Who has responsibility for access to essential medical drugs in the developing world?

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RÉSUMÉ

L'accès aux traitements de base est un enjeu crucial pour la santé, la pauvreté et le développement. La responsabilité en matière d'accès est alors une question essentielle. Le huitième Objectif du Millénaire pour le Développement postule qu'en coopération avec les firmes pharmaceutiques, l'accès aux traitements essentiels doit être assuré. Les principales parties prenantes qui doivent engager leur responsabilité pour l'accès aux médicaments sont (1) l'industrie pharmaceutique, (2) les gouvernements, (3) la société au sens large, et (4) les individus (qu'ils soient ou non malades). Quatre approches permettent d'appréhender la responsabilité : (a) l'approche déontologique ; (b) l'utilitarisme ; (c) l'égalitarisme ; (b) l'approche basée sur les droits de l'homme. Ces quatre arguments peuvent être utilisés pour assigner une responsabilité aux gouvernements dans l'accès aux médicaments. Le papier conclut qu'il est parfois difficile de distinguer entre ces quatre approches et qu'un « glissement-d'échelle » de la responsabilité est une voie utile pour appréhender les rôles des quatre principales parties prenantes dans l'accès aux médicaments, dépendant du pays ou de la région et de son environnement interne.

ABSTRACT

Access to basic medical treatments emerges as cause and effect of health, poverty and development. Where the responsibility for improving access to essential medicines lies is, therefore, a crucial question. Millennium Development Goal (MDG) number 8, states, "In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries" (UN 1). The key stakeholders who may take responsibility for access to drugs are (1) the pharmaceutical industry, (2) governments, (3) society at large, and (4) individuals (both with and without disease). Four lenses through which responsibility can be viewed are: (a) deontological; (b) utilitarian; (c) egalitarian; and (d) human rights-based approaches. All four arguments can be used to assign responsibility for improving access to drugs to the governments, especially utilitarian and human-rights approaches. The paper

concludes that it is sometimes difficult to distinguish between the four ethical approaches and that a "sliding-scale" of responsibility is the most useful way to view the roles of the four main players in access to essential drugs, depending on the country or region and its internal environment. Mots-clefs : enfants des rues, ville, travail, Cameroun, Madagascar

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INTRODUCTION

Health has been recognized as crucial to human development. Three of the eight Millennium Development Goals (MDGs) refer specifically to health issues, namely: reducing child mortality, improving maternal health, and combating HIV/AIDS, malaria, malnutrition and other diseases. The links between poverty and ill health are well established and attention has heavily focused on poverty alleviation as an important means of improving health.

MDG number 8, "Developing a global partnership for development" includes the objective, "In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries" (1). The World Summit on Sustainable Development (WSSD) in 2002 also emphasized the need for access to drugs in order "to strengthen the capacity of health care systems to deliver basic services to all" (2). The WHO has been producing guidelines for essential drugs for the last 25 years and there are 306 drugs currently on this list (3). Illnesses such as HIV/AIDS and coronary heart disease have stimulated much research and production of many new disease-modifying therapies, which are often widely available in richer countries. WHO states, "Essential drugs are those drugs that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford (3)." More than a third of the world's population has no access to essential drugs, and half of these people live in the poorest regions of Africa and Asia (4). Several factors determine the accessibility of drugs in developing countries, and several different parties are responsible to varying degrees for these factors.

The key stakeholders who may take responsibility for access to drugs are (1) the pharmaceutical industry, (2) governments, (3) society at large, and (4) individuals (both with and without disease). Broadly speaking, four widely used lenses may be used to view responsibility: (a) deontological moral; (b) utilitarian; (c) egalitarian; and (d) human rights-based approaches. Each of the four major actors will be considered, in turn, with reference to these ethical frameworks to assess relative responsibility for access to essential medicines.

These issues have never been more important, especially as the world's population continues to increase and over a billion people live on less than a dollar a day, more than 800 million are malnourished, and over two and a half billion lack access to adequate sanitation (4). Access to the most basic medical treatments emerges as a cause and an effect of health, poverty and sustainable development and the supporting data is unequivocal. The ethical question of where the responsibility for improving access to essential medicines lies is therefore a crucial issue in determining how access is practically improved.

THE PROBLEM

Massive inequalities between the developing and developed countries (and even within countries) make equal access to medical care unrealistic for the foreseeable future. It is more realistic to look at universal access to "essential drugs", rather than access to all drugs and treatments. The economic, social, technological, and political disparities that weigh so heavily on this discussion should not, however, be used as reasons to abandon the concept of "universal access". Figure 1 illustrates the two-way links between income poverty, ill health and sustainable development (5). Improving access to essential medicines represents a practical intervention to address health and income inequalities, while accelerating economic and social development. The careful selection of a limited range of essential drugs leads to a higher quality of care, better drug management (including improved quality of prescribed medicines), and more cost-effective use of health resources. There are 306 drugs currently on the WHO Essential Drugs List (3). Essential drugs should encompass all diseases deemed to constitute the main disease burden in a country or region.

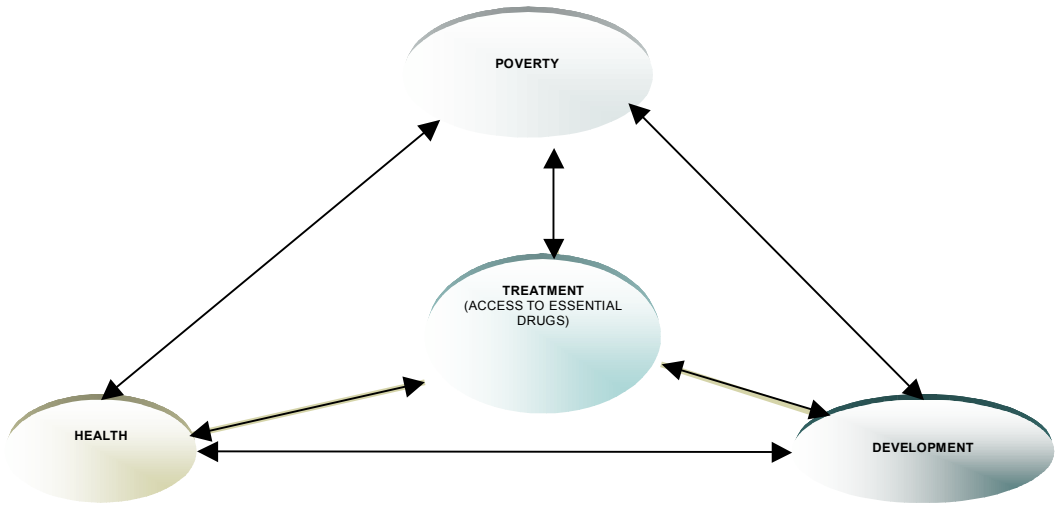

Figure 1. Linking access to treatment to the health-development framework (5)

