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

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Legislating for universal access to medicines: A rights-based cross-national comparison of UHC laws in 16 countries

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Abstract

Universal health coverage (UHC) aims to ensure that all people have access to health services including essential medicines without risking financial hardship. Yet, in many low- and middle-income countries inadequate UHC fails to ensure universal access to medicines and protect the poor and vulnerable against catastrophic spending in the event of illness. A human rights approach to essential medicines in national UHC legislation could remedy these inequities. This study aims to identify and compare legal texts from national UHC legislation that promote universal access to medicines in the legislation of 16 mostly low- and middle-income countries: Algeria, Chile, Colombia, Ghana, Indonesia, Jordan, Mexico, Morocco, Nigeria, Philippines, Rwanda, South Africa, Tanzania, Turkey, and Tunisia, Uruguay. The assessment tool was a policy checklist developed based on principles for medicines affordability and financing in the World Health Organization's (WHO) policy guidelines for essential medicines and international human rights law. It consists of 12 principles in three domains: legal rights and obligations, good governance, and technical implementation. Relevant legislation was identified, mapped, collected, and independently assessed by multi-disciplinary, multi-lingual teams. Legal rights and State obligations towards medicines are frequently codified in UHC law, while most good governance principles are less common. Some technical implementation principles are frequently embedded in national UHC law (i.e. pooled user contributions and financial coverage for the vulnerable), while others are scarce (i.e. sufficient government financing) or almost absent (i.e. seeking international assistance and cooperation). Generally, affluent countries tended to embed explicit rights and obligations with clear boundaries, and universal mechanisms for accountability and redress in domestic law while less affluent countries took different approaches. This research presents law makers with a policy checklist that also serves as wish list for legal reform for access to medicines, and examples of legal texts. It may support the WHO Medicines & Health Products Strategic Programme 2016-2030 to develop model legislation for medicines reimbursement (goal 7).

Introduction

Two billion people lack access to the medicines they need. (1) Frequent stock-outs in the public sector, high medicines prices (especially in the private sector), and inadequate basic health insurance are major access barriers in low- and middle-income countries. (2) Faced with illness, households may incur catastrophic spending on medicines and endure the impoverishing consequences. (2) Universal access to essential medicines is therefore an important aspect of global development and a crucial component of universal health coverage (UHC), affirmed in the Sustainable Development Goal (SDG) 3 for Health. SDG Target 3.8 on UHC aims to ensure that all have access to health services including essential medicines without risking financial hardship. (3) This target encompasses some aspects of the right to health, which offers a set of standards and principles for equitable and inclusive access to healthcare. (4,5) Under international human rights law, governments have the 'core obligation' to provide essential medicines on a non-discriminatory basis and with attention for vulnerable groups. (6–8) Yet, SDG Target 3.8 neglects important aspects of a right to health approach, such as prioritised care and financial protection for the disadvantaged, and international cooperation and assistance for cost sharing with low-income countries. (4,5)

According to the World Health Organization (WHO) "[l]aw is a powerful tool for ensuring that the poor and vulnerable are not deprived of access to health care services and other resources for leading a healthy life." (9) The International Covenant on Economic, Social and Cultural Rights (ICESCR) has been ratified by 165 States, and they therefore bear the irrevocable duty to ensure their domestic law, policy, and practice protects and promotes these rights. On the path towards UHC over 70 countries have sought guidance from WHO concerning their domestic health reforms. (10) WHO's Medicines & Health Products Strategic Programme 2016-2030 goal no. 7 is to develop model legislation for medicines reimbursement. (11) Indeed, some reforms have been associated with increases in proxy indicators of medicines access such as their sale and use. (12,13) However, UHC financing and access in other low- and middle-income countries disproportionately benefits the rich compared to the poor. (14,15)

Human rights are increasingly acknowledged to help close the equity gap in UHC. (10,16) They can also guide an inclusive and accountable formulation of universal access to essential medicines in national law and policy. (5,8,17) In 2017 WHO published guidance to advise Member States on including the right to health in domestic law, including for

UHC. (9) However, this guidance lacks a deep and comprehensive approach to essential medicines as a health systems commodity and a component of UHC. Moreover, no practical assessment tool is available to aid lawmakers in analysing the strengths and gaps in national law for access to medicines.

