Is access to essential medicines as part of the fulfilment of the right to health enforceable through the courts?

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Summary

Background  Most countries in the world have become States parties to one or more international human rights treaties, thus creating an obligation by the State to its people towards the realisation of the right to health, which includes access to essential medicines. But whether such access is enforceable in practice is unknown.

Methods  We did a systematic search to identify completed court cases in low-income and middle-income countries in which individuals or groups had claimed access to essential medicines with reference to the right to health in general, or to specific human rights treaties ratified by the government. We identified and analysed 71 court cases from 12 countries in which access to essential medicines was claimed with reference to the right to health.

Findings  In 59 cases, access to essential medicines as part of the fulfilment of the right to health could indeed be enforced through the courts, with most coming from Central and Latin America. Success was mainly linked to constitutional provisions on the right to health, supported by the human rights treaties. Other success factors were a link between the right to health and the right to life, and support by public-interest non-government organisations. Individual cases have generated entitlements across a population group, the right to health was not restricted by limitations in social security coverage, and government policies have successfully been challenged in court.

Interpretation  Skilful litigation can help to ensure that governments fulfil their constitutional and international treaty obligations. Such assurances are especially valuable in countries in which social security systems are still being developed. However, redress mechanisms through the courts should be used as a last resort. Rather, policymakers should ensure that human rights standards guide their health policies and programmes from the outset.

Introduction  Issues of human rights affect the relations between the State and the individual; they generate State obligations and individual entitlements. The promotion of human rights is one of the main purposes of the UN. For example, the WHO Constitution of 1946 says that “The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.” Article 25.1 of the Universal Declaration of Human Rights (1948) says that “Everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services”.

The right to health is also recognised in many other international and regional treaties, especially the International Covenant on Economic, Social and Cultural Rights (ICESCR) of 1966, an international treaty that is binding on States parties (States that have acceded to, signed, or ratified an international treaty) and provides the foundation for legal obligations under the right to health. In the ICESCR, States parties “recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”. In Article 12.2, the treaty lists several steps to be taken by States parties to achieve the full realisation of this right, including the right to: maternal, child, and reproductive health; healthy natural and workplace environments; prevention, treatment, and control of disease; and “the creation of conditions which would assure to all medical service and medical attention in the event of sickness”. Article 12 thus constitutes an important standard against which to assess the laws, policies, and practices of States parties.

The implementation of the ICESCR is monitored by the Committee on Economic, Social and Cultural Rights, which regularly issues authoritative but non-binding General Comments, which are adopted to assist States in their interpretation of the ICESCR. In General Comment 3, the Committee confirms that States parties have a core obligation to ensure the satisfaction of minimum essential levels of each of the rights outlined in the ICESCR, including essential primary care as described in the Alma-Ata Declaration, which includes the provision of essential medicines. General Comment 14 of May, 2000, is particularly relevant to access to essential medicines. Here the Committee states that the right to medical services in Article 12.2 (d) of the ICESCR includes the provision of essential drugs “as defined by the WHO Action Programme on Essential Drugs”. According to the latest WHO definition, essential medicines are: “those that satisfy the priority health care needs of the population. Essential medicines are selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness. Essential
medicines are intended to be available within the context of functioning health systems at all times, in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford. The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility.2–4

Although the ICESCR acknowledges the limits of available resources and provides for progressive (as opposed to immediate) realisation of the right to medical services, States parties have an immediate obligation to take deliberate and concrete steps towards the full realisation of Article 12, and to guarantee that the right to health will be exercised without discrimination of any kind.

Most countries in the world have acceded to or ratified at least one worldwide or regional covenant or treaty confirming the right to health. For example, more than 150 countries have become State parties to the ICESCR, and 83 have signed regional treaties.5 More than 100 countries have incorporated the right to health in their national constitution.

Some might argue that social, cultural, and economic rights are not enforceable through the courts, and some national courts have indeed been reluctant to intervene in resource allocation decisions of governments. Yet accountability and the possibility of redress are essential components of the rights-based approach. Being a State party to a human rights treaty that is internationally binding creates certain State obligations to its people. Do governments live up to these binding obligations in practice? If not, do individuals manage to obtain their rights? And if they do, which factors have contributed to their success?

