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ACCESS TO ESSENTIAL MEDICINES AS PART OF THE RIGHT TO HEALTH

Hans V. Hogerzeil

*Department of Essential Medicines and Pharmaceutical Policies,
WHO, Geneva*

Zafar Mirza

*Department of Public Health, Innovation and Intellectual Property,
WHO, Geneva*



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For additional information please contact
edmdoccentre@who.int

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When the right to health is debated in national elections, we know this is an issue whose time has come.

Mary Robinson and
Andrew Clapham
*Realizing the Right to
Health, 2009 (1)*

SUMMARY

- Human rights constitute an important principle of our time. These fundamental human rights translate the values of equity, freedom, fairness, social justice and non-discrimination into practical entitlements for individuals, which increasingly guide public policies and national judicial systems. Access to essential medicines as part of the right to health has been further refined in recent years.
- An increasing number of patients in developing countries, especially in Central and South America, are claiming their health rights through the courts. However, instead of leaving it to the judiciary to define people's rights, health policy-makers should ensure that human rights principles are incorporated in medicine programmes from the outset.
- The WHO World Health Assembly has agreed to use the legal recognition of the right to health as an indicator of a government's commitment to improving access to essential medicines. Access to essential medicines has also become one of five UN indicators to measure progress in the progressive realization of the right to health.
- At least one third of the world's population has no regular access to medicines. Inequity in access to essential medicines is part of inequity in health care. Key evidence to document such inequities is rarely collected. More than 30 countries have not yet ratified the International Convention on Economic, Social and Cultural Rights and 60 countries do not recognize the right to health in their national constitution.
- The concept of essential medicines with its focus on equity, solidarity and social justice is already very much in line with the principles of human rights. Yet the daily practice of national essential medicine policies and programmes can learn from the growing human rights movement and its emphasis on transparency, accountability and freedom from discrimination. This chapter sets out practical recommendations for governments, United Nations (UN) organizations and non-government organizations (NGOs) on ensuring access to essential medicines as part of the right to health.

1.1**INTRODUCTION**

Advocacy for equitable access to and rational use of quality essential medicines takes many different forms. At the time of the Alma-Ata International Conference on Primary Health Care in 1978, “Health for All” was the slogan that encompassed essential medicines. In the last decade, access to essential medicines was recognized as part of the fundamental right to the highest attainable standard of health (in short: “the right to health”). This new approach reinforces the arguments for universal access to essential medicines as part of the renewal of primary health care, and can serve as a guide to assess and further strengthen national essential medicines programmes.

Human rights constitute an important principle of our time. These fundamental human rights translate the values of equity, freedom, fairness, social justice and non-discrimination from abstract concepts into citizen’s rights and State obligations, which increasingly guide public policies and national judicial systems. Human rights mainly concern the relationship between the State and the individual; they generate State obligations and individual entitlements. Human rights are promoted by human rights law, which aims to protect individuals and groups against actions that interfere with their human dignity and their fundamental freedoms and entitlements. Most human rights are interdependent and interrelated. For example, the right to health is closely associated with the right to life: the right to freedom from discrimination and other civil, political, social, economic and cultural rights promoting social justice (2).

WHO’s perspectives and activities are strongly embedded in the right to health. As part of the UN family, WHO’s Constitution is inspired by the UN Charter and the second paragraph reads: *“Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. 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. Governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures”*(3).

The “right to health” approach reinforces the arguments for universal access to essential medicines.

1.1.1**The right to health in international treaties**

On 10 December 1948, the General Assembly of the UN adopted and proclaimed the Universal Declaration of Human Rights (UDHR) as a common standard of achievement for all peoples and all nations. Article 25 establishes that *“Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control”*(4).

In order to add more practical guidance to the UDHR, in 1966 the General Assembly adopted the International Covenant on Economic, Social and Cultural Rights (ICESCR). Article 12 of this treaty establishes: *“The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”*(5,6). The right to health is also recognized in many other binding international^{1,2,3} and regional^{4,5,6} treaties.

