



Universidade Nova de Lisboa

Access to essential medicines in Timor-Leste:
availability, prices and affordability

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**DISSERTAÇÃO PARA A OBTENÇÃO DO GRAU DE
MESTRE EM SAÚDE E DESENVOLVIMENTO**

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RESUMO

ACESSO A MEDICAMENTOS ESSENCIAIS EM TIMOR-LESTE: DISPONIBILIDADE, PREÇOS E CAPACIDADE DE AQUISIÇÃO

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PALAVRAS-CHAVE: disponibilidade de medicamentos, preços de medicamentos, capacidade de aquisição de medicamentos, regulamentação do sector farmacêutico em países de médios e baixos rendimentos, medicamentos em Timor-Leste.

O acesso a medicamentos essenciais a preços acessíveis de forma sustentável é um dos indicadores do cumprimento dos Objectivos de Desenvolvimento do Milénio e pode ser considerado como parte do direito universal à saúde. Tal como acontece com outros bens essenciais, o acesso aos medicamentos depende de múltiplos factores, como a sua disponibilidade, preços e capacidade de aquisição por parte da população. Na última década, foram efectuados mais de 50 estudos para avaliar esses factores, em países de baixos e médios rendimentos, utilizando uma metodologia desenvolvida pela Organização Mundial de Saúde e a organização *Health Action International*, numa tentativa de compreender as possíveis causas para o baixo acesso aos medicamentos. Os resultados destes estudos revelam uma baixa disponibilidade de medicamentos essenciais de um modo geral, sobretudo no sector público, e preços elevados, sobretudo no sector privado.

O objectivo deste estudo foi descrever a disponibilidade, os preços e a capacidade de aquisição de medicamentos essenciais em Timor-Leste, com recurso à metodologia da OMS/HAI. Foram recolhidos dados sobre a disponibilidade e os preços de uma lista de medicamentos em hospitais, centros de saúde e farmácias comunitárias.

Embora os resultados pareçam apontar para uma disponibilidade global razoável de medicamentos genéricos no sector público (59,2%), algumas substâncias activas e classes terapêuticas encontravam-se sistematicamente esgotadas em vários pontos do país. Nas unidades situadas em locais mais remotos, a disponibilidade de medicamentos chegava a descer para valores na ordem dos 47,5%. Verificou-se que a disponibilidade de medicamentos nas farmácias privadas era ainda mais baixa do que nos serviços públicos (38,0%). Os medicamentos são dispensados gratuitamente nos hospitais e centros de saúde, mas nas farmácias privadas chegam a ultrapassar 40 vezes os seus preços de referência internacionais, mesmo como genéricos. Consequentemente, estima-se por exemplo, que um funcionário público que utilize diclofenac para o tratamento crónico da artrose, tenha de trabalhar durante mais de 2 dias para pagar o seu tratamento mensal com o medicamento genérico, ou 12,5 dias, se for prescrito o medicamento de marca. Durante o estudo, foram detectados vários outros problemas que podem comprometer a qualidade e segurança dos medicamentos.

Apesar das limitações inerentes a uma investigação deste tipo, foi possível concluir através do presente estudo que, ao contrário da tendência geral observada em países similares, o sector público de cuidados de saúde em Timor-Leste parece ter um

melhor desempenho do que o privado. No entanto, as condições limitadas da maioria das unidades de saúde públicas pode forçar alguns doentes a recorrer ao sector privado, onde os preços pagos pelos tratamentos são inaceitavelmente elevados. A ausência de regulamentação do sector farmacêutico (e fiscalização insuficiente da existente) parece estar a contribuir para a estagnação do sector privado e a encorajar indirectamente a falta de transparência nas práticas farmacêuticas.

Dada a escassez de estudos sobre este assunto em Timor-Leste, espera-se que o presente trabalho forneça evidências importantes que possam ser utilizadas em estudos subsequentes e como base a uma intervenção por parte das autoridades com o objectivo de melhorar a disponibilidade de medicamentos no sistema público e de encorajar o desenvolvimento do sector privado como alternativa viável, segura e de custo aceitável.

ABSTRACT

ACCESS TO ESSENTIAL MEDICINES IN TIMOR-LESTE: AVAILABILITY, PRICES AND AFFORDABILITY

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KEYWORDS: drugs availability, drugs prices, affordability of medicines, access to medicines, pharmaceutical regulation in low- and middle-income countries, medicines in Timor-Leste.

Access to affordable essential medicines on a sustainable basis is one of the indicators of compliance with the Millennium Development Goals, and can be regarded as part of the human universal right to health. As with other basic commodities, access to medicines depends on multiple factors, like their availability, prices and affordability. Over the last decade, more than 50 surveys using a methodology developed by the World Health Organization and Health Action International have been carried out in low- and middle-income countries, to assess these parameters in an attempt to understand the causes underlying poor access to medicines. Findings typically reveal low availability of essential medicines, particularly in the public health system, and high prices, especially in the private for-profit sector.

The objective of the present study was to describe the availability, prices and affordability of essential medicines in Timor-Leste using the WHO/HAI methodology. Data on the availability and prices of a drug tracer list was collected from a sample of hospitals, community health centres and private retail pharmacies.

Although results seem to show a reasonable overall availability of generic medicines in the public sector (59.2%), some active substances and therapeutic classes were found to be consistently out of stock across the country. In facilities located in more remote areas, availability could be as low as 47.5%. Drug availability in private pharmacies was found to be even lower (38.0%). Medicines are dispensed free of charge in public health facilities, but in private pharmacies they were found to cost up to 40 times their international reference price, even as generics. As a result, it is estimated that a common government worker using diclofenac to treat chronic arthritis, for instance, would have to work 2.3 days to pay for his monthly treatment with the generic drug, or 12.5 days if the originator brand was prescribed. Other problems affecting medicines quality and safety were also detected throughout the study.

Despite its limitations, the present study concluded that, contrarily to the general trend observed in similar countries, the public healthcare system in Timor-Leste seems to perform better than private. Nevertheless, the far from ideal conditions of most public health facilities can still push some patients to the private sector where costs of treatment are unacceptably high. The lack of regulation of the pharmaceutical sector (and inefficient monitoring/inspection of the existing one)

seems to be contributing to the private sector's stagnation and indirectly encouraging lack of transparency in pharmacy practice.

Given the paucity of studies on the subject in Timor-Leste, it is hoped that the present work will provide an important evidence base for subsequent studies, and government intervention to better regulate the pharmaceutical sector, with the ultimate objective to improve the public drug supply, and encourage the growth of the private sector as a viable, affordable and safe alternative.

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LIST OF ABBREVIATIONS

CHC	Community Health Centre
CHR	Committee of Health Research
CIF	Cost, insurance and freight
COC	Combined oral contraceptives
CRAF	Comissão Reguladora das Actividades Farmacêuticas
DHO	District Health Office
DOP	Department of Pharmacy
EML	Essential Medicines List
HAI	Health Action International
HP	Health Post
IRP	International Reference Price
LPG	Lowest price generic
MDG	Millennium Development Goal
MIU	Million International Units
MNCH	Maternal, new-born and child health
MoH	Ministry of Health
MPR	Median price ratio
MSH	Management Sciences for Health
MSP	Manufacturer's selling price
NCT	New Delhi Central Territory
NDP	National Drug Policy
NGO	Non-governmental organization
NHS	National Health System
NSAID	Non-steroid anti-inflammatory drug
OB	Originator brand
ORS	Oral rehydration salts
SAMES	Serviço Autónomo de Medicamentos e Equipamentos de Saúde
SEAR	Southeast Asia Region
STG	Standard Treatment Guidelines

UN	United Nations
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
UNMIT	United Nations Integrated Mission in Timor-Leste
UNTAET	United Nations Transitional Administration in East Timor
USD	United States dollar
WB	World Bank
WHO	World Health Organization

INTRODUCTION

Access to medicines is widely recognised as a critical factor in ensuring people right to health. However, one third of the world's population still lack sustainable access to essential medicines. Medicines availability and prices, both in the public and private sectors, are often considered proxies for access to markets and to pharmacological treatment in low and middle-income settings. The patterns identified are generally comparable across the countries analysed, where low availability (particularly acute in the public sector) and selling prices that largely exceed their respective international reference price are often reported. Low availability in the public sector forces patients to use the private sector, where prices are typically much higher. As medicines are normally purchased through out-of-pocket expenses in low and middle-income countries, excessive prices make them highly unaffordable to large sections of the population.

The objective of this research is to explore the access of the population of Timor-Leste to essential medicines, in public or private sectors, and to analyze the impact a pharmacological treatment might have on household expenses. This study is based on the standard methodology for measuring drug prices and availability developed by the World Health Organization (WHO) in collaboration with the non-governmental organization Health Action International (HAI).

The structure of this thesis is as follows:

- Chapter 1: Literature review, which is divided in three parts: the first reviewing the existing body of knowledge around access to essential medicines; the second is a country overview, focusing on the structure of the national health system and pharmaceutical sector in Timor-Leste; finally, the last part describes the objectives of the present study;
- Chapter 2: Methods, data collection and data analysis; description of the WHO/HAI approach, and its application to the present research;
- Chapter 3: results obtained with this research;
- Chapter 4: Discussion of results, study limitations, policy implications, recommendations for future research areas and conclusions.

1. LITERATURE REVIEW

1.1. ACCESS TO ESSENTIAL MEDICINES

Having access to medicines has long been recognised as a critical factor in ensuring people's health.(1) Providing access to affordable essential drugs on a sustainable basis in developing countries is one of the targets included in one of the Millennium Development Goals¹ (MDG 8, target 8.E).(2) However, one third of the world's populations still lack sustainable access to essential medicines.(3) Essential medicines represent a crucial element for interventions aimed to achieve other Millennium Development Goals, such as MDG 4 (reduce child mortality), MDG 5 (improve maternal health) and MDG 6 (combat HIV/AIDS, malaria and other diseases).(4)

Access has been defined as a '*general concept that summarizes a set of more specific dimensions describing the fit between the patient and the health care system*'.(5) In fact, the term 'access' brings together several factors, which can include the population's care-seeking patterns, the location of facilities dispensing medicines and transport conditions within the country or region, availability of medicines at point of care and the population's ability to pay for medicines. Some dimensions of access have been identified as particularly relevant in the case of medicines and other health commodities: physical availability, affordability (or ability to pay), geographical accessibility and acceptability (or satisfaction).(6) The World Health Organization (WHO) also defines access to essential medicines from the patient's point of view as a situation when '*drugs can be obtained within reasonable travelling distance (i.e. are geographically accessible), they are readily available in health facilities (i.e. are physically available), and affordable (i.e. are financially available)*'.(7)

Although each one of these dimensions can be explored through a set of indicators, medicine's availability, prices and treatment affordability have been used as proxies for access to medicines in low and middle-income settings and several studies have been conducted using these two dimensions of access. The patterns identified are generally comparable across the countries analysed to date, where low availability

¹In 2000, 189 nations undersigned a promise to free people from extreme poverty and deprivations worldwide by 2015. This pledge – the United Nation's Millennium Declaration – was converted into the eight Millennium Development Goals.

(especially marked in the public sector) and high prices are often reported when compared to international reference prices.(8) As medicines in the private sector are normally purchased through out-of-pocket expenses in low and middle-income countries, high market prices make them highly unaffordable to large sections of the population, preventing individuals from accessing treatment in contexts where they cannot rely on the public health system for medicines. The situation is even more dramatic when chronic diseases, requiring long-term treatments, are considered.(8, 9)

This chapter describes the two dimensions of access commonly used to estimate the overall access to essential medicines – availability and affordability (through the analysis of prices), using one particular tool that has been especially developed for this kind of analysis.

1.1.1. Availability of medicines

The consultative meeting held between WHO and the non-profit international health organization Management Sciences for Health (MSH) to define the concept of access and its dimensions, refers to physical availability as *'the relationship between the type and quantity of product or service needed, and the type and quantity of product or service provided'*.(6)

Availability of essential medicines directly influences the capacity of the healthcare facility to immediately respond to patient's needs, but also indirectly, since confidence in the healthcare system depends on having resources to ensure care is provided when needed. The availability of essential medicines influences the health-seeking patterns of the population, encouraging them to use healthcare facilities if they know they can be adequately treated and/or benefit from preventive services and other health interventions. If drugs are constantly out of stock, attendance tends to be lower.(7)

Availability of (good-quality) essential medicines depends on an efficient supply system, which includes factors such as the selection, procurement and distribution of drugs. Availability is also influenced by the prescription and utilization patterns of healthcare personnel, and an adequate coordination between these two dimensions (supply and use) is a critical factor in healthcare provision at point of care.(3)

In some contexts, drug donations can also have an important role on the availability of medicines, but over the years many problems arose around this issue, which led WHO to release in 1996 a document of *Guidelines for Drug Donations* aimed to improve the quality of drug donations.(10) Despite the important contribution of this document there is still some evidence of inappropriate practices in some countries. An adequate communication system between donors and recipients has been identified as a crucial factor to ensure drug donations follow WHO's guidelines.(11)

Although different methods of measuring availability emerged in the past, one of the most common practices is to define availability as “the number of medicines – from a pre-defined list of indicator medicines – available across a set number of selected sites, summarised as a percentage”.(12) Medicines physical existence can be measured on site over a pre-defined period of time or on a specific date of visit. This kind of approach to measure of availability has been used in a wide range of recent studies.(8)

1.1.2. Medicines prices

Public policies on medicine distribution to the population vary among countries. In some countries, people pay for medicines provided by the national health system, although in many cases some groups are exempt (children, pregnant women, elderly). In other cases only a prescription fee exists or part of the costs are supported by the state. There are also countries where medicines in public health services are distributed free of charge, with no additional costs imposed by the health system.(8)

However, several surveys conducted in low-income countries over the last years consistently show a lack of availability of medicines in the public sector (3,9,13) forcing patients to search for their medicines elsewhere, in the private sector. However, the private sector is not always well regulated in these countries, and some availability problems also arise at this level. Additionally, even when medicines are actually available in the private pharmacies, prices are often very high, making them unaffordable for the most deprived population groups.

Several components can contribute to the final price of a medicine. These components correspond to the respective mark-ups applied to the baseline price of a medicine (MSP, or manufacturer's selling price) by the various market players along its

supply chain. These components can include freight or insurance costs, import taxes, port fees, margins applied by importers, wholesalers and retail distributors, as well as dispensing fees or other applicable fees. Depending on the market structure, these mark-ups typically range from 30 to 45% of the final price of the medicine, but can exceed 100%, depending on the pharmaceutical sector's regulation.(14)

Medicines price is a key factor for access to treatment. In 1986, the international organization MSH launched the annual publication *International Drug Price Indicator Guide*;(15) since 2000, WHO collaborates in its edition. The guide lists medicines supplier and buyer (tender) prices and estimates a median price based on the suppliers' prices to be used as the international reference price (IRP). The tender price is used for products that have no supplier price.(14) The objective of the price guide is to make information on drug prices widely available to help improving the procurement of medicines, since great variations can occur according to the procurement methods used or the negotiation capacity of the entity responsible for the procurement process. Price information is therefore crucial to ensure the efficiency of local procurement systems.

