

Neglected Diseases, Access to Medicines and Access to Knowledge

“Knowledge is not only power but also responsibility,
because it places us in a position to act”
Henry Shue¹

Introduction

To illuminate the field of health, the equity principle can be examined in light of social justice theories. Equity and Human Rights (HRs) frameworks suggest wealthy countries and powerful institutions, such as pharmaceutical transnational corporations (PTNCs), bear responsibility to tackle deprivation and ill health within and beyond their spheres of influence².

Regarding the design of health programs, neglected diseases (NDs) must be given priority as they significantly affect marginalized groups, perpetrating their poverty. Only through an equity and HRs perspective, will global health programs sustainably empower and develop affected communities.

My aim is to raise public awareness of the implications of health-related education, knowledge, and information. This includes benefits and applications of scientific innovations, amid public and private development of health policies.

I will first analyze the reciprocal interactions between HRs, the right to health (RtH), access to medicines (AtM), and access to knowledge (AtK), emphasizing their synergy. Drawing upon principles of equity, equality, and non-discrimination, I will address the current global health problem of NDs, and also addressing NDs as a HRs violation. I will subsequently compare and contrast two approaches to increasing research and development (R&D) for NDs in line with the aforementioned principles.

Health and HRs

HRs are legal entitlements, imposing legal obligations on duty-bearers, and granting rights to all individuals³. The traditional concept of HRs is state-centered; however, a broader concept is evolving, encompassing non-state actors⁴, including transnational corporations (TNCs) and particularly PTNCs, even with States as primary

¹ H. Shue, *The Interdependence of Duties*, in P. Alston, K.Tomasavski (eds), *The Right to Food*, Int'l Studies in Human Rights, Netherlands Institute for Human Rights, Martinus Nijhoff Publishers, 1984, p. 91

² P.Braveman, S.Gruskin, *Poverty, equity, HR and health*, In *Bulletin of the WHO*, 2003,081 (7), p. 541

³ According to Hunt, “HRs are entitlements underpinned by universally recognized moral values and reinforced by national and international legal obligations on duty bearers”. (TDR/SDR/SEB/ST/07.2, P.Hunt, *Neglected Diseases: a HR analysis*, In *Special topics in Social, economic, and behavioural research report series*, No. 6, 2007, p. 4)

⁴ A. Clapham, *Human Rights Obligations of Non-State Actors*, Oxford, OUP, 2006
P. Alston (ed), *Non-State Actors and Human Rights*, Oxford, OUP, 2005

duty-bearers⁵. PTNCs thus have HRs obligations, principally regarding the RtH, as they exercise direct influence over the realization of the right.⁶

As proclaimed by the WHO Constitution (1946), health is a state of complete physical, mental, and social well-being, not simply the absence of illness. Accordingly, the right to the enjoyment of the highest attainable standard of physical and mental health (RtH) is a fundamental HR, recognized in international⁷, regional⁸, and domestic⁹ legal systems.

Equality and Non-Discrimination

Discrimination refers to any sort of distinction, exclusion, restriction, or preference that poses obstacles to the equal enjoyment of freedoms and entitlements for all¹⁰. However, equality does not necessarily entail identical treatment, but equal regard before the law¹¹. Equity aims at minimizing inequalities¹² while equality and non-

⁵ P.Hunt, *Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines*, In *The General Assembly of the UN Special Rapporteur on the right to the highest standard of health*, 11 August 2008 (UN Doc: A/63/263)

P. Hunt, *The right of everyone to the highest attainable standard of physical and mental health*, 13 September 2006 (UN Doc: A/61/338)

J. Ruggie, *Report of the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises*, 7 April 2008 (UN Doc: A/HRC/8/5)

⁶ According to J. Ruggie, where a company's "activities or relationships" are causing actual harm, then remediation is part of a company's duty to respect human rights. (*Report of the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises*, 7 April 2008 (Un Doc: A/HRC/8/5).