This study analyses the question of whether access to essential medicines as part of the fulfilment of the right to health can be enforced through national courts (is justiciable) in low-income and middle-income countries. The study is part of a general attempt by WHO to integrate the promotion and protection of human rights into national policies and to support further mainstreaming of human rights throughout the UN.

Methods
A systematic search was done to identify completed court cases in low-income and middle-income countries in which individuals or groups had claimed access to essential medicines with reference to the right to health in general, or to specific human rights treaties ratified by the government. Six different search methods were used. A general boolean search of the internet was done with variations in the keywords that were linked together (such as human rights, essential drugs, access to medicines). An email survey was sent to a group of the most prominent non-governmental organisations (NGOs) working on the right to medicines that were noted from the internet search. The email requested assistance in finding information on cases, to which the Lawyers Collective in India responded with information. The following legal databases were accessed and searched: LexisNexis, Natlex, Ohada, Portal Droit Francophonie, CSA Illumina, Electronic Information System for International Law, Westlaw database, Eurolex, and the Legal Information Institute. Other databases consulted were The Economic, Social and Cultural Rights database on the internet ESCR-NET, the Asian Legal Resource Centre database, the AllAfrica database, the European Court of Human Rights database (HUDOC), the International Commission of Jurists website, the Inter-American Court of Human Rights, and reports from the UN Human Rights regional offices. Individual country searches were done for all low-income and middle-income signatories to the International Covenant on Economic, Social and Cultural Rights. The World Legal Information Institute was used to locate each country’s online national jurisdiction database. A further specific internet search was done on countries without any online national jurisdiction database, focusing on the country name and the search terms; this method considered each country in a thorough and systematic way.

Role of the funding source
The sponsor of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all data in the study and had final responsibility for the decision to submit for publication.
Results

The systematic search identified 73 cases from 12 low-income and middle-income countries. In five cases, only a brief summary of the judgment was available. In three of these cases, information was still sufficient to include them in the analysis. The full analysis is therefore based on 71 cases, of which 59 were won and 12 were lost (table 1). Of the cases included in the analysis, 14 successful and two unsuccessful cases specifically referred to one or more international human rights treaties signed by the government. The main characteristics of the cases are shown in table 2. Arguments used in the unsuccessful cases are shown in table 3. Full references and summary information for each case are available from the authors on request.

Of the 12 countries in which court cases were identified, 11 are State parties to the ICESCR; South Africa has signed but not ratified the ICESCR. In all countries except Argentina and India, the right to health is recognised in the constitution. In six countries the constitution includes a provision that international treaties signed by the State have constitutional rank, override domestic laws in case of conflict, or both (table 1).

More than 90% of cases are from nine countries in Central and Latin America. Between 1991 and 1997, three
countries (Colombia, Costa Rica, and Venezuela) had their first successful case; in the 7 years from 1998 to 2004 there were the first successful cases in seven other countries, including countries outside the Americas (South Africa and India). Most cases (50 cases, 70%) were individual; 27 (38%) were public interest cases, and 14 (20%) were supported by NGOs. In 61 (86%) cases the Social Security system or the Ministry of Health were the defendants. About half the cases related to potentially life-saving treatment of HIV/AIDS.

**Discussion**

This study has shown that access to essential medicines as part of the fulfilment of the right to health could indeed be enforced through the courts in several low-income and middle-income countries, with most of the experience to date coming from Central and Latin America. The most important success factor has been that certain rights are enshrined in the national constitution. Key constitutional provisions seem to be those on the right to health and on defined State obligations with regard to health care services and social welfare.

Human rights treaties ratified by the government have probably supported the creation of such constitutional provisions in the first place. When referred to in the courts they have usually provided additional force to such constitutional obligations, especially in the presence of a constitutional provision that international treaties supersede domestic law. One case in Argentina shows that international human rights treaties can also successfully be invoked in the absence of a constitutional right to health. In 80% of cases, the right to health was linked to the right to life. Most negative rulings were based on a recognition of the limitations specified in the national essential medicines list or social security benefits, although some courts also made their own analysis of the medical merits of the claim.

