS denialism, President Museveni quickly and openly recognized the presence of HIV, acting as a catalyst for the behavioural movements that emerged soon afterwards. In October 1986, the Ugandan government established the National Committee for the Prevention and Control of AIDS, later to become the National AIDS Control Programme (NACP). The initial social movement that was established by means of this mechanism was that of 'zero grazing', a double entendre referencing both livestock and sexual activities in the bedroom. By using agricultural vernacular that was familiar to the rural populations, Museveni encouraged Ugandans to talk about sex and about HIV via a comfortable, satirical perspective on the notion of sexual concurrency that stripped it of taboo (Kinsman, 2010: 74).

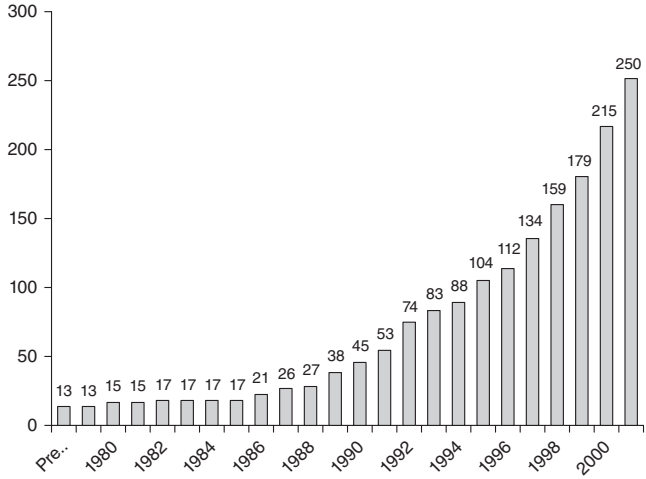
In 1986 and 1987, President Museveni gave speeches throughout local districts emphasizing that AIDS was not the result of witchcraft, mosquitoes, or an act of God, but of sexual contact. He assured that all people could get AIDS, that there was no cure, that it ended in death, and that Ugandans could fight it by having only a single sexual partner (Kirby, 2008: 14). While Museveni did mention that condoms could provide imperfect protection, he was hesitant, fearing that this would offer a false sense of security that might lead to increased sexual behaviour (Kirby, 2008: 14). Not only have the president's speeches at the time been characterized as 'impassioned pleas for people to change their behaviour' (Kirby, 2008: 15), but also he ended *every* major speech that he gave during the late 1980s and early 1990s with a message about HIV (Slutkin et al., 2006).

Uganda's initial openness to AIDS was the starting point in initiating behavioural change, and the country was unique in its ability to shed stigma and instead identify in an illness a common enemy. Factors that allowed Uganda to be far more open than its neighbouring countries included the lack of a tourist industry and the presence of a committed president. The civil war had devastated most of Uganda's national

parks, the only attraction that had sustained a small tourist trade, and thus acknowledgement of an AIDS epidemic was no threat to that sector (Kirby, 2008: 12). Comparatively, a country such as Kenya, which had a far more developed tourist industry, would have been affected by such acknowledgement and thus did not declare AIDS an emergency until 1999 (Kinsman, 2010: 65). Another factor that guided an open policy was the personal background of President Museveni: his military history and connection to the war that brought AIDS to Uganda, as well as his fear that many soldiers were being infected (his political power lay in the support of the army), led him to approach the illness as a personal battle more so, perhaps, than other leaders of his time (Kinsman, 2010: 65).

*Movement: Civil society and social change* The shaping of Uganda's response to the AIDS epidemic can be categorized into three periods, as outlined by Kinsman (2010: 68). During the first (1986–1992), there was a strategy focusing on faithfulness as the epidemic was being constructed and understood. Moreover, surveillance was being better established to track prevalence and incidence. With no drugs available, becoming HIV positive was essentially a death sentence during this phase. According to a previous adviser of the administration working with the NACP at the time, the policy was, 'Tell people, and then the instinct for self-preservation will help them avoid it' (Kinsman, 2010: 73). Most of the efforts of the early 1990s were focused heavily on being faithful and abstaining from sex, with condoms being a distant alternative (Kirby, 2008: 23). According to Dr Sam Okware, head of the NACP in 1987, condoms were not culturally appropriate, and thus 'zero grazing' and 'loving carefully' were the focal points of the campaigns (Kinsman, 2010: 74).

These early years of the epidemic were dependent on social movements among churches, mosques, radio stations, schools, and even members of civil society who would not typically be involved in health issues, including political, community, and religious leaders, who spread information about AIDS to the public (Green et al., 2006). Non-governmental organizations began addressing various aspects of the epidemic and grew exponentially in number throughout the 1990s (see Figure 9.5). In fact, Green and colleagues (2006) suggest that face-to-face communication within communities, facilitated particularly by NGOs and faith-based organizations, may have been




**9.5** Cumulative number of HIV/AIDS organizations registered with the Uganda Network of AIDS Service Organizations (UNASO) (*source*: Adapted from Kirby (2008))

the most important and distinctive aspect of the campaigns. Changes at the village level have been documented anecdotally, with reports of teachers and police officers who engaged in sexual relations with younger women being removed from their posts and forced to leave the village (Slutkin et al., 2006). The Catholic Church was involved in mobile care for AIDS victims, as well as support programmes for AIDS widows and orphans. The Islamic Medical Association of Uganda also began educational efforts to train religious leaders in rural areas and was successful enough to be named a UNAIDS 'Best Practices Case Study' (Green et al., 2006). The Anglican Church's peer education approach included AIDS education messages in sermons and a later evaluation by UNAIDS of those targeted by this project showed a significant reduction in number of partners during the early 1990s (Green et al., 2006).

In 1987, the United Nations Children's Fund (UNICEF) launched an AIDS education programme in schools for children aged 10 and over. Science teachers were trained to teach about HIV/AIDS, with a message of 'strictly abstinence', and students engaged in projects and presentations that taught about the effects of HIV on health (Kirby, 2008: 21). In addition, a School Health Education Programme was

initiated in 1987 that trained teachers to integrate HIV education and sexual behaviour change messages into the school curriculum. By 1987, the thirty-three district health educators had been trained in the curriculum as well (Kirby, 2008: 21). Radio stations all employed the same sombre drumbeat to be played before messages about 'Slim', the killer illness soon to be identified as AIDS (Kirby, 2008: 22). The Association of Performing Artists of Uganda created a nationwide competition in 1989 for the best plays, songs, and poems about AIDS, and celebrities also used performances to create a national dialogue regarding AIDS and its consequences (Kirby, 2008: 22). One such celebrity, Philly Lutaya, was the first major musician to reveal his serostatus (that is, his status as HIV positive), and he engaged in public speeches and presentations in several venues. The event at which he revealed his serostatus was attended by more than 10,000 students and workers, and his message was to love carefully and responsibly (Kirby, 2008: 22).

A number of local programmes and groups were also extremely important in communicating the message on the ground. Straight Talk, a mass media communication programme established in 1993 and still active today, used radio shows, newspapers, and health fairs, among other things, to create a network of educated youth who were aware of sexual infections such as HIV and were motivated to abstain from sex at a young age (Straight Talk Foundation, 2010). For example, Straight Talk published a four-page insert in Uganda's *New Vision*, the largest English-language newspaper in the country (Kirby, 2008: 37), in which it too emphasized that abstinence was the safest approach.

A combination of the government and external organizations was also highly impactful. The Ministry of Health and UNICEF printed thousands of pamphlets and stickers, most of which needed revisions over the years, because they still left people fearful of the possibility of spread through non-sexual contact or mosquitoes (Kirby, 2008: 13). Early in 1987, some 400,000 posters and 500,000 leaflets were printed in English and three Ugandan languages (Kirby, 2008: 13). By February 1988, they had been translated into twenty-two languages and by January 1989, according to local newspapers, 'Love Carefully' posters were ubiquitous (Kirby, 2008: 14). Members of mission trips to Uganda in the early 1990s recall the extent of messaging in Uganda appearing on posters, billboards, and other public materials; they claim that there was simply 'no comparison' between awareness

efforts in Uganda and those of other countries in the region, such as Rwanda, Burundi, Kenya, Tanzania, Malawi, and Zambia (Slutkin et al., 2006).

Interestingly, Uganda's approach effectively maintained a balance between raising awareness and perceptions of the risk of the disease and preventing its stigmatization (Halperin, 2006). As the first director of TASO remembers: 'Most of these initial campaigns adopted a "fear approach" to HIV prevention, based on the theme: "Beware of AIDS. AIDS kills" ' (Kaleeba et al., 2000: 12). Also, members of the NACP recalled that they first 'focused on instilling fear in the population', at which point behavioural change recommendations were taken more seriously (Okware et al., 2001: 1114). The arousal of fear was expected to force ownership of behaviour and to promote the acceptance of personal responsibility with regard to infection. This balance between fear and stigma is important, because it prevents the alternative reactions that result from either removing personal responsibility (when risk is downplayed) or creating stigma (when risk is overemphasized) (Halperin, 2006).

Undeniably, attitudes were largely affected by the individual biases of the participating organizations – especially religious ones. Churches were opposed to condoms as a tool for prevention, because they felt that it would not improve sexual behaviours and would instead encourage 'sinfulness'. The public's perception of the condom was quickly coloured by demonstrations at the Catholic Church, such as one in which pepper was shown to pass through the plastic of the condom suggesting that the virus would also be able to do so (Kinsman, 2010: 76). Thus the initial movements toward personal responsibility, faithfulness, and abstinence, and away from condoms, were largely buttressed by churches and mosques (Green et al., 2006).

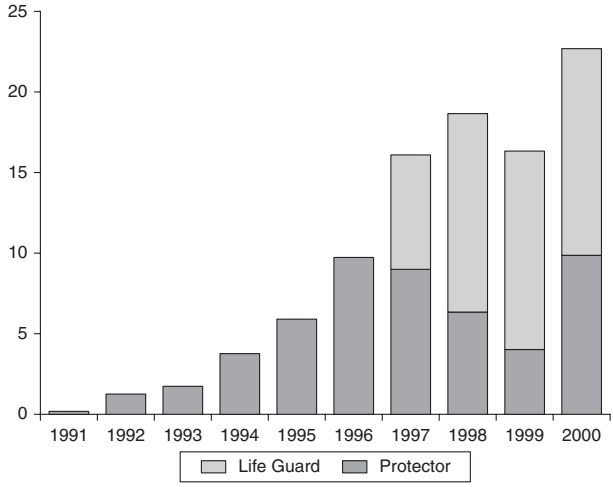
The actual effectiveness of these measures in terms of behavioural change is difficult to isolate, because surveillance was still in its beginning stages, but the atmosphere of activism, concern, and responsibility was definitely apparent by the early 1990s. As surveillance improved and data on prevalence were released in 1991, it seemed as though, despite the focus on abstinence and the educational campaigns, the virus was spreading at an increasing rate (Kinsman, 2010: 78). Antenatal mothers presenting in the national referral hospital in Kampala showed a prevalence increase from 25 per cent in 1988 to 39 per cent in 1990 (Kinsman, 2010: 78). It is likely, however, that this drastic

increase is accounted for by an increase in the availability of testing for those who would typically not have access to a testing centre or health facility. Nonetheless, the data convinced President Museveni to promote condoms despite his ideological leanings. While condoms seemed to be a short-term solution, their longer-term impact on the way in which the population would deal with the epidemic is a significant learning point in the context of the epidemic today.

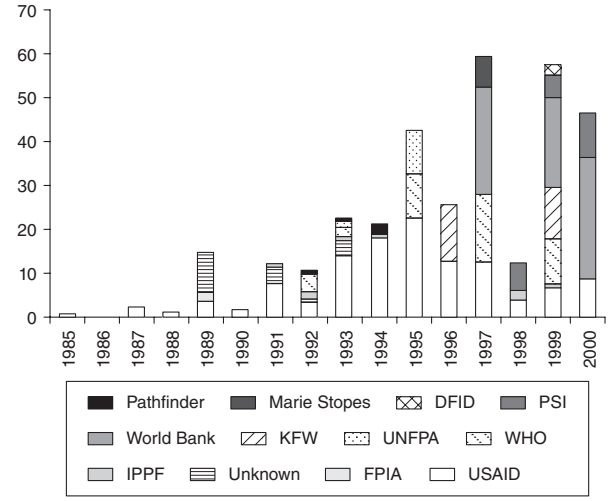
*Condoms: From condemning to condoning* The politics of perception are wholly relevant to condom promotion, as demonstrated by the initial backlash against condoms promoted especially by religious organizations. At first, local sentiment was marked by conspiracy theories about and fear of condoms, including myths that they were a means by which the West was trying to infect Africans with HIV or cause impotency (Kinsman, 2010: 78). How quickly condoms were actually taken up and used by the population is questionable, and the actual effect that condoms had on reducing incidence (that is, the number of new infections) and prevalence rates is also difficult to isolate. What is known is that incidence rates fell during the 1990s by more than half; results from the UK-funded Medical Research Council (MRC) Programme in Masaka showed a reduction from 7.6 infected per 1,000 people in 1990 to 3.2 per 1,000 in 1998 (Mbulaiteye et al., 2002).

It is important to examine HIV incidence and prevalence, and to attempt to align them with both behavioural interventions (abstinence and being faithful to one partner) and condom promotion. Estimates suggest that incidence fell between 1990 and 1995, and has since remained steady, while prevalence has been on a continuous decline since 1990 (UNGASS, 2010). However, condoms did not reach their zenith in Uganda until the late 1990s, with most growth occurring largely between 1995 and 1999 (see Figures 9.6 and 9.7).

According to the Masaka intervention trial, which compared two HIV prevention strategies in 1994, there were 'significant misconceptions about and opposition to condoms from the general community, and also ... small retailers feared ridicule and a loss of clientele if they stocked condoms' (Kinsman, 2010: 85). The success of condoms by 2000 is exemplary: the 2004 Uganda Sero-Behavioural Survey reported that 59 per cent of men and 38 per cent of women with non-regular sexual partners said that they had used a condom during




**9.6** Number of socially marketed condoms in Uganda (m) (*source*: Adapted from USAID (2002))




**9.7** Number of condoms received by Uganda per year (m) (*source*: Adapted from Kirby (2008))

*Note:* DFID = Department for International Development (UK); PSI = Population Services International; KFW = KfW Development Bank; UNFPA = United Nations Population Fund; WHO = World Health Organization; IPPF = International Planned Parenthood Federation; FPIA = Family Planning International Assistance

their last sexual encounter, and by the late 1990s condom use among commercial sex workers had risen to almost 100 per cent in Kampala (Green et al., 2006). Nonetheless, the time frame in which condom use grew and became accepted spans a period *after* incidence was already relatively stable and prevalence had already been declining for years, meaning that condoms were unlikely to be primarily responsible for the changing face of the epidemic.

Additionally, condoms may have inhibited Uganda's early behavioural movements from progressing into the next century. The concept of 'risk compensation', as applied to HIV prevention by Harvard scientist Edward Green, suggests that the availability of condoms may have had a somewhat counterproductive effect in certain circumstances, especially in Africa (Green, 2009). When people feel safer, they are willing to take more risks; when in the context of HIV-causing behaviours, a reliance on condoms may create a false sense of security that encourages sexual activity. Green and colleagues (2006) do note, however, that Cambodia and Thailand were able to effectively promote condom use in brothels, but in many African countries the epidemic derives from multiple-partner relationships, which may actually be exacerbated by condom use. According to articles published in local newspapers, wives complained that the free condoms provided to their husbands at work were encouraging the men to have sex outside of their marriages (Kirby, 2008: 43).