Human rights principles in national legislation are an under-explored tool to enhance equitable medicines access through UHC in the existing literature. In existing scholarship, multiple, in-depth analyses of a single or small selection of countries study the evolution and impact of UHC reform on medicines and other health services. (18–22) These studies heavily focus on measures of health system function (i.e. pre-payment, pooling risk, and purchasing) and of universal access (i.e. population coverage, services, and direct costs to patients). (23) However, these investigations neither use human rights law as the frame of reference, nor do they examine the content of national health legislation. Human rights principles (i.e. entitlements, State obligations, participation, and accountability) create an enabling environment for patients to claim their rights and hold their governments accountable; therefore, these principles are also important aspects of legislation. (24–26) Yet, previous studies of legal or policy interventions for medicines often source data from systematic literature reviews, the websites of international organisations and/or key informants, rather than the laws or policies themselves. (22,23,27,28) This is a pragmatic albeit a weak approach considering that no global repository of domestic health law exists and most health legislation is only available in the official national language(s). (29,30)

To address these shortcomings, we develop and apply a policy checklist to UHC legislation in 16 mostly low- and middle-income countries in order to identify legal texts that promote universal access to medicines. The policy checklist is based on WHO's policy guidelines for essential medicines and international human rights law in order to analyse domestic law for access to medicines. Our research presents examples of legal texts for lawmakers and establishes a baseline of legal commitments to essential medicines in national law; it may support the WHO Medicines & Health Products Strategic Programme 2016-2030 to develop model legislation for medicines reimbursement. (11)

Methods

This is a cross-national study of UHC legislation for access to medicines from 16 mostly low- and middle-income countries. It describes and compares legal texts against a policy checklist with 12 principles for essential medicines and human rights. A detailed description of the

methodology is in the online appendix. (31)

Policy checklist

To analyse the content of UHC laws, we developed a policy checklist to identify 12 principles that are important from the perspective of WHO's essential medicines policies (32–36) and international human rights law (6,7,37–42). (Selected international human rights law concerned States' obligations towards social or health rights, the core obligation to provide essential medicines, and/or rights related to good governance.) The principles are based on overlapping concepts related to access to medicines for vulnerable groups in the reference documents. The policy checklist was developed by two authors (KP, NVA) who shortlisted the relevant principles from source documents, independently piloted the shortlist on UHC laws to determine their applicability and adequacy, and revised the shortlist. Three right to health and pharmaceutical policy experts (HVH, BT, E'tH) reviewed the shortlist to ensure the principles were sufficient and correctly defined.

In the final policy checklist, we categorised 12 principles in three domains (Table 1): legal rights and obligations (i.e. government's commitments and duties), good governance (i.e. governance principles and processes), and technical implementation (i.e. policy measures to achieve government objectives). The domains correspond to the structure-process-outcome framework for monitoring and evaluating the realisation of human rights. (43) We describe the principles and domains in Chapter 2 and the online appendix. (31) We hypothesise that recognising all three domains in UHC legislation will generate more predictable, transparent, and accountable rights and obligations, leading to greater responsiveness to the poor and vulnerable, equity, and sustainability.

Country selection

We selected 16 countries that have ratified the ICESCR (and therefore have a higher chance of having integrated human rights language into their domestic law), have a national health insurance system; and had a low- or middle-income economy in 2015, as defined by the World Bank, with the exception of Chile and Uruguay which graduated from upper middle to high income countries in 2012. Our sample achieves maximum variation of WHO regions, legal families (as classified by WHO), and income economies (classified in 2015 by the World Bank) (Table 2). (44,45)

Collection of legislation

We convened multi-disciplinary country research teams (with backgrounds in law/medicine) fluent in the official national language and English. In addition to the research below, teams compiled country profiles (available in the online appendix) to describe the national health and legal context of access to medicines, and the relevant national laws (objectives, interrelationships with other legal instruments, and text related to medicines). (31)

First, teams identified relevant national laws by searching national government websites, online databases of national law and policy, the reference lists in related academic and policy publications, and cross-references in national legislation to other relevant laws. Second, teams mapped the relationship between laws, and cross-referenced our list with academic publications and governmental or other reports to verify that our collection was complete and current. Third, laws were selected for analysis if they were relevant for access to medicines for vulnerable groups and if they addressed at least one principle in the checklist. Laws governing the regulation, control, and marketing of pharmaceuticals, or private health insurance were excluded. Fourth, at least one pharmaceutical policy expert from each country except Nigeria and Algeria reviewed our list of legislation for relevance and currency.

Most legal texts were extracted from the legislation first by one research team member, followed by KP who verified and supplemented the initial text selection. For texts in Arabic, Indonesian and Turkish, a team member and KP worked together to identify, discuss, and extract relevant passages from legislation. Selected texts were translated to English by one team member and where possible peer-reviewed by a second team member.