Medicine prices have been collected in several surveys at national and regional levels. This type of analysis can focus on lists of essential medicines or on specific groups of medicines, such as cardiovascular therapy or reproductive health. Given the importance of generic medicines on equitable access to treatments, data is usually collected not only for originator brands but also for the generic equivalent of the same active substance. Recent data from a pooled analysis of worldwide price surveys indicate prices at least 10 times higher for originator brands and at least 2.6 higher for lowest-priced generics, with marked variations across world regions.(8)

1.1.3. Affordability of treatments

Medicines are estimated to represent 20-60% of all expenses related to health in low-income countries (3) and part of treatment costs are directly supported by patients (through direct or out-of-pocket payments).(16) For this reason, WHO has considered "affordable prices" as one of the four key factors on which access to medicines depends, along with rational selection and use of medicines, sustainable financing and reliable health and supply systems.(17)

Affordability is, however, a broad and vague concept, which depends to a great extent on the commodity it relates to.(18) Operationalizing the affordability concept in the field of medicines was therefore considered important to gain some insight into the impact of such commodities in household expenses and some attempts have been made to identify the best approach to measure it.

WHO and MSH considers affordability of medicines and other health commodities *'defined by the relationship between prices of the products or services and the user's ability to pay for them'*.(6) A list of indicators was developed to measure this relationship, including direct comparisons to international prices and the number of days lowest-paid government employee must work to pay for a standard recommended course of therapy for tracer conditions; this last approach has been used in many studies over the recent years. It consists of converting the price of one course of treatment into working days (i.e. the equivalent daily wage) of the lowest paid unskilled government worker. A course of treatment for a given condition is considered affordable if its price does not exceed the equivalent to one daily wage; treatments that go over this threshold are considered unaffordable.(8) This method is sometimes criticised when applied to low-income countries (18,19) since it is estimated that large sections of the population earn much less than the lowest paid unskilled government worker.

Some authors have suggested other different approaches to measure affordability applied to medicines.(18) Two alternative methods include the catastrophic impact of expenditures on medicines (which calculates the amount spent on medicines as a proportion of the household expenditures, classifying them as 'catastrophic' if they exceed a certain proportion) and the impoverishing effect of expenditures on medicines (which measures the percentage of the population that would be pushed below the poverty threshold – USD 1.25 or 2.00/day – after purchasing treatment).(20)

Nevertheless, none of the mentioned approaches takes into account other expenses related to seeking pharmacological treatment. The price of medicines alone doesn't fully reflect the costs associated to the treatment of a certain health condition, since other costs (such as transport to the point of care, doctor's fees, loss of working time for the individual and caretaker, among others), can impose additional expenses.(20) However, since the price of medicines normally represents an important

share of the overall cost of treatment, it is frequently used as a reasonable estimate of the affordability of treatments.

1.1.4. Measuring the access to essential medicines

Acknowledging the impact that medicines availability and prices have in the access of the population to adequate medical treatment, several civil society organizations started to carry out a few small-scale studies in developing countries to measure medicine prices and make international comparisons in the mid-90s. However, methodological discrepancies made comparisons between countries difficult.(14) In 2001, the World Health Assembly highlighted the importance of monitoring medicines availability and prices with the ultimate goal of overcoming inequities on the access to essential medicines.(21)

The need to collect consistent data on medicines availability and prices in different settings, allowing international and cross-country comparisons, was therefore recognised, leading to the development of a standard methodology through a collaborative project between WHO and Health Action International (Project on Medicine Prices and Availability, hereinafter referred to as WHO/HAI project or WHO/HAI methodology). The aim of this project was to consistently collect and analyse data on medicines availability and prices in order to produce reliable and comparable information that could be subsequently used as guidance by policy makers and other stakeholders in the health and pharmaceutical sectors to improve access to affordable medicines, especially in low- and middle-income countries.(14)

The methodology was launched at the 2003 World Health Assembly as a draft after which studies were undertaken to validate the sampling methodology and the price collection component. The results confirmed the appropriateness of the WHO/HAI approach.(14, 22)

To date, WHO/HAI methodology has already been used in several national and regional studies,(23-25) and can be adapted to focus on particular intervention areas or specific therapeutic groups. In fact studies have been conducted in diverse areas such as chronic diseases,(9) reproductive health (26, 27) or ARV drugs.(28) It also has the advantage of being specifically validated for low and middle-income settings (22) and available online (14), with a comprehensive manual, a pre-programmed data analysis

spreadsheet, templates and an exhaustive database including reports from previous studies which can serve as basis for future research. Analyses include availability and prices of medicines and affordability of common treatments. It also provides tools for an additional analysis of government procurement prices and of the components that contribute to the final price of medicines.

1.1.5. Access to medicines in low- and middle-income countries: present situation

By the end of 2007, over 50 surveys had been undertaken across the globe using the WHO/HAI methodology described in the previous section. The results of these surveys in low- and middle-income countries showed a general pattern of low availability of essential medicines, particularly acute in the public sector (where medicines are sold at lower prices or dispensed at no cost) forcing the population to purchase medicines from the private sector, where they are typically more available, but at a higher cost, often considered unaffordable to most of the population.(9,13,14) Results also pointed towards a general inefficiency in government procurement processes and identified numerous mark-ups, taxes and duties applied along the medicines supply chain, which amplify financial obstacles to access.

In 2008, a second edition of the WHO/HAI project manual was released, with updates to the methodology, based on the lessons learned from the field. Several other surveys have been carried out in low- and middle-income countries since 2008 and data was made available on the WHO/HAI Project on Medicine Prices and Availability database.(23)

The World Medicines Situation 2011 report, a pooled analysis of 53 studies on medicines prices, availability and affordability, completed between 2001 and 2008 (8) revealed a low availability in the public sector of both generic medicines (lowest price generics – LPGs) with less than 60% across all world regions, and originator brands (OBs), with governments generally favouring the procurement of generic medicines. In the private sector, generic medicines availability was higher than in the public sector across all world regions, but also lower than 60%; as for originator brands, availability in the private sector was globally lower than 25%, with the exception of the Eastern Mediterranean region. Most of the studies covered in this report followed the first edition (2003) of the WHO/HAI Project on Medicine Prices and Availability manual.

Table 1.1. below shows the most recent data from medicines prices and availability surveys conducted with WHO/HAI methodology between 2008 and 2011 in low- and lower-middle-income countries, included in WHO/HAI database.

Table 1.1. Mean availability of essential medicines¹ in low- and lower-middle-income countries,² recently surveyed.

Country	Public sector mean availability (%)		Private sector mean availability (%)	
	OB	LPG	OB	LPG
India (NCT state)	0.0%	32.8%	29.3%	68.8%
Indonesia	4.6%	55.1%	27.1%	49.4%
Burkina Faso	0.2%	72.5%	44.1%	63.5%
São Tomé and Príncipe	2.5%	55.1%	10.8%	24.3%
Haiti	1.9%	23.3%	6.4%	44.6%
Guatemala	– ³	46.0%	– ³	35.0%
Bolivia	0.2%	29.2%	4.7%	74.0%
Nicaragua	2.4%	47.8%	18.0%	72.9%

¹Results reflect overall availability of a basket of medicines, which may be different across countries surveyed.

²World Bank's classification

³Data for OB not available.

Although the common pattern of lower availability in the public sector when compared to the private was confirmed in many of these surveys, countries such as Indonesia, São Tomé and Príncipe, Burkina Faso and Guatemala seem to show an opposite trend.

In low- and middle-income countries, medicines represent out-of-pocket expenses for the majority of the population, since few of these countries have social insurance or health services subsidized by public funds.(29) Even in countries where medicines in the public sector are provided free of charge, their low availability often forces patients to purchase them in the private sector, incurring in significant expenses.(8,9) The same medicines show important price variations between countries and are sometimes even more expensive in developing countries when compared to industrialized nations.(30) Moreover, many studies have shown that affordability is unrelated to purchasing power.(14)

Medicine prices can be standardized to median price ratios (i.e. ratio local price/international reference price – refer to Chapter 2. Methods), to allow comparisons between countries. While direct price comparisons of individual items should be avoided, since they are relatively complex and require adjustments to several factors

(like standardizing to the same reference price year for studies carried out in different years, adjust for inflation/deflation and for the local currency's buying power),(14) with a sample or basket of medicines it is possible to have a rough idea of how more expensive medicines are, in general, in one country or region, when compared to others. Table 1.2. below shows a summary of median price ratios for a basket of essential medicines (only generic versions) across countries surveyed in the period 2008-2011.

Table 1.2. Median price ratios in the private sector of generic medicines¹ in low- and lower-middle-income countries,² recently surveyed.

Country	Median Price Ratio – Private sector patient prices (all LPG medicines surveyed)			
	N	Median MPR	Min MPR	Max MPR
India (NCT state)	43	2.83	0.56	9.73
Indonesia	37	2.00	0.46	10.42
Burkina Faso	43	2.92	1.21	12.56
São Tomé and Príncipe	39	13.76	0.09	107.51
Haiti	34	7.25	2.26	49.57
Bolivia	48	4.54	0.38	52.39
Nicaragua	41	5.73	0.69	21.30

¹Results reflect overall availability of a basket of medicines, which may be different across countries surveyed.

²World Bank's classification

The high prices of medicines invariably contribute to the unaffordability of pharmacological treatments. Results from more than 50 studies undertaken by the end of 2007 identified one-month treatments costing more than the equivalent to several day's wages of a common government worker in some countries.(14) In a recent survey carried out in São Tomé and Príncipe, for instance, treatment of common adult respiratory infection with a 7-day course of treatment with ciprofloxacin (500 mg, tablets) or ulcer with omeprazol (20 mg, capsules), both generic medicines, was found to cost close to 40 day's wages.(31)

The situation is obviously aggravated if patients suffer from chronic conditions and purchase the same medicines on a regular monthly basis for instance, or in the case of concomitant conditions requiring more than one medicine. In Ghana and El Salvador, for instance, concomitant monthly treatment of diabetes and hypertension were found to cost 10 or more times the daily wage of a common unskilled government worker.(8)

1.2. TIMOR-LESTE: COUNTRY OVERVIEW

Timor-Leste is located in the southernmost island of the Indonesian archipelago in Southeast Asia, occupying a territory of approximately 15.000 km² which comprises the eastern half of Timor island, Atauro and Jaco islands (to the north and to the east, respectively), and the Oecussi enclave on the north-western side of the island, within Indonesian borders (Figure 1).

Historically, the territory was under Portuguese colonial rule since the 16th century, and started a decolonization process in 1975, which culminated in a declaration of independence that launched the country into a civil war. Using the pretext of protecting its citizens in the Timorese territory, Indonesia invaded the eastern part of the island and annexed the territory as its 27th province nine days after the declaration of independence. For 25 years, Timorese kept a resistance movement fighting against the integration into Indonesia, which cost the lives of about one third of the population.

In 1998, under fierce international pressure, Indonesia accepted a referendum in East Timor territory in which people would be given the choice of autonomy (and integration into Indonesia) or independence. The referendum was held in 1999 and the population massively voted for independence. A wave of murders and mass destruction promoted by the pro-Indonesian militias and supported by members of the Indonesian army followed the announcement of the referendum results. The destruction of infrastructures (including many healthcare facilities and roads) was a serious setback to the development of the new fragile nation. The UN finally intervened, militaries were deployed to the country and a peacekeeping mission was established with the objective of disarming the militias and supporting the transition process and the country's reconstruction. Following this UN transitional administration (UNTAET), Timor-Leste² finally became an independent nation on the 20th of May 2002,(32) the date of the country's first constitution.

The first four years of independence witnessed several gains in capacity, like the establishment of tax and customs services and the delivery of health services. However,

²Since 2002, the country's official name is Timor-Leste (short for Democratic Republic of Timor-Leste), but throughout its history, this same territory has been known under different names: 'Portuguese Timor', during the period of Portuguese colonization (1512-1975), and 'East Timor', during Indonesia's time until the country became an independent sovereign state (1975-2002). Some reports and international media still refer to Timor-Leste using this last designation.

the government faced serious challenges during the post-independence phase, in terms of financial management and budget execution and a discontentment wave started to emerge among certain sectors of the society.(33) This military and civil uprising, coincident with the peacekeepers departure and the scaling down of UN activities, led to a crisis in 2006, which forced the Prime Minister to resign. Along with some casualties, this crisis led also to the displacement of approximately 15% of the population to temporary internally displaced people camps throughout the country, especially in Dili area. Upon Timor-Leste's official request for military assistance, international troops returned to the country to restore peace and the UN Security Council established an Integrated Mission in Timor-Leste (UNMIT), allowing for new presidential and parliamentary elections to take place in 2007, under international observation. This international presence was also crucial on the aftermath of the (unsuccessful) rebel attacks against the President (and Prime Minister) in February 2008. Fortunately, this episode had no serious consequences, and, since then, the country has enjoyed one of its longest periods of stability and economic growth.

According to the latest population census, Timor-Leste has an estimated population of 1.066.409 inhabitants and is administratively divided in 13 districts: Aileu, Ainaro, Baucau, Bobonaro, Cova-Lima, Dili, Ermera, Lautem, Liquica, Manatuto, Manufahi, Oecussi and Viqueque (Figure 1). Each of the districts comprises 4 to 7 sub-districts, further divided into *sucos* (villages). The main urban centres are Dili and Baucau (122 km east of Dili) but less than one third of the population is urban.³

Timor-Leste's official languages are Tetum and Portuguese; Indonesian bahasa is no longer an official language but, along with English, it has the status of a 'working language' under the Constitution. The country uses the north-american dollar (USD) as its circulating currency.

Despite all the country's achievements in terms of human development since independence (Timor-Leste currently occupies the 147th world position of the Human Development Index),(34) some indicators, namely in the health sector, still reveal the important challenges the country has yet to overcome.

³Census 2010. Available from: <http://dne.mof.gov.tl/> (accessed on 22 Jul 2012).

According to World Bank's latest data (2007), half of the population (49.9%) lives below the national poverty line and 37.4% below the poverty threshold of 1.25 USD/day⁴.(35)

Figure 1. Timor-Leste: administrative division (13 districts).



Source: Ministry of State Administration and Territorial Management of Timor-Leste. Available from: http://www.estatal.gov.tl/English/Municipal/Municipal_main.html (accessed on 22 Jul 2012)

1.2.1. Timor-Leste's National health system (NHS)

The Timorese health sector was critically affected by the devastating events that followed the vote for independence in 1999. It is estimated that more than one third of the existing health facilities were totally destroyed and most of the remaining infrastructures substantially damaged, a considerable part of the equipment had been stolen or was completely destroyed and more than 80% of medically qualified staff had returned to Indonesia.(36) The international community had to strongly assist the Timorese with the rehabilitation of the health system since very few nationals were experienced in health administration.

⁴Poverty headcount ratio at \$1.25 a day (PPP) (% of population).