¹ International Convention on the Elimination of All Forms of Racial Discrimination, article 5 (e) (iv), 1965

² Convention on the Elimination of All Forms of Discrimination against Women, article 11.1 (f) and 12, 1979

³ Convention on the Rights of the Child, Article 24 (1989)

⁴ European Social Charter, Article 11 (revised) 1965

⁵ African Charter on Human and People’s Rights, Article 16 (1981)

⁶ Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights, Article 10 (1988)

1.1.2

Immediate obligations and progressive realization of the right to health

It is important to recognize that all necessary actions to protect, promote and fulfil the right to health cannot be secured immediately because States Parties may not have the resources to do so. Yet it is a well-established principle that States Parties, within their available resources, should work towards “progressive realization of the right to health.” Within this allowance for delayed action the ICESCR still imposes on States Parties several *immediate obligations*, two of which are very relevant for the many developing countries with insufficient resources dedicated to health. Firstly, concrete steps must be taken towards progressive realization (Article 2.1). Secondly, the benefits of such steps should be equally available to all citizens without discrimination of any kind (Article 2.2)(7). In recent years, a body of indicators has been developed to independently measure such progress (Box 1.2).

Immediate obligations of States Parties include progressive realization of the right to health and that benefits should be equally available to all citizens without discrimination.

Failure to take at least some concrete steps towards progressive realization is therefore seen as a violation of the right to health. Listed examples of such violations are a failure to adopt or implement a national health policy designed to ensure the right to health for everyone: insufficient expenditure or misallocation of public resources; failure to monitor the realization of the right to health at a national level; and failure to take measures to reduce the inequitable distribution of health facilities, goods and services (8). This is generally interpreted to imply that retrogressive measures also constitute a violation of the right to health. This means that once States have taken certain practical steps towards the fulfilment of the right to health (e.g. free health care to some categories of patients) these cannot be withdrawn other than in exceptional circumstances (9).

The WHO Constitution, key international treaties and authoritative commentaries therefore have established the right to the highest attainable standard of health of every human being and have also made States Parties (those countries that have signed and ratified the relevant treaties) explicitly responsible to protect, promote and fulfil this right. But does the right to health also include the right to access to essential medicines?

1.1.3

Access to essential medicines as part of the fulfilment of the right to health

Article 12.2d of the ICESCR of 1966 mentions access to health facilities, goods and services. In 1978, the Alma-Ata Declaration on Health for All provided a comprehensive vision and framework for health services based on primary health care (PHC), declaring that “*the attainment of the highest possible level of health is a most important world-wide social goal*” (10). By including the provision of essential drugs as one of the eight listed components of PHC it established the link between the social goal of the highest possible level of health and access to essential medicines. WHO’s launch of the first Model List of Essential Drugs a year earlier, in 1977, had already set the scene for essential medicines as an integral part of the Health-for-All strategy.

In 1990, the UN Commission on Economic, Social and Cultural Rights further developed the concept of the right to health of the legally binding ICESCR into practical guidance, through its non-binding but authoritative “General Comments”. In General Comment 3, the Commission confirmed 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 (11). General Comment 14 of May 2000 (already quoted in section 1.2) goes even further and specifically 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*” (12).

Since 2008 WHO has been making serious efforts to renew PHC by promoting four components of PHC reform which are needed to refocus health systems towards health for all (13). The first component is universal access to health care which, as a matter of course, includes universal access to essential medicines.

With such strong global recognition of essential medicines as a key component of the progressive realization of the right to health and universal access to health care, it is important to assess how this recognition translates into action at the country level. How have these human rights been incorporated in the national constitutions and laws of countries that ratified the various treaties? And how do these treaties, national constitutions and World Health Assembly resolutions inspire social development and national medicine policies and practices?

1.2

RECENT DEVELOPMENTS AND CURRENT SITUATION

1.2.1

Appointment of a UN Special Rapporteur on the Right to Health

Several reports written by the UN Special Rapporteur on the Right to Health have promoted the international recognition of the issue of access to essential medicines.