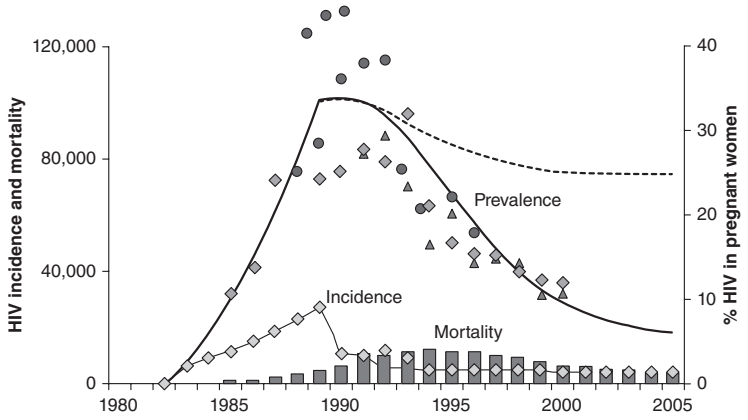
Condom usage has proven more complex than it might initially appear, particularly in Africa, for example the forced use of condoms in relationships being said to imply distrust between partners (Asiimwe et al., 2003). Along these lines, condom promotion is a symptomatic approach that neglects the realities of African life for both men and women: it does not address the central issues of gender and sexual inequality, or the cultural norms that have catalysed the spread of HIV (Asiimwe et al., 2003). Additional risk factors complicate the transmission of the virus: the number of sexual partners, the duration of relationships, the extent to which relationships overlap, the frequency of sex, specific sexual practices, the proper use of condoms, and the stage of infection of an HIV-positive partner are all additional factors that become relevant when looking at interventions other than absolute behavioural change (Cohen, 2004).

Ultimately, the evidence suggests that labelling condoms as the propellant of a waning epidemic is unlikely to be accurate: to some

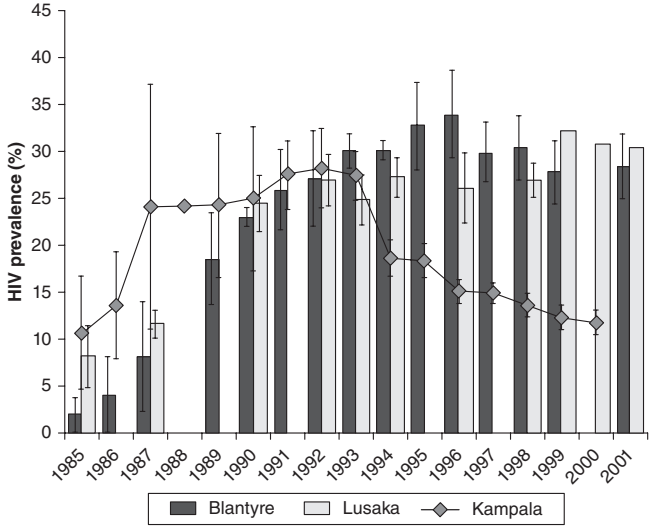
extent, condoms were culturally incongruous with African culture and social structures, thus are unlikely to have been responsible for the declining incidence or prevalence – and they may even prove counterproductive on occasion as a result of risk compensation.

*Attempting the impossible? Isolating behavioural change* While it is unlikely that condoms were the main agent responsible for Uganda's successful control of HIV, to say with reasonable certainty that it was indeed a socio-behavioural revolution would require the isolation of this as an independent variable. According to the models of Stoneburner and Low-Beer (2004), HIV incidence was likely already to have been in decline in Uganda by the late 1980s (see Figure 9.8).

By 1995, the incidence rate of HIV was lower than the HIV death rate, especially among younger cohorts, indicating a reversal of the epidemic and a declining prevalence. To isolate behavioural change as the possible critical factor, Stoneburner and Low-Beer (2004) traced the epidemic in Kenya, Zambia, and Malawi as well. The epidemic was afflicting these countries within one year of its emergence in Uganda and demonstrated similar growth curves with respect to initial prevalence. However, Uganda's declining prevalence – for example by 75 per cent in 15–19-year-olds and 60 per cent in 20–24-year-olds, according to data from Kampala and other urban sites (Stoneburner and Low-Beer, 2004) – was unmatched in the other countries (see Figure 9.9).



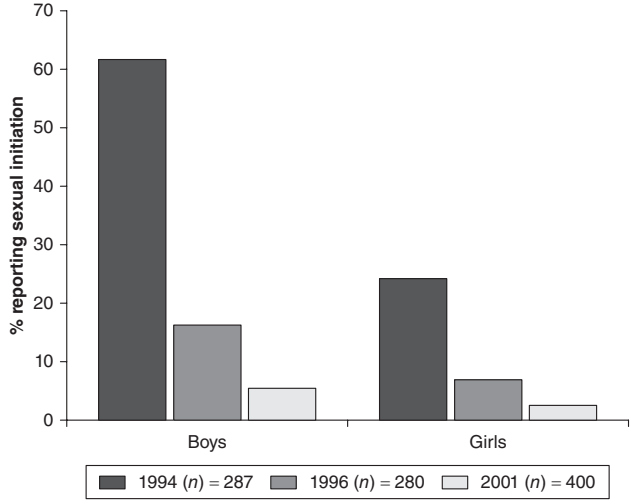

**9.8** Models of estimated HIV incidence in Uganda (*source*: Adapted from Stoneburner and Low-Beer (2004))



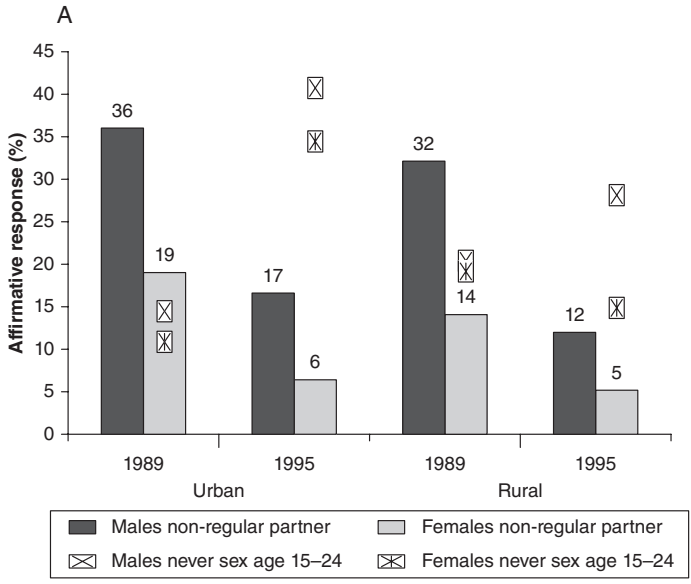

**9.9** Comparison of prevalence in antenatal surveillance sites (Malawi, Zambia, Uganda) (*source*: Adapted from Stoneburner and Low-Beer (2004))

Important behavioural changes that were determined included a rise in the age of sexual debut (see Figures 9.10 and 9.11), a decrease in indicators that would suggest casual or non-regular sexual partners (see Figure 9.11), and an increase in the use of condoms (Stoneburner and Low-Beer, 2004). In relation to the behaviours of the group most responsible for the spread of the epidemic, men with multiple sexual partners, among Ugandans in this population there was a decrease in the percentage of non-regular sexual partners from 15 per cent in 1989 to 3 per cent in 1995 – approximately the same years during which incidence was dropping (Stoneburner and Low-Beer, 2004). Moreover, the proportion of males reporting three or more non-regular partners fell between 1989 and 1995, from around 20 per cent to less than 5 per cent (Stoneburner and Low-Beer, 2004), all of which indicates that a shift in the sexual choices of individuals was at the core of Uganda's social movement.

In comparison, the proportions admitting to casual sexual partnerships in Malawi, Kenya, and Zambia at around this time were much higher, and the proportions of 15–19-year-olds who abstained from sex were much lower among males (Stoneburner and Low-Beer,




**9.10** Delayed sexual debut among primary school pupils (aged 13–16) following information education and communication, Soroti District, Uganda (*source*: Adapted from USAID (2002))




**9.11** Reduction in non-regular partners and age of sexual debut (*source*: Adapted from Stoneburner and Low-Beer (2004))

2004). In the meantime, condom use rose relatively equally in Uganda, Zambia, Malawi, and Kenya (Stoneburner and Low-Beer, 2004) – the years during which incidence was falling (UNGASS, 2010), which strongly suggests that behavioural change, as opposed to condom use, was responsible for the reduction of HIV incidence in Uganda during the mid-1990s.

The question remains, however, why this change occurred only in Uganda. Although behavioural movements are generally identified as the reason, it is important to look at the more tangible elements of these movements. Personal networks and personally knowing someone who had died from AIDS are reported as being important indicators, in line with Green and colleagues' (2006) assertion of face-to-face communication as the most relevant aspect of Uganda's social movement. In Uganda, 82 per cent of women had heard of AIDS through a personal network, as compared to 40–65 per cent in other sub-Saharan African countries (Stoneburner and Low-Beer, 2004). Also, by 1995, 91.5 per cent of Ugandan men and 86.4 per cent of women had known someone with AIDS, as compared to 68–71 per cent of the population in Kenya and Malawi, and less than 50 per cent in Zimbabwe and South Africa (Stoneburner and Low-Beer, 2004). In acknowledging Uganda's open policy towards AIDS, including the push for 'zero grazing', Stoneburner and Low-Beer (2004) substantially attribute Uganda's success not to condoms, but to 'public-health interventions that triggered a social process of risk avoidance manifested by radical changes in sexual behaviours'. By avoiding the waves of AIDS denialism that are present even today in countries in sub-Saharan Africa, Uganda was able to create internal change among its population.

Behavioural programmes did eventually catch on in other sub-Saharan African countries, where they have also showed successes. For instance, Zambia's 'Helping Each Other Act Responsibly' (HEART) programme, funded by the US Agency for International Development (USAID) evidenced promising outcomes after the first year of its initiation. Those who participated in the programme were 46 per cent more likely to delay sexual intercourse and 67 per cent more likely to have used a condom the last time they had sex as compared to pre-programme (USAID, 2008).

In the dialogue surrounding Uganda's success, the debate over whether abstinence or condoms was more effective has often emerged.

Many conclude that a derivative of the 'A' and 'B' of 'ABC' (that is, 'abstinence, being faithful, condoms') – the reduction of multiple partners and later sexual debut – was Uganda's primary cause of reduced prevalence and stabilized incidence (Kinsman, 2010: 97). However, regardless of how impactful condoms actually were in the Ugandan epidemic, it is counterproductive to pit one prevention strategy against another. This simply reveals the larger battle of ideologies, such as those of the church or bipartisan donor politics, which influence these policy decisions. Ultimately, it is more productive to accept that *both* strategies in conjunction with one another may be the most useful for the future.

*Shifting ideology: Dangers of dependency* Donor politics determine the fate of any dependent country and this dependency has proven dangerous in Uganda's past. In 2004, there was a shift back from condoms to the promotion of abstinence and being faithful, as a result of Republican political and ideological sentiments. Through its dependency on the United States, Uganda had put itself at risk of a massive public health disaster, first realized with the 2004 recall of Engabu-branded condoms because of issues of 'quality'. This recall (conveniently) occurred at the same time as PEPFAR delivered a $91 million grant – at a time when PEPFAR was shifting its ideological priority away from condoms, towards abstinence and monogamy (Kinsman, 2010: 102). The number of condoms being freely distributed in the country fell from 90 million in 2003 to 39 million in 2004 (Kinsman, 2010: 102). Stephen Lewis, UN Special Envoy on AIDS in Africa, openly blamed US policy for the shortage, claiming that the 'significant decline in the use of condoms ... [is] significantly orchestrated by the policies of the [US] government' (quoted in Kinsman, 2010: 103). There was immediate worry among those who had been fighting for condom promotion:

> 'We're almost back to square one,' one of the organization's staff members said, adding: '[B]ecause of our culture, it was very difficult for us to get people to use condoms. Now, trying to promote abstinence in this social environment is very difficult. If you tell people to abstain, they'll say, "You were the people telling us to use condoms, and now you're telling us to abstain. Does this mean condoms weren't effective and you were lying to us?"' (Cohen and Tate, 2005: 74)

The situation fuelled confusion about the best prevention strategy and paralysed the population (Kinsman, 2010: 102).

The international shift in strategy was mirrored by President Museveni, who was criticized for spreading contradictory messages during the Fifteenth International AIDS Conference in Bangkok in 2004. He first confirmed Uganda's national condom policy, saying that it was an 'effective means of preventing HIV/STI transmission', yet soon after he indicated that the condom was 'an improvisation, not as a solution' (Kinsman, 2010: 100). A few months later, State Minister for Information Dr Nsaba Buturo is quoted as saying 'we have erroneously given more prominence to condoms [than to abstinence and faithfulness] and this is going to change' (Kinsman, 2010: 101). Opinions on the ground strongly supported the notion that pressure from the Bush Administration is what caused Museveni to take his strongest stance against condoms since the early 1990s. Interviews conducted by Kinsman (2010: 101) exposed feelings that 'the Bush money has changed the way [Museveni] faces the epidemic'. One resident district commissioner appointed by Museveni himself explained that, 'having watched [Museveni] over the years, [he'd] never heard him so openly denouncing [condoms]', and the commissioner suggested that the 'strong message may have come from [Museveni's] Republican friends in Washington' (Kinsman, 2010: 101). The trouble, of course, was that while the supply of condoms could be stopped overnight, behaviours and culture cannot be so quickly changed. Once condoms were withheld, it was unreasonable to expect that levels of sexual activity would consequently decrease.

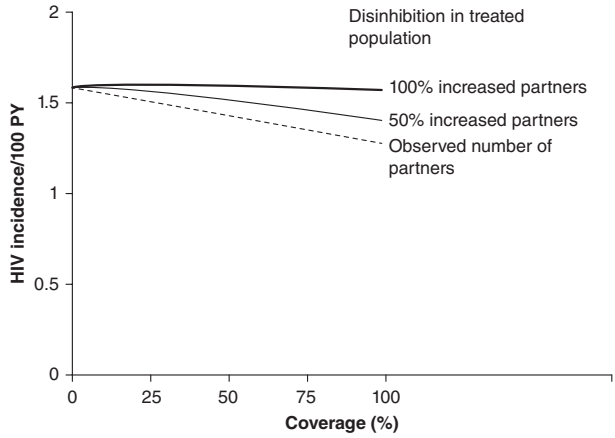
## Uganda in the age of antiretrovirals: Drawing parallels with the past

*From condoms to antiretrovirals: Same game, new name* On 28 January 2003, PEPFAR committed $15 billion towards combatting the AIDS pandemic, to be disbursed throughout Africa and the Caribbean (Kinsman, 2010: 93). Allocation of the funds was to see 55 per cent going toward treatment and 25 per cent towards prevention, with a third of this latter portion to be used to fund abstinence programmes. While there was debate over how prevention funds were to be allocated (Democrats wanted to promote condom use; Republicans wanted to preach abstinence), the shift from prevention towards treatment was clear.

