

ACCESS TO ESSENTIAL MEDICINES AND TECHNOLOGIES FOR NCDs

- Lack of adequate access and high cost of essential NCD medicines and technologies in many countries increases morbidity and mortality and cost of care that forces people and families into poverty due to disability and out-of-pocket expenses
- Governments are responsible for ensuring equitable reliable access to efficacious, safe and quality assured NCD essential medicines and technologies
- All countries, no matter how poor, can implement effective strategies and approaches that promote access to essential medicines for NCDs
- Effective policies and strategies exist to promote equitable access, including rational selection, evidence-based clinical practice guidelines, and policies to promote generic products
- Building capacity amongst health workers and the health system to manage NCDs is also a cornerstone of addressing the increasing burden of these conditions

Burden of Disease, Availability and Pricing

It is widely recognized that the global, regional and national burden of non-communicable Diseases (NCDs) is increasing in all regions of the world. The major burden of NCDs cannot be reduced without equitable and reliable access to essential medicines and technologies. Pharmaceuticals are an essential component of the treatment of cardiovascular diseases, diabetes, chronic respiratory diseases including asthma, many cancers (including pain relief and symptom control).

In most low- and middle-income countries (LMICs), access to essential medicines for the treatment of NCDs is inadequate.^{i,ii} Recent surveys in over 40 countries showed that in the public and private sector, generic medicines for the treatment of chronic diseases were between 11 and 20% LESS available than were acute disease medicines.^{iii, iv, v, vi}

When medicines are available in both public and private sectors, they are often priced to patients at a cost which is many times the actual procurement prices. When originator products are used instead of generic products the prices are between 1.3 and 3.5 times more expensive.^{vii} Families are being plunged into poverty by such unaffordable life-saving medicines.^{viii}

Lessons from AIDS Treatment Success

Since the UN meeting on HIV/AIDS in 2001, the world has learned how to deliver care effectively to patients living with AIDS, a complex chronic disease. Programmes to address NCDs can learn from the success of AIDS treatment programmes. One key difference from AIDS is that while all AIDS medicines were patent protected in 2001, nearly all essential NCD medicines are off patent or were never patented and are widely available as generic products at affordable prices. 94% of medicines on the WHO 2003 list of essential medicines were off patent.^{ix}

Low Cost, Quality Assured Medicines Exist

The majority of essential medicines to treat NCDs are extremely low cost. Glibenclamide 5mg, a key oral diabetes treatment, costs only 1/3 of a US cent to procure and would cost just over 10 cents per month if duties, taxes and mark-ups were removed. The same is true for many cardiovascular medicines. For diseases like Type 1 diabetes, which requires injectable insulin, or asthma, which requires inhalers, affordable quality assured medicines are available at a procurement cost of less than 3 to 4 US per month. For cancer, off-patent medicines such as tamoxifen for breast cancer are inexpensive. In many countries, the price charged to patients may be many times higher due to duties, taxes, mark-ups and other charges. The failure to use generic medicines also increases costs.

Procurement Prices of Common NCD Medicines with no duties, taxes or mark-ups

Product	Units per month	Median Unit Cost	Cost per month	Source
Glibenclamide 5mg tablet	30	\$ 0.0034	\$0.102	MSH 2010
Metformin 500mg tablet	60	\$0.0105	\$0.63	MSH 2010
Insulin NPH 100 IU/ml 10ml vial	1	\$ 4.20	\$ 4.20	MSH 2010 (Buy)
Salbutamol 100µg/puff, 200 doses, HFA inhaler	1	\$1.08	\$1.08	ADF 2011
Beclometasone 100µg/puff, 200 doses, HFA inhaler	1	\$1.28	\$1.28	ADF 2011
Aspirin (ASA) 100mg tablet	30	\$0.0019	\$0.057	MSH 2010
Simvastatin 20mg tablet	30	\$0.0286	\$0.858	MSH 2010
Hydrochlorothiazide 25mg tablet	30	\$0.0037	0.111	MSH 2010
Atenolol 50mg tablet	30	\$0.0095	\$0.285	MSH 2010
Tamoxifen 20mg tablet	30	\$0.0732	\$2.196	MSH 2010

Main Source MSH International Drug Price Indicator Guide 2010 and Asthma Drug Facility Price List (<http://erc.msh.org/mainpage.cfm?file=1.0.htm&id=1&temptitle=Introduction&module=DMP&language=English> and www.GlobalADF.org)

Guidelines, Marketing and Irrational Use

While some pharmaceutical companies have offered their medicines at differential lower prices or generics are available, problems of access and effective use remain. National evidence based guidelines may not exist and where they do, these may be

ignored. Marketing activities by originator or branded generic pharmaceutical companies may also contribute to irrational prescribing.