Data analysis

To apply the normative framework, two authors (KP, NVA) each independently graded the strength of each principle in the legal texts on a 3-point coding matrix (i.e. strong, weak, or absent text) shown in Table 1. Generally, strong text includes a clear State commitment and an action (i.e. to adhere to the concept of essential medicines and introduce a national selection committee). Coders discussed disagreements until consensus was reached. Pharmaceutical policy experts provided written comments on our preliminary results; minor changes were made to some codes due to more recent laws or differences of interpretation.

We reported the most and least frequent principles in national UHC law. For each principle we described the different approaches in different countries.

We also examined a relationship between the principles and national level of economic development (low and lower-middle vs. upper-middle and high) by converting legal recognition of each principle to a binary score: strong text or weak/absent text and compared with national economic development using the Fischer's Exact Test (performed with SPSS version 25 with significance set at p=0.05).

Results

We included 100 domestic laws from 16 countries, ranging from two laws per country (Nigeria) to 13 laws per country (Algeria) (complete list is in the online appendix). (31)

The strength of the 12 principles in UHC legislation is shown by country in Table 2. Legislation with innovative ideas is listed for each of the 12 principles in Table 3 and the full-text of these examples is available in Annex 2 to this thesis. (31)

The most common principles are pooling user contributions (n=10 countries), rights (n=9), accountability (n=9), obligations (n=8), and financial coverage for the vulnerable (n=8). The least common principles are from the governance domain (monitoring, transparency, participation, n=2-3) and the technical domain (international cooperation n=1). Overall, UHC legislation from Colombia, Chile, Mexico, and the Philippines codifies the most principles for essential medicines and human rights in national law.

12 principles for access to medicines in national law

1. Right to health

Medicines are an explicit entitlement in Colombia, Mexico, and Uruguay. A less specific universal right to health or services is found in Ghana, Tunisia, Chile, Indonesia, and Turkey. Other national legislation did not address the right to access health care nor medicines, except the Philippines (right is conditional on financial contribution) and Nigeria (all are entitled to a basic minimum package of health services).

2. State obligation

Chile, Colombia, Indonesia, Mexico, the Philippines, and Uruguay specify strong State obligations to pharmaceutical care. Uruguay and Chile require the State to guarantee access or ensure the availability of

medicines in the national formulary for all people. The State is explicitly required to ensure access to pharmaceuticals without payment at the point of service and without discrimination (Mexico), to make essential goods affordable to all (Philippines), or to guarantee that essential medicines are equally available and affordable to the public (Indonesia). The Colombian government is responsible for respecting, protecting and ensuring the enjoyment of the fundamental right to health (including the provision of medicines) in line with the terms in General Comment No. 14.

State responsibilities are somewhat weak and imprecise in Algeria, Jordan, Morocco, and Tunisia. In Algeria, medicines prescribed in public health facilities are provided free-of-charge for in- and out-patients. African countries generally did not codify any State obligations towards health, with the notable exception of Ghana (to attain UHC) and South Africa (to provide healthcare to those without other forms of insurance, and some women and children).

3. Transparency

Transparency in pharmaceutical policy is observed in South Africa (price transparency), the Philippines (price ceilings and public disseminating of that information), and Chile (database of drug prices and medicines evaluation reports). The Philippines law has a comprehensive dissemination strategy targeting newspapers, television and posters in public markets, supermarkets and other public places.

Domestic health law most often framed transparency as information about the benefits package and procedure for accessing it (South Africa, Ghana, Philippines, Mexico, Uruguay, Colombia), the rights of patients (South Africa, Nigeria, Rwanda, Ghana, Turkey, Chile), and the complaints procedure (South Africa, Nigeria, Ghana, Colombia, Chile).

4. Participation and consultation

Patient/consumer participation in domestic pharmaceutical policy is permitted by law in Colombia (users who are trained physicians can join the Pharmacy Commission), Chile (patients may participate in the technical advisory commission recommending priority for high cost medicines), and Mexico (community participation, including to inform the authorities about medicines-related side effects and adverse reactions).

General community participation or empowerment in relation to health involve users in national consultation forums, decision-making bodies, National Health Council, or Patient Rights Boards (Colombia, Mexico,

Philippines, Rwanda, South Africa, Tanzania, Turkey, and Uruguay). Laws require health authorities and governing boards to include geographic representatives and women (Nigeria, Ghana), workers (Algeria), or a representative of the national league for the defence of human rights (Tunisia). Jordan and Indonesia do not address the concept of participation.