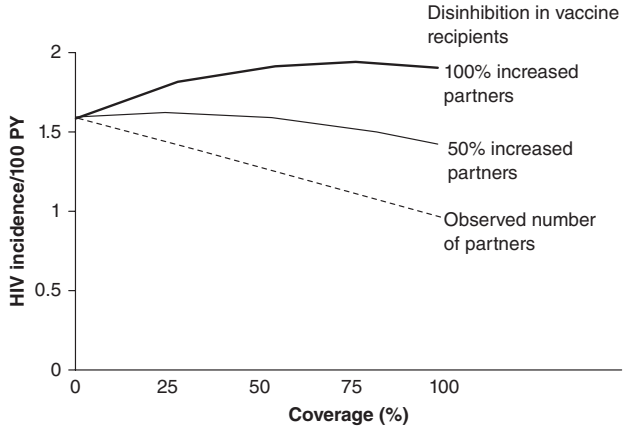
The introduction of free ART to Uganda in 2004 was a move that had been feared by many who advocated prevention for years before drugs first landed in the country. In the 1970s, access to drugs completely changed the landscape of sexually transmitted infections. One respondent described the feelings of the time as, 'You get it today; tomorrow, you go for treatment' (Kirby, 2008: 7). In fact, becoming infected was even incorporated into the culture as a symbol of pride: according to one interviewee of that era, 'A man who never suffered from syphilis or gonorrhoea was never a man' (Kirby, 2008: 7). Former World Health Organization (WHO) Director General Hiroshi Nakajima warned, shortly after ART was confirmed to be an effective treatment against AIDS, that 'new therapies must not lead policy makers to abandon their commitment to essential long-term activities such as preventions programs' (Kirby, 2008: 118). The same fear of risk compensation that was first voiced in relation to condoms was being raised again, now in relation to treatment. As one European official alleged, 'in the gay community, prevention just went out the window as soon as the drugs came in: now you could have sex without condoms again' (Kirby, 2008: 119).

The role of behavioural disinhibition that might result from the rollout of ART in sub-Saharan Africa was assessed in models by Gray and colleagues (2003). They found that a 100 per cent increase in the number of sexual partners for those on highly active antiretroviral therapy (HAART) would significantly attenuate the reduction of incidence, as would even a 50 per cent increase in the number of sexual partners (Figure 9.12). Moreover, an increase in the number of sexual partners by 25 per cent among those receiving a vaccine with 50 per cent preventative efficacy would actually lead to a rise in HIV incidence (see Figure 9.13).

Fears of increasingly risky behaviour after ART initiation were grounded in studies that documented a significant increase in the number of unsafe sexual episodes among men who had sex with men (MSM) in San Francisco in the late 1990s (Katz et al., 2002). In that study, the proportion of those who reported unprotected anal intercourse and multiple sexual partners increased from 24 per cent in 1994 to 45 per cent in 1999. Furthermore, a study by Stolte and colleagues (2004) found that gay, HIV-infected men who perceived less of a threat from HIV/AIDS were more likely to engage in unprotected anal intercourse. Additionally, studies showing the efficacy of behavioural interventions in the MSM




**9.12** HIV incidence, treatment, and behavioural disinhibition (*source*: Adapted from Gray et al. (2003))




**9.13** HIV incidence, treatment, and disinhibition with a preventative vaccine of 50% efficacy (*source*: Adapted from Gray et al. (2003))

population further supported behaviour change as a sustainable and preferable choice to ART overdependence (Herbst et al., 2005).

In response, a number of studies investigated whether this phenomenon of risk compensation had occurred with regards to the Ugandan epidemic. In a paper by Crepaz et al. (2004) published in the *Journal of the American Medical Assocation*, the unintended effects of

HAART were explored with regard to the prevalence of unprotected sex, as well as beliefs about viral loads and unprotected sex. While HAART reduces the chance of HIV transmission by means of lowering viral loads, it does not eliminate this chance – yet the study found that the likelihood of unprotected sexual behaviour was significantly higher in people who believed that HAART reduced HIV transmission, as well as in people who were less concerned about engaging in unsafe sex given the availability of HAART, partially countering the beneficial effect of lower viral loads (Crepaz et al., 2004).

Nonetheless, studies have also shown that HAART provision has reduced risky behaviour, when coupled with counselling and behavioural interventions. In rural Uganda, Bunnell and colleagues (2006) found that, after six months of ART, risky sexual behaviour among 926 HIV infected individuals was reduced by 70 per cent. 'Risky sexual behaviour' was defined as inconsistent or no condom use with partners of HIV-negative or unknown serostatus during the course of the previous three months. The conclusions of this study pointed to the efficacy of ART when coupled with behavioural interventions and counselling. More specifically, the behavioural interventions that all participants received included group education on ART, family VCT, and (perhaps most importantly) personal sexual behaviour plans in which participants assessed their current risk situation and how they might cope with increased sexual desires. Risk reduction options were listed as 'abstinence, condom use, reduced frequency of sex, and alternative forms of sexual expression'. Interestingly, 85 per cent of risky sexual behaviour occurred within married and cohabitating couples, among whom negotiation of condom use is notoriously difficult. Furthermore, both men and women experienced substantial increases in sexual desire and in opportunities to meet new partners after ART initiation, reinforcing the notion of risk inhibition.

In another study, this time in the context of an urban HIV/AIDS care centre in Kampala, receipt of ART was not found to be associated with a significantly higher likelihood of being sexually active (Bateganya et al., 2005). Both groups had 35 per cent of participants reporting one or more casual sexual partners in addition to a main partner – but this also points to the fact that ART counselling did not lead to a reduction in casual sexual partners. Like Bunnell and colleagues (2006), however, recipients of ART did report more consistent condom use than ART-naive participants.

A more recent study by Pearson and colleagues (2010) in Mozambique did not find results as promising as those of Bunnell and colleagues (2006). After twelve months of ART, there was found to be an increase in the proportion of participants having sex, the total number of partners, and the number of partners with HIV-negative or unknown serostatus. Like the other two studies, there was found to be an increase in consistent condom use, as compared to the baseline – but other findings were far more disconcerting, such as the fact that 96 per cent of concurrent relationships reported at twelve months were newly formed. Also, almost half of those reporting concurrent sexual partnerships also reported unprotected sex with their HIV-negative or unknown-serostatus partners. Both men and women believed that social and cultural factors encouraged men to have multiple sexual partners, and that non-disclosure of serostatus was correlated with concurrent relationships, as well as unprotected sex. The notable difference between the studies conducted by Pearson and colleagues (2010) and Bunnell and colleagues (2006) was the significant counselling that the latter provided to patients along with ART provision. Most importantly, the personal sexual behaviour plans seemed to demand personal responsibility and ownership of sexual actions independent of the benefits of antiretrovirals.

In support of this observation, a large observational cohort study carried out between 2003 and 2010 in South Africa found that while HAART did reduce sexual activity such as unprotected sex and concurrent sexual partners, the participants were enrolled in primary care programmes 'in which they received ongoing counselling and prevention messages' (Venkatesh et al., 2010). Thus a crucial role of HAART in sexual behaviour improvement is that it brings patients into contact with counselling and prevention; when it is not adequately coupled with behavioural counselling, such as in the Mozambique study (Pearson et al., 2010), HAART seems to have negative effects on sexual behaviour.

*Antiretrovirals and voluntary counselling/testing: Addressing the uninfected and unknown* In sub-Saharan Africa, according to ten national population-based surveys in 2010, less than 40 per cent of those living with HIV know their serostatus (WHO, 2010). A large scale-up of routine HIV VCT is occurring, but the effect of this on sexual behaviour is unclear. In a study by Kiene and colleagues (2010),

'risky sex' was classified as sex with a serodiscordant partner. The authors hypothesized that once an individual knows that he or she is positive, the infected person will avoid HIV-negative partners to reduce the risk of transmission (Kiene et al., 2010). Results after three months of finding out their serostatus showed that participants who found out they were HIV positive were no more likely to start using condoms during every sex act with a serodiscordant couple than were those who were HIV negative. Among those who were HIV negative and married, or in cohabitating relationships, there was not a significantly higher rate of partners being tested than there was among single participants. Also, there was a low rate of behavioural change among married and cohabitating partners, especially with regard to concurrent, non-marital partnerships. The percentage of concurrent, non-marital partnerships (between 14 per cent and 19 per cent) did not decrease following HIV testing. As was made famous by Epstein (2007), long-term concurrent relationships are the most troubling aspect of the African HIV pandemic and thus data showing that knowledge of serostatus does not result in behavioural change in this population is especially concerning.

These findings point to the deeper issues of a culture of concurrency that is ingrained in African communities. Kiene and colleagues (2010: 124) concluded that, '[d]espite evidence of some behaviour change, the magnitude of reduction in risk of HIV transmission in this sample was modest' and that the total number of risky sex acts across all participants only decreased by 4 per cent, which was a 'non-significant decrease'. The authors also promoted the notion of 'tailored risk-reduction counselling': a similar programme to that successfully implemented by Bunnell and colleagues (2006). Kiene and colleagues (2010) highlight the idea that even knowledge of serostatus is insufficient to stimulate behavioural change at the level that is required to curtail the pandemic – and this leads to a number of questions, one being the impact of myths ('ART cures HIV'; 'ART will always be available for free') on individuals who do not know their serostatus and on individuals once they find out their serostatus.

Unintentionally, the widening of ART availability has resulted in a neglect of prevention among the much larger, uninfected population (Okware et al., 2005). While risk compensation has been suggested as a factor among those using condoms and those provided with ART, attention should be turned to those yet to utilize these resources. Based on hearsay and face-to-face communication, it

seems that there may be a growing cohort of people affected by the security of knowing that drugs have helped others. Those that are still HIV negative and thus do not come in contact with the counselling that is provided when one is enrolled on ART are most likely to be misinformed about the extent to which antiretrovirals can save their lives, or about the difficulty of adhering to physically demanding drug regimens. As already noted, testing and the provision of ART has been proving inadequate in driving changed sexual behaviour absent the education and interventions that force participants to realize risk and to take personal responsibility. Such educational and behavioural interventions must therefore be scaled up to include those who are not currently being treated with ART, those whose serostatus is unknown, and those who are HIV negative. Many studies have indicated people's aversion to testing, based on factors including stigma and fear; unfortunately, this means that they are also avoiding the counselling that accompanies testing. It is imperative that people receive counselling that will dispel myths such as those regarding ART's curative ability (Hirsch, 2007), and it is this pre-emptive measure that will be absolutely crucial in preparing for the even greater drug shortages than are now being experienced.

*Antiretroviral myths and misconceptions: Fuelling dangerous dependency* While sexual behaviour studies and knowledge, attitude, and practice (KAP) studies focusing on people who are HIV negative or who have unknown serostatus are limited, it is likely that high-risk sexual behaviour has increased in these populations as a result of misconceptions regarding HIV and its treatment (Okware et al., 2005).

A study by Nyanzi-Wakholi and colleagues (2009) examined the role of HIV testing, counselling and treatment among people both with and without HIV infection. The study revealed the presence of significant myths about ART, as well as some recognition of the problems relating to adherence to the regimen. Some believed that, after sufficient ART, they would become HIV negative; the actual difficulties of being on ART were also voiced, however, with participants feeling overwhelmed at the need to swallow a pill for a lifetime.

Fears that the wider availability of ART may erode the previous achievements of behavioural interventions in Uganda were captured in a study by Atuyambe and colleagues (2008). The authors utilized

focus group discussions, with purposeful sampling, to create twenty groups comprising individuals who had relevant knowledge of reproductive health and HIV/AIDS issues, youths who were familiar with attitudes in the adolescent and young adult communities, and members of influential positions in local policy, such as officials in the Kampala city council. Among the participants, there was a strong belief that increased access to ART would result in a greater spread of HIV because of a rise in unsafe sexual behaviour. According to one local council official:

> When people see that [antiretrovirals] are now available, which makes the HIV dormant for some time, they know they can now engage in sex knowing that at the end of the day, before they die, a cure will be available. It looks as if it has now made people more promiscuous. Before, people knew that there was no alternative but death. But now, we see risky sexual activities begin to increase.

Opinions from a focus group of males in school, aged 15–18, included the following:

> I want to supplement what he has said, the drug [antiretrovirals] has increased the AIDS transmission rate because in the past people could protect themselves using condoms but now they no longer protect themselves since the drug is available.

Others reported that knowing that there were drugs available is what kept them from abstaining from sex:

> HIV transmission will continue to increase as long as drugs are available. Even though it was me, I can't abstain because I know there are drugs (laugh) but if there were no drugs, I would have abstained from sex.

Some male participants also presented the idea that the cheaper the drugs, the more women it would allow them to be with concurrently. Moreover, there was a concern for the development of a false confidence in the efficacy of ART to completely prevent infection, as demonstrated in the following:

> Automatically people's sexual behaviour has changed and people now go for unprotected sex because they know that there are [antiretrovirals] that can be used to weaken HIV/AIDS. Some people have hope now that there is medicine to use and keep them living hence having unprotected sexual intercourse.

Another finding of these focus groups was that HIV/AIDS was no longer perceived to be a large threat – namely, because of the availability of drugs that allowed people to live longer and appear healthier on the outside. Participants explained that:

> People no longer fear AIDS because there are drugs that fight against HIV/AIDS ... people no longer see it as a big threat because at first it was seen as a terrible disease. It could cut people's nails, remove people's hair, but now with use of ARVs, it is difficult to see such signs.

Moreover, the groups elaborated on misconceptions about ART that were of major concern, especially among people who were unaware of their status and thus had never been counselled. One male participant voiced the belief that 'even if [a person] is infected, he/she can swallow [antiretrovirals] and live for a long time'. Others claimed that many people think that ART 'can cure the disease so they are no longer afraid'.

Ultimately, the fears and concerns expressed by the participants point towards a need for counselling and education among not only those who are HIV positive and on HAART, but those whose status is unknown and those who are HIV negative. The misconceptions listed, such as ART being a cure, are most likely 'confirmed' by its success among HIV-positive people, who are living longer and remaining healthier because of the treatment. Similar misconceptions about the impacts of ART were noted in South Africa, where a cross-sectional study of 105 HIV clinic patients found that almost 50 per cent believed that ART could cure HIV and 36 per cent believed that ART would not cause side effects (Nachega et al., 2005). Additionally, programmes that include tailored counselling and testing are likely not only to change sexual behaviours, but also studies have shown that they significantly reduce HIV myths and false beliefs (Kalichman and Simbayi, 2003).

Ultimately, these misconceptions are extremely counterproductive and dangerous; it is therefore essential that they be addressed through behavioural and educational campaigns, especially delivered by those actually living with HIV/AIDS.

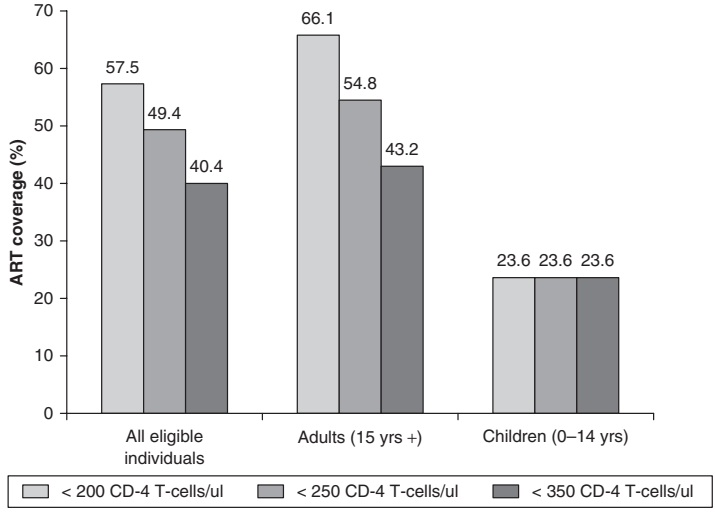
*Ideologies revisited: Danger, dependency, and the current situation* The dangers created by overdependence and faith in the curative effects of ART are obvious – and similar to those surrounding the use of condoms earlier in the epidemic. When patients believe that the intervention – be it condoms or ART – is effective enough to allow them to engage in higher levels of risky sexual activity, the benefit of the intervention is diminished. Furthermore, this creates a troubling culture of dependency in which the provision of the resource is necessary to maintain the status quo – and when the resource becomes unavailable, the results are disastrous. This was seen to some extent in the aftermath of the Engabu condom shortage in 2004 and it is on the verge with regards to HAART availability at time of writing in 2015.