In April 2002, the United Nations Human Rights Council established the mandate of the first Special Rapporteur on *the right of everyone to the enjoyment of the highest attainable standard of physical and mental health* (14). Special rapporteurs are independent experts appointed by the UN to examine and report back on a country situation or a specific human rights issue. This milestone appointment constituted the highest level global recognition of the importance of the rights-based approach in health. It was also significant because by virtue of this mandate the Special Rapporteur has to monitor the situation of the right to health throughout the world and to present annual reports to the Commission and to the UN General Assembly (15).

The Special Rapporteur has worked closely with many stakeholders, including the relevant departments of WHO. In close collaboration with WHO he also prepared several reports on access to essential medicines and the role of the pharmaceutical industry (Box 1.1). These reports have promoted international recognition of the issue and have provided very useful guidance on the practical implications of human rights obligations and simple indicators to measure progress. This work has laid the foundation for including progress by State Parties in ensuring access to essential medicines in the standard reporting format required by the monitoring bodies.

BOX 1.1

Reports by the UN Special Rapporteur on the Right to Health with relevance to access to essential medicines^a

Intellectual property and access to medicines. Doc.E/CN.4/2004/49/Add.1

The human right to medicines. Doc.A/61/338, pp.10–18 (2006)

The responsibilities of pharmaceutical companies. Doc.A/61/338, pp.19–21 (2006)

Health systems and the right to the highest attainable standard of health. Doc.A/HRC/7/11 (2008)

Guidelines for pharmaceutical companies. Doc.A/63/263 (2008)

Mission to GlaxoSmithKline. Doc.A/HRC/11/12/Add.2 (2009)

^a All these documents were issued by the United Nations in New York.

1.2.2

Treatment access campaigns for HIV/AIDS medicines

The last decade has also witnessed a wave of rights-based civic actions in support of universal access to treatment, especially in relation to HIV/AIDS and international trade agreements. The origin of this movement can be found in a new international patient solidarity, especially between vocal AIDS patients in the USA and the rapidly increasing numbers of patients in Southern Africa. The civil society movements for access to treatment for HIV/AIDS patients in countries such as Brazil, India, Malaysia, South Africa and Thailand have contributed greatly to raising global awareness of the inequitable access to essential medicines in general. For example, in Thailand a patients' movement, together with other civil society organizations, promoted their own version of the "National Health Security Act". In response the Government agreed to create a universal access scheme enacted in 2002. Three years later, HIV/AIDS treatment was included in the scheme.

At the global level, a number of international NGOs such as Médecins Sans Frontières, the Third World Network, OXFAM, Knowledge Ecology International and Health Action International have injected a strong human rights perspective into these discussions. Their campaigns have also raised the level of awareness about the possible negative implications of international trade agreements on the price of new essential medicines (see also the chapter on Intellectual Property, Trade and Medicines). These NGOs continue to closely follow and influence the multilateral negotiations on public health, innovation and intellectual property.

1.2.3

Developments within WHO

Through its focus on equitable access to essential medicines as part of PHC, in practice the core objectives of WHO's Action Programme on Essential Drugs have always been in line with the human rights concept presented above. However, the link between universal access and the right to health was recognized for the first time as a new priority in the WHO Medicines Strategy of 2004–2007.

The Department of Essential Medicines and Pharmaceutical Policies now actively promotes access to essential medicines as part of the right to health through studies, advocacy and policy guidance. For example, the new standard set of WHO indicators to measure access to essential medicines includes government recognition of access to essential medicines as part of the right to health in the constitution or national legislation. This same country progress indicator was later included in the WHO Medium-Term Strategic Plan for 2008–2013, approved by the World Health Assembly in 2007 (16). Government recognition as part of human rights has therefore become one of the core indicators for access to essential medicines. Conversely, access to essential medicines has also become an indicator for government commitment to the right to health (Box 1.2).