The Constitution of the Democratic Republic of Timor-Leste was approved in May 2002 and the Ministry of Health (MoH) was officially established later in September of the same year. The right to health and health assistance is referred in Timor-Leste's Constitution,⁵ as one of the basic rights of the population. In 2004, the Law on the Health System (Law no. 10/2004) was published, laying basis for the creation of a National Health Service of Timor-Leste (NHS) characterized for 'being universal with regard to the target population', 'assuring users equal access' and 'being inclined to be free of charge'. The NHS covers all Timorese citizens, as well as foreign nationals with residence in Timor-Leste.(37)

In addition to the NHS, the Timorese health system includes '*all other entities, public or private, whether lucrative or non-lucrative, which are directly or indirectly engaged in health prevention and promotion and disease treatment activities*', such as private pharmacies and private clinics.(37)

On the organizational chart of the MoH, under the National Directorate for Community Health, there is a Department of Pharmaceutical Services⁶ (also known as Department of Pharmacy, DOP) whose responsibilities include the development and supervision of programs and protocols promoting the rational use of medicines, assuring an efficient management of pharmaceutical products for the NHS and providing technical support to other authorities of the MoH for inspection and monitoring activities.

In the public health system, there are five levels of care. Level 1 (Health Posts [HP] and mobile clinics) include curative consultation, antenatal and postnatal care, immunization, growth monitoring and health promotion activities; level 2 Community Health Centres (CHC) provide promotion, prevention and curative services, including outpatient consultations and a simple laboratory; level 3 CHCs include all services provided at lower levels as well as basic emergency obstetric care and 5 to 10 observation beds; level 4 health centres include an inpatient department with 10 to 20 beds and include all services provided at lower levels and referral to higher levels if needed.(38) Finally, there is a network of 6 referral hospitals: Guido Valadares National Hospital in Dili (with 260 beds), Baucau Hospital (with 114 beds), Maliana, Suai,

⁵Constituição da República Democrática de Timor-Leste. Available from: http://www.jornal.gov.tl/public/docs/ConstituicaoRDTL_Portugues.pdf (accessed on 22 Jul 2012)

⁶*Departamento de Serviços Farmacêuticos*

Maubisse and Oecussi Hospitals (with 24 beds each).(38, 39) Under agreement with certain international organizations, patients can be referred from Dili National Hospital to other hospitals overseas, if needed.(40)

The stratification of healthcare facilities in the Timorese NHS is presented in Table 1.3.

Table 1.3. Public healthcare facilities in Timor-Leste by level of care.(41, 42)

Level	Type of facility	Location	Area of influence	No. of facilities
1	Health Posts/Mobile Clinics (SISCa)	<i>Sucos</i> /remote communities		210/473
2	Community Health Centres L2	Sub-district urban centres	1000-5000 inhabitants	59
3/4	Community Health Centres L3* / L4 [#]	District capitals	5000-15000 inhabitants	7
5	Referral Hospitals/ National Hospital (Dili)	District capitals	Entire district population	6

SISCa: *Serviços Integrados de Saúde Comunitária* (Community Integrated Health Services)

*Level 3 facilities are available in districts with no referral hospital bordering Dili: Aileu and Liquiçá.

[#]Level 4 facilities are available in districts with no referral hospital: Lautem, Viqueque, Manufahi, Ermera and Manatuto districts.

In the public health system, drugs are provided free of charge to all patients at all levels of care. The 2010 edition of the Essential Medicines List (EML) defines the level(s) of care for which each medicine should be available.(43)

Sub-district health centres and higher levels include a Division of Pharmacy among their minimum services to ensure a ‘continued availability of pharmaceuticals and consumables for the effective provision of the services assigned to the health centre.’(40) Currently, a pharmacy assistant or pharmacy technician is usually in charge of this department.

Procurement, storage and distribution of medicines and medical products for the public health system is carried out by a semi-autonomous central supply agency, Autonomous Drugs and Medical Equipment Service (SAMES)⁷, established by the Government Decree No. 2/2004.(44) SAMES receives its budget directly from the Ministry of Finance and is not allowed to supply the private sector. The agency is also responsible for storage and distribution of drugs procured for vertical programs (e.g.

⁷*Serviço Autónomo de Medicamentos e Equipamentos de Saúde.*

UNICEF, UNFPA and Global Fund). SAMES distributes medicines to hospitals on a monthly basis and to District Health Offices (DHO) in the districts on a quarterly basis;(45) staff from health posts and health centres must then collect their deliveries from the DHO (located in the district capital).

1.2.2. Private for-profit and other sectors providing healthcare in Timor-Leste

It is estimated that private healthcare facilities account for about one fourth of the basic health services provided in Timor-Leste.(46)

According to the information provided by the DOP, in July 2011 there were 28 licensed private pharmacies in Timor-Leste, the vast majority of which situated in Dili [22] and a few others in four urban centres in the districts – Baucau [3], Liquiçá [1], Maliana [1] and Viqueque [1].

Private not-for-profit clinics also provide health services throughout the country. For example, one NGO based in Dili runs eight fixed clinics (with services similar to the ones provided in public CHCs) and 24 mobile clinics in Dili and five other districts. Additionally, there are 32 mission clinics and other church related facilities working mostly with volunteers. Many of these clinics provide medicines at no cost to their patients.(46)

In 2011 there were 11 registered private importers of medicines and medical products in Timor-Leste, but no wholesalers or distributors of drugs. As there is no local manufacturing, all drugs available in the private sector are all imported, in most cases from Indonesia,(47,48) and are manufactured in India or Indonesia. Private importers have to previously register all imported medicines, but there are restrictions for certain medicines or therapeutic classes (e.g. psychotropic drugs and narcotics can only be imported by SAMES).

1.2.3. Human resources in the health sector

As in other nations in similar stages of development, human resources for health in Timor-Leste are insufficient. In the period of 2004 to 2010, the number of trained physicians per 1000 inhabitants has increased from 0.10 to 0.22.(41,49) However, it

remains below world and regional average numbers, much like the number of nurses and midwives.(50)

The latest available data on pharmaceutical professionals accounts for a density of 0.02 pharmacists per 1000 inhabitants.(49) From 2000 through 2005 there were no Timorese pharmacists with university training practicing in Timor-Leste.(45) In 2004 the Pharmacy Association⁸ had 43 members, all pharmacy assistants who had in most cases received training in Indonesia.(45) During the same period, technical assistance in pharmaceutical issues was provided by expatriate consultants, employed or recruited through international agencies and organizations. In 2008, the government introduced a one-year course in pharmacy (Diploma 1, Pharmacy technician) at the National Institute of Health.⁹

Currently, there are 11 pharmacists (bachelor degree), 50 pharmacy technicians (diploma I) and 106 pharmacy assistants (certificate level) in the country.(51) Many of these pharmacy technicians and assistants are responsible for drug management and monitoring in the pharmacy division of Community Health Centers and Hospitals; in HPs, nurses usually carry out such activities.

However, because most of this personnel lack adequate management skills, and no standard procedures are used, records of drug stocks are not consistent and depend on the individual organization of the pharmacy technician in charge. This obviously affects the supply by SAMES, which is based on the information provided by each individual facility, often miscalculated.(51)

1.2.4. Pharmaceutical sector regulation

In Timor-Leste as in many other low- and middle-income countries, the pharmaceutical sector is poorly regulated and implementation of the existing regulation is difficult due to important constraints in human and financial resources (which limit inspection activities for example). A summary of the main laws, regulations and other official documents affecting the pharmaceutical sector is presented in Table 1.4.

⁸*Associação dos Farmacêuticos de Timor-Leste.*

⁹*Instituto Nacional de Saúde, former Instituto de Ciências da Saúde de Timor-Leste.*

Table 1.4. Summary of current legislation relevant to the pharmaceutical sector in Timor-Leste.¹⁰

Document	Description
Decree Law No. 1/2008 Organic Statute of the Ministry of Health (Revoked the Government Decree No. 05/2003)	Establishes the structure of the public health sector, including services under direct state administration (such as the Department of Pharmacy) and indirect state administration (such as SAMES).
Government Decree No.2/2004 Autonomous Drug and Medical Equipment Service	Creates SAMES as the public agency for import, storage and distribution of medicines, medical equipment and other medical consumption goods
Decree-Law No.12/2004 Pharmaceutical Activities	Regulates the exercise of pharmaceutical activities and creates CRAF, the Regulating Commission of Pharmaceutical Activities
Ministerial Statute No.5/2004 Technical Rules for the Functioning and Good Practice of Pharmacies	Guidance on good practices for pharmacy premises, medicines storage, equipment, pharmacy staff, drug prescription and dispensing.
Ministerial Statute No.6/2004 Conditions of Hygiene and Technical Adequacy of Installations and Means of Transport of Pharmaceutical Activities	Establishes the basic infrastructures and conditions for pharmacies, warehouses and vehicles used in medicines transport.
Ministerial Statute No.7/2004 Applicable Rules for Donations of Medicines, Medical Consumption Goods, Medical Equipment and others, to Health Institutions	Defines the minimum requisites for donation of medicines and other medical products, for the public and private sectors.
Ministerial Statute No.8/2004 Labeling and Informative Brochures	Specifies the mandatory contents of drug labels and information leaflets, including permitted languages.
Decree-Law No.14/2004 (amended by Decree-Law No. 40/2011) Practice of Health Professions	Establishes the fundamental requisites for the practice of health professions, including pharmacy staff
Law No.10/2004 Law on the Health System	Establishes a legal basis for the national health system, including the role of pharmaceutical and complementary activities.
Ministerial Statute No.1/2008 Organic Statute of Central Health Services	Defines the structure of the Ministry of Health at central level, including the duties and responsibilities of each directorate and department.
Ministerial Statute No.3/2008 Organic Statute of District Health Services	Defines the structure and stratification of primary health care provided in district facilities, including the duties and responsibilities of the Division of Pharmacy.
Law No.8/2008 Taxation Law	Defines payable taxes for imported goods (including medicines) and business activities.
Decree-Law No.2/2009 Special Legal System on Supply to the Autonomous Department for Drugs and Health Equipment	Defines standard procedures for the procurement of medicines, medical equipment and other medical consumption goods to be followed by SAMES.
Ministerial Statute No.7/2011/VGC/MS Regulating Commission of Pharmaceutical Activities (CRAF)	Reactivates CRAF, expands the commission to sectors not previously represented and reinforces the commission's regulatory activities.

¹⁰ All legislation available from: <http://www.jornal.gov.tl/>

1.2.5. Timor-Leste's pharmaceutical system

The Decree-Law No. 12/2004 regulates the *'exercise of pharmaceutical activities relating to import, storage, export and sale, in bulk or retail, of medicines for human use'*.⁽⁵²⁾ This legislation established a Regulating Commission of Pharmaceutical Activities (CRAF),¹¹ a basic regulatory authority, composed by representatives from several government departments, which is responsible for granting licenses to pharmacies and companies with activities related to import, storage, distribution, sale and export of medicines. However CRAF is not an executive body and most regulatory activities, like the inspection of pharmacies, are actually carried out by the Department of Pharmacy. The DOP has other functions (such as supervising drug management in public health facilities, developing guidelines and recommendations), and relies on a reduced budget and staff number, so regulatory activities are very limited.^(45,47,51)

The regulation of pharmaceutical activities provides for the establishment of good pharmacy practices, hygiene conditions of facilities and vehicles used for the transport of drugs, drug donations, drug labeling and fees applicable to pharmaceutical activities. All these aspects have been covered in subsequent ministerial orders; however, most of these requisites lack full implementation and/or inspection.^(47,51) For example, according to the legislation, pharmacies must have a technical manager (pharmacist, pharmacy technician or pharmacy assistant), who should be present in the pharmacy for the entire working period, to supervise all activities related to drug dispensing. However this requisite is not followed by most private pharmacies where dispensing is generally done by unqualified staff.⁽⁵¹⁾ Free dispensing of prescription-only drugs (e.g. antibiotics), is frequent as well as illegal selling of controlled drugs (e.g. psychotherapeutic drugs and narcotics); in 2011, three private outlets had their licenses confiscated following an DOP inspection.⁽⁵¹⁾

1.2.6. Procurement, storage and distribution of medicines

A centralized procurement and supply agency, SAMEs, aimed at *'improving and rendering more efficient the supply of drugs, medical equipment and other medical*

¹¹Comissão Reguladora das Atividades Farmacêuticas.

consumption goods to institutions belonging to the health system, in particular to the National Health Service was created in 2004.(44) SAMES falls out of the scope of public procurement regulation and its activities follow legal procedures specifically created for the procurement of drugs and other medical goods (Decree-Law No. 2/2009).(53) SAMES is able to import all drugs pertaining to the EML without any additional license. Referral hospitals can require non-EML medicines, for which a previous approval (by CRAF) is required.

Currently, SAMES is not allowed to sell any products to the private sector and its budget comes directly from the Ministry of Finance. In 2011, the budget was about 3.8 million USD, but has been increased to 5 million USD in 2012. Additionally to the yearly budget, SAMES receives medicines for vertical programs from international agencies.(51)

Selection is made from the list of medicines included in the national EML, from pre-qualified suppliers, based on quality performance criteria; according to the regulations of the procurement process, this pre-qualification procedure should be done on a yearly basis. Depending on the amount involved or responding to exceptional circumstances, procurement can be done by (i) open tendering (open to national and international suppliers); (ii) partial invitation (pre-qualified suppliers); (iii) request for quotations (to a minimum of three known suppliers); or (iv) direct agreement (when special conditions apply or in emergency situations).(53) Bid evaluation, based on delivery deadline, goods quality and price criteria, is done by an appointed committee. Except for pre-qualification of suppliers based on technical specifications provided by suppliers, quality of imported drugs is hardly ensured.(45,47) Although SAMES established a small laboratory to test medicines quality in 2011, it is still poorly equipped (only dissolution tests for tablets can be performed) and testing is therefore very limited.(51)

In addition to SAMES, 11 private companies are also authorized to import and distribute medicines in Timor-Leste; most of the medicines imported in the private sector come from Indonesia. Private importers need to register all medicines prior to importation, but there is no evaluation based on the medicines technical file and no post-commercialization pharmacovigilance program. There is also no quality testing of drugs available in the private sector, no complete list of the medicines currently

registered in the country and no accurate information on how many drugs are actually on the market.(51)

Under the recent Decree-Law on Fair prices (DL No. 29/2011)(54) medicines should be subject to a monitored price regime (i.e. companies have to communicate their prices and margins to the competent authorities upon notification), but there is currently no regulation for setting prices or fixed margins for medicines at any stage of the supply chain.

1.2.7. Medicines taxes, duties and fees

A registration fee (due to the DOP) is required for all drugs imported to Timor-Leste, except in the case of SAMES. Additionally, all imported medicines (including medicines imported by SAMES) are subject to an import duty (2.5%) and sales tax (2.5%); medicines are exempt from the excisable tax applied to other imported goods, under the general Taxation Law (Law No. 8/2008).(55)

Apart from the above-mentioned taxes, no other taxes or fees are imposed on medicines at any stage of the supply chain. There are no port or airport inspection fees, no intermediaries in transport and/or storage of medicines (and therefore, no added mark-ups at this stage) and no additional taxes due to any other entity. Medicines procured for the public sector are stored in SAMES warehouse in Dili and distributed to the country's health facilities by the Ministry of Health. Private importers have their own warehouse facilities and local buyers generally use private vehicles to transport medicines.