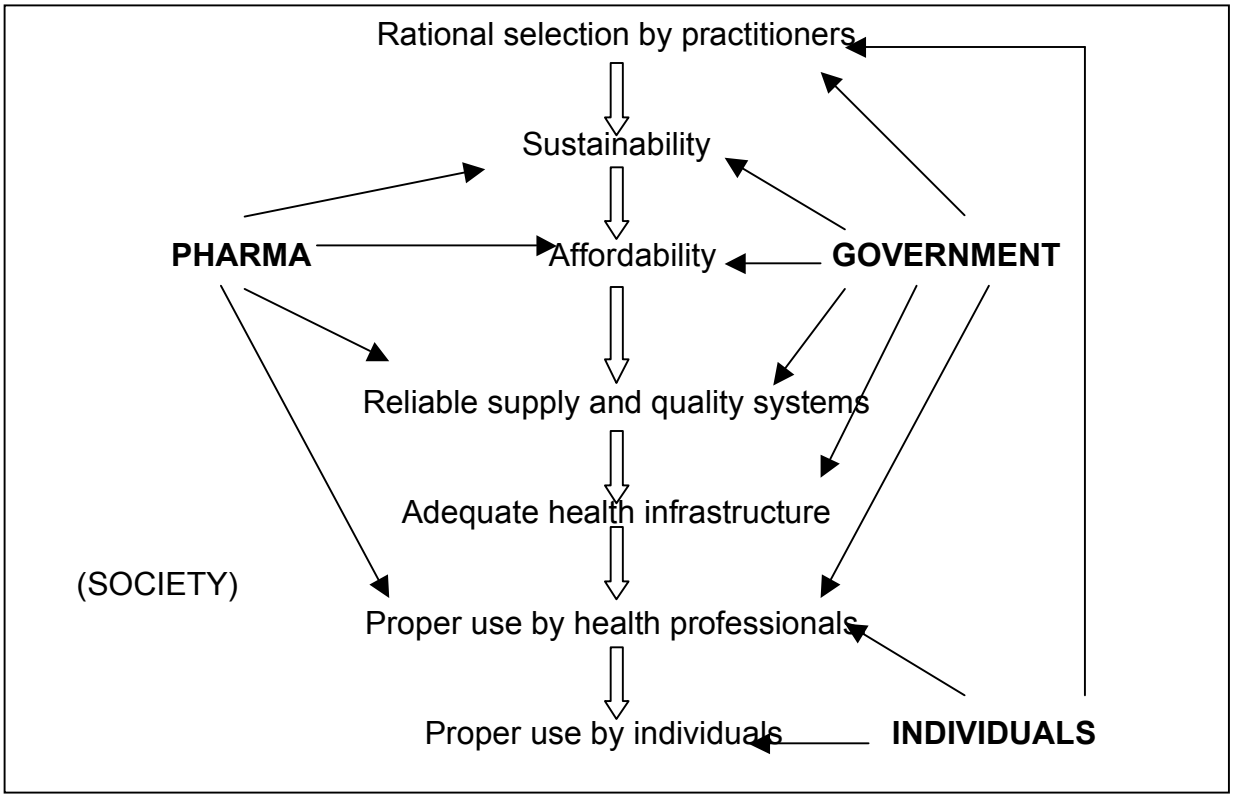

Figure 2. Access to medicines (6)

Figure 2 illustrates the processes involved in access to drugs, and how the different players influence access. Drugs can be treatment or prevention measures in relation to disease processes. Essential drugs only save lives and improve health when they are available, affordable, of good quality and properly used. Immediately we see that access is a multi-step process and is affected by governments, pharmaceutical companies, societies and individuals.

Spending on pharmaceuticals represents between 25% and 66% of health expenditure in developing countries (7). In most low-income countries, pharmaceuticals are the largest public expenditure item in health care after personnel costs and the largest household health expenditure. The expense of serious family illness, including drugs, is a major cause of household impoverishment (4). Therefore drug prices and access to drugs are crucial, and where the responsibility for this lies is a key question. Responsibility for access to drugs can be (a) forward-looking ("response responsibility"), in the sense that one is responsible for achieving (or maintaining) access; or (b) backward-looking in which a person or group

deserves ethical evaluation for presence or absence of access to essential drugs ("causal responsibility"). Both types of responsibility are important in determining where attentions should be focussed in efforts to improve access to drugs. If one has a response responsibility to improve access to medicines, then even if one is in the position to delegate that responsibility to someone else, one still must see that the responsibility is fulfilled.

Four ethical methodologies will be considered to assess claims, actions and responsibilities:
Deontological moral systems primarily focus upon adherence to independent moral rules or duties.
In the "results-oriented" approach, treatment and/or prevention of diseases with essential drugs is assessed in terms of effectiveness, where effectiveness is defined as reduction in mortality and morbidity and as knock-on effects on poverty and other aspects of development.
Egalitarianism fundamentally aims to reduce the inequalities in essential drug access within communities and countries, and between countries. Poor health limits opportunities. In order to ensure basic opportunity, for both the caregiver and the dependent party, "society" should take the responsibility for ensuring care, at least to an extent. The usage of the term "society" will be considered later in this article.
The rights-based approach goes a step further because it focuses on the (enforceable) right of an individual to certain basic necessities (in this case, access to essential medicines), whereas the egalitarian model focuses only on the opportunity to receive these necessities as a desirable policy goal. The pertinent issue for this discussion is where the responsibility for fulfilling this right lies. The human right to health has been used successfully as a tool against governments to gain access to treatment for HIV/AIDS in both developed and developing countries.