In August 2010, Dr Eric Goosby reversed the funding caps that prevented new patients from being accepted off waitlists, serving as a temporary solution for those in need of drugs (*Health E-News*, 2010). Supported by PEPFAR, he also allowed for a temporary infusion of additional antiretrovirals to address the widespread, extreme shortages (*PlusNews*, 2010). Nonetheless, the level of funding provided by PEPFAR has relatively flatlined, increasing just $2 million in 2008–09 as compared to almost $50 million in 2007–08 (PEPFAR, 2010b). In a statement on its website in early 2010, PEPFAR indicated that it would be taking a new focus on 'personalized risk' and placing more emphasis on prevention, as opposed to treatment (PEPFAR, 2010b). As the donor stance changes – as the United States shifts its goals from HIV/AIDS to maternal and child health – the resulting impact on recipient countries such as Uganda has been, and will continue to be, fatal (PEPFAR, 2010b).

Concerns from the outset of the ART scale-up had to do with its sustainability. As cautioned by a European Commission official in an interview in 2003: 'People will say "this is costing too much, we already have X,000 people on treatment, the economy cannot support this anymore"' (quoted in Kinsman, 2010: 122). The official continued to predict the dialogue: '"Sorry, we can't treat you, somebody has to die before you can get treated."' In an insightful

prediction, the official urged: 'Don't put people on treatment today that you can't afford to have on treatment in 20 years' time.' This is the very same dialogue that was heard in Uganda during personal interviews with heads of NGOs and government officials in July 2010: with treatment no longer available, a culture that had become dependent on donated drugs suddenly found itself suffocated and people were unsure what to do.

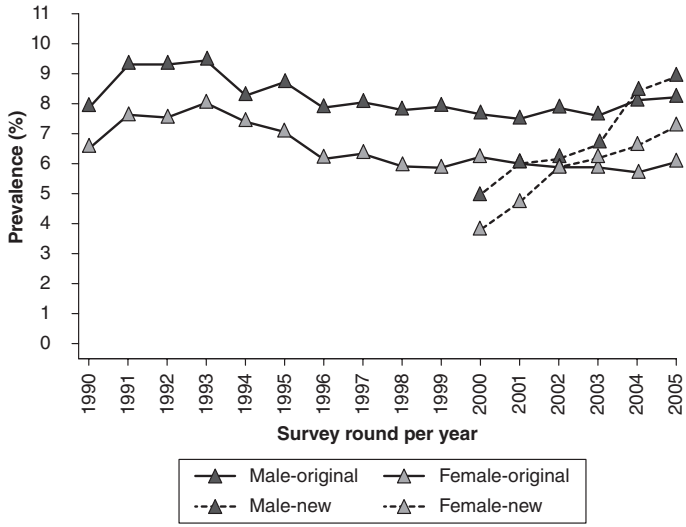
As noted already, the US government's approach now, under PEPFAR, is to focus on prevention rather than treatment. Arguments for prevention have long been voiced, with studies showing that prevention may be up to twenty-eight times more cost-effective in the long run than HAART (Marseille et al., 2002). Unfortunately, however, these arguments do not solve the dilemma with which Uganda is faced: only 37 per cent of those needing HAART in sub-Saharan Africa were receiving it by the end of 2009 (WHO, 2010). Coverage in Uganda was close to these levels, using various $CD_4$+ count scenarios (see Figure 9.14). Moreover, prevention will not protect those who are already infected: the nearly 4 million people in sub-Saharan Africa who are currently on HAART, nearly 220,000 of whom live in Uganda, will continue to need treatment for the rest




**9.14** Ugandan ART coverage using various criteria (*source*: Adapted from NACP (2010))

of their lives, or until a cure is found (NACP, 2010; WHO, 2010). Ultimately, then, treatment must be maintained, but prevention is the only sustainable solution for controlling the pandemic, given the reality of AIDS funding.

While funding is currently being maintained at stable levels, the HIV epidemic in Uganda may be worsening. Recent reports from studies conducted in small antenatal clinic sites are suggesting that prevalence and incidence are again on the rise (see Figure 9.15) (Shafer et al., 2008). Shafer and colleagues (2008) noted an increase in the proportion of participants reporting one or more casual partners between 1997 and 2004, and there was a significant drop in condom use among those aged 20–24 (from 74.1 per cent in 1997 to 50.7 per cent in 2005). One possibility for these observations, say Shafer and colleagues (2008: 1648), is that 'in the perception of the population, HIV has become ... a normal part of life'. Additionally, according the UNAIDS 2010 Global Report, Uganda's 2009 incidence was estimated at 0.74: a slight increase from the 2001 statistic of 0.71 (UNAIDS, 2010). These results are a cause for concern, and indicate that population-wide changes in behaviour and an increase in risk inhibition must be stimulated immediately. The parallel that can be drawn is clear: the




**9.15** HIV prevalence as observed in rural villages in southwest Uganda (*source*: Adapted from Shafer et al. (2008))

successes of Museveni's government and Ugandan civil society in the late 1980s and early 1990s must be replicated in the years to come.

*Addressing culture: Why prevention makes sense* While it may be convenient to call for a shift in sexual culture, prevention requires an extremely difficult and massive upheaval of social structures. However, successful treatment is limited by the same cultural factors and cannot succeed until these are fixed at their foundations – foundations that lie at the heart of prevention. The push for a reinstatement of national behavioural movements is supported by the inefficacy of ART and HIV testing based on complex social factors that impede the progress of a treatment-dependent culture. Issues of gender and sexual inequality impact testing, as well as initiation and adherence to ART.

For instance, reluctance to finding out one's serostatus has much to do with an individual's other life goals, such as marriage and fertility, which may be impeded should he or she be identified as HIV positive. A notion that is often undervalued in health care is that although biological health is important, for the patient it does not always take full priority over all other areas of life (Hirsch, 2007). For those who do test positive or who have partners who do so, the desire to form a family may still override a concern for transmission of the disease. As Hirsch (2007) elucidates: 'Many HIV-negative women in serodiscordant couples feel compelled to risk the physical death of AIDS rather than the social death of childlessness.' Moreover, the nature of sexual health is inherently gendered, which impacts on the level of access that men and women share disproportionately. For example, it may be taboo for a woman even to be tested for HIV, because the community may take this to mean that she is overly promiscuous. A study by Turan and colleagues (2011) found that pregnant women in Kenya were afraid of being tested, for they anticipated that it would break up their relationship or cause them to lose friends. Furthermore, the way in which individuals actually use medicines is impacted upon by the communities in which they live and often by the local methods of healing. The use of ART, with its specific regimens and fairly detrimental side effects, may be counter-intuitive in light of cultural norms of healing (Peltzer et al., 2008).

Another important point relates to antiretrovirals causing disinhibition. Hirsch (2007) highlights that the problem is often far more deeply rooted than something as simple as disinhibition. She

notes that, for many, having sex is far less a personal choice than it is often deemed to be. The societal factors that often push people on ART to have sex, including inequality and poverty, are exacerbated by the fact that antiretrovirals make people seem healthy and thus sexually safe again. Furthermore, when speaking of men who return to the sexual network once ART has improved their physical health, it is imperative to remember that they are also returning to a social network that is demanded of men in Ugandan society.

Ultimately, although treatment is seemingly utopian, it must deal with the same complex nets of anthropology that hinder effective prevention. The national behavioural change movements that are needed are those that will emulate the past by reducing stigma, incorporating local culture, and simultaneously reworking the way in which people behave on a regular basis. In effect, these movements will open avenues for both prevention and treatment.

*Sexual network: A cradle for the epidemic* The sexual network is one of the most important factors in terms of the spread of HIV in sub-Saharan Africa. This aspect of transmission is deeply ingrained in the culture and impacts on behaviour, while at the same time asserting the success of tangible interventions such as condoms and ART as reinforcement. The sexual network is mainly perpetuated by men who have concurrent partnerships. Traditionally, women in Uganda were expected to remain monogamous, while for men having multiple sexual partners was a sign of status and wealth (Kirby, 2008: 6). According to a survey in 1988, up to 80 per cent of rural women reported their husbands having multiple sexual partners (Kirby, 2008: 5). Furthermore, studies have indicated that the single most important behavioural characteristic associated with incident HIV infection was the number of times that a person had sex with people whom they suspected or knew were having sex with others – that is, what is termed 'concurrency' (Guwatudde et al., 2009).

More difficult to confront because of even deeper cultural inherencies are the traditions in particular rural areas that lead to concurrency. These include: adolescent males who are circumcised 'cleansing' themselves by having sex; polygamy among Muslim Ugandans; father-in-laws having first sexual rights to a new bride; and wife-sharing, which was supposed to show respect and hospitality to brothers or guests in the home (Kirby, 2008: 6).

Furthermore, in interviews with *boda-boda* men, the most 'common adult sexual partner' in Uganda (a *boda-boda* being basically a cheap taxi in the form of a motorcycle), several aspects of concurrency were elucidated (Nyanzi et al., 2005). For instance, sexual activity, and specifically promiscuity, was noted as a sign of manhood, which was measured by the number of sexual partners, while polygamy was reported as being institutionalized within the Buganda and Islamic cultures. Surprisingly, there were even myths that abstinence causes severe disease.

Even more disheartening was the notion of fatalism that pervaded the dialogue: many said that it was inevitable that they would catch HIV, if not through sex, then through another avenue, such as transfusions or hospital injections. One man was quoted as saying, 'everybody knows that all *boda-boda* men are infected with the virus' (Nyanzi et al., 2005: 117). This fatalism reinforces the sexual network by giving people no incentive to leave it.

The sexual networks will not succumb to symptomatic interventions such as drugs and condoms. They cost nothing, unlike drugs, which cost billions of dollars, and will outlive all Western donor efforts that do not include support for behavioural change. Unfortunately, these networks are reinforced by condoms and drugs: without them, AIDS would ravage the networks, killing those most involved. Simply put, the more sexual partnerships in which an individual is engaged, the higher the chance that he or she has of being infected and, ultimately, the higher the chance him or her dying. Those who choose to remain outside these networks would survive. It is an ethical imperative not to let this be the mechanism that curbs HIV in Africa. With the current funding situation as dire as it is, drugs are unlikely to sustain the lives of infected people in the sexual networks for much longer. If drugs become unavailable and people fail to realize that HIV can no longer be maintained as a chronic condition, the result will be several million deaths – unless behavioural and educational movements are established immediately.

## Moving forward: The future of HIV/AIDS in Uganda

*Looking ahead: What Uganda needs* It will be critical to approach the epidemic efficiently and effectively. Identifying sociodemographic factors could be beneficial in efficiently predicting risky sexual behaviour

and targeting interventions accordingly. In South Africa, HIV-infected individuals who were urban, young, married (or cohabitating) people without casual sexual partners, and with higher education and income levels, were more likely to use condoms consistently (Lurie et al., 2008). Predictors of sexual partners for men included being from urban areas, having higher education and income levels, and having $CD_4$ counts higher than 200 cells/$mm^3$. Furthermore, studies have shown that the presence of alcohol resulted in significantly higher instances of unsafe sex, that women were more likely than men to report unsafe sex at last sexual encounter (most likely because of the gender inequity that prevents the negotiation of condom use), and that disclosure of serostatus is associated with lower rates of unsafe sex (Lurie et al., 2008).

Furthermore, effective movements will need to capitalize on catchy slogans and pop culture. Artists such as Phil Lutaya, who tried to reduce the stigma around AIDS in the late 1980s, are being followed by young Ugandans such as Barbara Kemigisa. Kemigisa is an activist and artist living with HIV in Kampala who has recorded several songs about hope, confidence, and surviving the epidemic (Voice of America, 2012). Current successful campaigns to reinstate behavioural change include the 'OneLove' campaign by the Uganda Health Marketing Group, which uses the slogan 'Get off the sexual network'. The group has made clear the notion of a large sexual network in which all Ugandans are linked by the fact that they have multiple partners, and their partners have multiple partners, who have multiple partners, and so on. This approach drives people to withdraw from a constrictive and harmful network of which they may not have realized they were a part. The notion of this sexual network has also been taken up by Robert Thornton in his 'One, One, One' campaign. Thornton's approach encourages people to stick to *one* partner at a time, to wait *one* month before starting sex with a new partner (because people are most infectious during their first month of HIV infection), and to choose sexual partners from *one* geographic area. As proposed by Epstein (2007), sexual networks in Africa are particularly well suited to sustaining the spread of HIV because of the long-term, concurrent nature of many partnerships. Thus these campaigns are addressing the epidemic at its heart.

*Glancing behind: Learning from past weaknesses* Uganda's early successes included a multisectoral approach that involved organizations

and citizens at the national, district, and community levels. The Uganda AIDS Commission (UAC) was supposed to be the body overseeing the several ministries and organizations involved. However, from the start, a number of reports on inefficiencies within the Commission were filed, indicating wastage of large amounts of money as well as poor coordination of policy (Kirby, 2008). Thus it is important to be cautious of overcentralized, overly bureaucratic systems; work on the ground should instead be directed by those on the ground themselves and within the target communities.

The Masaka intervention trial (MIT), a large five-year study attempting to isolate a behavioural intervention programme, can provide valuable insight: contrary to expectations, it did *not* reduce incidence (Quigley et al., 2004). The trial was one of Uganda's most promising interventions, based on an information, education, and communication model that aimed to raise awareness of HIV and to promote safer sexual behaviour and practices through a community-based approach. Information was disseminated in an engaging manner through village drama and video shows, as well as group meetings and one-on-one discussions with community educators.

Quigley and colleagues (2004: 2056) note that 'suboptimal implementation of the intervention ... insufficient coverage ... or the intervention being inappropriate for the setting' could have been reasons for its failure. Furthermore, it may be that the intervention effected behaviour change and reduced incidence in a small number of individuals, meaning that large-scale changes on the community level would have been imperceptible. Kinsman (2010: 168) elaborates that there was extremely limited awareness of the study among relevant district officials. The results of the intervention did show a lower incidence in women who attended at least one intervention event, as compared to those who had not attended any, but there was no behavioural mechanism for the effect (Quigley et al., 2004). The lessons from the study included the need to identify subgroups not reached by behavioural interventions, the need to correct for reporting bias that occurs with sexual behaviour data by utilizing biological markers such as seroconversion, and the realization that randomized controlled trials may be insufficient to explain the mechanisms that dictate why behavioural interventions do or do not succeed (Quigley et al., 2004).

