

what is

ACCESS TO ESSENTIAL MEDICINES?

...and what it's like in Australia



“Essential

medicines are those that satisfy the priority health care needs of the population.

They are selected with due regard to public health relevance, 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 adequate information, and at a price the individual and the community can afford.”

- World Health Organization

From public health perspective, essential medicines save lives and improve health, when they are available, affordable, of assured quality, and rationally used.

In 1977, the WHO developed the first essential medicines model list. Since then, the list has been revised every two years. To date, there are more than 350 medicines included on the model list. Countries can use the model list to develop their own national essential medicines list, which is used as the basis for procurement and supply of medicines, development of reimbursement schemes, medicine donations and guidance for local medicine production.

Access to essential medicines is underpinned by four factors:

rational selection and use of medicines – the selection and appropriate use by governments and other health service providers of medicines that respond to the priority needs of their populations, and that represent the best balance of safety, efficacy, quality and cost.

affordable prices – to ensure that drug expenditure is cost effective and provides the best value for money.

sustainable financing – through the establishment of equitable financing mechanisms, such as social health insurance, and through appropriate models of drug development assistance.

reliable supply systems – medicines are supplied through both public and private sector means. Good health care depends on a regular supply of essential drugs of assured quality, and research and development of new drugs to address the priority needs for the population.

Clearly, equitable access to medicines is a complex, multi-faceted issue.

The high cost of drug development means that private pharmaceutical companies continue to dominate the development and manufacturing space. Without other incentives, they tend to focus on medicines that will generate greater financial return for them, meaning some diseases become neglected.

These companies would also want to price their products at levels that justify their investments. More often than not, it means without adequate government reimbursement, these drugs are unaffordable to ordinary patients.

Globalisation and the drive for efficiency and profit maximisation have resulted in the manufacturing of medicines being centralised to one or two global sites. Should the production be interrupted or malfunction at these sites, it would result in wide-spread shortage of those medicines globally.

Nationally, governments are responsible for developing their essential medicines list and relevant standard treatment guidelines, in order to guide the safe use of treatments that are most effective for a particular disease, and coordinate the funding and procurement of medicines for those treatments. This is important because guidelines are developed based on scientific evidence. Off-guideline treatments may result in sub-optimal efficacy and adverse side effects. In addition, limited resources should not be wasted on funding substandard or inappropriate treatment options. Adequate forward



procurement planning also ensures the timely supply of essential medicines.

Competition drives down price. Appropriate government policies that encourage generic competition helps keep medicines prices at affordable level. Such policies include incentives for pharmacists and consumers to choose generics over branded products, or the removal of patent exclusivity.

Individuals also have roles to play to ensure equitable access to medicines. Healthcare professionals are responsible for the rational use of quality medicines by adhering to evidence-based medicine and standard treatment guidelines, as well as educating patients on compliance, most notably

the use of antibiotics.

Before considering access issues in underprivileged areas in the world, let us look at our own issues here in Australia.

We can consider ourselves luckier than many others here in Australia. We have established standard treatment guidelines for most diseases, which underpin the rational use of medicines; our health professionals are well trained, therefore carry out evidence-based medicine most of the time; reasonable policies are in place to encourage generics competition to drive down price; most of the common medicines are funded through the PBS scheme; the supply system is generally reliable and supported by infrastructure.

Even so, access issues continue to plague our system. In 2011, 82% of cancer medicines seeking reimbursement on cost-effectiveness grounds were rejected by the PBS. It means that patients requiring these medicines will have to bear the full costs on their own, which can be as much as \$200,000 a year.

The process of listing with PBS is also complex and time-consuming, impeding the timely access to subsidised medicines.

With limited manufacturing capacity locally, we rely heavily on importing medicines from overseas.

With globally centralised manufacturing, any issues in the supply chain could result in wide-spread shortage. A recent example include the shortage of Diabex in 2012, a diabetes medicine, due to problems in manufacturing its active ingredient.

Pharmacists were forced to swap formulations to account for the shortage, which posed added risks for patients. The active ingredient is now manufactured in Queensland to ensure supply. Other shortage examples include injectable morphine due to overseas packaging delay, and

benzylpenicillin due to increased demand from flood and disaster affected regions of the world.

Generics competition helps drive down price, it also can help ensure supply, because multiple companies are able to manufacture the same medicine. However, patent exclusivity means that newer medicines are manufactured and marketed exclusively by one company. Until patent expires, generics companies are barred from producing the drug.