In this paper, the responsibilities of the main players (namely, the pharmaceutical industry, governments, "society" more generally, and various types of individuals) will be analysed, bearing in mind these four ethical frameworks (deontological, results-oriented, egalitarian and human rights). The following discussion aims to introduce the problem of access to medicines to a broader audience, in order to stimulate debate and further detailed analysis. It is beyond the scope of this paper to consider every possible permutation of disease and drug therapy.

WHO IS RESPONSIBLE?

1. The pharmaceutical industry

If a company came up with both the idea and the manufacture of a new drug, then it holds rights to that product and society should honour this fact. The extent of these rights is dependent upon local patent law and social norms. The rights of the company are complete only in extremely rare cases because all companies rely upon previous scientific knowledge and ideas generated by other people. Drug companies are also reliant upon societal facilities

(e.g. university research laboratories) that helped them to generate the ideas, and hence the rights are not total. On a global scale, drug patent laws do not enforce permanent patent rights for the drug company-at best the patentability lasts for 20 years, before cheaper generic versions of the drugs can be legitimately produced (see the discussion about TRIPS later). However time periods of 20 years may seem very long when judged against both the scale of contemporary medical needs and the speed with which drugs can become considered obsolete or simply ineffective (for example in the cases of drug-resistant strains of infectious diseases such as tuberculosis).

Should the pharmaceutical industry be viewed differently to, for example, the information technology or clothing industries, where intellectual property rights and copyrights to products are the norm? Does the pharmaceutical industry exist simply to make sales of medications or should it be viewed as allied to medicine, and therefore does it have similar duties of care and maintaining that standard of care to patients and society? "Professional responsibility" arises from the special knowledge that the pharmaceutical industry possesses. Since its special knowledge bears so directly and centrally on human well-being, it is constrained by special moral requirements to apply its knowledge in ways that benefit the rest of the society, and therefore the answer is that the drug industry should be viewed differently to other industries. The fact that this knowledge relies upon the prior work of other individuals, freely available in the public domain, and is also typically reliant upon publicly funded research and training adds strength to this argument.

This proposition, that health needs to be considered differently to other spheres and that therefore the drug industry (along with other actors in the health provision) has more responsibility than other industries, is true to a significant extent. Therefore access to drugs (which greatly influences health outcomes) must be considered differently to access to non-essential products such as cars or luxury clothing. It is, however, unfair to hold a single industry accountable in isolation for world suffering, if other industries are free to make profits without these ethical concerns. It is definitely unfair to hold the pharmaceutical industry solely responsible for inadequate drug access, because other parties also have responsibilities.

Should the pharmaceutical industry only be responsible for ensuring access to essential drugs in states of emergency? It is difficult to define when drug access becomes an emergency. The rapidly-evolving AIDS epidemic is definitely such an emergency, but does the same apply for coronary heart disease? If drugs are made available cheaply in developing countries, should pharmaceutical companies have the same responsibilities to provide cheap drugs in the developed world as well? The ideal that justice should be consistent suggests that this should be the case, but only for essential drugs. Pharmaceutical companies fear that if they concede on access to antiretroviral drugs for HIV/AIDS, the floodgates will be opened for many other drugs for many other conditions.

In 2001, it took the threat of bioterrorism, in the form of anthrax in the United States and an offer of cheap drugs from India, to highlight a problem familiar to people in poorer countries - the denial of access to affordable drugs because of tough patent laws. This led to calls to lift Bayer's patent on ciprofloxacin, the main treatment for anthrax. Anthrax was seen as a public

health emergency sufficient to override existing patent law even though the number of people affected by anthrax never exceeded double-figures. One way out for the United States was the "compulsory licensing" route allowed under the Trade Related Intellectual Property Rights (TRIPS), which enables WTO members to utilise cheap local manufacture in the public interest (8). But compulsory licensing, especially previous efforts in developing countries, had often been resisted by powerful drug trans-national corporations. Ironically, it was now the US that took India to the World Trade Organization (WTO) dispute settlement tribunal on exactly such an issue. Earlier, in 1999, it had compelled India to begin working on legislation to introduce product patents and to allow foreign patent holders exclusive marketing rights (EMRs) in the meantime.

For more than 30 years, Indian law recognized only process patents, not product patents. This allowed India's pharmaceutical companies to make inexpensive generic versions of patented drugs by "reverse engineering". Reverse engineering is the analysis of a completed system (in this case a drug) in order to isolate and identify its individual components or building blocks. India became one of the world's biggest producers of generic drugs. With overall production of $7.3 billion, Indian firms produce approximately 1.5% of the global pharmaceutical market of $480 billion (9). However, this small share, in value terms, belies the importance of the Indian industry in volume terms, estimated at more than 20% of global consumption, and the cost of drugs is often 7-10% of the Western price (9).

The generic pharmaceutical industries of countries such as India, Thailand, South Africa and Brazil have been instrumental in improving access to many essential drugs such as anti-retroviral therapies for HIV/AIDS. For example, it has been estimated that up to one-third of AIDS patients in the Third World relied upon India's generic pharmaceutical industry (9). The drug industries of these countries have shown a greater sense of responsibility for access to essential drugs in this sense than have their Western counterparts.

Corporations such as pharmaceutical companies are owned by their shareholders. According to conservative business ethicists such as Milton Friedman, money spent on "social responsibility" is effectively theft from those shareholders, who can decide for themselves if they want to give to charity. Another school of thought would argue that there are mechanisms in place for shareholders who disagree with a company's policy on social responsibility. They can try to change management decisions, or change the company's management, and finally sell their shares and invest elsewhere. The pharmaceutical industry, by any standards among the most profitable industries, makes the large bulk of its profits not in developing countries, where the vast majority of people are unable to purchase its products, but in developed countries. Companies have legal obligations to their shareholders, but even conservative "business ethicists" agree that the morality of business requires companies to promote "shareholder value", but not ignore the constraints of common human decency.