WHO has assisted the Special Rapporteur in preparing several reports related to access to essential medicines and the role of the pharmaceutical industry (Box 1.1). WHO has further promoted the rights-based approach as one additional means to promote access to essential medicines by collecting and disseminating information on successful court cases in developing countries (Box 1.3) and by formulating and providing practical advice to individuals and NGOs active in this field (17,18). WHO also published two documents on the right to health mainly for the general public (2,19) In 2008, in an open letter to *The Lancet*, the six regional directors of WHO expressed their support for the Director-General in the renewal of PHC, recognizing health as a human right (20).

BOX 1.2

Access to essential medicines as an indicator for the fulfilment of the right to health

In recent years two important mechanisms have been created to assess, as objectively as possible, the commitment and performance of governments towards the fulfilment of the right to health and both use access to essential medicines as an indicator.

Firstly, the UN High Commissioner for Human Rights has created sets of indicators for 12 aspects of human rights, including the right to housing and shelter, the right to education, the right to freedom of expression and the right to health (21). The indicators for the fulfilment of the right to health refer to five aspects which are often subject to inequity and discrimination: (1) sexual and reproductive health; (2) child mortality and health care; (3) natural and occupational environment; (4) prevention, treatment and control of diseases; and (5) access to health facilities *and essential medicines*.

Secondly, in 2008 *The Lancet* published a first independent assessment of the fulfilment of the right to health in all countries of the world (22). Of 72 indicators used, 8 measured access to essential medicines, largely taken from those used by WHO and by the UN High Commissioner for Human Rights.

BOX 1.3

Enforceability of the right to access to essential medicines through the courts

Most countries in the world have acceded to or ratified at least one global or regional covenant or treaty confirming the right to health. Ratifying such treaties creates binding State obligations and individual entitlements. But what does this mean in practice? Can these individual entitlements be enforced through the courts? In 2006, WHO presented the results of a systematic search to identify completed court cases in low- 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 their government (23). A total of 71 court cases from 12 countries were identified, mostly from Central and Latin America. In 59 of these cases access to essential medicines as part of the fulfilment of the right to health could indeed be enforced through the courts. The study concluded that individual cases have generated entitlements across a population group, that the right to health was not restricted by limitations in social security coverage, that government policies have successfully been challenged in court, and that skilful litigation can help to promote that governments fulfil their constitutional and international treaty obligations, especially when governments are developing systems of social security. However it should be noted that human rights accountability is more than the purely judicial accountability studied here. Sometimes referred to as "constructive accountability" this oversight may also include parliamentary committees, ombudsmen and national human rights institutions.

While constitutional recognition of the right to access to essential medicines is an important sign of national values and commitment, it is neither a guarantee nor an essential step taken by many countries.

1.2.4

Situation at country level

In September 2005, the UN General Assembly decided to integrate the promotion and protection of human rights into national policies and to support the further mainstreaming of human rights throughout the UN system (24). After years of international discussions on human rights law, an increasing number of governments are now pledging to move towards the practical implementation of their commitments to social justice.

When looking at government commitments to access to essential medicines as a human right at country level it is clear that most countries in the world have indeed acceded to and/

or ratified at least one of the global or regional covenants or treaties confirming the right to health. For example, 160 countries have become States parties to the ICESCR. By 2009, 135 countries had incorporated aspects of the right to health in their national constitution. Of these, 87 constitutions refer to the right to goods and services, and 4 specifically mention access to medical products and technologies. More recent constitutional texts seem to include stronger commitments, possibly reflecting the positive influence of the global development of the right to health over the past 50 years (25,26).

When comparing these statistics with the outcomes of WHO's four-yearly surveys of the pharmaceutical situation in countries, there seems to be little relation between the ratification of international treaties and the existence of operational national essential medicine policies and programmes. While constitutional recognition of the right to access to essential medicines is an important sign of national values and commitment, it is neither a guarantee nor an essential step. This is shown by the many countries with failing health systems despite good constitutional language, and by those countries with good access to essential medicines without it. Yet the many successful court cases on access to essential medicines in the Americas (Box 1.3) have shown that constitutional recognition creates an important supportive environment, especially in middle-income countries where health insurance systems are being created and where patients become aware of their rights and more vocal in demanding them.