Our study has two limitations. First, the fact that most cases were seen in Central and Latin America (despite intensive and targeted efforts to identify cases from other regions) suggests that the observations and conclusions are probably more relevant in this region than in the rest of the world. A possible explanation for this finding is that social security is much more developed in the Americas than in Africa and Asia, where most health care is paid for directly by the patient. Other reasons could be more developed legal systems and higher consumer expectations in the Americas. The second limitation is that adding up the arguments used in different cases from different countries might create a false sense of statistical probability that similar arguments could work in future cases in other countries. This assumption is of course not true, since each current and future case must be judged on its individual merits and within its national legal situation. Yet cases such as the ones reported here contribute to a worldwide body of jurisprudence, which might support further developments in this area. Within these two limitations, the intended value of our analysis is to present a first overview of the situation and to generate some ideas for further analysis and study.

A successful case is defined as one that has led to new, continued, or expanded access to one or more essential medicines for an individual or group. Constitutional provisions probably contributed most to successful outcomes. All countries except Argentina and India include the right to health in their constitution. In nearly all cases, this includes a definition of State obligations with regard to health care services and social welfare. In all countries except Panama and Nicaragua, one or more court rulings confirm that these constitutional rights are indeed enforceable (table 1). In six countries (Argentina, Colombia, Costa Rica, Ecuador, El Salvador, and Venezuela), international treaties enjoy constitutional rank, and domestic laws should follow international treaties.

<table>
<thead>
<tr>
<th>n (%)</th>
<th>Country</th>
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<tr>
<td>National list of essential medicines upheld</td>
<td>4 (31%) Argentina*, Colombia, Panama, South Africa</td>
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<tr>
<td>The medicine claimed was the wrong choice, lack of evidence on efficacy, or no need</td>
<td>3 (25%) Costa Rica (3+), El Salvador</td>
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<tr>
<td>The medicine had been supplied in the mean time</td>
<td>2 (17%) Colombia, Costa Rica</td>
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<tr>
<td>Court of Law not ready to decide on policy issues</td>
<td>1 (8%) South Africa</td>
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<tr>
<td>Case dismissed on technical grounds</td>
<td>1 (8%) Colombia, Costa Rica</td>
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<tr>
<td>Court refuses to hear the plaintiff because of fear of HIV infection</td>
<td>1 (8%) Nigeria*</td>
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*Cases referring to international treaties signed by the government.

Table 3: Main arguments quoted in unsuccessful cases (n=12)
Within our series, this case features the only clear ruling in which international human rights treaties have created a state obligation towards an individual entitlement in the absence of a constitutional right to health.

In El Salvador the same point was made. Here, a slowly progressing Constitutional Court case was accelerated by filing a parallel case before the Inter-American Commission on Human Rights, alleging the State’s failure to provide the plaintiffs with antiretroviral therapy. As a provisional measure, the Commission solicited the Salvadoran State to comply with its regional obligations and to provide the needed medications. Before the regional court started its hearing procedures, the Salvadoran Constitutional Court came to its decision in support of the plaintiff.11

We can conclude that human rights treaties usually provide additional force to existing constitutional obligations. Additionally, national constitutions could provide that international treaties supersede domestic law. The case in Argentina further indicates that international human rights treaties can successfully be invoked in the absence of a constitutional right to health.

In 49 (83%) of 59 successful cases and in all countries, the right to health was specifically quoted as being related to the right to life. Logically, this argument was usually linked to cases of life-threatening disease in which treatment was potentially life saving. In 24 cases, this argument was for treatment for HIV/AIDS, but was also used for diseases like leukaemia, and renal and liver transplantation. In non-life-threatening conditions, more general arguments such as human dignity and physical integrity were used. Therefore, in practice, the right to health seems more linked to the right to life as such than to the quality of life.

In 11 (19%) of 59 cases, acquired rights, in the sense of non-interruption of treatment already supplied for a period of time, were quoted. In three cases (severe congenital neutropenia in a child and two cases of HIV/AIDS), this argument was used when social security rights expired after a certain period of chronic treatment—eg, after 2 years. These cases seem to establish that in these countries the right to health cannot be limited by legal, financial, or administrative restrictions in social security coverage. Indeed, the argument could be made that the coverage of truly life-saving treatment should probably be life-long and not subject to a maximum period.