Health Systems

The treatment of patients with NCDs is different from the treatment of acute diseases. Patients with NCDs generally need long-term care, often for life, must have reliable medicine supply systems to avoid a break in therapy and have appropriately trained health workers to initiate and to continue care. Diagnostic and monitoring technologies are critical, as are registers, individualized patient records with appointment and follow-up systems, patient empowerment and self management education. Again, there are many lessons that can be transferred from HIV/AIDS programmes.

Quality Assurance

A key element of any NCD treatment programme is the constant availability of quality assured generic medicines. For AIDS, TB and malaria medicines, the UN Prequalification programme has assured the quality of these medicines and has been a crucial element of the success of the Global Fund programmes. Such an approach may also be useful for insulin or asthma inhalers and some cancer medicines. However, for the many other medicines used for treatment of diabetes, cardiovascular diseases and cancer, the best approach to assure the quality of medicines would be to strengthen national regulatory authorities.

The Right to Health

In 2008, The Lancet editorialized *"The right to health is a legal instrument—a crucial and constructive tool for the health sector to provide the best care for patients and to hold national governments, and the international community, to account"*.^x The hundreds of millions of people with NCDs have a right to expect care for their NCDs. As former WHO DG Brundtland stated, *"Access to essential medicines is a prerequisite for the progressive realisation of this fundamental human right, and, as such, is an issue of great consequence to the health and well-being of individuals throughout the world"*.^{xi}

Diabetes

More women than men die of diabetes, and a woman with diabetes has a greater risk of premature death than a man with diabetes.^{xiv} Insulin is vital for the survival of people, mainly children, suffering from Type 1 diabetes. Insulin is a life-saving treatment for Type 1 diabetes but it is not a cure. Insulin must be administered by daily injections throughout the life of the individual. From a global perspective, the most common cause of death for a child with diabetes is lack of access to insulin, which was discovered in 1921 and never patented. In the "Western" world, insulin has been made widely available since 1922.^{xv,xvi}

Type 2 diabetes not only requires weight reduction and increases in physical activity, but in most cases oral medicines, particularly as the disease progresses. For people

with Type 2 diabetes, insulin is also sometimes needed for proper management.^{xvii} Insulin and the oral medicines needed for Type 2 diabetes, metformin and glibenclamide are on the WHO Model List of Essential Medicines.

However, also of central importance are the means to administer insulin (syringe/needles), the means to monitor the response to insulin and other medicines (blood/urine tests) and an understanding of how treatment affects the life of the individual (trained healthcare workers). With access to all these elements and medicines people with diabetes can live long and healthy lives.

Chronic Respiratory Diseases

In many LMICs, the main barrier to proper management of chronic respiratory diseases (CRDs) is the poor availability and affordability of essential medicines.

This is particularly true for the inhaled corticosteroids (e.g. beclometasone) which are necessary for the long-term management of asthma.^{xviii} A survey conducted in 40 developing countries showed a mean availability of anti-asthmatic inhalers of 30.1% in the public sector and of 43.1% in the private sector.^{xix} Monthly treatment of a combination therapy made of inhaled bronchodilator and corticosteroids costs from 1.3 days' wage of the lowest paid government worker in Bangladesh to more than 9 days' wage in Malawi.^{xx}

In addition to the essential medicines, evidence-based national guidelines and proper training of health workers are also necessary to provide quality care.

The Asthma Drug Facility: A Practical Solution

The Asthma Drug Facility (ADF), a project of the International Union Against Tuberculosis and Lung Disease, is helping LMICs to obtain quality assured essential medicines at affordable prices^{xxi}. Through the ADF, the cost of one year of treatment for a patient with severe asthma has already come down to approximately 40 US\$^{xxii}. Since asthma inhalers are not yet part of the WHO Prequalification Program^{xxiii}, the ADF has developed its own quality assurance system based on WHO norms and standards to select manufacturers and products. The ADF prices are kept down by having a limited competitive process among selected manufacturers, based on annual estimated volumes. As a result, countries can then purchase these affordable inhalers through the ADF.

Cancer and Pain and Symptom Control

The effective and quality treatment of cancer requires a multi-faceted approach to early detection and treatment including access to essential cancer medicines, surgery and radiotherapy.^{xxvii} A number of inexpensive off-patent cancer medicines can substantially reduce the mortality rate for some cancer patients (e.g. Burkitt's Lymphoma), and greatly extend the life of others. With proper training, support and evidence-based guidelines, cancer medicines can be safely prepared and administered at national and district hospitals even in very low-resource countries.^{xxviii,xxix}