⁷ Universal Declaration of Human Rights - UDHR (1948), art. 25 (1);
International Covenant on Economic, Social and Cultural Rights - ICESCR (1966), art. 12;
International Convention on the Elimination of All Forms of Racial Discriminations - ICEFRD (1969), art. 5(e) (iv);
Convention on the Elimination of All Forms of Discrimination against Women - CEDAW (1981), arts 11 (1) (f), 12 and 14 (2) (b);
Convention on the Rights of the Child – CRC (1990), art 24;
International Convention on the Protection of the Rights of All Migrant Workers and Members of their families (1990), arts 28, 43 (1) (e), and 45 (1) (c);
Convention on the Rights of Persons with Disabilities (2008), Preamble (v), art. 16 (4), 22 (2), 25, 26 (1), 27(a) (b).

⁸ African Charter on Human and People's Rights (1986), art. 16; African Charter on the Rights and Welfare of the Child (art.14)

Additional Protocol to the American Convention on the HR in the Area of Economic, Social and Cultural Rights – Protocol of San Salvador (1999), art. 10;

European Social Chapter (1999), arts 11 and 13.

⁹ According to the former UN Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Paul Hunt, over sixty constitutions enshrine the RtH (E/CN.4/2003/58, UN Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, *Preliminary Report to the United Nations Commissions on HR*, New York, United Nations, 13 February 2003).

¹⁰ CCPR, General Comment No. 18, 1989, para 7

¹¹ CCPR, General Comment No. 18, 1989, para 13

¹² P.Hunt, *Neglected Diseases: a HR analysis*, In *Special topics in Social, economic, and behavioural research report series*, No. 6, TDR/SDR/SEB/ST/07.2, 2007, p. 16

discrimination have the potential to reinforce resistance to power imbalances¹³, providing a framework to enhance accountability and achieve equity in reality.

We will focus on NDs, as an outcome and cause of discrimination and social stigma, and as a consequence of lack of access to medicine and knowledge. These factors compound the vicious cycle of poverty and ill health¹⁴.

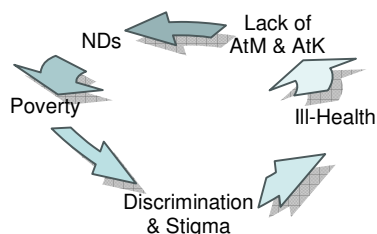


Fig. 1: The vicious cycle of Poverty, Discrimination and Stigma, Ill Health, Lack of Access to Medicines and Knowledge and Neglected Diseases.

Neglected communities affected by NDs are victims of discriminatory practices, given their health status or associated disabilities, leading to stereotypes and prejudice. Stigmatization then prevents diagnosis, deferring treatment and control. Therefore, access to treatment, including medicine and knowledge, is a powerful instrument to combat discrimination¹⁵. Access to health education, information, and knowledge, enhances awareness about prevention, treatment, control, and causes of diseases¹⁶. Both AtM and AtK are therefore crucial to ending the vicious cycle. International HRs law that prohibits discrimination in access to health-care facilities, services, and goods¹⁷ reinforces the responsibilities of duty-bearers.

AtM as a HR

AtM is a global concern, with numerous people threatened,¹⁸ as one-third of the world's population has no access to essential drugs¹⁹. Medicines are a critical element of

¹³ P.Farmer, *Pathologies of Power – Health, HR, and the war on the poor*, California, UCP, 2004.

¹⁴ NDs cause not only physical and mental suffering, but also a vast economic burden, given the highly cost treatments and the lost of productivity in work (P.Hunt, *Neglected Diseases: a HR analysis*, In *Special topics in Social, economic, and behavioural research report series*, No. 6, TDR/SDR/SEB/ST/07.2, 2007, p. 3)

Poverty leads to ill-health and ill-health leads to poverty (WHO, *Macroeconomics and Health: Investigating in Health for Economic Development: Report of the Commission on Macroeconomics and Health*, Geneva, 2001)

P.Braveman, S.Gruskin. *Poverty, equity, HR and health*, In *Bulletin of the WHO*, 081 (7), 2003, p. 539

¹⁶ CESCR, General Comment No. 14, para 36

¹⁷ CESCR, General Comment No. 14, para 18, 19.