1.2.8. Other relevant official documents – Essential medicines list (EML), Standard Treatment Guidelines (STGs) and National Drug Policy (NDP)

The first edition of an Essential Medicines List was published in 2003 and revised in 2004. In 2010, the DOP released a new edition including approximately 380 drugs categorized by level of facility where they should be available. Although it represents a big effort towards prescription standardization and rational use of medicines, this new EML edition (43) has been criticized for its format (not very practical for prescribers) and content (inconsistencies in medicines selection and a large

number of medicines included).(51) The DOP plans to release an EML update on a yearly basis.

To promote the rational use of drugs, a series of standard treatment guidelines (STG) were also updated in 2010,(56) covering primary and hospital care of the most common health conditions. A study on the adherence to previous versions of STGs for anti-retrovirals and malaria and diarrhoea treatments (39) reported a good knowledge of STGs, a favourable adherence profile and a generally positive impact of these STGs on medicines prescription patterns in CHCs. However, other more recent reports indicate that many practitioners do not follow guidelines because they find them not suitable, not matching medicines included in the EML, not translated into some of the working languages (STG for referral hospitals are written in English and for primary care in Portuguese, which limits the access of health personnel speaking Tetum and Indonesian), scarcely distributed (sometimes one copy per facility), and some health professionals were not even aware of their existence.(45,51)

An official national drug policy, establishing a full Drug Regulatory Authority was published in 2010, but most aspects covered have not been implemented. A new pharmacy law has also been under discussion, but to the present date no such document has been approved by the National Parliament.(45,51)

1.2.9. State of the art on availability, prices and affordability of medicines in Timor-Leste

Some availability and price surveys have been conducted in other countries within the Southeast Asia region, namely in Indonesia, India, Nepal, Sri Lanka and Thailand. In Timor-Leste, there is very little information on the availability of medicines within the public sector, due to an unreliable information system (47) and as for the private sector, there are no known reports specifically focused on the availability of medicines.

It is estimated that medicines represent one third of the overall costs of obtaining outpatient care in Timor-Leste (the higher costs are travel expenses to reach healthcare facilities).¹² Although no study has been conducted to describe the availability, prices

¹²Rannan-Eliya, RP. Out-of-pocket spending and health care inequalities in Timor Leste [unpublished]; 2011.

and affordability of medicines in Timor-Leste as yet, these sort of problems have been identified in similar countries in Southeast Asia. A first description of the country's situation could therefore be of great utility and lay basis to subsequent studies or interventions.

1.3. AIM OF THE STUDY AND OBJECTIVES

Accurate information is essential for identifying the sources of poor and/or unequal access to pharmacological treatments and for planning any potential actions to address these issues. The aim of the present study was to investigate the pharmaceutical sector in Timor-Leste, exploring the dimensions of availability, prices and affordability of common treatments, and to produce evidence that could be disseminated to government bodies and other relevant organizations engaged in the pharmaceutical sector. The study aimed at providing an evidence base to identify the challenges faced by the government in respect to pharmaceutical regulation, with the explicit focus on improving the access of the Timorese population to essential medicines, with adequate quality and affordable prices.

1.3.1. Aim of the study

To explore availability and prices of medicines in Timor-Leste, as well as affordability of treatments, with the objective to produce evidence that can be used by government bodies and institutions as a basis to regulate the pharmaceutical sector.

1.3.2. Objectives

- To determine the availability of essential medicines in Timor-Leste, in public and private for-profit sectors (and the variability across the two sectors);
- To determine the prices paid by patients/families for medicines (originator brand and its generic equivalent) in the private for-profit sector (retail pharmacies);
- To calculate the cost of a course of treatment, based on medicines prices (originator brands and generics) and determine if it is affordable for the population;
- To compare the results from Timor-Leste with other countries in the same world region and other similar countries where availability and price surveys were carried out using the same methodology;
- To produce information that can be disseminated to government bodies and other stakeholders in the pharmaceutical sector, providing a basis for a deeper analysis on

the access to essential medicines in Timor-Leste and the development of measures to strengthen the sector's regulation;

- To contribute for the international debate on the availability and prices of essential medicines in low-income countries.

2. METHODS

The present study was based on a standardized methodology developed by the World Health Organization and the non-governmental organization Health Action International (HAI) to measure medicines availability, prices and affordability.(14) The objective of this methodology is to obtain standardized and comparable data, which can be used as guidance for policy interventions aimed at improving access to medicines in low- and middle-income countries.

The WHO/HAI methodology is detailed in a manual (currently on its second reviewed edition) and includes a spreadsheet for data analysis, both of which are available online. Accessible on the website is also a database of previous surveys conducted with the same methodology as well as related studies, for comparison purposes.(23) Technical support is provided to investigators who wish to follow this methodology to conduct a survey.

Survey research is a quantitative approach, where instruments are used to observe and measure variables related to the information required according to the objectives of the investigation. The resultant quantified data can then be analysed through statistical procedures, allowing generalization and replication of the findings.(57) This kind of approach was considered adequate and in line with the objectives of the present study, since it provides tangible data on the availability and prices of medicines that can then be used: (i) to describe the current situation in Timor-Leste and (ii) to consistently compare the country's situation with other similar contexts and gain a better understanding of the factors that may be affecting the access to medicines.

2.1. SURVEY SAMPLE

WHO/HAI methodology relies on data collected from a sample of outlets where medicines are sold and/or distributed to the population: this can comprise the public and private sectors as well as other sectors relevant in the country (mission hospitals, NGOs, etc.). The WHO/HAI manual recommends a sample of 5 facilities (hospital and 4 others) within each sector, selected on a basis of proximity to the main hospital, in 6 different geographic areas.

Adaptations to the original methodology were necessary to suit the specific context of Timor-Leste and face the limitations encountered during the fieldwork. The sample surveyed in our study is described below, per sector.

2.1.1. Public sector facilities

For the purpose of this study, each of the 13 districts in Timor-Leste was considered as a separate geographic area. Our public sector sample was composed of a total of 22 public health facilities: 5 referral hospitals (out of 6 in the whole country) and 17 sub-district community health centres (out of 66 in the whole country), distributed across 5 geographic areas. Despite the fact that this sample is not in full accordance with the WHO/HAI recommendations (see Chapter 4. Limitations of the present study) more than half (52.1%) of the country's population live in these 5 geographic areas and 44.1% is covered by the public healthcare facilities included in our sample. Additionally, rural and urban settings are represented: from the 17 health centres considered, 9 are located in rural areas and 8 in urban centres. All hospitals are located in urban centres.

Table 2.1. Number of surveyed healthcare facilities in urban and rural areas.

Geographic area	Urban ¹	Rural
Dili	5	–
Baucau	2	3
Bobonaro	2	3
Covalima	2	1
Oecussi	2	2
Total	13	9

¹All hospitals are located in urban centres.

2.1.2. Private sector retail pharmacies

In the private sector, the particular distribution pattern in Timor-Leste led to the decision of surveying all existing private retail pharmacies located in the geographic areas selected for the public sector.

However, from the original list of 28 private pharmacies licensed by the Ministry of Health, updated in July 2011, four pharmacies in Dili area were automatically excluded for the following reasons: (i) two were already closed when the

data collection phase started; (ii) two others were found to be exclusively dedicated to Chinese medicines, out of the scope of the present study.

From the remaining group of 24 retail pharmacies, one (also located in Dili) was never open to the public during the whole study period (despite several attempts made to visit it and contact the owner/manager) – although the pharmacy’s closure was not officially confirmed by the Department of Pharmacy, it could not be visited and was therefore excluded. Finally, 2 new pharmacies were located in geographic areas not included in the initial protocol and were not possible to include later for reasons related to distance and schedule.

Thus, the private for-profit sector in the present study was represented by 21 retail pharmacies open to the public and located in four different geographic areas. Out of these 21, 16 were located in Dili city and 5 in urban centres of three other districts. No private retail outlets are currently registered in rural areas throughout the country.

Tables 1 and 2 (Appendix 1) show the list of health facilities visited for each sector; table 2.2. below summarizes the survey sample per facility type and geographic area.

Table 2.2. Survey sample per facility type and geographic area.

Geographic area	Public Hospitals	Public CHCs	Private pharmacies
Dili	1 (1)	4 (6)	16 (21)
Baucau	1 (1)	4 (6)	3 (3)
Bobonaro	1 (1)	4 (6)	1 (1)
Covalima	1 (1)	2 (7)	–
Liquiçá	–	–	1 (1)
Oecussi	1 (1)	3 (4)	–
Total	5 (6)	17 (66)	21 (24)¹

CHCs: community health centres (sub-district)

Note: numbers in brackets indicate the total number of the same type facilities within the geographic area considered.

¹Initial list of 28 registered private pharmacies provided by the Department of Pharmacy of the Ministry of Health (updated July 2011), excluding: (i) pharmacies closed to the public during the survey period and (ii) pharmacies exclusively dedicated to Chinese medicines.

2.1.3. List of medicines surveyed

According to WHO/HAI manual, a typical survey can include a list of up to 50 medicines, of which 14 belong to a standard core list, 16 to a regional list and 20 are supplementary medicines selected on basis of their importance at a national level.

A first preliminary version of the list was discussed in a meeting held with the Ethics Committee from the Cabinet of Health Research¹³ (see 2.4. Ethical concerns), after which a final list of medicines for our survey was selected. The final list included (i) 14 medicines from the WHO/HAI core list¹⁴; (ii) 6 medicines from WHO's SEAR regional list¹⁴; and (iii) 28 supplementary medicines, chosen from either WHO's list of priority medicines for mothers and children (58) (since maternal, newborn and child health [MNCH] is one of the priority areas in Timor-Leste) or a tracer list, previously adopted by the MoH to monitor medicines availability in public health facilities (currently underused). This tracer list (59) is based on the national EML and includes some of the most used medicines according to the country's disease patterns; in line with the CHR's recommendation, the investigator considered pertinent to include some of the medicines from the tracer list in the final list of medicines to be surveyed.

The final list of medicines for this survey is composed by 48 medicines and shown in Table 3 (Appendix 2).

The dosage form and strength of medicines included in the supplementary list was adjusted using the most recent edition of the national EML; international reference prices (IRP) were extracted from MSH's International Drug Price Indicator Guide.⁽¹⁵⁾ For medicines included in WHO/HAI core and regional lists, this information is automatically available in the spreadsheet provided with the manual.

¹³*Gabinete de Pesquisa e Desenvolvimento da Saúde*

¹⁴WHO/HAI manual recommends a list of 14 medicines to be included in all surveys for comparison purposes; to allow comparisons among countries of the same WHO region, specific regional lists were also developed.

2.2. DATA COLLECTION

A standardized data collection form generated by the WHO/HAI software (shown in Appendix 3) was used to collect the data in both public and private sectors. The data collection phase started with two pilot studies in Dili district: one community health centre (public sector) and one private pharmacy (private sector) were surveyed and the information provided was used to make final adjustments to the data collection form (namely in dosage forms and target pack sizes).

The principal investigator visited all outlets, public and private, in all geographic areas, and information was collected with the support of the pharmacist/nurse in charge of the dispensary and/or pharmacy warehouse, in the case of hospitals and CHCs. As for private pharmacies, information was either provided by the owner, responsible pharmacist or, in most cases, by any other non-technical pharmacy staff member. In private pharmacies, as well as in hospitals, it was sometimes necessary to set an appointment beforehand, but in CHCs it was generally possible to conduct the survey immediately at the time of the first visit.

The data collection phase took place between November 2011 and January 2012, over a period of approximately 9 weeks. Data collection forms were in English language¹⁵, but verbal contacts were usually made in Tetum and/or Portuguese and only in a few cases in English.

2.2.1. Availability of medicines (public and private sectors)

Availability of all medicines included in the selected list was determined on the day of data collection, in both public health facilities and private pharmacies. For each active substance two products were surveyed: the originator brand (OB) and the lowest price generic equivalent (LPG). OBs were previously selected for each medicine while LPGs were determined *in loco* at the time of data collection. In the case of medicines for which no originator brand is available, the field is automatically excluded from the data collection form and does not count for the availability final results.

¹⁵As medicines were presented in the formulary under international non-proprietary name (INN) or generic name, language-related communication problems were not expected to affect data collection at this point.

To be marked as ‘available’, a medicine had to be physically observed by the investigator; in the public sector, for instance, not all medicines were usually available within the pharmacy premises and other departments such as the maternal health, family planning or vaccination room were also visited.

2.2.2. Medicines prices (private sector)

In private pharmacies, medicines prices (for both OBs and LPGs) were also collected on the day of visit using the same data collection form. If the target pack size for one given medicine was not found in the outlet, the closest available pack size was selected *in loco*. Depending on the type of medicine, prices were then converted into unit prices (i.e. per tablet, ml, dose, etc). All prices were directly collected in US dollars (Timor-Leste’s official currency), so no conversion was necessary.

2.2.3. Medicines procurement prices (public sector)

Data on public procurement prices was obtained from 3 different contracts for the provision of medicines and other health products celebrated during 2011 between SAMES or MoH and different suppliers: one was an international contract and the remaining two were from a local importer/supplier. The currency used in all contracts was the US dollar.

2.3. DATA ANALYSIS

Data analysis was conducted using the workbook (MS Excel pre-programmed spreadsheet) provided with the WHO/HAI manual.(14) The investigator entered all data, which was then double entered by a second person, not related to the study, and finally checked using the checking tool integrated in the software, to correct all discrepancies and ensure maximum reliability.

After data entry is completed, the workbook is automatically designed to perform the following analysis:

(i) Mean availability of medicines, in all sectors included in the analysis (public and private for-profit in the case of Timor-Leste);

(ii) Medicines patient prices, presented as median price ratios (only for the private for-profit sector in the case of Timor-Leste)

(iii) Public sector procurement prices, presented as median price ratios;

(iv) Number of day's wages equivalent to a standard course of treatment with medicines for which ≥ 4 prices were found (with branded and/or generic medicines).

2.3.1. Availability of medicines

Defined as the percentage of medicine outlets in which the medicine was found on the day of data collection. The mean availability was calculated for both public and private sectors and for originator brands as well as lowest-priced generic equivalents for the initial basket of 48 medicines.

In the case of 8 medicines, no originator brand is available; such medicines were automatically excluded in the workbook not to influence the overall availability analysis for both public and private sectors. Four other medicines were excluded from the private sector analysis. All exclusions from the original medicines list and respective rationale are presented in Table 2.3. below.

Table 2.3. Medicines from originally included in the survey list (n=48) but excluded from the final analysis and respective rationale, per sector and medicine type.

Medicine name	Public/ Private	OB/LPG	Justification for exclusion
Artemether/Lumefantrine	Private	Both	Only procured for the public sector (via Global Fund)
Calcium gluconate	Both	OB	No OB
Diazepam 5mg	Private	Both	Only the SAMES is officially allowed to import psychotropic drugs
Ferrum sulphate	Both	OB	No OB
Folic acid/Ferrum sulphate	Both	OB	No OB
Magnesium sulphate	Both	OB	No OB
ORS	Both	OB/LPG	No OB/ LPG in a different pack size
Paracetamol suspension	Private	OB	OB comes in a different dosage
Ringer's lactate	Both	OB	No OB
Tetanus toxoid vaccine	Both	OB	No OB
Vitamin A	Both	OB	No OB

OB: originator brand; LPG: lowest price generic; ORS: oral rehydration salts.