5. Monitoring and evaluation

The Philippines' Act on Universal Access and Quality Medicines is the only law in our sample to adopt a patient-centred approach to monitoring medicines prices and affordability. It requires regular surveys of sales prices of medicines and their effect on the household income of different economic groups. Other medicines-specific monitoring is mentioned in laws from Nigeria ('good drug use'), Algeria ('the market situation' of medicines). Mexican legislation requires a periodic evaluation of the healthcare system related to eliminating financial and organisational barriers to accessing services and the access and supply of medicines. All countries except Turkey prescribe general monitoring of the health insurance or system.

6. Accountability and redress

The right to complain is codified in the domestic health legislation of Colombia, Chile, South Africa and Nigeria (about the manner of treatment), Turkey (in the event of infringement of patient rights), and Mexico and Rwanda (in relation to pharmacy services and code of ethics).

A detailed complaints procedure for patients who experience alleged violations of their health rights is described in legislation from South Africa, Ghana, and Indonesia. Innovative accountability mechanisms include a grievance committee at each health institution to decide on complaints (Philippines), a patient ombudsman to initiate or pursue complaints (South Africa), and patient rights units at health centres (Turkey). Most remaining countries reference a complaint or dispute settlement mechanism in health law (Nigeria, Rwanda, Tanzania, Algeria, Uruguay, Chile, Mexico).

7. Selection of essential medicines

In Colombia, Ghana, Indonesia, and Nigeria the concept of essential medicines informs the pharmaceutical benefits package or the medicines provided in public centres, and their selection criteria, procedure, and periodicity. Pharmaceuticals in other UHC packages are referred to as those on the national drug list (Rwanda), national formulary (Chile and

Uruguay), explicit medical benefits (Mexico), and reimbursed medicines (Algeria). In Mexico, the criteria for prioritising essential services are: the financial sustainability of the system, epidemiological profile and health needs, level of medical attention, which interventions are already covered, and the principles of equity and distributive justice.

8. Government financing

Nigeria is the only country to codify the State duty to allocate funds (specifically 20% of the Basic Health Care Provision Fund) to provide essential medicines, vaccines and consumables for primary care. Colombia, Mexico, the Philippines, and Turkey have a similar text but lack an explicit focus on essential medicines. In the Philippines, the government guarantees the financial viability of the health insurance program, which includes pharmaceuticals.

9. Pool user contributions

Mandatory pre-payment of UHC contributions is codified in domestic law in Colombia, Chile, Ghana, Indonesia, Jordan, Mexico, Morocco, the Philippines, Rwanda, Tunisia, and Turkey. These laws require user contribution towards health insurance except for those unable to pay.

10. International assistance and technical cooperation

Mexico is the only country to embed technical cooperation with the international community for health technology assessment in law. Chilean law permits contributions from the international community to the Fund for High-Cost Diagnostics and Treatments. Colombia and Chile are also part of the Andean Agreement Decisions (called REMSAA resolutions) for medicines. Other countries engage in international cooperation and technical assistance for other health matters (Indonesia, Nigeria, Turkey, South Africa).

11. Efficient and cost-effective spending

The principle of efficient/cost-effective spending and related policy measures are codified in legislation from Colombia, Chile, Mexico, Uruguay, Indonesia, Turkey and the Philippines. Mechanisms for efficiencies include a positive list for health insurance (Jordan, Uruguay) that is based on prioritisation (Chile, Mexico), exclusion criteria for medicines reimbursement (Colombia) based on health technology assessment (Indonesia, the Philippines), reference pricing (Algeria, Tunisia, Morocco), price ceilings/maximum retail prices (Rwanda, Philippines), regular pricing review (Ghana), generic promotion and/or substitution (Ghana, Algeria, Morocco, Mexico, South Africa), and the

establishment of a national committee on medicines pricing (Turkey, Colombia) or a committee to study medicines prices (Algeria). Of notable mention is the Philippine [Medicines] Price Act that prohibits profiteering and permits medicines price freezes in emergency situations or excessively high prices.

12. Financial protection of vulnerable groups

The government finances universal access to basic health insurance for the impoverished in Mexico, the Philippines, Indonesia, Colombia, and Chile. In Jordan, health care is provided free-of-charge to pregnant women and children, and to the poor who opt-in to insurance for a substantially reduced fee. Vulnerable groups and the impoverished are exempt from contributions for health services on certain conditions in Moroccan, Nigerian, Rwandan, Tanzanian, Ghanaian, and Turkish law.

Care is provided free-of-charge in public centres in Algeria (for people in difficulty), Tunisia (preventative and general health services up to a geographic quota), South Africa (primary care to all and health services to pregnant women and children under six years), and Rwanda (medicines and reproductive health care).