¹⁸ Approximately one billion people are affected by NDs in the world (WHO, *A HR-based approach to Neglected Tropical Diseases*, 2008. Available at: http://www.who.int/neglected_diseases/Human_rights_approach_to_NTD_Eng_ok.pdf)

the RtH, and must be available in sufficient quantity, physically and economically accessible, culturally and ethically acceptable, and of good quality. Additionally, they must be scientifically and medically approved. When it comes to medicines for NDs, accessibility is the most pressing problem especially for the neglected²⁰. Accessibility includes the right to pursue, receive, and communicate information and knowledge. This includes benefits and applications of scientific progress. However, socio-economic inequalities can prove to be obstacles.²¹

AtK as a HR

AtK is directly related to the right to enjoy the benefits of scientific progress and its applications²². The definition of AtK is rooted in four elements: information, knowledge, knowledge-embedded goods, and tools²³. It is a response to intellectual property (IP) rules, rejecting “intellectual enclosure”²⁴, seeking to promote balanced IP policies²⁵. The 2005 CESCR General Comment No. 17²⁶ describes IP as a social product with a social function. Consequently, wealthy states and powerful non-state actors should cooperate to foster new approaches to R&D for NDs²⁷.

The main challenge regarding neglected populations and NDs is innovation in non-market guided research, ensuring the inclusion, participation, empowerment, and development of neglected populations²⁸. Above all, AtK will be effectively realized only when public policies committed to HRs principles are enacted.

AtM as AtK

AtM and AtK are intrinsically linked. The relationships between health, HRs, AtM, and AtK are harmonized in the eighth Millennium Development Goal on Global

¹⁹ P.Hunt, *Neglected Diseases: a HR analysis*, In *Special topics in Social, economic, and behavioural research report series*, No. 6, TDR/SDR/SEB/ST/07.2, 2007, p.33

²⁰ P.Hunt, *Neglected Diseases: a HR analysis*, In *Special topics in Social, economic, and behavioural research report series*, No. 6, TDR/SDR/SEB/ST/07.2, 2007, p.31

²¹ Access to health care is not shared equally and significant disparities remains not only between countries, but al within the same country. (D. Tarantola *et al*, *HR, Health and development*, In *Australian Journal of HR*, Vol. 13 (2), 2008, p. 9)

²² UDHR, art. 27

²³ J.Balkin, *What is Access to Knowledge?* In *Balkinization*, April 21, 2006. Available at:

<http://balkin.blogspot.com/2006/04/what-is-access-to-knowledge.html>

²⁴ L.Shaver, *Access to Knowledge in Brazil – New Research on Intellectual Property, Innovation and Development*, Yale UP, 2008, p. 12

²⁵ WIPO, *The 45 Adopted Recommendations under WIPO Development Agenda*, 2007.

²⁶ Note: See Paragraph 35.

²⁷ P.Hunt, *Neglected Diseases: a HR analysis*, In *Special topics in Social, economic, and behavioural research report series*, No. 6, TDR/SDR/SEB/ST/07, 2007, p. 38

²⁸ “You can make drugs cheaper or you can give people information about their health. Why not do both? You can reduce the costs of information embedded goods, or you can free up access to knowledge tools, increase literacy rates, and let people build things together and share their efforts. Again, why not do both?” (J.Balkin, *What is Access to Knowledge?* In *Balkinization*, April 21, 2006. Available at: <http://balkin.blogspot.com/2006/04/what-is-access-to-knowledge.html>)

Partnerships for Development, in targets 17 and 18²⁹. Access to health-related information, knowledge, and education, including the benefits and applications of scientific progress, is a determinant of health and is essential to tackle prevention, treatment, and control of NDs.

The diagram below demonstrates the synergy and mutual reinforcement of AtM and AtK, and the interaction with RtH and HRs principles. This corroborates the relevance of a HRs-based approach to health policies, rather than short-term drug supply policies, which fail to consider poverty and ill health, lack of information, knowledge, and education.