2.3.2. Medicines prices (private sector)

Since medicines are distributed free of charge in the public sector, the analysis of patient prices was only conducted for the private sector. For comparison purposes, all prices found in retail pharmacies were calculated per unit dose and median results for each substance presented as a median price ratio (MPR); this ratio reveals how much higher or lower a price is in comparison to its international reference price (IRP) and is calculated dividing the price of a given medicine by its respective IRP. For instance, a medicine for which $MPR = 1$ has a price equivalent to its international reference price, whereas a medicine with $MPR = 2$ costs twice as much and conversely a $MPR = 0.5$, indicates the medicine costs half its IRP.

International reference unit prices were extracted from the 2010 edition of the International Drug Price Indicator Guide published by the organization Management Sciences for Health. Again in this case, no currency conversion was necessary since IRPs are presented in US dollars.

Only medicines found in 4 or more outlets were included to estimate the global median MPR, as well as the minimum, maximum and MPR percentiles. The same analysis was done for originator brands and generic medicines.

2.3.3. Medicines procurement prices (public sector)

Similarly to the analysis of patient prices, procurement prices, extracted from government procurement documents, were presented as a median price ratio (MPR). The objective is to assess the efficiency of public procurement: if procurement prices are similar to IRPs (i.e. the market's international reference price), the procurement process can be considered efficient. International reference prices were extracted from the same source described in the previous section.

2.3.4. Affordability of treatments

Affordability of purchasing treatment in the private sector was also measured according to the WHO/HAI's approach. The median price of one complete course of treatment with medicines included in our list was calculated based on the median prices obtained in the private pharmacies, considering the number of days usually required to treat a common health problem. For medicines belonging to WHO/HAI core list, the workbook is already programmed to calculate a standard course of treatment; for medicines included in the regional and supplementary lists, the dosage and treatment duration was manually entered, based on common affections described in the last edition of the Standard Treatment Guidelines for Timor-Leste.⁽⁴³⁾ The methodology defines courses of treatment for acute conditions as the treatment of one single episode; for chronic affections, calculations are generally made for one month of treatment. The price of a complete course of treatment was then converted into the number of working days of the lowest paid unskilled government worker. The salary of the lowest paid government worker was obtained from the government's salary tables for public administration workers.⁽⁶⁰⁾

According to this approach, a course of treatment that costs up to the equivalent of one daily wage of the lowest paid government worker is considered affordable, while treatments exceeding that threshold are generally considered as unaffordable.

Affordability analysis was conducted for originator brands and generic medicines, whenever data on prices was found in a minimum of 4 outlets.

2.4. ETHICAL AND LEGAL CONCERNS

Prior to data collection, the protocol was first presented to the Ethical Committee of the investigator's institution (*Instituto de Higiene e Medicina Tropical*) and no ethical or legal issues were identified.

According to the usual procedures in Timor-Leste, all studies related to health topics have to seek approval from the Ethics and Technical Committee of the Cabinet of Health Research (Ministry of Health). The authorization request was followed by a meeting where the investigator presented the study protocol before the members of the committee, who granted permission for the study to take place in Timor-Leste. Some of the committee's suggestions raised during the presentation were integrated in the initial protocol (see in Chapter 2.1.3. List of medicines surveyed).

An introduction letter, explaining the study's main objectives and procedures was always presented to the responsible person of the facility/outlet (or substitute) during the first visit. The presentation letter was translated into Tetum, Portuguese and English, to minimize language obstacles and ensure that the study's objectives and procedures were clear to all involved staff members before data collection. Whenever necessary, the approval document issued by the Ethics Committee was also presented.

3. RESULTS

The results section is structured to reflect the different aspects of general access to medicines. A first part is dedicated to medicines availability in the public and private health sectors, followed by an analysis on medicines prices and affordability focussing exclusively on the private sector, since medicines in the public sector are distributed free of charge to the population. The last part covers the public sector procurement process, and procurement prices as compared to international reference prices.

3.1. MEDICINES AVAILABILITY

3.1.1. Public sector

Overall, 22 public health facilities were surveyed: 5 referral hospitals and 17 sub-district health centres, located in five different geographic areas (Dili, Baucau, Bobonaro, Covalima and Oecussi districts). The list of the public sector facilities where the study was conducted is presented in Table 1 (Appendix 1).

The national results of the availability survey, as well as the results for each district, are presented in Table 3.1. below. Two districts (Dili and Baucau) have an overall availability above the national average for generic medicines (but lower among originator brands), while Bobonaro and Covalima show a mean availability lower than average. Oecussi, has an availability within national average for generic medicines and higher than average for originator brands.

Table 3. 1. Mean availability (%) of a basket of 48 medicines in public health facilities (n=22), per medicine type (OB or LPG) and geographic area.

District	OB	LPG
Dili (n=5)	6.0	67.2
Baucau (n=5)	7.0	63.0
Bobonaro (n=5)	7.0	52.3
Covalima (n=3)	8.3	54.6
Oecussi (n=4)	8.8	59.6
National (n=22)	7.3	59.6

OB: originator brand; LPG: lowest price generic

Among sectors, a higher availability was found in hospitals, when compared to sub-district health centres (9.5% vs. 8.0% for OB and 66,8% vs. 59.0% for LPG respectively). Focusing our analysis to hospitals, the mean availability of generic medicines ranges from 76.6% in Baucau Hospital to 55.3% in Maliana Hospital (Bobonaro). The hospitals with a higher availability were also the ones where a larger number of donated medicines were found (Baucau, Oecussi and Dili).

As for CHCs, Dili is the area where the highest availability was observed (66.9% for LPGs) and Covalima shows the lowest availability among CHCs (52.5% for LPGs). When analysing results individually, the highest availability of generic medicines was found in one CHC located in Dili (75.0%), while the lowest was found in CHCs located in Baucau and Bobonaro districts (both with 47.5%); all these three locations had a similar mean availability for OBs: 6.1%.

The mean availability of generic medicines in the public sector, per district and level of care, is presented in Table 3.2., with higher and lower percentages highlighted.

Table 3. 2. Mean availability (%) of a basket of generic medicines, per district, in hospitals and sub-district level community health centres.

District	Hospitals	CHC1	CHC2	CHC3	CHC4	Total CHCs
Dili	66.0	55.0	65.0	72.5	75.0	66.9
Baucau	76.6	47.5	70.0	62.5	60.0	60.0
Bobonaro	55.3	62.5	47.5	55.0	57.5	55.6
Covalima	66.0	57.5	47.5	—	—	52.5
Oecussi	70.2	62.5	50.0	55.0	—	55.8

CHC: community health centre

A summary of the specific mean availability for each of the medicines surveyed in the present study, in the public sector is presented in Table 3.3. It is important to mention that the percentages shown may not always reflect the real availability of some active substances included in our list; for some medicines the study dosage was not found, but there was an alternative dosage available (e.g. ciprofloxacin 250 mg instead of 500mg; folic acid and ferrum sulphate individually, instead of combined; vitamin A 200 MIU instead of 100 MIU) (see also Chapter 4. Limitations).

Table 3. 3. Mean availability of medicines in the public sector, per type (OB or LPG).

No.	Medicine	OB	LPG
1	Acetylsalicylic acid	0.0%	95.5%
2	Amitriptyline	0.0%	60.0%
3	Amoxicillin	0.0%	100.0%
4	Ampicilin injection	0.0%	72.7%
5	Artemether/lumefantrine	100.0%	- ²
6	Artesunate	0.0%	4.5%
7	Atenolol	0.0%	81.8%
8	Beclometasone inhaler	0.0%	22.7%
9	Benzathine benzylpenicillin injection	0.0%	59.1%
10	Calcium gluconate injection	- ¹	9.1%
11	Captopril	0.0%	90.9%
12	Cefixime	0.0%	0.0%
13	Ceftriaxone injection	0.0%	100.0%
14	Chloramphenicol injection	0.0%	45.5%
15	Chloramphenicol tablets	0.0%	81.8%
16	Ciprofloxacin	0.0%	45.5%
17	Clotrimazole topical cream	0.0%	4.5%
18	Co-trimoxazole suspension	0.0%	100.0%
19	Co-trimoxazole tablets	0.0%	77.3%
20	Diazepam	0.0%	68.2%
21	Diclofenac	0.0%	80.0%
22	Doxycycline	0.0%	95.5%
23	Enalapril	0.0%	20.0%
24	Ethinylloestradiol/levonorgestrel (COC)	59.1%	0.0%
25	Ferrum sulphate	- ¹	90.9%
26	Folic acid + ferrum sulphate	- ¹	72.7%
27	Gentamicin injection	0.0%	77.3%
28	Glibenclamide	0.0%	50.0%
29	Hydralazine	22.7%	4.5%
30	Hydrochlorothiazide	0.0%	86.4%
31	Ibuprofen	0.0%	100.0%
32	Magnesium sulphate injection	- ¹	22.7%
33	Medroxyprogesterone acetate injection	86.4%	0.0%
34	Metformin	0.0%	60.0%
35	Metronidazole injection	0.0%	40.9%
36	Metronidazole tablets	0.0%	95.5%
37	Misoprostol	0.0%	20.0%
38	Omeprazole	0.0%	45.5%
39	Oral rehydration salts (ORS)	- ¹	95.5%
40	Oxytocin injection	0.0%	72.7%
41	Paracetamol suspension	0.0%	86.4%
42	Paracetamol tablets	0.0%	95.5%
43	Ranitidine	0.0%	95.5%
44	Ringer's lactate	- ¹	95.5%
45	Salbutamol inhaler	22.7%	59.1%
46	Simvastatin	0.0%	0.0%
47	Tetanus toxoid vaccine	- ¹	86.4%
48	Vitamin A	- ¹	31.8%

OB: originator brand; LPG: lowest price generic; COC: combined oral contraceptive

Notes: ¹Medicine with no originator brand; ²Medicine excluded from the analysis. (see Chapter 2. Methods).

As shown in the table above, the mean availability of medicines in the public sector was clearly higher for generic medicines than for originator brands: 59.6% vs. 7.3% respectively. This is consistent with the national guidelines, which specify preference for the procurement of generic medicines for the national health system.

Out of the 48 medicines surveyed, only 5 were found as originator brands. Three of those belong to either malaria or family planning programs, which follow specific procurement procedures (via Global Fund and UNFPA) and are always purchased as branded medicines from prequalified suppliers. The remaining 2 (hydralazine injection and salbutamol inhaler) were found either as originator brands or generics.

From our original list, 4 generic medicines were available in all public facilities visited (amoxicillin, ceftriaxone injection, co-trimoxazole suspension and ibuprofen), 21 had an availability $\geq 75.0\%$ and 12 had an availability below 25.0%. As for originator brands, only 2 medicines were available in $\geq 75.0\%$ of the public facilities surveyed (artemeter/lumefantrine and medroxyprogesterone injection).

If we look at groups of medicines per therapeutic category, it is possible to identify higher availabilities among certain groups of medicines (like NSAIDs or oral antibiotics, with 90.5% and 74.4%, respectively, for LPGs) and lower among others (like priority medicines for MNCH 40.1% if we consider only LPGs, higher if we consider both OBs and LPGs, 49.8%). Availability for the medicines comprised in the WHO/HAI's global list (n=14) was 69.1%, while medicines included in the SEAR regional list (n=6) show a mean availability of 63.0%; in both cases OBs availability was below 2%. The lists of medicines included in this group analysis are presented in table 4, Appendix 4.

3.1.2. Private sector

The private sector in Timor-Leste is represented in this study by 21 private retail pharmacies located in 4 different geographic areas: 16 in Dili, 3 in Baucau, 1 in Bobonaro and 1 in Liquiçá. A list of all private pharmacies surveyed is presented in Table 2 (Appendix 1).

Table 3.4. shows the mean availability of medicines in the private sector. Most pharmacies included in this study are located in the central area of Dili. The pharmacies

located outside the capital clearly show a much lower availability, less than half if we consider originator brands and slightly more than half in the case of generics, when compared to the pharmacies in Dili.

Table 3. 4. Mean availability (%) of a basket of medicines in private pharmacies (n=21), per medicine type.

Geographical area	Originator brand	Lowest price generic
Dili (n=16)	10.3	42.4
Districts (n=5)	4.9	24.0
National (n=21)	9.0	38.0

Similarly to the situation observed in the public sector, generic medicines are more widely available than originator brands. The mean availability of generic medicines in the private sector is lower than in the public sector (38.0 vs. 59.6%); for originator brands, the mean availability in the private sector is slightly higher than in the public sector (9.0 vs. 7.3%).

Table 3.5. below shows the mean availability in the private sector for all medicines included in our analysis.

Considering only generic medicines, there are important differences among therapeutic groups, even more marked than in the public sector. Oral antibiotics, for instance, show in general very high availabilities in private pharmacies (e.g. amoxicillin: 95.2%; ciprofloxacin: 90.5%; co-trimoxazole tablets 95.2% and an overall group availability of 67.3%), and the same happens with NSAIDs for adults and children (with a group availability of 82.1%). The lowest availabilities are found among injectables (mostly antibiotics) and medicines that require cold chain storage (unavailable in most pharmacies). Medicines for MNCH show in general low availabilities (except contraceptives), both OBs and LPGs, and the overall availability of medicines in this group (OB and LPG) is 22.4%. Availability of LPGs from the WHO/HAI's global list (n=14) was 60.7%, while medicines included in the SEAR regional list (n=6) showed a mean availability of 50.0%; OBs availability was 12.8% and 12.7%, respectively. The lists of medicines included in this group analysis are presented in Table 4, Appendix 4.

Table 3. 5. Mean availability of 48 medicines in the private sector, per medicine type.