To summarise, principles of corporate social responsibility can be invoked to urge the pharmaceutical industry to improve access to drugs. In addition, the economic impact of improving access to essential drugs in poor countries would be minimal for the drug industry, compared with the profits they reap from developed nations. Drug access for poor

people in the developing world is a greater moral responsibility than a responsibility to shareholders to obtain marginally higher profits. This is a corollary of the principle that the role of the pharmaceutical industry in the health sector affords drug companies a special moral responsibility.

The debate around access to medicines in the last ten years has been firmly fixed on the issue of affordability of essential drugs and the effects of increasingly far-reaching and enforced intellectual property laws for pharmaceutical compounds. Most of the debate has concentrated on HIV/AIDS and its therapies, but the disease burden in poor countries and globally consists of several other key infectious and chronic diseases, whose drug treatments also need to be considered.

The TRIPS (Trade-Related aspects of Intellectual Property rights) agreement of 1995 means that all WTO member countries are expected to grant and enforce 20-year patents on innovations (8). In the field of medicine, especially with regard to antiretroviral drugs for HIV/AIDS, there has been much controversy and apprehension about how implementation of TRIPS will impact access to essential drugs in the developing world. If we refer back to figure 2, TRIPS and patent laws only indirectly affect affordability, and we see that the other factors may have as much effect on access to medicines. In addition, the final price of a drug includes taxes and duties, retail, distribution, and producer's costs (6). Drug prices are not only affected by patents, and access to drugs is not only affected by drug prices. Even when drugs are affordable, there may not be adequate infrastructure to ensure correct usage and distribution.

95% of the drugs on the WHO Essential Drug List are no longer under patent protection (9) and so are not affected by patent law. Indian firms are well placed to continue to make cheaper generic drugs (at less than 10% of the cost of the Western counterparts) available to poorer populations for not only HIV/AIDS but many other diseases. Since existing generic compounds can continue to be produced under the new patent laws, and since 95% of the essential drug list is off-patent, the immediate effect on access to generic drugs (such as the antiretroviral therapies on the WHO Essential Drugs List) is expected by Grace to be minimal, if any at all (9).

Intellectual property protection is not automatically related to access to drugs, but could cause a "potential change in industry structure and types of competition and this can lead to changes in prices, quality levels and physical availability" (9). The fears over patent law are mainly concerned with the future effects on new drugs which may become essential for treatment of the diseases which constitute the major global disease burden. Such drugs would include new treatments for HIV/AIDS, and preventive therapies for coronary heart disease (such as cholesterol-lowering drugs and new anti-hypertensive medications). It will be more difficult for India and other generic producers to manufacture cheaper versions of these new drugs and costs are likely to increase for the developing world consumer. Even if the cost increased from the existing 10% of Western prices to 'only' 20%, there will definitely be a deleterious effect on access to drugs. A small increase in cost of drugs may cause huge effects on individual and household finance, with resources diverted away from other essential needs such as food, shelter and education.

The most likely scenario seems to be one where the Indian firms have two strategies: (a) maintaining their low-priced/high volume generic industry for poorer countries and (b) expanding the generic industry to developed country markets. Ironically, consumers in the USA and Europe stand to benefit from the introduction of product patents in India since Indian firms are increasing their focus on exports to these markets, in response to the reduced growth potential from future domestic sales. The end result of this export focus will most certainly be more competition and lower prices in the developed world for generic drugs (10).

In summary, patent laws will not immediately dramatically affect access to medications in developing countries because (a) these drugs are largely generic compounds which are off patent; (b) there are many factors affecting drug pricing besides patent law; (c) access to drugs is influenced by factors other than cost. However, there are legitimate concerns regarding the effects of inevitably increasing costs of new drugs in the future and the impact this will have on health and other spheres of life. Although it is difficult to assign full responsibility to pharmaceutical companies for access to essential medications using utilitarian arguments alone (about impacts on health, poverty and development), their relative responsibility is expected to increase as newer essential drugs become more expensive.

In Rawls' theory of luck egalitarianism, individuals are not responsible for outcomes due to "brute luck", but with "option luck" there is some possibility for control over risks and so there is personal causal responsibility (11). Brute luck is the operation of factors over which there is no responsibility or choice (such as disabilities from birth). Option luck also involves factors over which there is no responsibility, but in addition, there is an element of choice (e.g. heart disease as a result of the active decision to smoke cigarettes).

If we extend Rawls' theory to global "society", a luck egalitarian stance could be that the pharmaceutical industry has a role to play in reducing inequalities in developing countries in need (e.g. increasing access to anti-TB drugs or antiretroviral drugs for HIV/AIDS), since these inequalities are partly caused by actions by the drug industry and therefore represent "brute luck" for disease-sufferers. This applies to inequalities both within the poor countries and between those countries and the richer, developed countries. It cannot be argued that an individual in a poor country who has HIV/AIDS, coronary heart disease or colon cancer caused his/her lack of access to relevant drugs, and so this is brute luck and not option luck. Although the same might apply to a patient in the developed world, his or her "response capability" and therefore "response responsibility" is greater. For example, the AIDS sufferer in the UK who has the financial means, opportunity and education to procure the necessary drugs has a response responsibility for access to these essential drugs, unlike the poor AIDS sufferer in Somalia. In reality, there is probably a spectrum from pure brute luck to pure option luck, and so the causal responsibility of the drug industry is variable. Based on resources available to the patient, the response responsibility of the drug industry is also variable.

2 - Governments

"We could try to blame science for having failed to perform research that affects international public health. But (in addition) the transition from successful clinical research to implementation of public health rests in the hands of governments (12)."

Walzer viewed health as a separate 'sphere' of life and whilst differences in socio-economic status might be deemed acceptable, the health inequalities they engender would be viewed as unjust (13). Achieving the highest attainable standard of health, as well as equality in health are public health's primary goals. This "partial" utilitarian view places priority on health, and therefore on increased access to essential drugs.