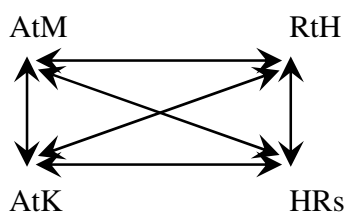


Fig 2. The reciprocal interactions existing between Access to Medicine and Access to Knowledge, in connection with the Right to Health standards and the Human Rights principles.

According to Balkin³⁰, drugs are goods embedded in information and knowledge. Currently, control over information and knowledge progressively defines global health and power³¹. Therefore, I argue that the most suitable policies addressing NDs are based on a public-private partnership (“PPP”), guided by HRs principles, RtH standards, AtM, and AtK goals. This PPP should not merely supply drugs, but ensure meaningful participation, inclusion, empowerment, and development of afflicted communities. Thus, guaranteeing access to health-related information, knowledge, and education.

The problem of neglected diseases (NDs)

NDs³² are those maladies that primarily afflict neglected populations. Despite their pervasive nature, these diseases often receive limited to no resources³³. There are insufficient market incentives to research and develop vaccines and medicines for NDs,

²⁹ MDG 8: *Develop a Global Partnership for Development*

Target 17: *In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries*

Target 18: *In cooperation with the private sector, make available the benefits of new technologies, especially information and communications technologies*

³⁰ J.Balkin, *What is Access to Knowledge?* In *Balkinization*, April 21, 2006. Available at:

<http://balkin.blogspot.com/2006/04/what-is-access-to-knowledge.html>

³¹ On the topic of NDs and the power imbalances entailing the problem: P.Farmer, *Pathologies of Power – Health, HR, and the war on the poor*, California, UCP, 2004.

³² According to the WHO definition, NDs are those affecting almost exclusively poor and powerless people living in rural parts of low-income countries. (WHO/CDS/2003.15, M.Kindhauser (ed), *Communicable Diseases 2002: Global defense against the infectious diseases threat*, Geneva, WHO, 2003).

³³ Approximately one billion people are affected by NDs in the world (WHO, *A HR-based approach to Neglected Tropical Diseases*, 2008. Available at:

http://www.who.int/neglected_diseases/Human_rights_approach_to_NTD_Eng_ok.pdf)

as affected people are mainly poor and unable to pay for them. Attention should focus on NDs as they perpetuate the vicious cycle of poverty and ill health,³⁴ disproportionately affecting the poor, and exacerbating poverty³⁵.

R&D is crucial to foster availability, accessibility, and quality of new vaccines and drugs for NDs. The current imbalance in R&D, known as the 10/90 gap³⁶, reflects a failure of the market and public health policies. Market-determined R&D does not correspond to the health needs of the poorest and most marginalized communities, with low purchasing power.

Powerful states and non-state actors have engaged in framing the global public health agenda, cooperating in the prevention, treatment, and control of diseases³⁷. We will therefore analyze two proposed solutions to the problem of NDs, and their plausibility in light of equity and HRs principles, particularly regarding AtM and AtK goals. The scrutiny of NDs through the lens of HRs demonstrates that a health policy research agenda needs to go beyond drug provision and R&D.

Proposed solutions to increase R&D for NDs

Existing medical R&D incentives generally follow two types: government research grants and subsidies or sales revenues. The former area pushes funding mainly directed to basic research, while the latter are pull investments usually granted to PTNCs for applied research on specific drugs. This system of finance, combined with a temporary monopoly on patents for the inventor, results in unaffordable drug prices for the poor.

The world response to the current health crisis is diverse, incorporating initiatives ranging from the WHO/UNAIDS program to the DNDi, or Drugs for NDs Initiative³⁸.