We identified trends (described below), but, no significant relationships between specific principles and income economies.

Discussion

Our study presents a policy checklist for access to medicines in national law and a cross-national snapshot of legal texts from 16 mostly low- and middle-income countries. Legal rights and State obligations towards medicines are often embedded in national UHC law, while most principles for good governance are much less common. Some technical principles to implement medicines affordability and financing are frequently embedded in national UHC law (i.e. pooled user contributions and financial coverage for the vulnerable), while other principles are infrequent (i.e. sufficient government financing) to almost absent (i.e. seeking international cooperation). We also identified several trends in the legal text of countries from different levels of development (see below). To our knowledge, this is the first study to provide an in-depth qualitative analysis of legal text for access to medicines by systematically collecting and assessing domestic legislation against a policy checklist based on WHO's policies on essential medicines and international human rights law. Our policy checklist serves as both an assessment tool for analysing national law and policy, and a 'wish list' to guide legal reform.

Trends in legislation

The core purpose of this research was to fill a critical gap in knowledge by describing and comparing legal provisions for access to medicines. In addition to this objective, we identify four legislative trends more common (albeit not significant) in the upper-middle income countries (and those recently graduated to high income) than the sampled low and lower-middle income countries. These relationships should be interpreted as hypotheses for further exploration in a larger sample of countries and/or more data points, as follows.

Trend 1: Explicit individual rights and state obligations.

Affluent countries tend to codify universal entitlements and government duties. Some even include the right to free care at public health centres (Algeria, South Africa). This vague entitlement lacks clear State obligations and lines of accountability. On the other hand, less affluent countries generally refrain from guaranteeing the right to basic healthcare for all.

Some countries from all economic classes protect public health in legislation by prohibiting the denial of emergency medical treatment (Nigeria, Algeria, South Africa). This legal guarantee concerns only ad-hoc care for the immediate continuation of life; it fails to take a holistic approach to health that includes disease prevention and health promotion in the absence of illness and treatment of chronic diseases.

Trend 2: Clear boundaries to entitlements and obligations.

The second trend concerns the inevitable boundaries that must be established for basic health packages. No government can provide universal access to all possible health interventions. Affluent countries tend to limit the scope of medicines provided by adopting the principle of essential medicines and mechanisms for their selection in UHC law. These countries also often recognise the principle of cost-effectiveness in relation to medicine selection/reimbursement and use health technology assessment (HTA) as the mechanism. HTA is an objective, transparent, and predictable method for establishing the boundaries of an essential health services package. It also shapes the population's legitimate expectations about which health interventions they are entitled to under UHC.

Conversely, less affluent countries define patients' entitlements to health interventions based on the principle of available public resources (Nigeria, Tunisia). Despite being a recognised principle in the right to health, the concept of 'available resources' yields vague obligations and

opaque entitlements when transplanted in national legislation. State action and rights realisation are difficult to assess against these flexible standards, complicating the redress of violations.

Trend 3: Mechanisms for accountability and redress.

Legislation in affluent countries affirms the right to hold the government accountable and outlines procedures to seek redress for rights violations. The Turkish Patient Rights Regulation entitles patients with health needs that cannot be met presently to request the objective justification of the State's priority ranking on the basis of medical evidence. The right to question State decisions to provide some medicines and not others, and to receive a response, is the essence of accountability. South Africa has introduced a Patient Ombudsman who is responsible for investigating cases of rights violations in healthcare, based on complaints or his/her own initiative.

While less affluent countries do include some mechanisms for accountability and redress in their UHC laws, these are often limited to the (contributing) members of UHC schemes, thereby excluding the general public who is not eligible for or cannot afford coverage (Ghana, Tanzania, and Rwanda).

Policy implications for WHO Member States

Our findings respond to the legitimate concerns of policy makers who hesitate to embed human rights principles in domestic law out of concern that they may trigger (further) rights-based medicines litigation. We provide a menu of principles and legal texts that, when applied together, may help to prevent such spurious claims. These texts establish health entitlements with boundaries through objective criteria (including cost-effectiveness), transparent and participatory decision-making processes, and non-judicial accountability mechanisms to redress violations before having to resort to the courts. Recognising the legal boundaries of the right to access to medicines informs patients' reasonable expectations of their health system. It can also protect against excessive or unreasonable claims for immediate access to treatments at any cost. Starting from this basic package, governments should apply the human rights principle of progressive realisation by continuously and expeditiously expanding the boundaries of access to medicines for all. (46)

National law makers can undertake a 'check-up' of access to medicines using our policy checklist to identify strengths and gaps in existing domestic law. Our policy checklist and the example legal text we identified can also be used as a guide for writing future legislation (in Table 3 and Annex 2 of this thesis). Particularly, less affluent countries

may seek inspiration from the language that more affluent countries codify in order to develop their UHC schemes and scale-up access to medicines.