Developing world governments have embarked on a major publicity campaign against pharmaceutical companies with good reason. However, even if drug prices would come down dramatically, and even if local production began as a consequence of compulsory licensing, developing the necessary delivery infrastructure is expensive. Pharmaceutical companies cannot be held accountable for infrastructure within a country. Without adequate distribution frameworks, actions by the pharmaceutical companies will have little impact on this massive problem of drug access (see figure 2). Governments have a responsibility to their citizens to put health before other budgetary claimants, such as military expenditure, which will not lead to the same gains in wellbeing as, for example, increasing access to essential drugs, whether the comparisons are on moral grounds or 'effectiveness' grounds. Effectiveness in this sense refers to how far government policies achieve their aims and encompasses many factors, such as increase in life expectancy and increase in gross domestic product.

Peter Piot, UNAIDS' Executive Director, stated, "In the North, in return for innovation, intellectual property is protected and profits are made. This has benefited both Northern shareholders and society. But it doesn't work for the South, where 95 percent of the world's population of 36.1 million with HIV/AIDS lives (14)." Rich Western countries have dominated the world pharmaceutical stage in terms of research and development of new drugs and also in terms of profits via patent laws. So-called blockbuster drugs (those which generate more than $1 billion annual revenue) do not tackle the disease burden of poor countries and are not available in those countries.

In this world of "haves" and "have-nots" international inequality places a major hurdle to improved drug access in poorer countries. However, from a global egalitarian stance, if drugs are available to a sufferer of a disease in the developed world then they should be available to the developing world as well. There is evidence that the rules can be relaxed in developed countries, when necessary. The case of "Cipro" during the anthrax crisis in the USA has already been discussed. In low-income countries, it is paradoxically more difficult to enact the same changes because of the greater relative power of the big pharmaceutical companies, especially when now backed up by rather than regulated by their rich-country governments. Both egalitarianism and rights stances demand that justice must be consistent and so the situation where a human life in a rich country is de facto valued as more than

hundreds or thousands of lives in a poor country is not acceptable ethically. The same philosophical arguments for governmental responsibility can be used on the international stage, e.g. for the World Health Organisation or the United Nations system as a whole to improve drug access in poorer countries.

As signatories of the basic human rights treaties and conventions, governments are bound by the terms of those treaties. In the current discussion, the duties to promote health and development are only really applicable to all government signatories of those treaties. The relevant texts are included here for completeness:

"Everyone has the right to a standard of living adequate for ... health and well-being of himself and his family, including food, clothing, housing, medical care.... Motherhood and childhood are entitled to special care and assistance....(15)" (Universal Declaration of Human Rights, Article 25)

"If social and economic inequalities are powerful determinants of health, then signatories to the Covenant would seem to be obligated to narrow these inequalities, or to find ways to reduce their impact on health and longevity (16)." (Covenant on Economic, Social, and Cultural Rights, Article 12)

"States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health...(17)." (Convention on the Rights of the Child, Article 24)

"States Parties shall ... ensure to [women] ... access to specific educational information to help to ensure the health and well-being of families, including information and advice on family planning.... States Parties shall ... eliminate discrimination against women in ... health care ... to ensure, on a basis of equality of men and women, access to health care services and.... that [women in rural areas] ... have access to adequate health care facilities, including information counselling and services in family planning...(18)." (Convention on the Elimination of All Forms of Discrimination Against Women, Articles 10, 12, and 14)

"States Parties undertake to ... eliminate racial discrimination ... and to guarantee the right of everyone, without distinction as to race, colour, or national or ethnic origin, the right to public health, medical care, social security and social services...(19)." (Convention on the Elimination of All Forms of Racial Discrimination, Article 5)

Therefore, a government has certain obligations to make it possible to have that degree of health, and this must include access to essential drugs. In the luck egalitarian approach, if the government fulfils these obligations, then "brute luck" is minimised and option luck becomes the major factor. If excess mortality and morbidity associated with socio-economic inequality are due to individuals, where these inequalities arise from freely chosen differences in lifestyles (like smoking), then a government cannot be held responsible.

All rights are of "equal status, indivisible and interdependent" (15), but in reality, civil and political rights have often "trumped" economic, social and cultural rights. Quite often

property rights (including rights to intellectual property) have trumped the other social and cultural rights. This prioritisation is counter-intuitive when we consider that the right to health is the basis for other rights or is constitutively linked to many other rights (see figure 1), both civil and political, – e.g. rights to life and not to be subjected to cruel, inhuman or degrading treatment – and economic and social – e.g. rights to food and work. "This can be seen…[in] the role health plays in our enjoyment of other rights – an unhealthy citizen is not able to play a full and active part in society either economically or politically" (20).

The Declaration of "The Right to Development" in 1986 by the UN General Assembly centres on the right of individuals to national and international development policies that improve their well-being, equitably and with their full participation (21). The Right to Development is a right to a process through which all human rights and fundamental freedoms are fully realized. The Right to Development concept rejects the notion of accepting trade-offs between one right and another or between human rights and economic growth, requiring an integrated conception of all human rights. This could be interpreted as holding that while trade-offs between two different rights are often inevitable at a particular time if all other things are kept equal, it is not acceptable to have less of either and it is both imperative and possible to adjust the other factors in the situation to ensure that one does not get less of any basic human right. The compelling arguments for the two-way relationships between access to health care (particularly essential drugs), poverty and sustainable development have already been put forward. By deduction, both the right to health and the right to development imply or include the right to access to essential medicines.

Traditionally, health issues when they reach the courts have tended to be dealt with "from a negative civil liberties perspective rather than consideration of the positive state obligations to provide adequate resources or access to treatment for effective enjoyment" (20). The fundamental human right to access to these medicines remains a challenge and will require further action at the national and international levels. The ethical debate around essential drugs programs exemplifies questions concerning the ethics of scarcity and sacrifice. In the case of Soobramonay vs Minister of Health (Kwazulu-Natal), a diabetic man with chronic renal failure was refused the dialysis treatment due to lack of resources, despite his claim to a "right to life" (22). In Section 27(3) of the Bill of Rights of the South African Constitution: "No one may be refused emergency medical treatment". "Emergency medical treatment" may be possibly open to a broad construction which would include ongoing treatment of chronic illnesses for the purposes of prolonging life (e.g. essential medicines), but this was judged not to be the ordinary meaning of this term. But in a landmark case, the South African government was found to have acted unreasonably in 2001 in (a) refusing to make an antiretroviral drug, nevirapine, available to the public health sector, where the medical doctor considered it medically indicated; and (b) not setting out a time-frame for a national programme to prevent mother-to-child transmission of HIV (23). The weight of case law from around the world, including India and Latin America, is showing that lack of explicit incorporation in a legal code is not a bar to consideration of health issues by the courts (20).