Challenges to the actual implementation of behavioural change were also noted by a regional project in Uganda, Kenya, Tanzania, and

Ethiopia, undertaken by the African Medical Research Foundation, which worked with young people (Amuyunzu-Nyamongo et al., 1999). In this study, the situations that were found to lead to sexual intercourse were often informal and not readily conducive to use of a condom, or were too sudden to address by saying 'no'. Furthermore, many adults were wary of allowing children to be given sexual information, even though the average age of first sexual intercourse is 12–14 – and even younger in slums and poorer areas. As mentioned earlier, condom use and even condom promotion are impeded by large challenges, not least opposition among religious groups and a general cultural conservatism in the public arena regarding sex. Furthermore, some participants were noted as expressing the belief that 'everybody will die anyway' and such fatalism is difficult to expunge. Gender imbalances were pervasive too, with boys indicating that a girl who carried a condom would be seen as a prostitute or as having AIDS herself. Amuyunzu-Nyamongo and colleagues (1999) suggest that the debunking of rumours and myths surrounding such matters as condom use should be incorporated into marketing strategies; moreover, to address the sense of indestructibility found among these young people, having HIV-positive peers speak to them would be particularly meaningful. Working with religious organizations was also suggested as likely to be beneficial – but only those organizations that are progressive, and willing to acknowledge that abstinence and core behavioural changes are to be reached only via more piecemeal approaches first, including condom use.

### Anecdotal evidence: Homegrown strategy

To determine the vision of Uganda's future AIDS policy among the several entities involved, a number of interviews were conducted with members of leadings NGOs and care facilities, including TASO, the JCRC, the PEPFAR team at the US Embassy, and the AIDS Control Programme in the Ministry of Health.

Godfrey Musaaya, TASO regional manager in the northern Gulu district, indicated in a personal interview that there was at TASO a sense of frustration with the government's neglect of health as one of Uganda's priorities (interview with the author, July 2010). Currently, the government of Uganda does not meet the requirements under the 2001 Abuja Declaration, which called for African countries to allocate at least 15 per cent of their budgets to the health sector (Uganda currently allocates 9 per cent), and it has declared that it does not have

enough money to meet this promise (Womakuyu, 2010). The failure to meet this goal, along with instances of corruption with regards to aid money, has heavily contributed to Ugandan aid being cut (Nyanzi, 2011).

In another personal interview, Dr Elizabeth Namagale, head of ART Rollout at the Ministry of Health's AIDS Control Programme, suggested that the Ugandan health sector is unlikely to be able to supplement the lost PEPFAR funding and lamented that Ugandans had developed a mentality that 'drugs should be free', which will certainly prove disastrous given the funding dilemma (interview with the author, July 2010). As of February 2012, Uganda had also suffered severe funding cuts from the Global Fund, receiving the least among the East African countries: only $300 million compared to $1.2 billion in Ethiopia and $1 billion in Tanzania (*The Monitor*, 2012).

According to a personal interview with a TASO medical coordinator in Mulago Hospital, Kampala, smaller clinics in the area had been sending their waiting-list patients to TASO because of the drug supply shortage (interview with the author, July 2010). She explained the need to use fear to promote prevention: staff are now saying to family members of patients, 'If you get the disease, you will die.' The coordinator described it as 'reverting back to mechanisms when drugs actually weren't available', and also added that success in treatment and behavioural change is 'largely based on perceptions'. This method of fear arousal is parallel to the movements in the 1990s identified by Halperin (2006).

In another personal interview, Nicholas Mugumya, the deputy director of TASO, said that he felt that while the Ministry of Health could allocate more money to HIV, it was impossible to expect the Ministry to sustain the health sector of the country (interview with the author, July 2010). Mugumya also commented that most people were unaware that slots for ART were quickly diminishing – a fact that, if known, would surely facilitate changes in sexual behaviour.

Deputy PEPFAR Coordinator of Uganda Reuben Haylett recognized Uganda as having several internationally recognized figures and a very strong civil society, as compared to a weaker base of human rights activists and a government that was weakening under the weight of corruption and scandals (interview with the author, July 2010). He further commented that small, unpublished surveys showed that while knowledge of HIV-related material is relatively good, risk-taking

behaviours have become significantly worse as access to testing and ART has increased. On both a societal and individual level, then, the scenario today is the exact opposite of that in the late 1980s.

## Final thoughts: Case for a socio-behavioural movement

With all of this in mind, what is Uganda's path forward in battling the HIV epidemic? While it may be infeasible for Uganda to assume the costs of programmes such as PEPFAR and the Global Fund, it may not need to do so completely. Because donor funding is approaching flatlined levels, incidence must be brought down quickly, because maintenance of a non-zero incidence would require a growth in the amount of funding received. Assuming that funding levels are steady over the next few years, Uganda must take the following steps.

First, a move towards meeting requirements under the Abuja Declaration is critical. As of 2014, Uganda is allocating only 8 per cent of its national budget to the healthcare sector (State House of Uganda, 2014) – an amount that has been in steady decline since 2010 (with around 9 per cent allocated at that time) and is far from the 15 per cent proposed at the Abuja Declaration. Uganda therefore needs to allocate a greater proportion of its national budget to health.

In practice, this means funding both treatment and prevention. However, more specifically, this means a replication of the societal change that took place in the late 1980s and throughout the early 1990s. This change is to be fuelled by a mobilization of the masses, including teachers in schools, religious leaders in churches and mosques, figures in the film and music industries, children and youths, traditional healers and village heads, local and national politicians, people living with HIV, and (first and foremost) President Museveni and the government who first spearheaded this effort twenty years earlier. Mr James Kigozi, spokesperson for the Uganda AIDS Commission, commented that donor largesse has made Uganda complacent and that HIV is no longer receiving the government attention that it did in the past because of the 'tremendous donor support' (Rukmundo and Lirri, 2010). The reality of the donor situation must therefore be made publicly known, and it must be reinforced that while treatment will continue for those infected, funding cannot accommodate the growing number of HIV-positive persons that it has over the past few years. Moreover, the culture of dependency on free drugs and the expectation that free drugs will always stock the local clinics must be replaced with

the harsh reality of personal responsibility for their own sexual actions among those who are HIV negative or who have unknown serostatus.

Additionally, as emerged from the personal interviews with TASO managers and directors, it is clear that the government must abandon its traditions of excessive bureaucracy, instead providing oversight and decentralization in its efforts for both treatment and prevention. Following the success of TASO, the Ministry of Health must find ways in which to engage and work with civil society adopting a bottom-up approach. Empowering local organizations and local leaders is the key to social mobilization and culture-shifting. Many successful activities have been coordinated by NGOs located within the communities and these should be capitalized upon, just as they were in the 1990s.

The corruption and lack of transparency within the government must also be addressed. Scandals such as that relating to the Global Fund in 2005 must be avoided, for they exploit the dire political strife that has made donor aid difficult to secure and, more importantly, they dishearten the public and challenge the legitimacy of leaders (*Washington Times*, 2006). For those who are HIV-positive, the continuation of HAART should be coupled with public demonstrations and education about what a life with HIV actually entails for others. People living with HIV/AIDS are bound to be the most influential in any behavioural movement: they will be the most credible in dispelling myths about HIV and ART, and will be able to expose the realities of how difficult adhering to drug regimens is, how physically and mentally taxing antiretrovirals are on the body, and how personal sexual choice is one's only means of overcoming the epidemic.

This raises the more complex notion of addressing the culture that bars the prevention of HIV from being as simple a matter as exercising personal sexual choice – that is, the inequality, poverty, and issues of gender and discrimination that make sex far more than a straightforward physical act. It is absolutely crucial to begin by incorporating messages within cultural frameworks. The sexual networks must be counteracted through culturally tuned educational movements such as the Uganda Health Marketing Group's 'OneLove' and Robert Thornton's 'One, One, One'. For example, the OneLove campaign used billboards that portrayed a child asking his mother and father to please get off the sexual network and enjoy a happy life. Smart, culturally sensitive messages such as these are bound to succeed. Moreover, by working with leaders within communities – such as heads of villages and traditional

medicinal healers – the cultures of structural violence may be mitigated and eventually eliminated. Target groups that have an influence on public life, such as *boda-boda* men, should also be identified and micro-mobilized as starting points.

Ultimately, fear arousal may be the catalyst that any successful behavioural change movement will need, and this may be promoted both formally and informally. As was the case in TASO Mulago, family members and HIV-negative people may have to be warned that if they contract HIV, they are likely to die. Educational demonstrations should be provided free to the public, with graphic images or documentation of the ill effects of HIV on the body, to recreate a level of concern regarding HIV that, it is claimed, has been lost (Nyanzi-Wakholi et al., 2009). Of course, this must be balanced against an attitude of fatalism that itself allows individuals to abdicate personal responsibility, meaning that a careful mediation of messages must be established. It will also be important to explain the fact that treatment is available for those who find out their serostatus (at time of writing, at least), so as to increase testing willingness among those with unknown serostatus – for prevention is useless without the promise of treatment for those who are already infected.

The replication of Uganda's past successes may be hindered by the unstable donor politics that have already engendered a level of distrust among the populace. As mentioned in interviews conducted by Cohen and Tate (2005), the condom recall in 2004 led to confusion about whether condoms worked at all and reinvigorated myths that condoms were actually a cause of HIV or conspiracy theories of an ulterior motive among the US donors. Another sudden shift – from treatment to abstinence – will perhaps cause a similar reaction: people may question whether ART was effective at all. If not carefully framed, this may be counterproductive and future antiretroviral regimens may not be taken seriously by misinformed masses. Public transparency of the Ugandan government's underfunding of the health sector must be made clear and the shifting HIV strategy must be linked to the economic downturn, not to a message that behavioural change is necessarily better than ART. The reality is that *both* are needed: they are complementary to one another, as evidenced in the successful sexual behaviour monitoring programmes linked with treatment in clinics, and they are likely, in combination, to be a solution to the spread of HIV in sub-Saharan Africa (Bunnell et al., 2006). Unfortunately, however, when ART is

withdrawn, a behavioural change movement will become that much more critical.

Lastly, the government must avoid creating and propelling stigma around people living with HIV/AIDS. The HIV Prevention and Control Act, passed by the Ugandan Parliament in 2014, serves to criminalize those who intentionally transmit HIV/AIDS, and mandates testing for pregnant women and their partners (Human Rights Watch, 2014). While this law is meant to curtail the spread of illness, it does so in a way that fails to promote partnership between the government and the public, and which may actually serve to scare people further away from testing. Laws should instead be sensitive to the reality that HIV continues to be stigmatized in the African – and, in fact, the global – context.

Uganda's future success in changing culture and behaviour is not a pipe dream. The country that once served as a beacon of hope in the fight against AIDS may yet do so again in the face of the tragedy that is both donor politics and the global economic crisis. This unfortunate combination of politics and economics is quickly becoming the largest challenge to the fight against HIV/AIDS, and is a direct call for a united and mobilized African continent in the coming years. Hopefully, in a not-too-distant future, Dr Goosby will be acclaiming the 'Kampala situation' as an example that the epidemic can be curtailed by people's capacity to change their behaviours and, as a result, to change the world.

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# 10 | HEALTH IMPACT FUND: ALIGNING INCENTIVES

*Thomas Pogge*[1]

The pharmaceutical industry has a poor reputation around the world. This is surprising because its products have a much more positive impact than those of other widely disliked industries, such as arms, coal, and tobacco. Much public opinion about the pharmaceutical industry makes it sound as though its leaders are especially immoral in comparison to other captains of industry. This chapter is based on a different hypothesis: the pharmaceutical industry is widely regarded as especially immoral because it is placed under rules that create exceptionally sharp tensions between the objectives of acting morally and making money. These tensions often lead pharmaceutical firms to act in ways that are morally regrettable and, as understood by the public, these tensions also sustain the perception that these firms must be having a poor moral record, especially when they are thriving economically. Both problems can be much diminished by reducing the tension. This requires a reform of the way in which pharmaceutical companies are rewarded for their innovative work. We should institute an incentive and reward system that is better aligned with the key moral purpose of the pharmaceutical industry: to promote progress in human health. We should place pharmaceutical firms under rules that are so designed that these firms will do well by doing good.

To explore what such rules might look like, we can begin with three obvious desiderata that would make a system for the provision of medicines highly effective in improving human health. In light of these facts, a reasonable system for the provision of medicines under modern conditions ought to display the following three features.

1 *Access* Given that medicines, once they are known, can be mass produced at a marginal cost that is very small relative to the human and economic harms that they forestall, any important existing medicine should be accessible to all patients who need it, regardless of their income and nationality.

2 *Tracking* Investments in research and development (R&D) should always be concentrated on those innovation efforts from which the most cost-effective health gains can be expected.
3 *Efficiency* The entire system should be made cost-effective by avoiding deadweight losses and by ensuring that the money spent on paying for medicines is used to sustain the R&D, as well as the manufacture and distribution, of medicines.

Currently, most basic pharmaceutical research is done with public funds at universities and governmental institutions. The later stages of development and testing are typically funded by pharmaceutical companies. When such firms begin work on a promising compound, they patent it around the world, thereby securing a temporary monopoly on its manufacture and sale once it is allowed on the market. During this period of market exclusivity, companies can drastically mark up the price of their medicine, selling it at many times the average manufacturing and distribution cost. At the end of the period, competing generic producers usually make the medicine available at much lower prices.

This system for encouraging and rewarding pharmaceutical innovators has been extended worldwide and made uniform under the 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS),[2] which the United States, with other affluent countries, imposed as a condition for membership in the World Trade Organization (WTO). The Agreement entitles an innovator firm to protect new medicines with twenty-year *product patents*, which allow it to veto the manufacture and sale of patented medicines, and then to sell them at prices far above the average manufacturing and distribution cost. Product patents can be contrasted with *process patents*, which allow the patent holder to veto only a specific way of making the medicine. To be TRIPS-compliant, countries had to phase out process patents in favour of twenty-year product patents (WHO, 2011). A key example of this transition is India, the leading supplier of medicines in the less-developed countries (LDCs). Under TRIPS, India was required to replace its process patents with twenty-year product patents by 1 January 2005; India complied by passing appropriate national legislation in December 2004.

The next three sections demonstrate that the TRIPS regime does poorly in regard to the three features that a system for the provision of medicines ought to possess under modern conditions.

## Access

Progress has two essential components: *innovation* (creation, invention, discovery) and *diffusion* (dissemination, uptake). A key problem with the present system is that it rewards innovation with very large mark-ups that greatly impede diffusion. As a result of high failure rates and the high costs of clinical trials, developing a new safe and effective medicine is very expensive. Under the TRIPS regime, the only way in which pharmaceutical innovators can recover such large R&D expenses and make a profit is through mark-ups during their period of market exclusivity.

A firm will try to price its product so as to maximize its profit, which is the mark-up multiplied by the sales volume. The profit-maximizing price level depends on the demand curve, which plots the sales volume as a (typically decreasing) function of the sales price. Important medicines inspire a strong willingness to pay a high price, but ability to pay is, of course, very unequally distributed among households and national health systems. Table 10.1 shows the 2008 distribution of global household income.[3]

Table 10.1 shows at a glance that making patented medicines affordable to the world's poor would require massive price reductions that could not be fully compensated through larger sales volumes. In fact, a firm choosing a single price for the global market would rarely find it profitable to make an important medicine affordable even to the third decile of humanity. Certainly, firms have some limited opportunities to increase their profits by charging differential prices across countries.[4] But even intra-national inequalities are nowadays so large that, in many

TABLE 10.1 Distribution of global household income, 2008

| Segment of world population | Share of 2008 global household income | Average monthly per capita income (US$) |
|---|---|---|
| Richest decile | 66.546% | $2,522.98 |
| Second decile | 18.342% | $695.41 |
| Third decile | 6.340% | $240.37 |
| Fourth decile | 3.442% | $130.50 |
| Fifth decile | 1.993% | $75.56 |
| Third quarter | 2.403% | $36.44 |
| Poorest quarter | 0.934% | $14.16 |

LDCs, an important medicine's domestically profit-maximizing sales price will place it out of reach of the majority of the country's population (Flynn et al., 2009). In so far as existing institutional arrangements are unjust on account of the excessive economic inequalities that they engender, the poor suffer a double penalty, because the impact of their excessively low incomes is compounded by higher prices for vitally important medicines. Given high income inequality, the TRIPS regime foreseeably guides pharmaceutical innovators to mark up the price of their patented products to twenty, fifty, or even 100 times the marginal cost of production.