Policy implications for WHO

WHO should develop a publicly accessible online repository of national health legislation where Member States' laws can be uploaded, retrieved, and possibly translated. Our proposal echoes the call of other global health researchers. (29)

WHO should also publish technical advice for Member States legislating for access to medicines in UHC schemes, in line with the goal of WHO's 2016-2030 Medicines & Health Products Strategic Programme. (11) This advice can use our policy checklist as a starting point and expand on the examples presented. Our examples translate some recommendations of the WHO Consultative Group on Equity and UHC for making fair choices on the path to UHC into provisions for domestic law. (10) WHO's technical advice could especially catalyse national governments to embed in their domestic legislation some of the chronically under-addressed essential medicines and human rights principles we identified (i.e. duty of government to sufficiently finance essential medicines and to seek international assistance).

Monitoring bodies (i.e. WHO, Office of the High Commissioner for Human Rights) can use our results to expand their indicator of government commitment to health rights, which is currently a right to health in constitutional or other national law. (43) Other sub-indicators could track specific State duties in national health legislation, such as for (i) the control of medicines prices, and (ii) the sufficient financing of essential medicines for the poor and vulnerable. Embedding these sub-indicators in national law may have a more direct effect on patient-level access than governments codifying a constitutional right to health. Legalising these State obligations can also support accountability and redress if rights are violated.

Future research

Our study of 16 mostly low- and middle-income countries does not investigate other nations making important strides towards UHC, such as Thailand, Viet Nam, and Kyrgyzstan, because we lacked the language capacity. Future research should contribute additional analyses of legislation from these and other low- and middle-income countries.

The private sector plays a crucial role in developing, manufacturing and supplying medicines, and is an increasingly active in UHC schemes as

a health insurer and provider. (47) Future research should continue to examine rights-based legal approaches to regulating the private sector in the context of UHC. (48,49)

National health policies, particularly for pharmaceuticals, health, and intellectual property, can instruct the development of health law or substitute it entirely by directing State policies and programming. Future research should investigate the content, implementation, and impact of national policies in relation to access to medicines as part of the right to health.

The role of international human rights law, and specifically the right to health, in the governance, implementation, and outcomes of legislative reform for UHC is under-addressed in scholarship. (50) Future studies should elucidate whether and how human rights principles are factors for inclusive and responsive reforms, and whether those guiding principles help attain a more equitable and universal provision of health care, including essential medicines, in practice.

Strengths and limitations

This study has several limitations. First, we present the results of a purposive sample of 16 mostly low- and middle-income countries. Although the sample is not representative of all low- and middle-income countries with UHC, it includes countries from all world regions with a diversity of legal traditions and income economies. Most low- and middle-income countries should be able to locate a comparable country in our sample and learn from its examples.

Second, to our knowledge, this is one of the first analyses of national legislation for access to medicines, which brings its own challenges. We minimised the risk of reporting bias by working by working with trained research assistants fluent in the national languages. We also verified our collection of legislation and preliminary findings with national experts, except for Nigeria and Algeria. Our sources are more objective than similar studies that rely on interpretations of law and policy in academic literature and from key informants. Yet, our conclusions only reflect the retrievable laws and may under- or overestimate the observed trends.

Third, to minimise the risk of incorrect translation or inconsistent interpretation, all research assistants were trained in the standard terminology and definitions of the 12 principles. Translations from French, Indonesian, and Spanish were peer-reviewed.

Conclusion

This is the first study to systematically map, collect, and assess national UHC legislation for attributes related to access to essential medicines, particularly for vulnerable groups. Our research offers domestic law makers an assessment tool that is both a checklist and a wish list for legal reform for access to medicines. We present examples of legal texts from a range of mostly low- and middle-income countries providing essential medicines through UHC. These examples may inspire other WHO Member States to adopt a human rights-based legal framework for universal access to medicines and sustainable development; they may also support the WHO Medicines & Health Products Strategic Programme 2016-2030 to develop model legislation for medicines reimbursement (goal 7).

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Table 1. Policy checklist for access to medicines in national law and policy.