3 - Society

Society is defined as: "A particular community of people living in a country or region, and having shared customs, laws, and organizations (24)." Note that several societies in this sense may exist within a region or within a country. However, the inclusion of "society" as a player in its own right in this discussion of access to essential drugs serves to capture the sense of collective responsibility of a group of people-whether that means a local, regional, national or international community. Besides responsibilities of a whole community as such, we look at responsibilities of individual well-to-do members and at firms outside the pharmaceutical industry, with reference to their general corporate social responsibilities.

The health of the public is a social good, valued as a worthy goal beyond our preference for it or the satisfaction we may get in achieving it, and improving access to essential drugs is part of this social good. The same is true of scientific knowledge. These goods imply a set of responsibilities and therefore duties, tasks, and actions. If we hold that health for communities and for society at large is a social good that has value beyond the fact simply of our desiring it, and if it is a value to which we have committed, then we assume a responsibility for it. We have, in other words, an obligation to take positive action for its actualization.

It is important to distinguish between duty and charity. Charity involves the liberty to divert one's giving elsewhere if it suits one, and to convince oneself of the right to desist if the recipient is "ungrateful" or "undeserving". Such charitable donations are not a reliable resource. Duty, in this case the duty to prevent preventable deaths where one can, is not optional but required. This distinction between duty and charity illustrates how it is difficult to completely consider each of the players in this discussion in isolation. For example, an individual is a member of "society at large" or a sector of society, whether as part of a profession (doctors or nurses), corporation or group (e.g. sick individuals). There is an inevitable overlap between the moral arguments for responsibility of the different players. Here we are considering duty and charity with regard to society, but these arguments can equally be applied to the individuals of that society, as done by the Australian philosopher, Peter Singer, who argues strongly for personal responsibility for responding to developing world problems (25). We can adapt his arguments for addressing world poverty and suffering to the specific issue of improving access to essential drugs, as a social priority, as follows:

If it is in our power to reduce preventable morbidity and mortality (suffering and deaths) by increasing access to essential drugs without thereby sacrificing anything of comparable importance, we ought, morally, to do it.

Proximity in terms of physical distance and association with events may make us more likely to assist but this does not show a greater responsibility to help someone. Just because a person is in the UK, his moral responsibility for people in Sudan who do not receive aspirin and basic antibiotics is not necessarily less than towards the people in his own town.

The number of people in a similar position to help does not lessen an individual's obligation to mitigate or prevent the disease burden due to lack of access to essential medicines. This is controversial because it would mean that even if a government is predominantly responsible for social inequalities and poor access to medicines, the individual still has to exercise his duty. In this scenario, the counter-argument would be that the exercise of this individual's duty is futile and irrelevant because their impact will be minimal until the main responsible party or parties fulfil their duties.

Addressing the most basic needs is not "superogatory"-an act which it would be good to do but not wrong not to do. The case of access to essential drugs, where, for example, the inter-relationships between health, poverty and development are so well-characterised—is a case of duty to help, rather than a case for superogatory charity.

Do other firms also have a corporate social responsibility to contribute to access to essential drugs? Corporate social responsibility (CSR) is an expression used to describe a company's obligation to be sensitive to the needs of all of the stakeholders in its business operations. A company's stakeholders are all those who are influenced by, or can influence, a company's decisions and actions. These can include: employees, customers, suppliers, community organizations, subsidiaries and affiliates, local neighbourhoods, investors, and shareholders. CSR proposes that enterprises should be obliged to make decisions based not only on the financial/economic factors but also on the social and environmental consequences of their activities. It is easier to argue that the pharmaceutical industry bears CSR than, for example, the telecommunications industry. For the latter we would have to argue that a collective responsibility for, in this example, access to essential drugs is more important than the telecommunication industry's responsibility to shareholders. Of particular note, probably the two most substantial corporate contributions relevant to drugs access have come from the IT and finance sectors (from Bill Gates and Warren Buffet); and in fact strictly speaking from hyper-wealthy individuals rather than from their original corporations.

The 1997 Jakarta Declaration on Health Promotion into the 21st Century called for new responses to address emerging threats to health (26). The declaration placed a high priority on promoting social responsibility for health. An especially important arena for healthy public and private policy development is the local community and settings such as schools and workplaces.

There are strong utilitarian arguments for local social responsibility for improving access to essential drugs. Policy-making at macro levels may not be sensitive to the diversity of local conditions that directly affect the access to medicines and therefore the health of different communities. "Beyond that, important health-related planning, policy-making and action originate at the local level. Also, the motivation of local leaders to practise healthy policy-making should be high, since they are affected by their own decisions" (26). In fact, direct motivation can still be low if a leader is a selfish decision-maker for say 50,000 others; but the possible greater pressure from other key local stakeholders may make a difference for the decision-maker at local level.

4 - Individuals (who actually or potentially need medical drugs, and their families)

The question of where the responsibility for an individual's health should lie is crucial in the consideration of issues such as allocation of limited health care resources, health policy and justice in health care. "The locus of blame is key, for if blame is placed on the individual, social structure is exculpated, and the resulting suffering and premature death will not be counted as a social injustice (11)." Wikler summarises: "In addition to maintaining a health system for prevention and therapy, society can try to create a healthy social and physical environment, and can also provide information on risk factors. For their part, individuals can use this information, along with their own knowledge and common sense, to maintain their health as best they can to reduce the need for care (27)."