It is not hard to understand why the wealthier countries have been pressing – and continue to press – the LDCs to extend market exclusivity and to strengthen enforcement efforts.[5] Thanks to their large capital advantage, firms in the wealthier countries are leading innovators and eager to profit from their innovations through sales to affluent people in the developing world. But the moral downside of these efforts is evident as well: under the TRIPS regime, poor people are excluded from many advanced medicines that, without TRIPS, would have been available to them as cheap generics. As a side effect of ensuring that well-off people in the developing world, as well as populations of the affluent countries, pay for pharmaceutical innovation in the form of hefty mark-ups, the TRIPS regime causes grave harms and deaths among poor people in the developing world who cannot afford these high prices now charged for patented medicines.

Proponents of broad and vigorously enforced intellectual property rights often defend them in strong moral language, levelling accusations of theft, counterfeiting, and piracy against generic firms, and also against those countries that they view as insufficiently protective of intellectual property. This strong language conveys the idea that the unlicensed copying of an innovation is a moral crime that any decent legal system must criminalize and suppress. But, thus far, no sound defence of this loud claim has been provided. The crucial move is evidently to liken intellectual property to physical property: just as an owner of physical property must be free to do with it as he or she pleases, so an owner of intellectual property ought to be free to dispose of it as he or she sees fit. But this appealing analogy is difficult to support. The difficulty lies in explaining how one owner, by configuring his or her physical property in a certain way, can unilaterally make it wrong for another owner to do likewise. Suppose that I have made some new medically effective

molecules from chemicals that I justly own: why should this act morally entitle me – unilaterally (that is, without any voluntary undertaking on your part) – to divest you of your right to convert chemicals that you justly own into molecules of the same kind? On reflection, the invocation of physical property rights not merely fails to support, but actually undermines, the moral case for intellectual property rights.[6]

Certainly, there is the pragmatic argument that broad and vigorously enforced patents do more good than harm in the long run by stimulating innovations that will eventually also benefit the poor. This argument may well show that the current TRIPS regime is morally preferable to a system under which pharmaceutical innovation is not rewarded at all. But to use this argument in defence of the TRIPS regime is to appeal to a false dichotomy. As we will see, pharmaceutical innovation can be incentivized through rewards other than patent-protected mark-ups in ways that do not exclude poor patients.

## Tracking

Existing massive income inequalities also lead pharmaceutical innovators to prioritize even minor ailments of the affluent over diseases concentrated among the poor. Innovators can make large profits from a new remedy against hair loss, erectile dysfunction, or minor skin ailments. But it is difficult or impossible to profit from a new remedy against Dengue, pneumonia, or tuberculosis, because the innovator is forced to choose between accepting either a tiny mark-up or a tiny sales volume. This distortion of research incentives leads to the so-called 10–90 gap: only 10 per cent of pharmaceutical R&D expenditure worldwide is focused on diseases that account for 90 per cent of the global burden of disease, and vice versa – that is, 90 per cent of pharmaceutical R&D expenditure worldwide is focused on diseases that account for only 10 per cent of the global burden of disease. The accuracy of these figures is contested and difficult to assess in the absence of reliable data about the actual R&D spending of pharmaceutical companies. But it is indisputable that the composition of the disease burden differs substantially across global income groups and that many serious diseases that do great damage to poor populations are very rare in the richest quarter of humanity, which drives the pharmaceutical innovation efforts. The current TRIPS regime leads profit-oriented innovators to neglect such diseases even when additional research on them would deliver disproportionately cost-effective health gains.

## Efficiency

Primarily affecting poor and marginalized people, the access and tracking problems are unlikely, by themselves, to motivate successful reform efforts. It is therefore important to add that the TRIPS regime is not doing well in terms of serving the interests of affluent populations either.

Humanity spends close to US$1 trillion on medicines each year: about 1.2 per cent of world income. Is this money well spent? Data for answering this question are sparse. While new medicines must pass through elaborate clinical trials before they are allowed on the market, there is little systematic study of their subsequent use and impact. We do not know to what extent medicine dispensed (a) is actually used, (b) while it still has its potency, (c) in accordance with the correct instructions, (d) by patients for whom it is indicated, and (e) whose condition and circumstances allow them to benefit from it. Given the magnitude of the expenditure, we ought to learn more. But we know enough to conclude that there are huge inefficiencies in the current system.

The current TRIPS regime predictably creates much unneeded innovation. When one company pioneers a genuinely new type of medicine, other firms scramble to introduce similar drugs. The availability of more than one medicine in a therapeutic class can be beneficial because physiological variations among patients affect how well they respond to specific treatments. But this benefit rapidly declines as additional 'me too' drugs are introduced: the ninth cholesterol-lowering product, for example, adds little value for patients. It can, however, add much value to the bottom line of the company introducing it, especially because competition among patented medicines rarely results in meaningful price reductions.

This leads to four important *in*efficiencies.

1. The incentives for copycat innovations are too strong: too much is spent on developing and introducing me-too drugs that barely improve our pharmaceutical arsenal.
2. The incentives for genuine breakthrough innovations are too weak: the profits of the first-in-class innovator are predictably decimated as me-too competitors gain market share at its expense.[7]
3. Marketing battles among therapeutically similar high-margin drugs are extremely costly and represent a major component of total industry expenditures.

4 Such marketing often has adverse effects, inappropriately influencing doctors and patients to prefer a suboptimal product, or one that does not benefit the patient at all.

The TRIPS regime also sustains three important biases that cause additional inefficiencies. One bias is against medicines likely to come into wide use only after their patent has expired. To prevent the build-up of drug resistance, medical practitioners use certain advanced treatments only on patients who do not respond to the usual 'first-line' regimens. It is extremely important to have such last-resort treatments available (for drug-resistant tuberculosis, for instance, which is infectious and unresponsive to any of the standard treatments). But the resulting anaemic outlook for profits – dependent as they are on sales volume prior to patent expiration – provides only weak incentives for developing such drugs.

The second bias favours maintenance drugs and disfavours vaccines. The former are to be taken continuously in order to relieve patients' symptoms and perhaps to prolong their lives. They tend to earn much more for their patentees than do cures of similar therapeutic benefit. Preventative medicines (such as vaccines) tend to earn even less, because they are typically bought by large purchasers (such as states, international agencies, or non-governmental organizations – that is, NGOs) who can press for substantial reductions in the mark-up. This bias not only influences the approach that pharmaceutical companies prefer to take against some given disease, but also affects even more profoundly their research priorities: in favour of diseases for which research is likely to yield a maintenance drug and against diseases for which a vaccine or cure is the likely outcome.

Already discussed in relation to 'Tracking', the third bias disfavours research on diseases concentrated among the poor.

Poor people are also the main victims of two further inefficiencies engendered by monopolies. Owing to the large gap between price and marginal manufacturing cost, a patentee loses many profitable sales to patients who are willing and able to pay more than the marginal cost of manufacture and distribution, but not the much higher monopoly price. The patent-holding firm may wish to sell to the poor at lower prices, but if it were to serve the poor more cheaply, then many of the more affluent would also find ways in which to buy at lower prices. Thus the poor are excluded and humanity loses mutually beneficial sales. The monetary value of this loss can be estimated. Suppose a patent holder is selling

a medicine at the profit-maximizing price $r$, while its marginal cost of production is $m$. And consider a potential buyer who is willing and able to pay up to $p$ for the product (with $m<p<r$). Here, buyer and seller would find it mutually beneficial to transact at any price $n$ between $m$ and $p$. Because this transaction does not come about, the frustrated buyer incurs a loss of $p-n$ and the frustrated seller incurs a loss of $n-m$. These two losses total $p-m$. Adding up all forgone mutually beneficial sales of all patented medicines, these so-called deadweight losses are likely to be in the hundreds of billions annually. And, of course, the problem is not only dead money, but also dead people: millions of poor patients avoidably die or suffer because generic manufacturers are no longer able to serve and save them under the tight patent rules that affluent states have entrenched as a condition of WTO membership.

When life-saving medicines are known to be available at huge mark-ups, the desperation of poorer patients creates illegal supply. Some such illegal products are bioequivalent to the genuine article, but most are not. Common in LDCs are counterfeit products that contain a much-diluted dose of the genuine medicine. The product makes patients feel a little better (so they buy more) – but it may have the pernicious effect of allowing the disease to survive and to adapt to the medicine. Diluted counterfeits accelerate the development of drug-resistant strains of the target disease, which, in the case of communicable diseases, endanger us all.

Patent litigation constitutes a tenth major inefficiency. Innovators patent their discoveries in many countries, monitor all of these jurisdictions for possible infringements, and then fight protracted legal battles with other innovators and especially with generic suppliers. This activity has very little social value. But it sharply reduces the profits of pharmaceutical companies – as does the extensive lobbying that these firms undertake toward defending and expanding their patenting and other privileges. Countless billions are wasted annually on these rent-seeking activities, which are funded out of medicine sales, but contribute nothing to human health.

## A way forward

The great inefficiencies of the TRIPS regime are well known, as are the burdens that it places on the poor – but what choice do we have? If high mark-ups protected by patents were to be discontinued, most commercial pharmaceutical R&D would cease – and, in any case, there

is no chance in the WTO for the unanimous decisions that any revision of TRIPS would presuppose.

Yet we do have a choice – and it's a good one: we can create the Health Impact Fund as a complement to the TRIPS regime. The HIF would be a pay-for-performance mechanism that would offer innovators the option – but no obligation – to register any new medicine or, under certain conditions, also a traditional medicine or a new use of an existing medicine. By registering a product, the innovator would agree to make it available, during its first decade on the market, wherever it is needed at no more than the lowest feasible cost of manufacture and distribution (at which we will look shortly). The innovator would further commit to allowing, at no charge, generic manufacture and distribution afterwards.

In exchange, the registrant would receive, during those ten years, annual reward payments based on its product's health impact.[8] Each reward payment would be part of a large annual payout – initially, some $6 billion, perhaps – with every registered product receiving a share equal to its share of the assessed health impact of all HIF-registered products in the relevant year.[9] The amount of $6 billion is only 0.6 per cent of current annual global spending on medicines, but its health impact per dollar would be vastly larger. Funded at this level, the HIF would be expected to support between twenty and thirty new medicines at any given time, with two or three entering and two or three expiring each year.[10] If all countries were to participate, a contribution of 0.007 per cent of gross national income would suffice to reach the initial $6 billion per annum. Realistically, however, a higher rate would be necessary. At a contribution rate of 0.03 per cent of gross national income, the HIF would need only the support of China plus the United States, or of Brazil plus the European Union, to commence operations. Once the HIF were working smoothly, its annual reward pools could be scaled up to attract an increasing share of new medicines.

The HIF would greatly mitigate the greatest injustice of the current system by limiting the price of any registered medicine to the lowest feasible cost of manufacture and distribution. This price ceiling would enable humanity's poor majority to gain immediate access to the fruits of pharmaceutical innovation – either through their own funds or through national health systems, NGOs, international agencies, or insurance programmes (all of which would be able to serve more patients more cheaply thanks to much lower medicine prices). In addition, the HIF

would foster the development of new high-impact medicines against the formerly neglected diseases of the poor. As a further bonus, the HIF would also motivate registrants to ensure that their products are widely available, perhaps even below the price ceiling, and that they are competently prescribed and optimally used. Registrants would be rewarded not for merely selling their innovative products, but also for making them effective toward better health around the world.

If some pharmaceutical R&D were financed through HIF rewards, most of the cost (allocated among countries in proportion to their gross national income) would be borne by affluent populations and people – as it is today. But by funding innovation through health impact incentives rather than through patent-protected mark-ups, affluent populations would avoid the need to exclude the poor. Including the poor in this way costs the affluent nothing, because the cost of manufacturing additional doses is covered by the sales price. The expansion of production may even benefit the affluent through lower unit costs and generally better global health.

The HIF would also benefit the affluent by changing profoundly the marketing and promotion of new medicines. The HIF would pay nothing for the creation or promotion of a 'me-too' product that merely takes market share from a competitor's earlier no-less-effective medicine. And even with a highly superior product, a HIF registrant would make no profit from the sale of its medicine as such, but would profit only in so far as this medicine were actually made effective toward improving human health. Thanks to this new incentive, all patients would be more likely to receive medicines that would actually improve their condition.

## Secure funding

Before registering a new medicine with the HIF, a pharmaceutical innovator will wonder whether the promised rewards can really be counted upon. Absent convincing assurance, the HIF will elicit few or no product registrations – or so one might worry (Buchanan et al., 2011).

There is an obvious partial solution to this problem: the contracts offered by the HIF should entitle the innovator to withdraw the registration of its product as soon as the HIF fails to meet its obligations, for example because it lacks the funding necessary to underwrite reward pools of the advertised minimum size. With this escape option,

registrants have little to lose if the advertised reward pools do not materialize – and much to gain, because the more reluctant other innovators are to register products with the HIF, the more profitable registration will be. The HIF, after all, promises to distribute pools of $6 billion each year and to include each registered product in ten such distributions. Therefore, by being the sole registrant or one of a few, an innovator can earn very substantial amounts (up to $60 billion on a single product),[11] while also enjoying the assurance that, should the flow of HIF money ever run dry, it can easily switch its product back to the mark-up track. Given these conditions, the HIF would certainly attract product registrations.

This conclusion is further supported by the existence of innovators – notably so-called public–private partnerships (PPPs) or product development partnerships (PDPs) – with standing commitments against charging high prices. An organization such as the Drugs for Neglected Diseases Initiative (DNDi), for example, would have little reason not to register any of its innovations: it has no interest in marking up its product in any case. And it would have strong reasons in favour of registration, because any reward payments that it received from the HIF would facilitate work to which it is deeply committed: the development of additional new medicines for neglected diseases.

Certainly, the escape option described is only a partial solution to the assurance problem, applicable to medicines that commercial innovators develop regardless of the HIF's existence. Estimating that one of its products can earn more on the HIF track than on the conventional mark-up track, an innovator could register this product with the HIF confident that if the HIF were not to pay up for any reason, the product could be switched over to the mark-up track. This is only a partial solution, because the HIF is meant to encourage innovators not only to forgo mark-ups on some of the more important new medicines that they are developing anyway, but also to conceive and develop new medicines that they would not have found it profitable to pursue for the sake of patent-protected mark-ups. In particular, the HIF is meant to encourage neglected-disease research that, absent the HIF, would not be undertaken at all. To stimulate such research, the HIF must inspire long-term confidence because pharmaceutical innovation takes time: candidate medicines must go through years of testing before they are allowed on the market, and then another ten years will go by until an R&D effort will have been fully rewarded. Given these substantial

lags, the HIF will encourage additional innovation only if its annual reward pools are judged secure far into the future. This is problematic because it is not easy to make credible financial promises that extend twenty years into the future – even for governments, which are typically not authorized to commit their successor's tax revenues in legally binding ways. Is there nonetheless a sufficiently credible agreement that governments might be willing and able to execute?