Rather surprisingly, non-discrimination, which is a cornerstone in human rights law and is included in many constitutions, was invoked in only seven (12%) of 59 cases, often together with arguments of social justice. In only two of these cases was there actual discrimination between individuals in equal circumstances: in South Africa’s only a few HIV-infected mothers in a few hospitals could receive treatment to prevent mother-to-child-transmission, whereas large numbers in the rest of the country could not; and in Venezuela,16 army officers were entitled to antiretrovirals whereas ordinary soldiers were not. Non-discrimination therefore seems a potentially powerful argument when certain treatments are unequally available within a country, for example only in certain types of hospitals, or only for certain categories of people.

Ten successful cases that were supported by national public health interest NGOs are among the most important and far-reaching—although to prove that NGO support was essential to the successful outcome is difficult. The first NGO-supported case took place in 1995 in Colombia.17 Active lobbying led to a legal reform in 1997 by which antiretrovirals were included in the official medicines list. The first collective action by NGOs took place in Argentina18 and led to a Supreme Court ruling in 2000 that confirmed that the Ministry of Health was responsible for the effective implementation of the AIDS programme; this ruling immediately benefited 15,000 people.

The South African case12 is well known. In a joint claim against the Ministry of Health, national health advocacy NGOs and individuals challenged a government restriction on the supply of nevirapine to prevent mother-to-child transmission of HIV to 18 public hospitals undertaking a pilot study. In July, 2002, the Constitutional Court upheld earlier rulings that this restriction was unconstitutional and ordered the government to assure the general availability of this medicine. The lawsuit came after 5 years of active lobbying by civil-society organisations.

Another example is recorded in Venezuela, where a national NGO named Acción Ciudadana Contra el Sida supported a carefully constructed series of consecutive court cases between 1997 and 2001. In one case19 on behalf of four soldiers, the organisation asked the medical services of the Venezuelan Ministry of Defence for prescription drugs for the treatment of HIV/AIDS. The Court voluntarily extended its decision to all army members in the same circumstances. A subsequent case20 challenged the medical services of the Venezuelan Ministry of Health for its failure to ensure coverage for HIV/AIDS medications through the public health-care system for those who were not eligible under the social security scheme. This case was also awarded, but only to the plaintiff. In the next case,21 similar to the previous one but filed by over 170 people, the collective interest was accepted by the Court. In a final case22 of 29 people living with HIV/AIDS, a ruling in support of the regular provision of antiretrovirals and laboratory tests was extended to all people in the same circumstances.

In these cases careful litigation, supported by NGOs, has forced the government to implement its constitutional and human rights treaty obligations and has served the public-health cause of improving equitable access to essential medicines. The legal, financial, and moral support of NGOs and their effective networking have assisted plaintiffs in the presentation and defence of their case and in subsequent appeal procedures. NGOs have also mobilised public support and media interest.

All these factors seem to have contributed to the positive outcome of the case. But not all cases were successful, and
lessons can be learned from the 12 cases with a negative outcome, which we have been able to identify.

Rejection of a claim for non-life-saving treatment might seem acceptable, although it could leave a question about the quality of life. But what about rejected claims for potentially life-saving medicines? Six of the 12 unsuccessful cases (table 3) relate to such medicines, five of them for HIV/AIDS. In one case, the medicine requested was supplied in the mean time, and so could in fact be seen as a successful case. In three other HIV cases, the court upheld the national essential medicines list and ruled that there was no medical need for the requested medicine for this patient. The fifth case was dismissed because the medicine was not considered to be a cure. However, in 1997 the Court changed its opinion and ruled in favour of the plaintiff; although the requested antiretroviral medicines were not included in the official national medicines lists. The judges based their decision on the right to life and health as enshrined in the national constitution and as endorsed by Costa Rica in international treaties. In South Africa, the negative outcome in the renal dialysis case in 1998 mentioned previously was followed in 2001 by the successful nevirapine case.

