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The right to health as the basis for universal access to essential medicines

Perehudoff, Sammi-Jo Katrina

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Summary

An estimated 2 billion people lack regular access to essential medicines. Many of these people live in low- and middle-income countries. Low- and middle-income countries with inadequate health insurance or universal health coverage (UHC) schemes often have a large proportion of financially-vulnerable people who are dependent on government-subsidised essential medicines. Some UHC initiatives demonstrate increases in medicines sale and use, which can be seen as proxy indicators of access. Poorly designed or implemented UHC schemes can also perpetuate health inequities. How national governments design and implement UHC schemes to finance and supply essential medicines can have a major impact on health equity. Indeed, legal rules structure much of our environment, from the organisation and provision of health care to the social conditions that influence well-being. Yet, there is a dearth of guidance from the World Health Organization (WHO) to advise its Member States on legislating for equitable access to essential medicines.

Human rights have the potential to transform social, political, and legal norms. In 2000, the Committee on Economic, Social and Cultural Rights broke new ground by publishing its first-ever authoritative interpretation of State obligations towards the right to health (enshrined in the 1966 International Covenant on Economic, Social and Cultural Rights). General Comment No. 14 established that State parties have the minimum core obligation to provide essential medicines, defined by WHO, without discrimination. Despite this development, access to essential medicines for the world's poor and vulnerable has made little progress, except for a few medicines such as antiretrovirals. The central premise of this thesis is that human rights principles and language, when embedded in domestic law and policies, can remedy the widespread political and legal indifference in attaining universal access to essential medicines, particularly for the most vulnerable.

This thesis aims to determine how international human rights law has been embedded in national law and policy, and been implemented and enforced in practice to promote universal access to medicines. This thesis presents the first systematic inquiry into how international human rights law can be translated into policy lessons for domestic law and policy makers about access to essential medicines.

This thesis examines which global human rights standards apply to essential medicines, how they correspond to targeted policy measures, and how governments have legalised, interpreted, enforced, and implemented those measures through national law and policy. The specific research questions are: 1) what action should governments take from a human rights perspective to provide essential medicines

in relation to their available resources; 2) how are government commitments to provide medicines embedded into the text of domestic law and policy; 3) how do governments implement their obligations to achieve access to essential medicines in national health systems; 4) how do domestic courts interpret these legal commitments in the context of litigation for access to medicines.

Principles identified in international human rights law and policies of the WHO can be assembled in a normative framework to evaluate State action to provide essential medicines. This thesis uses legal analysis of authoritative texts from the International Covenant on Economic, Social and Cultural Rights, the International Covenant on Civil and Political Rights, General Comments and Statements, and WHO policy documents to develop a framework consisting of 12 principles in 3 domains: legal rights and obligations, good governance, and technical implementation. From a health policy perspective, this thesis developed a normative compass that governments and judiciaries can use to navigate the ethical and economic challenges associated with public medicines provision. Other stakeholders can use these authoritative norms and legal texts as advocacy tools for expanded access to essential medicines.

Our study identifies example texts from national laws and policies that express those duties in legal language. Legal texts for access to medicines are derived from domestic constitutional law, national pharmaceutical policies, UHC legislation, and domestic case law. These practical examples for essential medicines show that human rights language - once thought of as a discourse of global health policy and a few domestic jurisdictions - has permeated many domestic legal spheres.

The thesis also measures States' achievement of their right to health obligations using eight indicators for access to medicines. Data collected in 2015 from 195 countries is compared to data from a 2008 report of the same indicators by the United Nations Special Rapporteur on the Right to Health. Our research illustrates that many countries for which data were available have progressed on most of the indicators of access to medicines; yet most still fail to meet official targets. The systematic collection and reporting of data is improving, which is the first step towards rights realisation. Nevertheless, we demonstrate that the challenges of monitoring access to medicines globally, highlighted during the tenure of the Millennium Development Goals, regrettably persist in the era of the Sustainable Development Goals (SDG). A human rights framework is dynamic and can be used to establish or describe norms and track real time progress towards those standards.

Our case study of enforcing legal commitments to essential medicines in Uruguay shows that even the most rights-compliant legislation is nevertheless subject to the unique interpretation by domestic courts. We also show that national judiciaries may diverge from authoritative interpretations of the right to health. In summary, our legislative and judicial evidence further substantiates that human rights law yields both legally binding standards and authoritative social norms.

Our research demonstrates that WHO policies for essential medicines, although non-binding, appear to be instructive for domestic law and policy. For example, since 2008, more countries have adopted a national medicines policy and an essential medicines list, which is consistent with WHO's support for national governments to develop and implement these policies. Our investigation also shows that WHO's 2001 guidelines for developing a national medicines policy introduce human rights commitments congruent with our normative framework; and that some of these principles are significantly more frequent in national medicines policies adopted in or after 2004.

National policy makers can use the example texts in this thesis as a starting point to design medicines legislation and policy for equitable, transparent, and accountable access to medicines in UHC schemes. We note that not all principles in our checklist are embedded in domestic UHC law and national medicines policies. Therefore, more structured guidance is needed to promote the further uptake and consistent interpretation of human rights principles into domestic legal instruments.

In summary, international human rights law imparts important principles that are commonly embedded in the text of national law and policy for access to medicines. These examples are tools to enforce governments' human rights obligations to provide essential medicines to the poor and vulnerable on the path to UHC. WHO should support rights-based legal reform for essential medicines by using these findings to develop guidelines for national legislators. In line with SDG Target 3.8 on universal access to essential medicines, national health policy makers should use these examples to codify legally enforceable government commitments towards promoting medicines affordability and equitable financing.