To meet this challenge, agreement to fund the HIF should take the form of an international treaty that clearly specifies, inter alia, each country's obligations, sanctions for non-compliance, and procedures for exit (Hollis and Pogge, 2008: ch. 5). This agreement should allocate burdens in such a way that all countries can expect, over time, to be net beneficiaries, or at least not to be significant net losers. When these two conditions are met, international agreements work quite well, as is shown by examples such as the UN Convention on Contracts for the International Sale of Goods (CISG),[12] WTO Agreement on Technical Barriers to Trade (TBT),[13] International Telecommunications Convention,[14] Convention on International Civil Aviation,[15] International Air Services Transit Agreement,[16] International Convention for the Safety of Life at Sea (SOLAS),[17] International Convention for the Prevention of Pollution from Ships (MARPOL),[18] Montreal Protocol on Substances That Deplete the Ozone Layer,[19] Antarctic Treaty System,[20] and World Health Organization (WHO) Framework Convention on Tobacco Control.[21]

Mindful of such successful examples, let us explore whether the proposed HIF can be shaped to meet these two conditions. Suppose a national government, G, considers three possible outcomes: (a) the HIF is created, backed by a fully credible treaty to which G is a party; (b) the HIF is created with some start-up funds and pledges by G and other governments; or (c) the HIF does not come into existence at all (the status quo). It is fairly clear that G will find option (b) inferior to option (c). Relying on pledges only, the agreement might unravel and the start-up expenses would then be lost. Even if the agreement based on pledges were to last, it would be disadvantageous for governments, making them overpay for innovation. They would be overpaying because pharmaceutical innovators, when considering a research project that would not be profitable on the mark-up track, would naturally discount monies allocated to future HIF pools by the probability that these monies would not actually be forthcoming. This

would substantially reduce the number of such projects that innovators would pursue and thereby increase the HIF reward rate. The greater doubt lies in whether governments will actually stick to their pledges the more money that they end up paying per unit of health impact. This is analogous to what goes on in credit markets: the more doubt there is about whether some would-be borrower will repay, the higher the rate of interest that this borrower will have to pay to find a willing lender. It is thus collectively advantageous for the funding partners underwriting the HIF, much as it is advantageous for borrowers in the credit markets, to make its promised future payouts as ironclad as they can be. The more credible the governments' commitments are, the less they will end up paying, through the HIF, per unit of health impact.

Can a government make ironclad commitments if it chooses? Simply put: yes. A government can issue and then gift to the HIF long-maturity or perpetual bonds[22] backed by its full faith and credit, for example, or it can make an interest-free loan to enable the HIF to buy such bonds. Interest on these bonds could be inflation-adjusted or pegged to the country's gross national income to ensure that the value of the annual reward pools does not decline over time. If these bonds were freely tradable, the HIF might sell some of them to create a diversified endowment, managed to maintain its real value over time and to generate a stable income stream that would cover at least a substantial portion of the annual reward pools. The HIF endowment could accept contributions also from international and NGOs, foundations, corporations, individuals, and estates. It would follow the example of private US universities, which have enjoyed excellent credit ratings despite many adversities and have grown their endowments while funding up to about a third of their operating budgets from endowment income.

Another solution is a dedicated international tax on financial transactions, for instance, or on pollution. Such taxes would be beneficial on the revenue side by moderating speculative excesses in financial markets or by slowing greenhouse gas emissions. And they could be useful on the expenditure side as well – by funding the HIF, for example. A similar proposal is that of an alternative minimum tax for multinational corporations, which often manage to pay few or no taxes on their worldwide profit. Various proposed international taxes would each raise in the tens of billions of dollars annually. Commencing with an annual budget of $6 billion, the HIF would consume only a fraction of such a revenue stream.[23]

### Health Impact Fund in relation to other global health initiatives

The initiative for, and design of, the HIF owe much to other global health initiatives, such as the Global Fund, the patent pool initiated by UNITAID, and advance market commitments. The HIF would nonetheless play a unique role that cannot be filled as well by these other mechanisms.

The initiatives mentioned all fit the label 'development aid': predominantly funded by the affluent, they are designed to benefit poor populations. By contrast, the HIF would be jointly funded by rich and poor countries, with each funding partner contributing according to its gross national income. The HIF would also benefit rich and poor populations alike through lower drug prices, and by stimulating much greater efforts toward ensuring that medicines are directed to the right patients and used to optimal effect.

While the Global Fund supports large purchases of medicines, it does not aim to incentivize innovation. One might say that its purchases do have an incentive effect: innovators can now expect that if they develop a high-impact medicine for AIDS, tuberculosis, or malaria, they will earn money from mark-ups on sales supported by the Global Fund in behalf of poor patients. This is true, but the HIF would provide more suitable incentives because its funding would be locked in for a longer time period and also because it would offer rewards based not on how much a new product can achieve, but on how much *more* it *does* achieve than the current standard of care enjoyed by the various patient groups. The present system provides large rewards for a new medicine that is only slightly better than the treatment that patients would otherwise have had: as buyers (including the Global Fund) switch over to the better medicine, this medicine now appropriates all, or nearly all, the profits of its predecessor. The HIF would reward a new medicine only for the improvement that it brings relative to the treatment that patients would otherwise have had. In this way, the HIF would incentivize innovators to concentrate their efforts on those areas in which they can realize the largest *incremental* health benefits. This is not a criticism of the Global Fund, which was not designed to stimulate innovation – but it shows how the HIF would usefully complement the Global Fund by rewarding more accurately the innovation component of new drugs. The Global Fund could then purchase these new drugs without mark-up. The HIF has been designed in

collaboration with the Global Fund, which may end up hosting the HIF in Geneva much as it is now hosting the Affordable Medicines Facility – malaria (AMFm).

UNITAID has created a patent pool intended to facilitate licensing by pharmaceutical innovators to generic firms, initially limited to HIV/AIDS medicines in specified developing countries and improving access to existing or slightly modified HIV/AIDS treatments. So far, this improvement has typically been tightly limited, excluding the populations of many low- and middle-income countries. The benefits of this pool are likely, over time, to be extended to more countries and more therapies. But the patent pool does not (and is not meant to) stimulate pharmaceutical R&D and therefore does not obviate the need for the HIF. Conversely, the HIF does not obviate the need for the patent pool: even with the HIF in operation, UNITAID's patent pool would continue to be useful for facilitating access by poor people to products unregistered with the HIF, including combination therapies.

Similar points apply to compulsory licensing, as provided for in TRIPS Article 31 and clarified in the 2001 Doha Declaration. Under TRIPS, governments may compel a patentee to license a domestic company to manufacture and sell its medicine, in exchange for a (typically small) licensing fee, the rate of which is set by the government and which the generic manufacturer pays to the patentee. The point of compulsory licences is to enable governments to make important new medicines accessible to their populations. Although compulsory licences are perfectly legal, they have been issued only rarely – mainly because pharmaceutical companies lobby strongly against them, often by calling upon the support of agencies of their own government (such as the Office of the US Trade Representative, which can inflict serious penalties upon countries deemed to be hostile to US economic interests presented as free trade principles). Compulsory licences have given poor patients access to urgently needed medicines – and they might come to do so on a grander scale if LDCs were to combine more effectively against political pressures from the leading pharmaceutical innovator states. But compulsory licences do have a dampening effect on innovation by creating uncertainty about the extent to which successful innovators will be allowed to profit from their innovations. Unlike the HIF, compulsory licences cannot stimulate innovation (especially against the diseases

of the poor), nor can they provide incentives to market and promote medicines for optimal health impact. Even if compulsory licences were deployed in the best possible way, they would not undermine the need for the HIF.

Advance market commitments (AMCs), a leading species of innovation prize, assure profitable sales to developers of a predefined vaccine or other medicine. An AMC may legally guarantee, for example, that the first 200 million doses of a new kind of vaccine – if they meet certain specific requirements and are sold into LDCs at $3 a dose – are rewarded with an additional subsidy of $15 per dose. The described AMC would incentivize an innovator firm to work hard to collect as much of the $3 billion prize as possible: by developing a qualifying vaccine more quickly than its competitors, and by selling doses of it sooner and faster into the developing world.

Although AMCs are more similar to the HIF than the other three mechanisms, they are inferior in five significant ways.

1 Each innovation prize targets a specific disease, which is chosen by politicians, bureaucrats, or experts – presumably with an eye to selecting that disease against which the most cost-effective health gains can be achieved. The HIF, by contrast, would let each innovator firm decide which disease(s) to target. The latter design is superior because insiders have proprietary information that gives them a much better understanding of how they can reduce the global burden of disease most cost-effectively. Insiders also have powerful incentives to get it right: if they do well in setting research priorities, they will end up with products that will bring large health gains and hence large health impact rewards. Innovation prize designers lack such incentives: they lose nothing by selecting an inferior research target, and lobbying by companies and patient groups may then easily lead them to do just that.
2 Funding of innovation prizes depends on donor willingness, which can easily dry up because the subsequent prizes will be for different diseases. Guaranteeing annual reward pools far into the future, the HIF would be a permanent source of pharmaceutical innovation, supporting some twenty or thirty products at any given time. Undoubtedly, this advantage comes at a cost: establishing the HIF in the first place will be much harder than getting funding for an innovation prize.

3 Innovation prizes must specify rather precisely what is to count as a qualifying innovation; yet such a precise 'finish line' is difficult to specify optimally in advance of the research that the prize is yet to encourage. Suboptimal specification may lead to no qualifying innovation (with much wasted effort) or to qualifying products that, with a little extra effort, could have been substantially better. The HIF needs no advance specifications; it simply rewards each registered medicine according to its measured health impact.
4 An innovation prize must fix the size of the reward – in the case of an AMC, the subsidy per dose and the number of doses to be subsidized. Since innovators have every reason to conceal and exaggerate the true cost of their R&D, it is likely that an innovation prize, if it motivates successful innovation efforts at all, will pay more than would have been necessary, thereby producing a windfall profit for innovators. Rewards under the HIF would, by contrast, be paid at a self-adjusting (dollars per QALY) rate that reflects the innovators' own and accurate assessment of their R&D costs.[24] A reward rate perceived as rich would soon decline as it encouraged additional HIF registrations; a reward rate perceived as puny would soon increase by discouraging some new HIF registrations. Such self-adjustment assures taxpayers that their funds are spent efficiently, while also assuring firms that they will earn a decent return on their HIF-registered products.
5 An AMC gives any successful innovator strong incentives to sell doses eligible for the subsidy quickly, but no reason to care about what happens to these doses beyond the point of sale. The innovator's earnings are unaffected if some of the sold medicine is never used, loses its efficacy, is taken by patients who do not benefit from (or are even harmed by) it, or is consumed without adherence to the proper protocol. The HIF, by contrast, would pay according to the product's actual health impact, thereby incentivizing the innovator to take all cost-effective measures toward increasing this impact: to safeguard freshness, to ensure supply to patients who benefit the most, to lower the price below the ceiling in order to reach additional patients, and to instruct medical personnel and patients in how the product is to be taken for optimal effect.

While AMCs can work better than simpler innovation prizes, especially in stimulating the development of new vaccines, the HIF would be much more cost-effective in terms of its impact on global health.

**Lowest feasible price**

The HIF would contractually constrain registrants to ensure that their medicine is supplied wherever it is needed at the lowest feasible cost of manufacture and distribution. In exploring the diverse ways of specifying and implementing this requirement, the guiding consideration should be to maximize the health impact of the HIF itself. We should want the HIF to be constructed so that its operation contributes as much as possible to human health.[25]

One way in which to promote access to HIF-registered products is to require the registrant to offer zero-cost licences immediately upon registration, so that competing generic suppliers can compete down the price.[26] But such open licensing is not always the best method for achieving low prices, for example in small markets with inadequate competition. Another problem is that generic firms compete not merely over ultimate purchasers (such as patients, NGOs, national health systems, or international agencies), but also over intermediaries (such as wholesalers and pharmacies). Such intermediaries care less about the price at which they buy than about the mark-up that they are allowed to charge. They may therefore prefer to move or stock a more expensive generic version of a medicine than a less expensive one if the former offers them a higher profit margin.

Competition among generic suppliers can be organized in a different way that will typically work better in terms of access and efficiency. With this method, a HIF registrant would be permitted to retain exclusive marketing rights, but required to put the manufacture of the product out for tender, with two-thirds of manufacturing going to the lowest bidder, perhaps, and a third to the second-lowest. The registrant would then buy the medicine at these lowest bid prices and sell it on without any mark-up. The tender process should be repeated every few years to capture any new price advantages afforded by improved manufacturing technologies.

This tender method would typically be a more effective way of organizing competition among generic manufacturers.[27] This is so in part because of improved economies of scale: instead of many firms gearing up to produce the product in many countries, only two (the winners of the tender) do so and then produce much larger quantities. Moreover, generic firms will be more willing to compete, and to cut their price to the bone, when they can hope to win a large share of the entire global market rather than only a slightly increased share of some

national market. Furthermore, intermediaries face only a single source of supply – the innovator/registrant of the medicine – and thus have no opportunity to play off competing suppliers against one another in pursuit of a higher profit margin. With the tender method, the bargaining power of such intermediaries derives exclusively from the threat not to move or stock the medicine at all – and this threat has limited effect because, by fulfilling it, an intermediary would erase its own profit. To find wholesalers and pharmacists willing to move and stock its product, a registrant must allow these intermediaries mark-ups that make their collaboration profitable for them. The registrant need not allow larger mark-ups to win the collaboration of intermediaries in the face of competing suppliers of the same medicine (because, under the tender method, such competing suppliers do not exist).

It is worth mentioning, as an ancillary point, that the tender method is especially favourable to smaller manufacturing firms, because, by winning the tender to produce one or two HIF-registered medicines, they could take advantage of the same substantial economies of scale that larger firms exploit for several dozen products. With open licensing, by contrast, small suppliers labour under a handicap, because they must compete with larger firms that manufacture the same products in much larger quantities for a global market.

There are three further reasons for favouring the tender method over open licensing. First, assessing the impact of the introduction of a new product is much easier and cheaper if sales all pass through the registrant; such assessment is much more difficult and expensive when there are many other authorized sellers who may not want to provide accurate sales data to the HIF.

Second, the registrant will find it profitable voluntarily to sell its product below cost in very poor areas whenever it gains more from the extra rewards for additional health impact than it loses on the sale price; competing generic firms, by contrast, will sell above their cost.

Third, with only one authorized seller, the timing of HIF rewards can be adjusted for the special case of medicines the long-term utility of which is endangered by the development of resistance. For example, the important goal that new anti-infectives should be used sparingly, only in cases in which the older products fail, is best promoted when distribution is controlled by a single agent incentivized to maintain the medicine's efficacy for as long as possible (Outterson et al., 2011).

Weighty as they are, these reasons do not show that the tender method is best in all cases. When there is doubt about which of the two methods would produce the best outcomes, a subtle compromise method is possible: let the registrant choose between the two methods. Since the registrant earns money only through health impact rewards, it will try to choose the method under which health impact is larger (Hollis, 2009). With HIF registrations of an unpatented medicine (Syed, 2009) or of a new use of an off-patent medicine (Hollis and Pogge, 2008: 16, 86), the tender method is not an option, because open licensing is already a reality. Finally, in cases in which competition among manufacturers is expected to be anaemic – perhaps because the worldwide market is small and/or because the manufacturing capacity is unusually expensive to acquire – neither method may be satisfactory. In such cases, the HIF might negotiate with the registrant a price ceiling based on independent estimates of the lowest achievable average cost of production. This ceiling could be periodically adjusted to reflect new experience and cost changes.