In November 2007, the WHO Regional Office for the Western Pacific was the first to hold an informal inter-country consultation to identify possible ways to incorporate the human rights approach in efforts to improve access to essential medicines, taking into account the situation in different countries. At this meeting five assessment questions formulated by WHO (Box 1.4) were for the first time used in practice to assess the national medicine policy of a country, the Philippines. An important observation made at that meeting was that a focus on the right to health within a national medicine policy automatically moves the policy discussion towards promoting equity, universal access and solidarity with the poor and disadvantaged. The rights-based approach provides a strong foundation for promoting universal access to health care.

In September 2010, the 50th Directing Council of the Pan-American Health Organization adopted a resolution in which all countries of the Americas committed themselves to working with governmental human right agencies to evaluate and monitor the implementation of international treaties and standards, with a particular emphasis on the right to health for vulnerable groups, including people with mental disorders or disabilities, older people, women and adolescents, people with HIV and indigenous peoples. In particular, the countries committed themselves to: (1) strengthen the technical capabilities of government

BOX 1.4

Five questions to assess the rights-based approach in national essential medicine programmes (21)

1. Which medicines are covered by the right to health, as committed to by the Government?
2. Have all beneficiaries of the medicine programme been consulted?
3. Are there mechanisms for transparency and accountability?
4. Do all vulnerable groups have equal access to essential medicines? How do you know?
5. Are there safeguards and redress mechanisms in case human rights are violated?

health and human rights agencies to monitor health services' compliance with international human rights treaties and standards; (2) promote systematic technical cooperation in the design of health legislation, plans and policies; (3) strengthen health workers' knowledge and skills in the use of international human rights instruments; (4) adopt legislative, administrative and educational measures to improve the dissemination of international norms and standards that protect the right to health; and (5) strengthen civil society organizations and combat stigma and discrimination.

1.3

Inequity and discrimination in access to essential medicines remain the key public health challenge of our times.

FUTURE CHALLENGES

Despite the advances described above, inequity and discrimination in access to essential medicines remain the key public health challenge of our times. A recent study found that in 36 low- and middle-income countries public sector facilities had essential medicines in stock only one third of the time, and in the private sector availability was only two thirds of the time (27). This first exact measurement of access, combined with the results of recent household surveys, comes uncomfortably close to the longstanding WHO intuitive estimate that one third of the world's population have no access to essential medicines (and less than half in some areas).

Inequity in access to medicines is part of inequity in health care. In relying on medicine supply through the private sector and financing through out-of-pocket payments, many governments choose to ignore the fact that this policy largely excludes the poor and vulnerable from obtaining even the most basic essential medicines. Those who need essential medicines the most include the poor, women and girls, the elderly, the internally displaced, people with disabilities, religious or ethnic minorities, and prisoners. Key evidence to document such inequities through disaggregated statistics or targeted surveys is rarely collected, again reflecting a lack of interest in these groups.

While judicial redress systems seem to work in Latin America, they are largely lacking in most African, Asian and Middle-Eastern countries.

The rights-based approach is specifically relevant to address such inequities. But while many countries have indeed ratified the ICESCR, more than 30 countries have so far failed to do so and of those who have, many do not implement it in practice. One third of countries do not recognize the right to health in their national constitution, and a similar number do not have an updated national medicine policy. Over 50 countries do not have an updated list of essential medicines as the basis for public supply or reimbursement. Only four countries (Mexico, Panama, the Philippines and Syrian Arab Republic) have made a constitutional commitment to ensure access to essential medicines for their population, although it should be noted here that the number of countries which have made other legally binding commitments is not known. While judicial redress systems seems to work in Latin America, they are largely lacking in most African, Asian and Middle-Eastern countries. The "right to redress" included in UN Guidelines for Consumer Protection of 1985 is often ignored.

1.4

PRACTICAL RECOMMENDATIONS

To address the widespread inequity and discrimination in access to essential medicines, the following practical recommendations are made to governments, NGOs and UN agencies including WHO. They are largely based on general human rights principles and on the specific developments and observations related to essential medicines as mentioned above.