Checklist	Human rights principle	WHO essential medicines policy	Coding matrix
Legal rights and obligations			
1. Right to health	Right to the highest attainable standard of health	Human rights are a 'value'. (35)	**Black** = Universal entitlement to health coverage includes medicines. **Grey** = Vague entitlement to health 'protection' or similar, but not necessarily to care or medicines. May be limited to certain populations or conditional on payment. **White** = No entitlement.
2. State obligation to provide essential medicines	Core obligation to provide essential medicines defined by WHO		**Black** = Absolute State obligation to realise/guarantee UHC and (affordable) access to medicines/essential medicines/essential goods. (= duty to realise the end result of access for patients). **Grey** = State duty to take action/steps for health care (= duty to make an effort to provide healthcare, but not necessarily realise the end result of access for patients). **White** = No obligations .

Good governance			
3. Transparency	Transparency	Information to assess service access and coverage, and publicly available price information for medicines. (32, 34) Also an aspect of good governance for medicines. (36)	**Black** = Information / transparency for patients in relation to medicines affordability and accessibility. **Grey** = General transparency/information about health services and/or patients rights related to health services/UHC. **White** = No information mechanisms.
4. Participation & consultation	Participation	Collaboration and accountability of all health systems actors, and stakeholder consultation. (32, 34) Also vaguely referenced in good governance for medicines. (36)	**Black** = Principle of participation/consultation and establishes a mechanism for this. Participation is in relation to medicines policies. **Grey** = General participation principles or mechanisms, but not in explicit relation to medicines. **White** = No principles and mechanisms for participation.
5. Monitoring & evaluation	Monitoring	Achieved through explicit government commitment, indicator-based surveys, and independent impact evaluation. (32, 34) Also a component of good governance for medicines. (36)	**Black** = Monitoring of users' affordability and/or access to medicines within the UHC system. **Grey** = General monitoring of the UHC system no specific mention of affordability nor access. **White** = No monitoring.

6. Accountability & redress	Accountability	Accountability of all health systems actors. (34) Also a component of good governance for medicines. (36)	**Black** = Principle of or right to accountability AND mechanism for patients to make complaints / seek accountability. **Grey** = Vague concept(s) or right(s) for accountability. **White** = No accountability nor redress.
Technical implementation			
7. Selection of essential medicines	(Assured) quality of health services (of the AAAQ)	Includes the essential drugs concept, procedures to define and update the national list(s) of essential drugs, explicit, evidence-based criteria that includes cost-effectiveness, and selection mechanisms. (32,33)	**Black** = Comprehensive approach (principle of medicines selection AND mechanisms for selection) **Grey** = Vague principle OR a single policy measure without a comprehensive approach to essential medicines. **White** = No principle or mechanisms for medicines selection.
8. Government financing	Duty to adopt appropriate administrative, budgetary and other measures to a maximum of its available resources. Core obligation to provide essential medicines as defined by WHO.	Requires adequate funding and mobilising all available public resources and increase funding for priority diseases, and the vulnerable. (32,33,34)	**Black** = Clear State obligation to finance (essential/UHC) medicines. May mention adequate/sufficient financing or impose a minimum threshold. **Grey** = Vague State commitment (i.e. to finance UHC but not specifically medicines) or shared responsibility of State and others. **White** = No government financing.
9. Pool user contributions		Medicines reimbursement with user charges is a (temporary) financing option. (33,34)	**Black** = Compulsory pre-payment of UHC contributions with exceptions for those who can not pay. **Grey** = Compulsory or prepaid contributions

			(not both); or concept of cost recovery or joint responsibility of the State and users. **White** = No concept of nor criteria for contributions.
10. International assistance and technical cooperation	Duty to seek international assistance and technical cooperation	Includes the possibility of using development loans for medicines financing. (33)	**Black** = Financial aid or/and technical assistance from the international community (not only the private sector). **Grey** = Reference to international cooperation for health/UHC. **White** = No means for international cooperation.
11. Efficient and cost-effective spending	Duty for the efficient use of available resources	Includes the efficient use of resources and affordable pricing through: price control; a pricing policy for all medicines; competition through generic policies and substitution; good procurement practices; price negotiation and information; and TRIPs-compliant measures such as compulsory licensing and parallel imports. (32,33,34)	**Black** = Principle of cost-effectiveness / efficiency, AND one or more mechanisms in relation to medicines. **Grey** = Either the principle OR mechanisms for cost-effectiveness/efficiency, but not both. More generally about health care/UHC. **White** = No principle and mechanisms for spending.
	Duty to take appropriate steps to ensure that the private business sector is aware of, and consider the importance of, the right to health in pursuing their activities.		
	Duty to prevent unreasonably high costs for access to essential medicines from undermining the rights		

	of large segments of the population to health. Duty to seek low-cost policy options		
12. Financial protection of vulnerable groups	Duty towards non-discrimination and attention to the vulnerable	Increase government funding for poor and vulnerable groups and reduce the risk of catastrophic health spending. (33,34)	**Black** = Clear State duty to finance UHC package / essential medicines for all vulnerable people. **Grey** = Vague State duty (i.e. exemption for some vulnerable people but unclear whether State finances their medicines). **White** = No financial coverage of the poor .