The use of human rights to hold governments accountable for access to essential drugs has already been discussed. When rights are given to an individual, two forces work to diminish those rights: the rights given to other individuals, and the increased power of governments to intervene on behalf of the individual. There is a danger that when rights are upheld by legal systems, the rights of one individual are competing with the rights of other self-interested individuals asserting their own rights. Instead of freedom of the individual being an end unto itself, the mutualist model views it as a means to achieving a meaningful and fulfilling existence within the context of community. Companies and managements have responsibilities to shareholders, employees and societies at large; employees have responsibilities to customers; customers have a responsibility to give businesses feedback on products, majorities have a responsibility to keep their minorities happy. In a meaningful democracy, all individuals and institutions who claim any kind of right need to accept certain responsibilities, and the same applies when we consider the right of an individual to access to essential medicines. However, this "utopian model" assumes that all individuals are able to exercise their basic human rights equally. The reality is that some people are more equal than others when it comes to access to essential medicines, whether we are looking at the situation at local, regional, national or international level. Therefore, it is impossible to assign total responsibility to individuals for their access to essential drugs.

The actual consequences of the health choice of an individual partly depend on factors outside the individual's control. Another view states an obligation to help people in extremis no matter why they are in such a situation provided that helping is possible. The argument of non-neutrality is concerned with the possibility that only certain types of risky behaviour will be identified as "of special concern" (28). What kind of risky behaviour should be identified as of special concern? Sen divides health into "achievement" and "capability", on the one side, and "the facilities socially offered for that achievement" (such as health care), on the other (29). He argues that there are many factors that can contribute to health achievements and failures (including genetic predisposition and diet), not just health care, and therefore neither social nor personal responsibility is absolute, and this includes for access to medicines. When we consider access to essential drugs, stressing personal responsibility (causal or response) is not a defensible concept, since we would be blaming people in the developing world for the consequences of their actions, and doing the opposite in developed

countries with publicly supported health systems. This is particularly unjust, given that many of the drugs in question are not affordable to the individual in the poor country.

To apply a "luck egalitarian" framework to an individual's responsibility for access to drugs in the nationalised health system of a developed country (e.g. UK), "brute luck" is removed as a factor because all people have access to essential medicines. If a person chooses to smoke, this is "option luck" since an active decision has been made to increase risk of cancer, lung and heart disease, and personal responsibility ensues. However, if there is poor education about diseases, "brute luck" predominates, and the person is absolved of at least part of the responsibility.

In order to illustrate the interplay of responsibility, brute luck and option luck in developing countries, we will consider three patient scenarios, which I introduce below:
(1) Robert is a 3 year old South African boy who has HIV/AIDS. It was transmitted to him by his mother during pregnancy. His only hope is lifelong treatment with anti-retroviral drugs (ARVs).

(2) Manisha is a 27 year old Indian woman, who works as a sex-worker in Mumbai and was diagnosed with HIV/AIDS 3 years ago. She grew up in extreme poverty in a village and was sent to work in the city at the age of 14. She requires antibiotics for recurrent pneumonia and ARVs.

(3) Jerome is a 54 year old Sudanese man who had a heart attack 4 years ago. He has had high blood pressure for 10 years and diabetes for 3 years. He smokes 5-10 roll-up cigarettes per day and suffers from angina. This case illustrates an adult (capable of making decisions and exercising causal and response responsibility) with a chronic disease. This disease is caused by a complex interplay of risk factors over a period of time. Drug treatment can be (i) treatment of the active problem (anti-anginal therapy or aspirin for a heart attack); (ii) primary prevention (modification of risk factors before the first heart attack has occurred); and (iii) secondary prevention (modification of risk factors after the heart attack to prevent further heart attacks).

There are four situations when responsibility might rest upon an individual requiring treatment. Firstly, in socialized care settings (e.g. UK or Australia), the government might already be doing a great deal in terms of healthcare provision, including access to drugs. In this case, "causal and response responsibility" for not having access to essential drugs must be assigned to some extent to the individual. For example, in the UK, an intravenous heroin user who, due to a chaotic lifestyle, is unable to use oral antibiotics effectively to treat his chest infection cannot claim that he does not have access to essential medicines. This principle is true for all actors in a "sliding scale" approach; if the other actors are bearing their required response responsibilities, then the party failing to meet its role must bear more response responsibility for a shortcoming and for achieving improved access to essential drugs. Some responsibility for health in this case and therefore for treatment must be taken by individuals. This is less true in all three patient scenarios described above, where only the most basic of drugs may be available, even for the most significant causes of the burden of disease. In an ideal world, all players would fulfil their relative responsibilities in a "scale of

responsibility". If key players fail to fulfil their responsibilities, the scale "slides" to increase the relative responsibilities of other players. If this did not happen then no party would take eventual responsibility and the end goal (in this case access to essential drugs) cannot be realised. The term, "sliding scale" is used to capture the reality of changing relative responsibilities of key stakeholders.

Secondly, when rationing of resources is necessary due to resource availability and cost considerations in a public sector setting, a person's causal responsibility for their illness may have to be considered. People rarely fall ill without certain risk factors interplaying, and the individual may be causally responsible for risk behaviours. For example, unsafe sex practices make HIV/AIDS more likely and smoking increases the risk of coronary heart disease. Advocates of personal responsibility might argue that if a person displayed risky behaviours, then they must take the blame for the outcome, possibly including responsibility for drugs and medical treatment. If a person is conclusively shown to have causal responsibility for their illness then perhaps they should be more accountable for its treatment than somebody who was just unlucky in becoming ill.

Robert has indisputably no causal responsibility, firstly because he is an infant unable to make decisions affecting his health, and secondly because his illness was contracted by no fault of his own (complete brute luck).

Manisha contracted HIV/AIDS through her work as a sex-worker. She was forced to follow this line of work by extreme poverty, poor education and other socio-cultural barriers. The environmental factors in this case far outweigh her power over the decision to have high-risk sexual intercourse and therefore, due to the predominance of brute luck, she is absolved of personal causal responsibility.

Jerome suffers from coronary heart disease (CHD) because of the interplay of smoking, diabetes and hypertension. Although he continues to make the conscious decision to smoke, he has been smoking since he was 12 years old. He never received any treatment or follow-up for his diabetes and high blood pressure (which also increase his risk of CHD) due to lack of clinics, hospitals and doctors in his village. Through smoking, Jerome has some causal responsibility for his disease. However, the option luck of smoking is lessened by the fact that he became habituated when only 12 years old. The brute luck of his untreated diabetes and hypertension also greatly reduce his causal responsibility.