³⁴ NDs cause not only physical and mental suffering, but also an vast economic burden, given the highly cost treatments and the lost of productivity in work (TDR/SDR/SEB/ST/07.2, P.Hunt, *Neglected Diseases: a HR analysis*, In *Special topics in Social, economic, and behavioural research report series*, No. 6, 2007, p. 3)

Poverty leads to ill-health and ill-health leads to poverty (WHO, *Macroeconomics and Health: Investigating in Health for Economic Development: Report of the Commission on Macroeconomics and Health*, Geneva, 2001)

P.Braveman, S.Gruskin. *Poverty, equity, HR and health*, In *Bulletin of the WHO*, 081 (7), 2003, p. 539

³⁵ P.Braveman, S.Gruskin. *Poverty, equity, HR and health*, In *Bulletin of the WHO*, 081 (7), 2003, p. 542

³⁶ As explained by Hunt, the 10/90 gap refers to the current fact that only 10% of global fund for research is directed to those diseases that afflicts 90% of the world's population. Also, as reported by MSF, of the 1393 total new drugs approved between 1975 and 1999, only 16 (which corresponds to 1%) were designed for ND treatment. (TDR/SDR/SEB/ST/07.2, P.Hunt, *Neglected Diseases: a HR analysis*, In *Special topics in Social, economic, and behavioural research report series*, No. 6, 2007, p. 38).

³⁷ D. Tarantola *et al*, *HR, Health and development*, In *Australian Journal of HR*, Vol. 13 (2), 2008, p. 10

³⁸ There are important initiatives including the WHO/UNAIDS program, The U.S Emergency Plan for Aids Relief, the public-private partnerships (such as the Global Alliance for Vaccines and Immunization and the Global Fund to Fight Aids, Tuberculosis and Malaria), PTNCs' drug donations, the DNDi (Drugs for NDs Initiative), Roche's Initiates on R&D For Neglected Tropical Diseases and on Access to Medicines and Diagnostics, The AstraZeneca TB Research Initiative in Bangalore/India, The Schering-Plough Charitable Contributions Program, to name but a few.

Despite improving the health situation in many communities, they are not sufficient to end the current health crisis, merely neutralizing the patents system burden imposed on the poor.

The Health Impact Fund

Assuming that a reform of unjust global institutional arrangements³⁹ will end the cycle of poverty and ill health, Aidan Hollis and Thomas Pogge propose restructuring the current scheme of incentives for new medical treatment R&D⁴⁰. The proposed solution would be optional, complementing the existing patent regime. The creation of a health impact fund (HIF) would allow pharmaceutical innovators the choice to forego the current market-exclusivity system in exchange for a reward. By voluntarily registering the patent with HIF, the inventor would agree to sell at a low price, near to cost of production, but would receive an annual reward within a set time period. This would depend on both drug cost-effectiveness ratio and global health impact.

HIF would stimulate additional pharmaceutical research, particularly on NDs⁴¹. This would overcome the failure of the traditional market, since PTNCs would compete to earn HIF share, developing and ensuring widespread drug distribution to achieve the largest possible global health impact.

The Prize System

Knowledge Ecology International (KEI) and others react to HIF with skepticism. Since it is essentially a voluntary prize fund without open-licensing, HIF would undermine generic drug competition in developing countries, and provide very little real relief to market exclusivity⁴².

Alternatively, James Love and Tim Hubbard defend the approach. Prizes would replace high prices and exclusive rights as R&D incentives⁴³. A treaty would settle the prize, where the inventor agrees to a license, enabling generic competitors to produce the drug, leading to lower prices and greater access⁴⁴. The license provision would cover know-how and patents, including royalties. Thus, it would ensure reasonable rewards to inventors, whilst allowing technology transfer, generic production, and compliance with AtK goals⁴⁵.

³⁹ T. Pogge, *World Poverty and HR*, 2nd ed, Cambridge, Polity Press, 2008

⁴⁰ T. Pogge, *The Health Impact Fund: Boosting Pharmaceutical Innovation Without Obstructing Free Access*, In *Health and HR*, Cambridge Quarterly of Healthcare Ethics, 2009, 18, pp. 78-86

⁴¹ A.Pinzani, *Global Justice as a Moral Issue – Interviewing Thomas Pogge*, in *ethics@*, Vol. 4 (1), 2005, pp. 1-6.