No.	Medicine	OB	LPG
1	Acetylsalicylic acid	0.0%	4.8%
2	Amitriptyline	0.0%	14.3%
3	Amoxicillin	0.0%	95.2%
4	Ampicilin injection	0.0%	52.4%
5	Artemether/lumefantrine	- ²	- ²
6	Artesunate	0.0%	4.8%
7	Atenolol	19.0%	23.8%
8	Beclometasone inhaler	0.0%	0.0%
9	Benzathine benzylpenicillin injection	0.0%	0.0%
10	Calcium gluconate injection	- ¹	9.5%
11	Captopril	0.0%	85.7%
12	Cefixime	0.0%	0.0%
13	Ceftriaxone injection	0.0%	38.1%
14	Chloramphenicol injection	0.0%	4.8%
15	Chloramphenicol tablets	0.0%	76.2%
16	Ciprofloxacin	0.0%	90.5%
17	Clotrimazole topical cream	61.9%	14.3%
18	Co-trimoxazole suspension	19.0%	85.7%
19	Co-trimoxazole tablets	0.0%	95.2%
20	Diazepam	- ²	- ²
21	Diclofenac	23.8%	61.9%
22	Doxycycline	0.0%	85.7%
23	Enalapril	0.0%	0.0%
24	Ethinylloestradiol/levonorgestrel (COC)	76.2%	0.0%
25	Ferrum sulfate	- ¹	47.6%
26	Folic acid + ferrum sulphate	- ¹	0.0%
27	Gentamicin injection	0.0%	33.3%
28	Glibenclamide	4.8%	57.1%
29	Hydralazine	0.0%	0.0%
30	Hydrochlorothiazide	0.0%	52.4%
31	Ibuprofen	0.0%	85.7%
32	Magnesium sulphate injection	- ¹	0.0%
33	Medroxyprogesterone acetate injection	0.0%	61.9%
34	Metformin	14.3%	38.1%
35	Metronidazole injection	0.0%	14.3%
36	Metronidazole tablets	9.5%	9.5%
37	Misoprostol	4.8%	9.5%
38	Omeprazole	0.0%	85.7%
39	Oral rehydration salts (ORS)	- ¹	- ²
40	Oxytocin injection	0.0%	14.3%
41	Paracetamol suspension	- ²	90.5%
42	Paracetamol tablets	85.7%	90.5%
43	Ranitidine	0.0%	76.2%
44	Ringer's lactate	- ¹	23.8%
45	Salbutamol inhaler	14.3%	33.3%
46	Simvastatin	0.0%	28.6%
47	Tetanus toxoid vaccine	- ¹	4.8%
48	Vitamin A	- ¹	9.5%

OB: originator brand; LPG: lowest price generic; COC: combined oral contraceptive

¹Medicine with no originator brand; ²Medicine excluded from the analysis. (see Chapter 2. Methods).

3.2. MEDICINES PRICES

Medicines in the public sector are distributed free of charge to the population, regardless of the therapeutic class or population group. There are also no fees related to medical services or any prescription charges in the public health facilities. Patient price analysis is therefore not applicable to the public sector in Timor-Leste.

As for procurement prices, no procurement documents from private importers/retailers were collected for this investigation. Analysis of procurement prices focussed only on medicines procured for the national health system.

3.2.1. Private sector patient prices

Only medicines with at least 4 prices obtained in different outlets were included in the price analysis. Since generics are more commonly available than originator brands in the Timorese private sector, from our original sample of 48 medicines, the results were calculated with data obtained from 6 OBs and 25 LPGs and are presented in Table 3.6. in this section.

This table shows that medicines selling prices in the private sector in Timor-Leste are considerably higher than international reference prices, both for OBs and LPGs. Differences are even more substantial among originator brands, with median MPRs ranging from 6.40 for oral contraceptives to 186.05 in the case of diclofenac. For generic medicines, patient prices are lower than originator brands but still very high when compared to their IRP, as high as 36.84 times in the case of atenolol for example.

Extending our analysis to individual medicines, we can observe an important variability in prices across outlets, which is more evident among certain medicines. Table 3.7. shows examples of medicines for which maximum price (expressed as MPR) was at least 5 times higher than minimum MPR found across outlets surveyed.

Sometimes, despite the price difference, private pharmacies are the only alternative to obtain certain treatments. Clotrimazole 1% topical cream, for instance: its price (OB) was approximately 37 times more expensive than the corresponding IRP, but it was still available in more than 60% of the private retail pharmacies visited, in

contrast with the same medicine distributed free of charge in the public sector but where its availability is below 5%.

Table 3. 6. Median MPRs, for medicines with ≥ 4 prices available, per type.

Medicine name (INN) and pharmaceutical form	MPR Originator brand (n=6)	MPR Lowest price generic (n=25)
Amoxicillin 500mg tablet		3.45
Ampicilin 1g injection		12.06
Atenolol 50mg tablet	118.42	36.84
Captopril 25mg tablet		8.33
Ceftriaxone 1g injection		3.99
Chloramphenicol 250mg tablet		6.45
Ciprofloxacin 500mg tablet		4.90
Clotrimazole 1% topical cream	37.04	
Co-trimoxazole 8+40mg/ml suspension	57.14	3.95
Co-trimoxazole 480mg tablet		9.43
Diclofenac 50mg tablet	186.05	34.88
Doxycycline 100mg tablet		12.82
Ethinylloestradiol/Levonorgestrel tablet	6.40	
Ferrum sulphate (60mg Fe) tablet		21.74
Gentamicin 40mg/ml injection		22.42
Glibenclamide 5mg tablet		29.41
Hydrochlorothiazide 25mg tablet		27.03
Ibuprofen 400 mg tablet		10.64
Medroxyprogesterone 150mg/ml injection		1.42
Metformin 500mg tablet		11.90
Omeprazole 20mg capsule		8.33
Paracetamol 120mg/5ml suspension		4.26
Paracetamol 500mg tablet	22.22	11.11
Ranitidine 150mg tablet		7.50
Ringer's lactate infusion		3.33
Salbutamol 100mcg/dose inhaler		4.41
Simvastatin 20mg tablet		5.11

MPR: Median price ratio (ratio median observed price/International Reference Price – MSH 2010); INN: international non-proprietary name.

Table 3. 7. Examples of price variations across private pharmacies for the same medicine (only LPGs).

Medicine name and pharmaceutical form	Minimum MPR	Maximum MPR	Ratio max/min
Captopril 50mg tab	2.92	25.00	8.56
Chloramphenicol 500mg tab	2.90	16.13	5.56
Hydrochlorothiazide 25mg tab	6.76	54.05	8.00
Metformin 500mg tab	4.76	23.81	5.00
Omeprazole 20mg cap	2.78	16.67	6.00
Ranitidine 150mg cap	2.50	12.50	5.00
Simvastatin 20mg tab	5.11	34.92	6.83

MPR: median price ratio; LPG: lowest price generic

The global results for our initial basket of 48 medicines are summarized in Table 3.8. below.

Table 3. 8. Summary of medicine median price ratios (MPRs) for medicines for which ≥ 4 prices were available.

Median Price Ratio	OB (n=6)	LPG (n=25)
Median MPR	47.09	8.33
25%ile MPR	25.93	4.41
75%ile MPR	103.10	12.82
Minimum MPR	6.40	1.42
Maximum MPR	186.05	36.84

OB: originator brand; LPG: lowest price generic

The price variations between originator brands and lower price generic equivalents were even more visible when MPRs for the originator brand and lower price generic equivalent were compared for the same medicine. The results of this paired analysis (which comprised only medicines for which both prices were found in at least 4 outlets) is presented in Table 3.9. In the case of co-trimoxazole suspension for example, the originator brand's price was more than 14 times higher than its lower price generic equivalent.

Table 3. 9. Comparison between MPRs for originator brand a lower price generic equivalent of medicines for which ≥ 4 prices were available for both OB and LPG.

Medicine name and pharmaceutical form	OB (n=4)	LPG (n=4)
Atenolol 50mg tab	118.42	36.84
Co-trimoxazole 8+40mg/ml susp	57.14	3.95
Diclofenac 50mg tab	186.05	34.88
Paracetamol 500mg tab	22.22	11.11

OB: originator brand; LPG: lowest price generic

Although prices tend to be higher in the sub-group of pharmacies located outside Dili (n=5), which buy their medicines mostly from the same importer/supplier in Dili, the global median MPRs for generic medicines do not seem substantially different when compared to the sub-group of pharmacies in Dili (n=16), showing only variations for minimum and maximum MPR values, as can be observed in Table 3.10. below.

Table 3. 10. Comparison of medicine MPRs for generic medicines for which ≥ 4 prices were available in private pharmacies in Dili and in the districts.

Median Price Ratio	Dili (n=16)	Districts ¹ (n=5)
Median MPR	8.33	8.45
25%ile MPR	4.41	6.27
75%ile MPR	11.90	11.62
Minimum MPR	1.32	4.31
Maximum MPR	34.88	22.22

MPR: median price ratio

¹ Baucau (3 outlets), Bobonaro (1 outlet), Liquiçá (1 outlet)

3.2.2. Public sector procurement prices

As described before, the procurement of medicines for the public sector is (generally) done by SAMES, which is a semi-autonomous agency whose budget comes directly from the Ministry of Finance (government budget). In special cases, such as emergency purchases, the MoH can use a different procedure and sign contracts with authorized local suppliers.

However, in some specific cases, the procurement is not handled by SAMES. Medicines for Malaria, TB and HIV/AIDS programs are procured through Global Fund's procurement procedures (handled by the GF office in the country) and, likewise, contraceptives are procured via UNFPA, all from prequalified suppliers and all as originator brands. In our study, this is the case of 3 medicines: *Coartem*, *Microgynon* and *Depo-Provera*, which are therefore not included in the present analysis.

The objective of this analysis was to compare SAMES and MoH purchase prices (from international and national suppliers) to international reference prices (IRP). Data collected refers to 3 contracts (2 from SAMES and 1 for an emergency supply from the MoH, all celebrated between June and August 2011), where one procurement price was obtained for 18 generic medicines included in our basket of 48. Like for patient price analysis, for procurement price analysis, prices were converted to a ratio of the International Reference Price (median price ratio or MPR), where a MPR > 1 indicates a purchase price higher than the IRP, whereas a MPR < 1 indicates that the medicine was procured at a price below the IRP.

For the 18 medicines included in our analysis (i.e. for which one price was obtained), the median procurement MPR was 1.06, showing a general alignment with international reference prices. However, a deeper analysis reveals values ranging from 0.47 for hydralazine LPG and 3.65 for salbutamol inhaler LPG. The lowest MPR was for one medicine procured from an international supplier while the highest procurement MPR corresponded to a medicine purchased directly by the MoH from a national supplier. However, the data of just 3 procurement documents is not consistent enough to allow a more robust analysis of procurement prices and public procurement efficiency.

Table 3.11. below summarizes the main findings of this section.

Table 3. 11. Summary of medicine specific median price ratios (MPRs) for medicines with ≥ 1 procurement price available (all LPGs).

Median Price Ratio	LPG (n=18)	Remarks
Median MPR	1.06	
25%ile MPR	0.74	
75%ile MPR	1.85	
Minimum MPR	0.47	Hydralazine injection, international supplier
Maximum MPR	3.65	Salbutamol inhaler, national supplier

LPG: lowest price generic

The calculations were made based on the prices CIF¹⁶ found in public sector procurement contracts with different suppliers. In addition, importers (be it SAMES or any private importer) pay an import duty of 2.5% and a sales tax of 2.5%, as specified in the Taxation Law (Law 08/2008). Under the same legislation, medicines are exempt of excise tax, applicable to other goods for sale.

¹⁶CIF: price includes cost, insurance and freight.

3.3. AFFORDABILITY OF TREATMENTS

Since, as previously mentioned, medicines in the public sector are distributed free of charge to the population, the analysis of this parameter refers only to medicines purchased in the private sector. The affordability analysis is therefore based on the median prices obtained in private pharmacies for medicines used to treat common health conditions.

In the present study, the affordability analysis follows the WHO/HAI methodology and is based on the salary of the lowest paid unskilled government worker. The methodology defines a course of treatment as unaffordable if it costs more than the equivalent to one day's wages; treatments are considered affordable if they cost the equivalent to one day's wages or less.

The salary of the lowest paid government worker in Timor-Leste was, at the time of the study, 115 USD. This corresponds to a daily wage of 3.83 USD.

Table 3.12. shows examples of treatment affordability for common conditions treated with some of the medicines surveyed. For some conditions, multiple treatment options are presented. In the case of acute conditions the usual course of treatment for one episode (in dose and number of days) was considered, while for chronic conditions the duration of treatment based on which calculations were made was one month.

Treatment of acute infections with antibiotics was, in general, considered affordable (except in the case of systemic infection treatment with gentamicin injection), as well as the treatment of mild pain/fever in adults and children (0.2 for paracetamol suspension to 0.3 or 0.6 for paracetamol tablets LPG or OB, respectively). This reasoning is valid for one course of treatment of one single episode and not in case the illness episode is repeated and/or there is more than one family member in need for treatment. The use of oral or injectable contraceptives (0.5 day's wages/cycle in both cases) was also considered affordable.

The treatment of all other conditions presented in Table 3.12. is generally unaffordable, if the patient uses generic medicines. The treatment with the equivalent originator brand is at least twice as expensive (paracetamol tablets) up to almost 15 times more expensive (co-trimoxazole suspension) than when using generics. The two treatment options considered in the present analysis for the treatment of diabetes

(glibenclamide and metformin) and the two treatment options for hypertension (atenolol and captopril), for example, are considered unaffordable according to our definition.

Table 3. 12. Median expenditure (day's wages) the lowest paid government worker would have to spend in medicines used to treat common conditions.

Condition	Medicine	Treatment duration (days)	OB	LPG
Asthma	Salbutamol 100mcg/dose inhaler	as needed		2.0
Diabetes	Glibenclamide 5mg tab	30		1.6
Diabetes	Metformin 500mg tab	30		2.9
Hypertension	Atenolol 50mg tab	30	8.8	2.7
Hypertension	Captopril 50mg tab	30		1.8
Hypercholesterolemia	Simvastatin 20mg tab	30		2.3
Adult resp. infection	Ciprofloxacin 500mg tab	7		0.5
Adult resp. infection	Amoxicillin 500mg tab	7		0.5
Adult resp. infection	Ceftriaxone 1g inj	1		0.7
Paediatric resp. infection	Co-trimoxazole 8+40mg/ml susp	7	4.4	0.3
Arthritis	Diclofenac 50mg tab	30	12.5	2.3
Arthritis	Ibuprofen 400mg tab	30		2.3
Pain/inflammation	Paracetamol 24mg/ml susp	3		0.2
Pain/fever (mild) adults	Paracetamol 500mg tab	3	0.6	0.3
Ulcer/dyspepsia	Omeprazol 20mg cap	30		2.0
Ulcer/dyspepsia	Ranitidine 150mg tab	30		2.3
Contraception	EE/LVG (COC) cycle	30	0.5	
Contraception	Medroxyprogesterone 150mg inj	30		0.5
Topical fungal infection	Clotrimazole 1% cream	as needed	1.3	
Adult systemic infection	Gentamicin 40mg/ml inj	7		11.0

OB: originator brand; LPG: lowest price generic; EE/LVG (COC): ethinyloestradiol/levonorgestrel (combined oral contraceptive)

4. DISCUSSION AND CONCLUSIONS

In the following section the factors that can limit access of the population of Timor-Leste to affordable pharmacological treatments (availability, prices and affordability) are discussed, exploring the limitations of the study and the possible interpretation of the findings from the survey. International comparisons were made with data from other surveys conducted throughout the world since 2008 (based on the methodology described in the manual's 2nd edition) in low- and lower-middle-income countries.¹⁷

4.1. KEY FINDINGS

4.1.1. Availability of medicines

Following WHO/HAI's ranges for availability (< 30% very low; 30-49% low; 50-80% fairly high; 80% high), (61) mean availability of generic medicines in the Timorese public sector can be considered comparatively acceptable, ranging from 52.3 to 67.2% across the five districts surveyed. In contrast, originator brand availability is very low, which suggests that the government's policy intended to favour generic medicines is being followed in public procurement processes. In fact, from the list of medicines surveyed in the present study, practically all OB medicines found in public outlets were medicines procured through funded programs (Global Fund for HIV/AIDS, malaria and TB and family planning vertical programs), which follow donor's specific procurement guidelines and the public procurement agency (SAMES) is only responsible for medicines distribution. This preference for the use of generic medicines in public health services has been generally observed in recent surveys conducted in several low- and lower-middle-income countries (refer to Table 1.1. Chapter 1).