1.4.1**Recommendations to national governments**

- 1. Ensure that constitutional and other legal provisions on the fundamental right to the enjoyment of the highest attainable standard of health, on the right to life and on the right to non-discrimination are in place.**

Justification: This will express and enshrine government values and commitments and will create a supportive environment for promoting and enforcing universal access.

- 2. Specify the obligations of the government and other stakeholders with regard to social welfare, the provision of health-care services and access to essential medicines, with an emphasis on vulnerable groups; this includes a national medicine policy with an implementation plan and an updated national list of essential medicines.**

Justification: This will establish a further expression of government commitment, and will also serve as a basis for planning, monitoring, transparency and accountability.

- 3. Collect and publish disaggregated statistics and targeted surveys to monitor access to essential medicines by gender and by vulnerable groups.**

Justification: This will identify vulnerable groups and will serve as a basis for advocacy and for monitoring progress.

- 4. Create the necessary legal instruments for enforcement and redress.**

Justification: This will support different forms of accountability and will create a possibility for the population to monitor and challenge the government.

- 5. Report regularly (e.g. every five years) on the progressive realization of the right to health, preferably on the basis of disaggregated statistics on access to essential medicines.**

Justification: This will create an opportunity for the government to make an inventory of activities and report on achievements; and for monitoring bodies and civil society to monitor progress. The use of WHO indicators allows for comparisons between countries and over time.

1.4.2**Recommendations to nongovernmental organizations and civil society at large**

- 1. Campaign for constitutional provisions and national redress mechanisms.**

Justification: This will support the development and recognition of human rights values by the government, as the basis for policies, programmes and enforcement.

- 2. Prepare shadow (parallel) reports to international monitoring bodies on country progress towards the fulfilment of the right to health, including access to essential medicines, following the standard access indicators developed by WHO.**

Justification: This allows civil society to make its own assessment of progress, as compared to the official government reports. The use of WHO indicators allows for comparisons between countries and over time.

- 3. Support targeted litigation cases in support of the development of social security and access to essential medicines.**

Justification: This is especially relevant in middle-income countries when social security and health insurance are being developed.

4. Monitor and hold accountable pharmaceutical companies in relation to their human rights responsibilities and access to medicines.

Justification: The duties of pharmaceutical companies in this regard have been defined by the report of the Special Rapporteur (Box 1.1) and the Access to Medicines Index of 2010.¹ These constitute excellent tools for external evaluation.

1.4.3

Recommendations to the United Nations, including WHO

1. Continue reporting on access to essential medicines in its annual reporting on progress in reaching Millennium Development Goal 8.²

Justification: This will continue to attract government attention to essential medicines as part of the right to health and as part of achieving the Millennium Development Goals.

2. Include reporting on access to essential medicines in the standard requirements for national reporting on progress towards respecting, protecting and fulfilling the right to health.

Justification: This will force national governments to monitor and report on access to essential medicines as part of the right to health.

3. Prepare model texts for national constitutions on government commitment to the fulfilment of the right to health, including access to essential medicines.

Justification: Political opportunities to update the constitution occur from time to time, presenting a chance to align national values and aspirations with international human rights standards. At such moments, governments are known to have come to WHO for guidance.

1.5

CONCLUSION

Governments and health policy-makers should be aware of the increasing trend of the population to demand justice as a right, not as a form of charity. While mechanisms for redress are part of any rights-based approach, governments would do much better to plan their health programmes in line with the principle of the fundamental right to the highest attainable standard of health. The concept of essential medicines with its focus on equity, solidarity and social justice is already very much in line with the principles of human rights. Yet the daily practice of national essential medicine policies and programmes can learn from the growing human rights movement and its emphasis on transparency, accountability and freedom from discrimination.

¹ <http://www.accesstomedicineindex.org/>

² MDG8: Develop a global partnership for development. In particular. Target 8E: In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries.

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ABBREVIATIONS

ICESCR	International Covenant on Economic, Social and Cultural Rights
NGO	Nongovernmental organization
PHC	Primary health care
UDHR	Universal Declaration of Human Rights
UN	United Nations