⁴² B.K.Baker, *Skepticism about the Health Impact Fund*, Health Gap, 24 Nov 2008. Available at: www.healthgap.org/trips/bakeronHIF.htm

⁴³ J.Love, *Prizes, not Prices, to stimulate antibiotic R&D*, 26 March 2008. Available at: <http://www.scidev.net/en/opinions/prizes-not-prices-to-stimulate-antibiotic-r-d.html>

⁴⁴ J. Love, T. Hubbard, *The Big Idea: Prizes to Stimulate R&D for New Medicines*, In *Chicago-Kent Law Review*, Vol 82, No 3, November 2007, pp. 1519-54.

⁴⁵ R. Marchant, *Managing Prize Systems: Some Thoughts on the Options*, in *KEStudies*, Vol 2, Feb 2008

The scheme would be non-voluntary, because a compulsory prize mechanism would ensure incentives needed in case of Type III, and some Type II diseases⁴⁶.

Final remarks

Having demonstrated the reciprocal interactions between HRs, RtH, AtM, and AtK, two proposed solutions to R&D for NDs were proposed. Ultimately, I defend a broader equity and HRs-based approach to health policies.

HIF goes beyond the mere development and distribution of medicines. It is conceived under a more comprehensive institutional reform, as a solution to the pricing dilemma⁴⁷. As HIF rewards are based on global drug accessibility, if high prices were applied to HIF-registered medicines, this would substantially diminish the medicine's influence, and consequently reduce the value of the reward. The HIF also responds to HRs principles, particularly equality and non-discrimination. This stimulates PTNCs to address the local needs of the most vulnerable, marginalized, and disempowered communities, particularly through the provision of health education.

HIF also complies with RtH and AtM concerns, encouraging control and prevention, since the health impact incorporates the new drug's influence on mortality and morbidity worldwide. Concomitantly, HIF targets a bigger challenge, stimulating PTNCs to go beyond, also protecting and fulfilling the RtH. This is done by providing access to health information on the use of the drug. However, HIF does not ensure the participation and development of communities, as it fails to deal with exclusivity in technology.

HIF would be strengthened through a mandatory license provision linked to its reward system. Clearly, compulsory participation would be highly controversial, but it may be the only way to ensure political will from PTNCs and governments. To ensure commitment of PTNCs throughout the drug development process, distribution, and education, requires a detailed agreement. An established evaluation committee would monitor the progress achieved after drug distribution to better comprehend the actual global health impact of the new drug.

⁴⁶ "Type I diseases are incident in both rich and poor countries. Type II diseases are incident in both rich and poor countries, but have the larger proportion of cases in developing countries. Type III diseases are those that are overwhelmingly or exclusively incident in developing countries. Experiments with prizes could focus on particular diseases, like tuberculosis, malaria or American trypanosomiasis, or more generally on Type II or III diseases." (R. Marchant, *Managing Prize Systems: Some Thoughts on the Options*, in *KEStudies*, Vol 2, Feb 2008).

⁴⁷ "Optimal policies and programs must simultaneously consider the implications for health, development and HR, maximizing overall benefit and minimising pitfalls and potential harms". (D. Tarantola *et al*, *HR, Health and development*, In *Australian Journal of HR*, Vol. 13 (2), 2008, p. 14)

Abstract

In the first part of the article, I demonstrate the reciprocal interactions among human rights, the right to health, access to medicine, and access to knowledge. I highlight their connection to the twin principles of equality and non-discrimination, in relation to the vicious cycle of poverty and ill health. In the second part, I address the case of neglected diseases as a grave violation of these rights. I then compare and contrast two proposed solutions aimed at increasing research and development for neglected diseases, namely, the health impact fund and the prize system. I defend a broader equity and human-rights-based approach to global health policies, as opposed to a short-term policy seeking to merely provide drugs. My paper contends that a combination of both solutions, with detailed agreements and oversight, would be ideal to respond to both access to medicines and access to knowledge concerns.

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