Availability is higher in hospitals than in CHCs, which is not surprising if the distribution system is taken into account. At district level, regular distribution of medicines coming from SAMES is centralized in District Health Services; each sub-district CHC then collects and transports medicines to their final destination (in a van allocated to the CHC). Because this transport depends on road and vehicle conditions,

¹⁷ World Bank classification. Available from: <http://data.worldbank.org/about/country-classifications/country-and-lending-groups> (accessed on 22 Jul 2012).

availability of medicines is usually lower in more remote locations, while hospitals and CHCs located in urban centres are favoured due to their location closer to SAMES warehouse (in the case of Dili) or district level storage facilities. Another reason which for higher availabilities found in Dili is that some of these CHCs receive donated medicines from NGOs with more activities in the capital (donations were not found at CHC level in any other districts). In one CHC in Dili, for example, donations also included equipment such as an air conditioning system, which clearly improved the pharmacy's storage conditions.

Given the fact that medicines are supplied to and within the districts mostly by road,¹⁸ availability in districts with better road conditions (Dili and Baucau) was generally above national average. These regional differences have been observed in previous studies in similar contexts,(31) although sometimes the link between availability and geographic location is weak and non-significant.(22) Nevertheless, these data seem to support the idea that investment is still necessary to improve the access of populations living in remote (and poorer) locations to medical treatments, and that this effort should focus also on infrastructures and logistic conditions in order to reduce geographic obstacles to access.

When specific therapeutic groups are considered, availability is high for NSAIDs and fairly high for oral antibiotics and oral cardiovascular medicines, which reflect a rather good provision of some essential medicines to the population. In contrast, however, availability of selected medicines for maternal and children care remains below 50% in the public sector (both for OBs and LPGs). Reproductive health indicators remain an important challenge in Timor-Leste; for instance, lifetime risk of maternal death was found to be 1 in 35(62) and under-five mortality remains at 56 per 1000 living births.(63) MNCH has been identified as a priority area for intervention in Timor-Leste;(64) however, these low availability results suggest that the government probably needs to give more emphasis to pharmaceuticals as a component of MNCH programs.

Similarly to what has been observed for the public sector, availability of OBs in the private sector is also very low, despite considerable variations across the 21

¹⁸In the case of Oecussi, medicines are normally transported by boat to the district capital, Pante Makasar, and to the subdistricts by road.

pharmacies surveyed. As for generic medicines, however, while availability in the public sector is generally considered as fairly high (close to 60.0%), in private retail pharmacies it is generally low (less than 40.0%). No medicine from our list was consistently found in all the outlets surveyed in the private sector (in the public health facilities, in contrast, 6 medicines had a mean availability of 100%).

In Timor-Leste, despite the limited budget for medicines,(51) the government has managed to maintain medicines availability in the public sector at reasonable levels, diminishing, to a certain extent, the role of the private sector in the provision of pharmaceuticals to the population. For instance, recent data show that 77% of oral contraceptives are obtained in public health facilities in Timor-Leste, and less than 14% from the private for profit sector.(65)

Although most private pharmacies are concentrated in Dili, and district data was limited, it was still possible to observe marked regional differences: in the case of generics, pharmacies in Dili (n=16) show a mean availability which can be classified as low, while in pharmacies outside Dili (n=5) availability is very low, almost half when compared to Dili. The same pattern is observed for originator brands, although overall availability is very low for both types of medicines. The most likely explanation for this difference is that, as the supply chain for medicines in Timor-Leste does not include wholesalers or distributors, private pharmacies in the districts must get their supplies from Dili by their own means, traveling only when medicine stock levels become critically low. These observations indicate that if people with more financial resources living in Dili can still rely on some private pharmacies to buy medicines not found in the public healthcare facilities, outside Dili, the private system is hardly a viable alternative.

When looking at the existing literature on medicines availability, prices and affordability the pattern described is normally one of low availability in the public sector (where medicines are free or sold at a lower price) forcing the population to purchase medicines from the private sector, more available, but at a higher cost.(8, 9, 13) When we analyse Timor-Leste data, though, another pattern prevails: the public sector shows a higher availability than the private for most medicines considered.

Timor-Leste is not an isolated case as this ‘opposite pattern’ has been found in some other countries (refer to Table 1.1. Chapter 1). Lower availabilities in the private

sector are generally seen in countries where the private sector is poorly regulated and the few existing regulations are not monitored. Data from these studies suggests that poor regulation in these contexts might be preventing the development of a strong private sector.

While the pattern found in Timor-Leste has been observed in other countries in Southeast Asia region, Indonesia and Thailand, as well as in other world countries in comparable stages of development (Burkina Faso, Guatemala, São Tomé and Príncipe),(23) it is still interesting to see that Timor-Leste's results are opposite to what is generally observed in countries where no fees apply to medicines in the public sector.(23)

4.1.2. Private sector patient prices

As previously pointed out, in the public sector medicines are distributed free of charge to the population and no fees apply to patients using public health facilities in Timor-Leste. Thus, patient price discussion only applies to the private sector.

Contrarily to procurement prices, where a cut-off point of acceptable/non-acceptable MPR is fairly easy to define, patient prices in retail pharmacies are a combination of the manufacturer's selling price and additional costs resulting from the various steps of the supply chain, which add up to the final price. It is therefore difficult to draw a line between what can be considered as an acceptable selling price and what is excessive. A WHO/HAI comparison report on price, availability and affordability of medicines used the cut-off point of $MPR \leq 2.5\%$ in order to facilitate discussion(61); this criterion has been adopted by other studies(31) and will be used in this analysis.

Only one medicine from our list (for which at least 4 retail prices were found) showed a MPR lower than the 2.5 threshold – generic medroxyprogesterone 150 mg/ml injection. All other MPRs found for generic medicines can be considered high according to the above-mentioned criteria. Originator brands considered in this analysis were found to have MPRs 2-14 times higher than their generic equivalent, and were unacceptably expensive when compared to international standards. Price variations across private outlets were also substantial for some essential medicines – captopril 50 mg tablets for example can be 8.5 times more expensive depending on the private pharmacy visited. These results clearly reflect the inexistence of government regulation

on retail prices and margins. Pharmacy prices even showed variations within the same outlet, whether medicines were purchased following a medical consultation held in the pharmacy's premises or with another/no prescription; again, no regulation exists aimed at controlling this kind of practice.

Our findings raise doubts on the effective role of private retail pharmacies in the Timorese health system, given the lower availability and higher prices of essential medicines when compared to the public sector. One explanation could be the far from ideal conditions of the public health facilities, generally overcrowded (and with limited working hours in case of CHCs), which can push some people to seek more expensive care in less crowded retail points in the private sector, where primary care and medicines can also be provided. Another explanation could be that the private sector is mainly serving certain sections of the population, with a larger level of income, who choose the private sector's (slightly) better ancillary conditions. Nevertheless, these possible explanations only apply to Dili (and Baucau, to some extent), since the private sector in the rest of the country is practically inexistent. The private not-for-profit sector (NGOs for instance) might also have an important role in the provision of medicines in target intervention areas, constituting an alternative to both the NHS and private retail pharmacies.

Additionally, some larger private pharmacies belong to local companies with license to import and supply medicines and other health commodities to the public sector (through the public procurement agency – SAMES – or the Ministry of Health) and other smaller private pharmacies. The retail business could therefore serve only as a secondary/complementary business for these companies who would get most of the profits from their activity as 'wholesalers'.

Prices in the private sector in Timor-Leste are among the highest found in recent surveys carried out in low- and lower-middle-income countries, regardless of the world region considered (refer to Table 1.2. Chapter 1). The situation in Timor-Leste is similar to what has been described in countries with higher patient prices in the private sector (like São Tomé and Príncipe and Haiti) do not have specific regulation on prices and margins or have some regulation but it is not efficiently monitored.(31,66)

It is interesting to observe, though, that in Indonesia, the median MPR found for a basket generic medicines surveyed was relatively low. Since most medicines sold in

private retail pharmacies in Timor-Leste are imported from Indonesia, this suggests that either private importers are systematically not able to negotiate better prices with Indonesian suppliers (which could be due to the low amount of drugs imported) or that substantial margins are added locally by Timorese market players.

Caution is necessary, however, when comparing prices across different countries and survey years, as price adjustments are necessary given the differences in medicines reference prices in different years, inflation rates and purchasing power of the local currency of countries considered.

4.1.3. Public sector procurement prices

Public procurement efficiency was evaluated by comparing MPRs of procurement documents with international reference prices.

Public procurement data in Timor-Leste was obtained from three tender documents, two of which from a national supplier and one from an international supplier. From the medicines included in our list, one single price was found for 18 different medicines, which considerably limits any discussion over this matter. Nevertheless, this limited information reveals a median MPR of 1.06, which according to WHO/HAI methodology reflects a fairly efficient procurement system ($MPR \leq 1$ is considered efficient, meaning drugs are procured for prices which are equal or below IRP). Although data does not allow price comparison for the same medicine, if we analyse the international tender process (international contest) vs. locally procured medicines (procured using a request for quotations from pre-selected suppliers), some differences seem to arise: while MPR referring to medicines procured from the international supplier (n=4) range between 0.69 and 1.02 (and the process can be considered efficient), MPRs from the local supplier (n= 14) range between 0.47 and 3.65, and for 9 out of 14 medicines MPRs are actually ≥ 1 . Although limited, this brief analysis suggests that despite government's recommendations to procure drugs through international tender processes, some drugs are being procured from pre-selected local importers (mostly in case of emergency supplies, due to stock-outs), at higher prices.

Reports from other low- and lower-middle-income countries where this analysis was recently undertaken, show a similar procurement median MPRs for medicines procured by the public sector, except for Philippines and Indonesia (Table 5, Appendix

5). The fact that most local private importers use Indonesian medicines suppliers might be one of the reasons for the high prices observed in the private sector in Timor-Leste.

As mentioned in the previous section, caution is necessary when interpreting unadjusted MPRs across multiple studies.

4.1.4. Affordability of treatment

Affordability analysis using the WHO/HAI standard methodology compares the costs of pharmacological treatments to the salary of the lowest paid unskilled government worker, based on the assumption that this reflects the country's cost of living. (see below in Chapter 4.2.1. Limitations of the original WHO/HAI methodology).

A course of treatment is considered affordable if medicines costs do not exceed the salary equivalent to one working day and unaffordable when it goes beyond this amount. However, according to the latest World Bank data, more than one third of the Timorese population lives below the 1.25 USD/day poverty line, which means that even treatments considered 'affordable' according to this methodology might not be truly affordable to many people. Nevertheless, this approach allows international comparisons with similar contexts, which can give a rough idea of the situation in Timor-Leste.

While antibiotics, common painkillers and contraceptives are generally affordable as per the WHO/HAI standards, other medicines such as anti-hypertensives, NSAIDs, medicines to treat ulcer/dyspepsia and anti-diabetics generally cost more than one daily wage. These last two therapeutic groups are interesting to analyse, since contrarily to the general availability trend found in our study, the two anti-diabetics included in our list (glibenclamide and metformin) and one of the most common medicines used to treat peptic ulcer (omeprazol) showed a higher availability in the private sector when compared to the public sector. This may suggest that for specific medicines or therapeutic groups, private pharmacies may actually have an important role in the system, filling the low-availability gap in the public sector. Nevertheless, for most of the population these treatments remain not only unaffordable, but also inaccessible since this reasoning applies almost exclusively to Dili, where most private retail pharmacies are concentrated. Unaffordability of treatments with originator brands

is even more marked, and can represent more than the equivalent of 12 working days for the medicines considered in our study. However, the adherence to generic medicines in Timor-Leste seems quite high (as shown by the extremely low availability of originator brands in the market, which suggests a very low demand), so high prices of OBs are likely to represent a minor issue when compared to other problems in the sector.

Looking at other countries in Southeast Asia where the same methodology was applied for medicines affordability analysis (India NCT and Indonesia), Timor-Leste is clearly the country where treatments purchased in the private sector (even when lowest price generics are available) were most inaccessible due to cost barriers. Results are, nonetheless, comparable to other similar low- and lower-middle-income countries analysed in recent surveys in Central and South America and Africa (Table 6, Appendix 5).(23) Findings for specific therapeutic groups also seem consistent with previous individual and multi-country reports: antibiotics are generally more affordable for the population than treatments for chronic diseases such as hypertension, diabetes, asthma or peptic ulcer.(13)

4.2. LIMITATIONS

4.2.1. Limitations of the original WHO/HAI methodology

Caution is necessary when interpreting availability results in this type of survey, since results refer only to the day of observation and may not reflect availability over time. This type of analysis also does not take into account other dosage forms or possible alternative treatments for the same health condition. For instance in Timor-Leste, ciprofloxacin in tablet form and 500 mg strength was systematically reported as unavailable in the public sector; however, in most facilities visited, 250 mg tablets of the same medicine were usually found as an alternative (but not considered as per WHO/HAI methodology).

Additionally, the fact that one medicine is physically present in the healthcare facility (thus available), does not necessarily mean it has adequate quality. An appropriate storage and distribution system is necessary to ensure medicines safety, efficacy and quality according to internationally accepted standards.⁽⁶⁷⁾ By focusing only on physical availability, this important aspect affecting the access to adequate treatment is overlooked by the methodology.

Affordability analysis also followed the methods described in the WHO/HAI manual, based on the salary of the lowest paid unskilled government worker. This kind of approach has been widely used in other studies (namely in studies that follow WHO/HAI's procedures, for comparison purposes) as a measure of the financial impact medicines have on the population. Despite its simplicity and straightforwardness the application of this kind of approach (in the field of medicines as in other fields) has been criticised for not reflecting the real population's ability to pay for medicines. In Timor-Leste the salary of the lowest paid government worker is set in 115 USD and calculations for the affordability of a standard treatment for several conditions were made based on that amount. However, the population of Timor-Leste working in public administration is only about 2.2%.¹⁹ On the other hand, latest available data from the WB (2007) places more than one third of the population (37.4%) below the poverty threshold of 1.25 USD/day. This means that in Timor-Leste, as well as in other similar countries, the majority of the population earns much less than the salary of the lowest

¹⁹Census 2010. Available from: <http://dne.mof.gov.tl/> (accessed on 22 Jul 2012).

paid unskilled government worker. Additionally, an affordability analysis based solely on the price of medicines does not take into account other factors that affect the population's ability to pay for medical treatments, or indirect costs, like private doctor fees and/or transport costs to healthcare facilities, which can be significant, particularly in a context where all private pharmacies are located in urban centres.

4.2.2. Limitations of the present study

The whole data collection task was undertaken by one investigator alone, and not by teams of two, as recommended in the manual; data collection forms were checked at the end of each working day by the same investigator. Although this can be seen as an advantage in terms of standardization of the data collection procedure, it can increase the probability of systematic errors.