As individuals, you may feel powerless to make a difference, or think that it is the government's

responsibility. However, there are simple things you can do as health professionals. For example, adhere to standard treatment guidelines and evidence-based medicine; educate yourself and your patients in the rational use of medicines; keep up to date about any shortage and know the contingent plans should that happen; lend your voice to credible organisations that advocate for equitable access. As active players in the healthcare system, your actions will have a direct impact in promoting the equitable access to essential medicines. ■

Further reading

1. WHO essential medicines, policies and fact sheets
<http://goo.gl/c0Ltba>
2. WHO essential medicines definition and access framework
<http://goo.gl/zEcFPF>
3. Report on access to cancer medicines in Australia by Deloitte
<http://goo.gl/fM1CTT>
4. Read about how the lack of platelets affected a junior doctor, see attachment – *'Nightmare in Gippsland'*
5. Factors affecting supply, see attachment – *'Securing the supply chain', De Somer, E 2011*
6. News article on shortage of essential medicines in Australia, see attachment – *'A case for our own medicine', The Australian, March 2012*

Relevant organisations

1. Doctors Without Borders (MSF) Access Campaign
<http://msfaccess.org/>
2. Health Action International
<http://haiweb.org/>
3. HAI Asia Pacific
<http://haiasiapacific.org/>

Case study: *Nightmare in Gippsland*

Platelets are essential blood products that are used to treat a variety of diseases, and they are in chronic short supply globally, partly due to their short shelf life (5 days).

The shortage is exacerbated in regional and remote locations, due to barriers in acquisition, transportation and storage.

In this case study, we will look at how the shortage of platelets in a regional hospital affected a junior doctor, and put a patient's life in danger.

Location

A major regional hospital in Gippsland, Victoria, 200km from Melbourne

Hospital annual patient admissions

~12,000

Hospital staff number

~1,200

Time

5 a.m.

Junior doctor Sarah* was called into the hospital by a concerned nursing staff.

Third year out of university, she was on her three-month registrar rotation at the regional hospital. It also meant that most of the time, she was the most senior medical staff on site.

The medical emergency that brought in Sarah involved a patient with late stage sigmoid colon cancer, which had eroded the nearby artery and resulted in



massive bleeding from the rectum. The amount of blood loss from the patient was like nothing the junior doctor had ever seen, and the patient's blood pressure was dangerously low.

Immediately, Sarah started the patient on blood transfusion. However, over a period of two hours, the patient continued to lose

large amount of blood. After receiving four bags of blood, the patient still could not achieve stable blood pressure and was drifting in and out of consciousness.

At this point, Sarah decided to implement the massive transfusion protocol, which indicated the transfusion of red cells, cryoprecipitate, platelets and plasma.

However, upon requesting the blood products from the regional blood bank, Sarah was told that there was only limited cryoprecipitate available, and no platelets at all in the whole of Gippsland region. The only way to get platelets in was by train from Melbourne.

The patient was not going to wait for the train.

Sarah had no choice but to go ahead and administer the protocol. By now, the patient had three cannulas in his veins, and the nurses were squeezing blood products in with their hands, because even the highest setting on the mechanical pump was not enough to compensate for the rate at which the patient was losing blood.

*Fictional name

Sarah soon ran out of cryoprecipitate, and without the platelets, it was extremely difficult to restore the balance of blood contents and stabilise blood pressure, which were required before the patient could be operated on.

'I'm going to die, I'm going to die.', the patient moaned, and Sarah was getting more and more worried.

Thankfully, Sarah and the nurses eventually managed to control the patient's blood pressure, and the patient was rushed to the theatre.

While taking stock, Sarah realised that the amount of blood loss was equivalent to the patient's total blood volume, and three times of that was administered from all the fluids given to the patient by Sarah.

While the patient survived the ordeal in the end, their life was placed at great, unnecessary danger.

The crisis was primarily due to issues in reliable supply, and it could have been caused by a number of reasons. For example, a failure in forward planning

and coordination to ensure stock level adequacy; a sudden increase in demand in the region; disruption in initial plan to deliver the products with no contingent plan in place.

We are likely to encounter similar situations at some point in our career as health professionals. It highlights how access issues can acutely affect us and our patients. As a result, it is every health professional's responsibility to recognise, understand and address these issues, in order to promote and achieve equitable access to essential medicines for all. ■