Abbreviations used in this table: WHO=World Health Organization; TRIPs=Trade Related Aspects of Intellectual Property; AAAQ=Availability, Accessibility, Acceptability, and Quality as elements of health services under the right to health.

Table 2. Overview of the 12 principles for access to medicines in national UHC legislation of 16 mostly low- and middle-income countries.

Income economy	Country	WHO Region	Legal family	1. Right to health	2. State obligation	3. Transparency	4. Participation & consultation	5. Monitoring & evaluation	6. Accountability & redress	7. Selection of essential medicines	8. Government financing	9. Pool user contributions	10. International assistance & cooperation	11. Efficient & cost-effective spending	12. Financial protection of vulnerable groups
Low	Rwanda	AF	CIV CUS												
	Tanzania	AF	CIV CUS												
Lower-middle	Ghana	AF	COM CUS												
	Nigeria	AF	COM CUS ISL												
	Tunisia	EM	CIV ISL												
	Morocco	EM	CIV ISL												
	Jordan	EM	CIV CUS ISL												
	Indonesia	SEA	CIV CUS ISL												
	Philippines	WP	CIV COM												

Upper-middle	Algeria	AF	CIV ISL												
	South Africa	AF	CIV COM												
	Turkey	EU	CIV												
	Colombia	AM	CIV												
	Mexico	AM	CIV												
High	Uruguay	AM	CIV												
	Chile	AM	CIV												

Legend: Black=Strong text, Grey=Weak text, White=No text. Abbreviations used in this table: AF=Africa, EM=Eastern Mediterranean, SEA=South-East Asia, WP=Western Pacific, EU=Europe, AM=Americas, CIV=civil law, COM=common law, CUS=customary law, ISL=Islamic law.

Table 3. Innovative ideas for access to medicines in national UHC legislation.

1. Right to health including essential medicines
Indonesia - Law No. 36/2009 (2009)
Mexico - General Health Law (2017)
2. State obligation to provide pharmaceuticals
Philippines - National Health Insurance Act (2013)
Mexico - General Health Law (2017)
3. Transparency
Philippines - Republic Act No. 7581 (1992), Republic Act No. 9502 (2008)
Chile - Law No. 20584 (2012)
4. Participation and consultation
Colombia - Law No. 100 (1993)
Chile - Law Nº 20850 (2015)
5. Monitoring and evaluation
Philippines - Republic Act No. 9502 (2008)
Mexico - Regulations of the General Health Law in the matter of social protection in health (2014)
6. Accountability and redress
Turkey - Patient Rights Regulation (2016)
South Africa - National Health Act No. 63 (2003) as amended by the National Health Amendment Act No. 12 (2013)
7. Selection of essential medicines
Ghana - National Health Insurance Act No. 852 (2012)
Indonesia - Law No. 40/2004 (2004), Law No. 36/2009 (2009)
Uruguay - Law No. 18.211 (2007), Decree No. 265/006 (2006)

8. Government financing for essential medicines
Nigeria - National Health Act No. 8 (2004)
Philippines - National Health Insurance Act (2013)
9. Pooling user contributions
Ghana - National Health Insurance Act No. 852 (2012)
Philippines - National Health Insurance Act (2013)
Turkey - Law No. 5510 (2006)
10. International assistance and cooperation
Nigeria - National Health Act No. 8 (2004)
Mexico - Internal Regulations of the Health Secretariat of 19 January 2004
11. Efficient and cost-effective spending on essential medicines
Philippines - National Health Insurance Act (2005) amended by National Health Insurance Act (2013), Republic Act No. 7581 (1992), Republic Act No. 9502 (2008)
Indonesia - Regulation No. 28/2014 (2014), Law No. 36/2009 (2009)
12. Financial protection of the poor and vulnerable
Chile - Ministerial Decree No. 1 (2006), Law No. 19966 (2004), Law No. 20850 (2015)
Colombia - Law No. 1751 (2015)
Jordan - Civil Health Insurance of 2016, Decision of Council of Ministers No. 5157 on 13/8/2014 on the mechanism of coverage of poor families under the umbrella of civil health insurance, Instructions No. 9 (2006) to include pregnant women in civil health insurance, Instructions No. 3 (2008) on maternity services, childhood and family planning

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