These considerations show that it is very difficult to specifically define the "option luck" component and to apportion blame for an individual's illness in poorer countries because a disease process occurs as a complex interaction of genetic and environmental factors. The environmental factors include parental input, education, information availability and socioeconomic status which may not be under an individual's control, and may play a major role in causation of the disease process. In these cases, an individual cannot hold full causal responsibility (if any) for their disease and therefore for its treatment. Even if full causal responsibility can be demonstrated, response responsibility is dependent upon capability to obtain access to medicines. Jerome, Manisha and Robert are all lacking in capability to buy the essential drugs for their diseases.

Thirdly, in countries or regions where there is not enough government provision, there is a moral paradox because more forward-looking or response responsibility is apportioned to the individual, particularly as the need and the level of poverty increases. For example, in the USA, even though an individual may lack health insurance, the price of essential drugs (particularly generic medicines) may not be prohibitive, and there is some free or subsidised provision for the lowest-income groups within the population. On the other hand, in a low-resource setting such as Tanzania, the only way that a patient may gain access to an essential drug (in an emergency scenario) is by out-of-pocket-payment. Knowing this fact, the individual will have to bear the responsibility to obtain that treatment. The American individual in this scenario may have more causal responsibility in his lack of independent acquisition of drugs and more capability, but paradoxically shoulders less response responsibility than his Tanzanian counterpart. Jerome, Manisha, and Robert's family all have to exercise response responsibility despite minimal capability.

Fourthly, in treatments (and therefore illnesses) which are not considered essential (by general consensus), an individual becomes responsible (forward-looking) for bearing the cost. If an essential treatment is available but an individual requests a different standard or type of care, the cost of the treatment should be borne by the individual.

Carers and relatives of patients often play a role in access to essential medicines, particularly in procurement of drugs. Treatment of a chronic disease may have serious implications for a household's income. Should the degree of responsibility for a patient's essential drug therapy depend upon the extent of the relationship between the patient and carer/family member? By this logic, would a father be more responsible for acquiring his son's treatment than a nephew for acquiring treatment for his uncle? In cultures where the extended family set-up predominates, family members definitely take more part in the medical/nursing care of their relatives. On the other hand, In the USA or UK, there are often instances where family members are not involved in such matters and it is left to the health service or the government to take response responsibility for the individual's care. Ironically the culture of the "extended family" tends to be more common in poorer countries. Again, in these countries or regions where there is not enough government provision, there is a moral paradox where more responsibility will in practice fall upon the family despite its lower income. It is ideologically difficult however to legally impose responsibilities for access to essential drugs on to carers and family in wealthier countries, because socio-cultural factors are so variable.

Doctors and health professionals are governed by professional moral codes of practice of "beneficence, non-maleficence, justice and veracity". Using these principles, they must attempt to provide access to medicines and treatment in health systems with limited resources. In every setting, some form of rationing will be necessary and health professionals at some level will have to decide between providing different treatment based on factors such as numbers of lives saved (using measures such as disability-adjusted life-years, or DALYs) and other types of cost-effectiveness, duration of patient follow-up, and public and governmental pressures. The concept of "essential" drugs should, in theory, remove this difficulty because all essential drugs should be available to everybody regardless of resource

constraints. Through their professional knowledge, health professionals are morally responsible (in the forward-looking sense) for using drugs properly and maximising availability to patient populations.

CONCLUSIONS

If we refer back to figure 2, availability of proper drugs is not the only requirement for ensuring successful therapy. Having educated personnel, and laboratory and other infrastructure is also important. If those are inadequate, the advantages of having potent drugs at hand will be lost or even reversed (30). Even if only well-selected, essential medications are available, their correct use is not guaranteed. Access to essential drugs is a complicated issue and is affected by many factors and actors.

Responsibility is only meaningful in the context of capability, or "the power to exercise" that responsibility. It is not possible to assign responsibility for access to essential drugs to an individual who has no way of achieving this goal due to factors outside of his/her control. There is inter-dependence between the different players mentioned in the preceding discussion, which means that any attempt to achieve access to essential medicines must acknowledge their specific responsibilities. Even if a pharmaceutical company makes drugs available for free, they might not reach all patients due to lack of infrastructure or due to lack of education on the part of the patient. In this case, the government must also bear some of the responsibility. Governments and the pharmaceutical industry have the greatest power to institute change in the structures which have most influence on drug access and so the greatest responsibility and response must be borne by these two players. If as much as possible is done by them to make the drugs available and affordable to everyone, then persistent lack of access to medicines must to some extent occur due to failure of individual responsibilities by exclusion. However, from the preceding discussion, it is clear that in developing countries, it is typically almost impossible to argue the case of option luck and personal causal responsibility, even though in reality, individuals and their families often end up bearing the brunt of the response responsibility for access to essential medicines. In other words, it is difficult to assign absolute responsibility for drug access but the relative responsibility of governments and pharmaceuticals is greater than other players. The views proposed in this paper connect elements of individual responsibility with elements of mutualism and solidarity, to form a workable framework for access to essential medicines.

As Peter Singer wrote, "What is the point of relating philosophy to public (and personal) affairs if we do not take our conclusions seriously? In this instance, taking our conclusion seriously means acting upon it (25)." Stakeholder analysis provides information to evaluate and understand stakeholders in terms of their relevance to a policy or specific activity. Stakeholder analysis aids evaluation, implementation, planning and management activities (30, 31). It is "an approach, a tool or a set of tools for generating knowledge about actors – individuals and organizations – so as to understand their behaviour, intentions, interrelations and interests and for assessing the influence and resources they bring to bear on decision-making or implementation processes" (32). Ethical responsibility should be part of this

stakeholder analysis of any programme to improve access to drugs. Alternatively, a separate "relative responsibility analysis" of the different players should be done to show who should be pushing this issue forward.

How do we adhere to fundamental medical principles with restricted or shrinking economic resources? How restrictive should the essential drugs lists be? How should the individual rights of patients be handled in the face of the compelling needs of society? (33) These are central questions for the use of human rights and ethics to uphold access to essential medicines as a means of addressing poverty, inequality and development, and require much further targeted research.

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