18 cases from Bolivia (one case), Colombia (14), and Costa Rica (3) concluded that the right to health is not restricted by limitations in social security coverage. Some of these cases were linked to the exhaustion of time-limited coverage, the non-payment of contributions by the employer, or even giving the same rights to people not covered by social security at all. In Colombia and Costa Rica, the right to health was also defined as extending beyond the limits of the essential medicines list used to define insurance coverage. In both countries, judgments awarded life-saving treatment with antiretroviral drugs while these were not on the national list of essential medicines and were, for that reason, not made available.

From a public health point of view these judgments have both a positive and a negative side. Such judgments have led to the availability of antiretroviral treatment to patients with HIV/AIDS, which shows the value of the courts in ensuring the human rights principles of accountability and redress mechanisms. The negative side is that these cases overruled the official medicines list used for reimbursement. In the case of life-saving treatments, one could argue that this overruling is a necessary outcome if the list was not adequate or out of date. However, in another case from Costa Rica, potentially life-saving treatment of leukaemia was awarded that had specifically been excluded from social security benefits because of its high cost; and in yet another case the patient won access to a branded medicine rather than the generic alternative supplied through the social security scheme. Is this a positive or a negative outcome?

In some Latin-American countries, such as Colombia and Brazil, the situation is now becoming out of hand. In Colombia, most of the later successful cases in our series refer to medicines outside the national essential medicines list that is used to define the limits of social security. The first case refers to international human rights treaties, and obviously established the principle; subsequent cases only refer to the constitution and to the right to health in general. In Brazil the situation is even worse, with thousands of court cases since 1991 awarding medicines not yet approved for reimbursement, with reference to the right to health mentioned in the constitution.

The solution is probably in the wording of the right to health. In Brazil, the constitution of 1988 recognises the right to health and guarantees nearly unlimited health-care benefits to all citizens. The constitution of Venezuela of 1999 defines the responsibilities of State in more detail. However, the constitution of South Africa stands out in its simplicity and clarity. Section 27 of the constitution states that everyone has the right to have access to health-care services and social security, and that the State must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.

Most public budgets are not infinite and at a certain moment choices have to be made. Progressive implementation of the right to health requires a State to choose which components should be implemented first. Under such circumstances, should courts of justice or national committees of experts decide how public funds are spent in the most equitable and cost-effective manner? The recent case of the British nurse fighting to receive a new anti-cancer medicine not yet approved for reimbursement proves that this question is also relevant in developed countries. The dilemma is well described by Justice Sachs in the renal dialysis case in South Africa:

“...The courts are not the proper place to resolve the agonizing personal and medical problems that underlie these choices. Important though review functions are, there are areas where institutional incapacity and appropriate constitutional modesty require us to be especially cautious...Unfortunately the resources are limited and I can find no reason to interfere with the allocation undertaken by those better equipped than I to deal with the agonizing choices that had to be made in this case.”

Many successful cases have had a substantial effect. In several countries, the court cases have led to a general
availability of antiretroviral treatment for HIV/AIDS patients. In 14 cases from six countries the judgment was extended to other individuals in similar situations. In two landmark cases from Argentina and South Africa, government policies have successfully been challenged in court. Our study therefore shows that careful litigation has been one additional mechanism to promote the right to health and to encourage governments to fulfil their constitutional and international treaty obligations. In our opinion, this finding is especially relevant for countries in which social security systems are not yet fully developed.

We also conclude that constitutional guarantees on access to health care services should be well defined, for example through reference to a national list of essential medicines, to prevent abuse. Such guarantees might especially be relevant for countries with more mature social security systems. In those countries, transparent procedures should be available to define the range of goods and services covered by the social security, with the role of the judiciary focusing on general rather than on specific aspects of reimbursement.

Health policymakers in low-income and middle-income countries and the international public-health community should be aware of the increasing trend towards successful litigation. Redress mechanisms through the courts are an essential function in society, but should preferably be used as a measure of last resort. Rather, policymakers should ensure that standards for human rights guide their health policies and programmes from the outset, and should publicly be perceived as such.

Contributors

This study was conceived, planned, and supervised by H V Hogerzeil, who also completed the analysis and wrote the article. J V Casanovas, M Samson, and L Rahmani identified and summarised the cases.

Conflict of interest statement

We declare that we have no conflict of interest.

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