Access to opioid medicines for pain relief and symptom control is essential as most people with cancer will have clinically significant pain as a result of the cancer and/or treatment.^{xxx} Morphine, the mainstay of treatment for cancer pain, is off-patent, and inexpensive. However, each year, tens of millions of people suffer pain without adequate treatment, including 5.5 million terminal cancer patients.^{xxx1} Enhancing access to opioids requires regulatory reform, awareness-raising and public education activities, health professional training, and coordination with suppliers to improve procurement and distribution.^{xxxii}

Cardiovascular Disease

Cardiovascular diseases (CVD) include coronary heart disease (heart attack), cerebrovascular disease (stroke), peripheral artery disease, high blood pressure, rheumatic heart disease, congenital heart disease, and heart failure. Various treatment guidelines for CVD in children and adults list routine use of several essential medicines for people who have had an event (e.g., heart attack or stroke) or are at high risk period. Although these core medicines have been shown to reduce morbidity and mortality, they are not always available and have insufficient use in LMICs.^{xxxiii,xxxiv,xxxv}

These core medications that are useful and effective include Aspirin, ACE inhibitors, β -blockers, diuretics particularly thiazides, statins and penicillin.

Additionally, rheumatic fever/rheumatic heart disease (RF/RHD) is a major cause of chronic heart disease in children and young adults in developing countries. Although the precipitating cause of RF is a streptococcal infection, the development of RHD is a chronic NCD. Penicillin is the mainstay of treatment for both primary and secondary prevention. This strategy has been demonstrated to lead to regression of existing heart valve lesions and to reduce RHD mortality.^{xxxvi}

KEY RECOMMENDATIONS

At a national level

- Assess existing guidelines, prices, availability, financing and quality of medicines and services for NCDs and analyse how these services are being delivered.
- As part of the process to develop a national NCD strategy for prevention, treatment and monitoring, ensure that “expert” patients with long experience of the conditions are fully represented.
- Promote the use of a limited range of essential medicines and technologies through national evidence-based guidelines independently developed leading to rational selection of essential medicines and technologies for training, supply and reimbursement.
- Update the national Essential Medicines List to include the essential medicines recommended in the national guidelines, avoiding conflict of interest is avoided in this selection process.
- Organise training of health care workers independently to ensure correct prescribing and delivery of essential medicines combined with patient education within the national health system.

- Strengthen the capacity of the national medicines regulatory authority to promote the quality, safety and efficacy of essential medicines and technologies available in the country.
- Ensure that the procurement options used to achieve the most affordable quality-assured essential medicines and technologies including diagnostics such as policies to promote generic products, fair competition, transparency, and price reporting do not impact availability.
- Ensure the government budget includes procurement of essential medicines and technologies for NCDs through the national public procurement system as a safety net for the most vulnerable populations and those not covered by health insurance.
- Where health insurance exists, ensure that essential medicines for NCDs, diagnostic and monitoring technologies are covered.
- Implement pricing policies to promote affordable treatment through public and private systems, ensuring control of wholesale and retail mark-ups to guarantee the availability and affordability of treatment for the end-user.
- Improve the affordability of essential medicines and technologies through the removal of ALL import duties and ALL taxes including VAT.
- Increase the availability of controlled medicines for pain relief and symptom control through regulatory reform, awareness-raising, health professional training, and coordination with suppliers to improve procurement and distribution.
- Work closely with NGOs in monitoring, pricing, availability and affordability of NCD medicines and identifying and promoting successful interventions to improve access.
- Use procurement initiatives at international level, such as the ADF, when the expressed needs and finances are insufficient at national level to obtain the best prices and benefit from an international quality assurance system.
- Require all pharmaceutical companies to abide by the WHO ethical criteria for medicinal promotion/marketing.
- Require all pharmaceutical companies and other organisations to abide by interagency guidelines for drug donations.
- Invest in operational research to strengthen the evidence base to support treatment strategies that are feasible and appropriate in all resource settings.

At a global level

- Develop and maintain evidence based diagnostic and clinical guidelines to guide countries in the selection of essential medicines and technologies for NCDs.
- Support countries in strengthening their national medicines regulatory agencies through technical support, development of international norms and standards, and support for regional harmonisation activities with the promotion of inter-country communications.
- For critical products such as insulin and asthma inhalers, consider extending the scope of the WHO Prequalification Programme to support the procurement of quality assured products at country level.
- Promote policies that favour lower cost generics and fair competition through the collection and dissemination of independent data on availability and prices of various treatment alternatives to ensure most cost-effective choices.

- Promote the use of existing standard assessment tools to measure and report the availability, price, affordability and use of essential medicines and technologies for NCDs.
- Mobilize additional resources and support innovative sustainable approaches to financing essential medicines to address the increased needs for NCD medicines and technologies.
- Support countries to conduct analysis to inform policy decisions that remove financial barriers such as reducing out-of-pocket spending and finance mechanisms such as targeted subsidies and insurance programs.

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