The choice among these four methods depends on the technological characteristics of production in a specific market; there is no reason to suppose that a single mechanism will fit every circumstance.

### Tightening Health Impact Fund registration conditions

Those who favour open licensing often also believe that the HIF should require registrants to relinquish their right to control follow-on innovations.[28] As the critics contend, this requirement would helpfully remove an impediment to collaborative research. But it would also be costly in terms of innovation: the more registrants are required to give up as a condition for participating in the HIF reward pools, the more reluctant they will be to register and the higher the reward rate will therefore tend to be. This means that the proposed requirement would come at the expense of achieving health impact. We believe that this requirement would be costly in terms of raising the reward rate and that, even without it, the HIF would give a substantial boost to open science.[29]

Similar remarks apply to the suggestion that the HIF should favour manufacturers or innovators from the Global South. Automatic disqualification of Northern manufacturers (from tenders and contracts based on independent estimates) would probably make little difference, because Southern manufacturers, especially in India, are already far

more cost-effective than manufacturers in affluent countries. But it would still seriously disturb the presentation of the HIF as a global public good, the costs and benefits of which are equitably shared by all of humankind. The same can be said about automatic disqualification of Northern innovators, which would also lose some very cost-effective product registrations and thereby reduce the overall cost-effectiveness of the HIF. Even without a special handicap, the HIF would shift the balance in favour of Southern innovators who find it difficult and expensive to compete in the development of drugs against global diseases, on which 'big pharma' has already spent untold billions. The HIF would, first and foremost, encourage new research on the more neglected Southern diseases, and here Southern innovators are much more competitive because they have easy access to patients and because better resourced Northern firms have not yet invested much effort.

These considerations notwithstanding, we do not believe that the HIF should impose no constraints at all. One constraint that seems compelling is the requirement that all HIF-rewarded products must be manufactured under decent labour conditions, even when medicines manufactured under sweatshop conditions would lead to lower prices.

### Piloting the Health Impact Fund

Governments will muster the political will to create the HIF only if they are convinced that it would work. In this regard, a main concern is the measurement of health impact: is it really possible, at reasonable cost, to assess credibly the therapeutic benefits of a new medicine in poor and rich countries around the world? The best way to reassure governments and innovators on this point is to conduct a 'pilot' of the HIF concept. Such a pilot would consist of a contractual arrangement in which a firm or other organization is rewarded on the basis of the health impact it achieves with one product in one jurisdiction. Depending on the size of the jurisdiction and the volume of drug sales, a pilot could be run at relatively low cost.

A pilot would demonstrate the feasibility of reliable health impact assessment and show the effect on behaviour of rewarding an organization according to health impact, rather than through mark-ups. A pilot would also provide practical evidence on the best methods for assessing health impact and opportunities to learn how to write contracts governing rewards based on health impact.

In a suitable pilot, a firm would agree to reduce the price of a newly launched (or existing) product in one jurisdiction, which could be a city, province, country, or region. In exchange, it would receive rewards based on its product's measured health impact. The incentives should be designed so that if the firm appropriately responds to them (enhancing the health impact of its product by safeguarding freshness, focusing on patients who benefit the most, and promoting proper adherence to a treatment protocol), its profits would be no less than what they would be without the pilot. For example, in the case of an antiretroviral, a firm would receive no reward for patients switched from an equally effective antiretroviral, small rewards for patients switched from a less effective antiretroviral with greater toxicity and therefore typically lower compliance, and large rewards for patients who had previously had no treatment at all. The scheme of rewards would be agreed with the firm in advance.

We have made preparations for pilots in two major meetings. In April 2010, we made substantial progress on the measurement of health impact at a collaborative workshop with various health economists and epidemiologists at the National Institute for Health and Clinical Excellence (NICE) in London. Concrete pilot possibilities were then discussed at a three-day workshop held in May 2011 at the Rockefeller Foundation's conference centre in Bellagio, with experts in epidemiology, health economics, health outcomes, and trial design from Canada, China, Colombia, India, Mexico, South Africa, the United Kingdom, the United States, and Vietnam. The latter workshop settled on the following five desiderata.

1 A pilot must involve a change in practice – ideally, the introduction of a new drug or a reduction in price – that has a measurable impact on health. To be measurable, the impact must be substantial and capable of being documented with suitable evidence. If the pilot involves a reduction in the price of an existing drug, the health impact may arise from improved take-up of the drug owing to increased volume or a shift in take-up towards patients who benefit more.
2 A pilot should be cost-effective from a health or humanitarian perspective – that is, it should lead to measurable health improvements at reasonable cost. Here, it is helpful that, because the rewards paid to the firm are based on assessed health benefits, their cost-effectiveness

is known in advance. If the firm's efforts to enhance the health impact of its product bear little fruit, the cost of the pilot is correspondingly reduced.

3 A pilot must be feasible in a defined area so that its cost can be controlled by limiting the territory in which data on health outcomes and drug usage must be obtained.

4 A pilot should not undermine market competition. When a firm is rewarded for selling at a low price, it may be able to undercut other firms in the market. This unfairness should be avoided by ensuring that if a product is already available generically, all firms selling this product are offered the same rewards. Even if the product is not yet generically available, the rewards should be designed so that they do not inhibit generic entry in the future.

5 To demonstrate the feasibility of the HIF, several pilots should be run. There is great international diversity in conditions relevant to health impact assessment, including diversity in the availability, reliability and cost of data, in the prevalence of insurance coverage, in the extent to which medicines are supplied through the private sector, and in the extent to which prescriptions are required. Moreover, medicines themselves differ in various important ways, such as mode of action, time lag, risk of product deterioration, and importance of compliance. A variety of pilots, involving different medicines and diverse locations, would provide much better preparation for the creation of the HIF than any single pilot could.

Various promising pilot projects have emerged, and we are now involved in specifying each pilot plan so that it is acceptable to the company whose product is to be marketed in the new way, to the funder(s) of the health impact assessments and reward payments, and to the relevant political authorities in the pilot jurisdiction.

## Joining forces for justice in global health

The current international system for encouraging pharmaceutical innovation is highly inefficient because the rewards it offers are only very tenuously related to health outcomes. This system is unsustainable because even the wealthiest countries cannot afford skyrocketing healthcare costs forever. The HIF is a concrete proposal for tying cost to therapeutic benefits in the important domain of pharmaceutical innovations. The HIF is not cheap, and its creation therefore involves

financial and political risks. These risks can be greatly reduced through appropriate pilots. The paramount task now is to gather financial and political support for a suitable set of pilots, each of which requires a willing firm, a cooperative jurisdiction, funding for the reward payments, and funding for the health impact assessment. Fortunately, these pilots have their own intrinsic value in the form of delivering health improvements at reasonable cost. But their potentially much greater value consists in preparing the way for the HIF itself, which could be an amazing revolution in global health and a concrete model of a just global institution.

Should the HIF work as expected, the medicines that it supports would bring enormous health gains, especially in the world's poorer areas, even while its net costs would be negligible or (more likely) negative. While funding the HIF, taxpayers would save through reduced expenses on public health facilities, foreign aid, insurance premiums, and private drug purchases. They would save expenses for costly hospitalizations averted by additional, earlier, or more effective pharmacological interventions. And they would benefit from the diffuse economic effects of a massive reduction in the global burden of disease. Last and foremost, humanity would have taken an important step toward global justice by reducing the artificial exclusion of poor people from the fruits of pharmaceutical R&D. Let us at least explore this great opportunity through a set of suitable pilots.

## Notes

1 An earlier version of this paper was presented in September 2011 as the Mahbub ul Haq Memorial Lecture at the meeting of the Human Development and Capability Association in The Hague, then published as Pogge (2012). I am grateful to the editors of the *Journal of Human Development and Capabilities* for their kind permission to reprint it here. Many persons have been contributing to the work on the Health Impact Fund (HIF) proposal. This ongoing collaboration is documented online at http://www.healthimpactfund.org, which also offers free downloads of the first full statement of the HIF proposal (Hollis and Pogge, 2008).

2 Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed on 15 April 1994 and entered into force 1 January 1995.

3 The figures show that average income in the top decile (tenth) of humanity is nearly seven times the global average, while average income in the bottom quarter is 1/27 of the global average. One person in the top 10 per cent has as much income, on average, as 178 people in the bottom quarter. The income data used here were kindly supplied by Branko Milanovic, lead economist in the World Bank's Research Department, in a personal email communication dated 7 December 2012, on file with the author. Milanovic is the leading authority on the measurement of economic inequality and his published

work contains similar, albeit somewhat less frequently updated, information (see Milanovic, 2005, 2009, 2011). Wealth is even more unequally distributed than income: the poorest 69 per cent of humankind has only about 3 per cent of global private wealth versus 8 per cent of global household income (Crédit Suisse Research Institute, 2013: 93).

4 These opportunities are limited by parallel import problems, which involve the illicit importation of medicines from countries in which they are cheaper to countries in which they are more expensive. They are also limited by practices of reference pricing, whereby a national health system agrees to fund or reimburse only medicines the domestic price of which is in line with their price in other countries.

5 Recent examples of such pressure include concerted efforts to wrest data exclusivity provisions from poor countries. Such legal provisions discourage market entry by generic firms even after patent expiration by assigning the patentee exclusive rights to the clinical data that it initially submitted to obtain marketing approval. As a result, a generic firm cannot win marketing approval simply by showing that it has a bioequivalent product; instead, it must bear the substantial – and socially wholly wasteful – expense of producing its own clinical data to show that the medicine is safe and effective.

6 A further problem with the analogy is that it fails to provide any rationale for limiting the duration of intellectual property to twenty years (or any other specific period). Libertarian and other defences of the status quo are much more extensively discussed in Hollis and Pogge (2008: ch. 6).

7 These two points are more fully discussed in Hollis (2004).

8 Health impact can be measured in quality-adjusted life years (QALYs) saved. The QALY metric has been refined over the last twenty years and is already extensively used in many contexts, including by public and private insurers for deciding which new drugs to cover (Phillips, 2009). Its basic idea is straightforward: giving a patient an additional year of life in good health is worth one QALY. Appropriate fractions of QALYs are awarded for additional years in less than good health and also for life years in which patients are in better health than would otherwise have been the case. QALY awards for periods longer or shorter than a year are proportionately adjusted. A new medicine's impact is to be assessed relative to the standard of care that patients would have received in its absence or before its introduction. For many poor patients, this would be no effective care at all. Assessments of health impact would draw on data gathered from clinical trials, pragmatic or practical trials, sampling of product use in different environments and demographic groups, audited sales data, and correlation with global burden of disease data.

9 The costs of the HIF's own operation – which are mostly costs of health impact assessment – should be covered from registration fees rather than from the annual HIF budget. Overall, this comes out in the wash: if registrants cover these costs, then there is more money in the annual pools to be distributed to them. But at the level of individual registrants, there is an important difference. If operational costs are paid out of the annual pools, then the most successful medicines will contribute the most and medicines with little health impact will contribute little. Yet it is evidently undesirable to pay part of the cost of assessing weak and poorly promoted products out of the reward shares of innovators with really strong and well-promoted products. It makes more sense to avoid such cross-subsidization by making each innovator pay its own

way: by making each innovator pay a fee that roughly covers the cost to the HIF of assessing its registered product(s). This cost allocation discourages innovators from registering products in which they have little confidence; it also encourages any innovator to promote its registered products so as to enhance their health impact (because none of the extra reward resulting from better product promotion is lost to an increased contribution to operational expenses).

10 Lower funding levels would lose economies of scale in health impact assessment and would also lead to an excessively volatile reward rate (dollars per QALY), which would discourage registrations.

11 To ensure that the HIF is cost-effective relative to other public health expenditures, there should be a ceiling specified on the reward rate, a maximum dollar amount per QALY. With this ceiling in place, only a genuine miracle drug could by itself collect the full $60 billion. Still, if the reward rate ceiling is set at a generous level, then, given the escape options, registrations are bound to occur.

12 Creating a uniform regime for the international sale of goods, improving certainty and reducing transaction costs in transnational transactions – one of the most universally adopted international agreements.

13 Increasing international uniformity in technical regulations and product standards, and working with developing countries to allow them to participate in standards-setting.

14 Establishing the International Telecommunications Union for the purposes of unifying and coordinating international telecommunications standards.

15 Establishing a specialized UN agency to coordinate international aviation rules and establishing early rules for international air travel.

16 Facilitating international air travel by allowing, inter alia, aircraft access to foreign airspace.

17 International maritime safety treaty considered essential for guaranteeing the safety of merchant ships in international and foreign waters.

18 Creating rules for dealing with spills of oil and other hazardous materials carried in bulk.

19 One of the most widely adopted and implemented international environmental treaties, with high rates of compliance, expected to produce real reversals in ozone damage.

20 Promoting peaceful scientific cooperation and exchange on the Antarctic territories.

21 Causing some 120 states parties, after ratification, to adopt or strengthen their tobacco control legislation. Very substantial help from Megan Corrarino in the composition of this paragraph is gratefully acknowledged. For further discussion, see Chayes and Handler Chayes (1998), Goldsmith and Posner (2005), Haffeld, Siem, and Røttingen (2010: esp. 616), Hathaway (2002: esp. 1942–1962), Koh (1997), and Vagts (2001: esp. 313 and 331).

22 Perpetual bonds are bonds without a maturity date. The borrower need never repay the principal, but must pay interest forever. The British government issued such bonds ('consolidated annuities', or 'consols') in the 1750s and is still paying the interest on them. Various banks have issued US dollar-denominated perpetual bonds in recent years, including Credit Suisse Group AG, BNP Paribas SA, and HSBC Holdings plc.

23 For the various proposals of an international financial transaction tax, see the Wikipedia entry online at http://en.wikipedia.org/wiki/Financial_transaction_tax. For a proposed scheme that would raise money in combination with slowing environmental degradation

and natural resource depletion, see Pogge (2008: ch. 8).

24 This model was first proposed and explored in Abramovicz (2003).

25 Strictly, the objective is to maximize the health impact of the HIF per dollar of net cost. Here, net cost is the funding absorbed by the HIF *less* the savings realized by buyers of medicines that they would otherwise have purchased with a high mark-up.

26 I initially favoured this option across the board (Pogge, 2005, 2008: ch. 9), but extensive discussions with Aidan Hollis and others (in December 2007) have convinced me that other options are superior in many cases. See Hollis (2009) for an excellent treatment that informs and complements the present section.

27 The following thoughts were in part developed in response to Sakiko Fukuda-Parr, who was the official respondent to my Mahbub ul Haq Memorial Lecture. She argued that allowing HIF registrants to retain exclusive marketing rights would, relative to open licensing, lead to higher prices and heavy concentration in the pharmaceutical industry. Her critical comments, composed with Proochista Ariana, are available, along with our replies, on the website of Intellectual Property Watch, online at http://www.ip-watch.org

28 This point is made, for instance, in the critique by Fukuda-Parr and Ariana, cited in the preceding endnote.

29 This issue is further discussed in HIF (2010), the September 2010 IGH Newsletter, available online at http://us1.campaign-archive.com/?u=098b142792357c7a0d980ed67&id=a8766ac893

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