Limitations related to lack of transport or bad weather conditions limited the access to some geographic areas and/or health facilities; it was therefore impossible to fully comply with the sampling process recommended by WHO/HAI. However, given the small dimension and population of Timor-Leste, it was considered that the sample chosen for the public sector could still represent the country as a whole since facilities surveyed covered 44.1% of the country's population, with a suitable balance between urban and rural population (52.5% and 47.5%, respectively). As for the private sector, the particular distribution pattern made the WHO/HAI sampling recommendations unfeasible. Nonetheless, almost 90% of all private retail outlets registered in the country at the time of the study (21 out of a total number of 24, if we exclude 2 already closed when the study started and 2 exclusively dedicated to Chinese medicines) were actually surveyed (16 out of 19 in Dili, and 5 out of 7 in the districts), which can probably be considered as representative of the private sector in the country.

Given the above-mentioned limitations, a two-month period was necessary to complete the study. As medicines supplies are received by CHCs in the districts on a quarterly basis, some differences in the availabilities observed between the districts may have reflected this time gap.

The WHO/HAI complements the analysis of procurement prices with a price components study. The objective of this analysis is to help clarify the impact of the various additional costs added to the medicine's selling price along the supply chain

until they reach the final consumer; this information can be crucial when planning policies aimed at improving the price regulation in the pharmaceutical sector. However, given the sensitivity of the matter and lack of regulation in Timor-Leste (which can give rise to some not so transparent practices), pharmacy owners and other actors related to the pharmaceutical market were usually afraid or not willing to disclose this kind of information for the investigation. Therefore, we decided to exclude price component analysis, as per WHO/HAI standards, from our study, limiting our understanding on how the pharmaceutical market works in Timor-Leste and failing to give us some insight on how it might be improved as far as medicines prices are concerned.

Finally, as price comparison between different countries requires more complex calculations, taking into account factors such as inflation rates and purchasing power of local currencies, no comparisons were made for individual medicines and caution is necessary when comparing general results for baskets or samples of medicines, with different compositions. International comparisons of availability and affordability are not affected by the factors described above and may be performed without further adjustment.

4.3. POLICY IMPLICATIONS OF STUDY FINDINGS

Over the past 10 years, more than 50 surveys using the same standard methodology have been carried out in low- and middle-income countries, highlighting the importance of these parameters for the identification of the root causes of poor access to medicines. Scant evidence exists that governments have used results from these surveys as guidance to take action and develop policies aimed at improving the availability of essential medicines at affordable prices. However, it is hoped the findings from this study can be regarded as an opportunity to improve the pharmaceutical sector in Timor-Leste.

Although a fairly high availability of essential medicines was found in the public sector, some improvements are still necessary in order to ensure access to (good-quality) medicines to the population of Timor-Leste. Efforts have been made in recent years to update documents such as the essential medicines list (EML) and standard treatment guidelines (STG) for primary care. However, doctors working in the national health system (including many expatriates) are not fully aware of the utility of following these documents and there is some lack of coordination between available drugs (SAMES uses EML guidance for drug procurement) and prescription patterns. Large quantities of untouched medicines close to expiry date or expired were consistently found in the facilities visited. It is therefore necessary that the government takes action to improve the adequate dissemination of these documents within the system (which includes translation of English versions into the main working languages in Timor-Leste – Tetum, Portuguese and Indonesian) as well as to promote training of health professionals (doctors, nurses and pharmacy personnel) on rational use of medicines in order to improve the system's performance and reduce drug waste, in line with what has been suggested in previous reports. A reduction in the number of medicines included in the current EML as well as a better stock monitoring system in the public health facilities might also contribute to improve the efficiency of the procurement system, avoiding the procurement of unnecessary drugs and insufficient amounts of the most commonly used drugs, leading to stock-outs.

In Timor-Leste drug regulation is very patchy, and regulatory and monitoring responsibilities are not concentrated in one fully empowered regulatory authority, but scattered between various state-controlled entities (DOP and CRAF, but also SAMES in

the case of drug quality testing). As pointed out in a recent WHO report,(51) the government is currently evaluating a national drug policy but the draft version has not been approved by the parliament to date. Medicines policy, according to WHO, should have the following objectives: (i) the equitable availability and affordability of essential medicines; (ii) the quality, safety and efficacy of all medicines; and (iii) therapeutically sound and cost effective use of medicines by health professionals and consumers.(68) Many of these aspects are actually already covered in current legislation and guidance documents; however, as in many other low- and middle-income settings, implementation of existing policies has not been fully established. For instance, monitoring and inspection of activities and common practices in the private sector is very inefficient; this situation constitutes a public health issue (e.g. psychotropic medicines are imported and sold despite government's recommendations, antibiotics are freely sold over the counter in many pharmacies), but offenders are seldom detected. It is therefore important that action is taken, not necessarily through the creation of new legislation, but starting by urgently reinforcing the existing one, and then incrementally move on to the other areas requiring the regulator's attention. A drug policy implementation plan should clearly define the main activities to be undertaken, responsibilities for undertaking these activities, among the various departments and agencies involved, and estimate the resources that should be available in order to carry them out. The reduced number of human resources with adequate training limits the number of professionals that could be involved in pharmaceutical inspection and monitoring activities; this aspect seems nonetheless crucial at this stage and is still worth mentioning.

Currently, profit margins applied to medicines in the private sector are not regulated. This is probably contributing to create an unfavourable environment for the private sector, since small businesses are unlikely to survive in a system where a few vertically integrated groups (importers with their own retail pharmacy) control market prices (and practices). Although it is known to increase efficiency in some cases, vertical integration can also limit competition and consumer protection.(69) Regulation on medicines prices, like the establishment of maximum margins, could be useful not only to make them more affordable to the population but also as a mechanism to favour the development of the private sector.

As the private sector develops, established businesses groups become increasingly dominant, influencing regulation favouring their vested interests.(69) Since the private sector in Timor-Leste is still emerging, this is probably the most appropriate moment for the government to consider the development and reinforcement of legal mechanisms before they become harder to implement.

Another possible topic of discussion could be the long-term sustainability of a publicly funded pharmaceutical system. Although availability of drugs surveyed in the present study was considered reasonable, insufficient funds for the procurement of drugs have been identified as one of the main reasons for stock-outs at SAMES. Some countries facing the same problem have introduced user fees in order to help financing the public system – user fees can be re-invested in the health system to improve the quality of services provided, for instance, the availability of medicines.(12) Although the success of user fees implementation is not consensual,(70) a debate over the sustainability of the public health system should be considered by the Timorese authorities, particularly given the population growth rate observed in the country and the intention to expand the health services to serve more remote communities.

4.4. FUTURE AREAS OF RESEARCH

As described in the study limitations, the survey conducted in Timor-Leste focused only on availability and prices of medicines and did not explore the price components as per WHO/HAI's methodology. It would therefore be useful to complement the present availability and price survey with a study focussing on price components and margins applied by the various market players, with the objective to provide policy-makers with firm evidence on what drives the sector's performance. Additionally, it would be interesting to look more deeply at the private sector consumer profile (vs. public) to gain a better understanding of the role the private retail pharmacies may have in the Timorese health system.

In the present study, drug availability was measured using a list of 48 medicines covering several therapeutic/intervention areas. However, one problem identified throughout the survey in the public sector was that some drugs, although available, were seldom prescribed by doctors working in the health facility and remained in the shelves untouched until expired. Although there have been some efforts to update the national essential medicines list and standard treatment guidelines, a gap is still apparent between procurement options and real needs. The rational use of medicines is not a new issue and has been addressed before in Timor-Leste, but an updated comprehensive study on the adherence to the national EML and most recent STGs complemented by the evaluation of prescription patterns should also deserve some attention in future research given the limited resources for medicines in the public sector.

As pointed out in the introduction section, availability of (good-quality) essential medicines depends on an efficient supply system, which includes factors such as the selection, procurement and distribution of drugs. The adequate distribution of drugs in turn, depends on factors such as transport and storage conditions. In some of the facilities visited storage conditions are far from ideal (high temperatures with no air conditioning system, no plague control, open-air storage, no segregation of expired items), which can critically affect the final quality of medicines provided to the population. Even though this type of study would be likely to involve considerable resources, it would be useful to analyse the real quality of drugs supplied by the public health system, since this can seriously affect the efficacy and safety of treatment provided.

Finally, the approach used to measure affordability in the present study, based exclusively on medicines prices, has several limitations. Not only the salary of the lowest paid government worker is not representative of the monthly income of most of the population, but it also does not take into account indirect costs that families have to face in order to receive the medicines they need. Even when medicines are dispensed free of charge by the national health system, transport to the closest healthcare facility in remote locations for example, may represent a cost beyond people's reach. It would therefore be interesting to evaluate the impact of other costs related to treatment in order to have a better idea of real affordability of obtaining pharmacological treatment in Timor-Leste.

4.5. CONCLUSIONS

Over the past 10 years, more than 50 surveys using the same standard methodology developed by HAI and WHO have been carried out in low- and middle-income countries, highlighting the importance of these parameters for the identification of the root causes of poor access to medicines. To date, no study had been conducted to describe the availability, prices and affordability of medicines in Timor-Leste; however, comparable issues have been identified in Southeast Asian countries and other countries in similar stages of development. Taking stock of the country's situation was therefore considered of great utility and provide a basis for subsequent studies, recommendations and interventions.

Between November 2011 and January 2012 a survey was conducted in five districts of Timor-Leste using the WHO/HAI methodology, adapted to the Timorese context. In the public health system, mean availability of a selected list of essential medicines was 59.6% for generics and 7.3% for branded medicines; in private retail pharmacies mean availability was even lower for generics (38.0%), and comparable (9.2%) for originator brands. Prices of medicines in the private sector can go up to 186 times their international reference prices, in case of brands and to 35 times more in case of generics, respectively. In a country where still more than one third of the population lives with less than 1.25 USD/day, this translates into some pharmacological treatments being unaffordable to a large section of the population. Additionally to high prices, some other issues affecting medicines quality were also detected during the study, which further contribute to compromise the access of the Timorese population to adequate treatment.

In some countries, governments have used results from these surveys as guidance to take action and develop policies aimed at improving the availability of essential medicines at affordable prices. Accurate information is essential for identifying the sources of poor access to pharmacological treatments and for planning any potential actions to address these issues. We hope this first description of the country's situation and the results obtained in the present study will be useful and lay basis to subsequent studies and/or government interventions to better regulate the pharmaceutical sector, improving the public health system's drug supply and quality,

and encouraging the growth of the private sector as a viable, affordable and safe alternative.

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APPENDIX 1. SAMPLE SURVEYED

Table 1. Public healthcare facilities surveyed, per district (n=22).

District	Hospital (district)	Community Health Centre (sub-district)
Dili (n=5)	Guido Valadares National Hospital	Cristo-Rei (Becora) Dom Aleixo (Comoro) Na'in Feto (Formosa) [#] Vera-Cruz (Bairro Pite)
Baucau (n=5)	Baucau Hospital	Laga Vemasse Venilale Wailili
Bobonaro (n=5)	Maliana Hospital	Atabae Balibo Bobonaro Maliana
Covalima (n=3)	Suai Hospital	Suai Villa Zumalai
Oecussi (n=4)	Oecussi Hospital	Bacqui Oesilo Passabe

[#]Pilot study.

Table 2. Private retail pharmacies surveyed, per district (n=22).

District	Pharmacy
Baucau (n=3)	Bonita B Farmacia Kabitan Farmacia Samea Farmacia
Bobonaro (n=1)	Ainara Farmacia (Maliana)
Dili (n=16)	Baratu Farmacia Bidau Farmacia Bonita A Farmacia Cini Farmacia Citu A Farmacia Citu B Farmacia Centro Farmacia Delmi Farmacia Flodova Farmacia Foho Osan Mean Farmacia Forte Farmacia Istana Farmacia Moris Foun Farmacia [#] Mother of Perpetual Help Farmacia Murak Medic Farmacia Prima Medica Farmacia
Liquiçá (n=1)	Primeiro Socorro Farmacia

[#]Pilot study.

APPENDIX 2. MEDICINES SURVEYED

Table 3. List of medicines surveyed, therapeutic category and international reference price (n=48).

No.	Medicine (INN)	Strength	Pharm. form	Therapeutic category	List	IRP (MSH 2010)
1	Acetylsalicylic acid	300 mg	cap/tab	Antithrombotic agents	Supplementary	\$0.0027
2	Amitriptyline	25 mg	cap/tab	Psychotherapeutic medicines	Global	\$0.0076
3	Amoxicillin	500 mg	cap/tab	Antibacterials	Global	\$0.0290
4	Ampicilin	1 g/vial	vial	Antibacterials	Supplementary	\$0.1659
5	Artemether/lumefantrine	20+120 mg	cap/tab	Antimalarials	Supplementary	\$0.1000
6	Artesunate	50 mg	cap/tab	Antimalarials	Supplementary	\$0.1667
7	Atenolol	50 mg	cap/tab	Antihypertensives	Global	\$0.0095
8	Beclometasone (inhaler)	250 mcg/dose	dose	Antiasthmatic and drugs for COPD	Regional	\$0.0170
9	Benzathine benzylpenicillin	2.4 MIU	vial	Antibacterials	Supplementary	\$0.2457
10	Calcium gluconate (injection)	100 mg/ml	millilitre	Water, electrolyte and acid-base balance	Supplementary	\$0.0218
11	Captopril	25 mg	cap/tab	Antihypertensives	Global	\$0.0120
12	Cefixime	400 mg	cap/tab	Antibacterials	Supplementary	\$0.2960
13	Ceftriaxone	1 g/vial	vial	Antibacterials	Global	\$0.6900
14	Chloramphenicol (injection)	1 g/vial	vial	Antibacterials	Supplementary	\$0.3614
15	Chloramphenicol (tablets)	250 mg	cap/tab	Antibacterials	Supplementary	\$0.0155
16	Ciprofloxacin	500 mg	cap/tab	Antibacterials	Global	\$0.0306
17	Clotrimazole (topical cream)	1%	gram	Antifungals for topical use	Regional	\$0.0135
18	Co-trimoxazole (suspension)	8+40 mg/ml	millilitre	Antibacterials	Global	\$0.0042
19	Co-trimoxazole (tablets)	480 mg	cap/tab	Antibacterials	Supplementary	\$0.0106
20	Diazepam	5 mg	cap/tab	Psychotherapeutic medicines	Global	\$0.0061
21	Diclofenac	50 mg	cap/tab	Non-opioid analgesics and NSAIDs	Global	\$0.0043
22	Doxycycline	100 mg	cap/tab	Antibacterials	Regional	\$0.0117
23	Enalapril	5 mg	cap/tab	Antihypertensives	Supplementary	\$0.0102
24	Ethinylloestradiol/levonorgestrel	30+150 mcg	cycle	Hormonal contraceptives	Supplementary	\$0.3125
25	Ferrum sulphate	60 mg Fe eq	cap/tab	Antianemic preparations	Supplementary	\$0.0023
26	Folic acid + ferrum sulphate	400 mcg + 60 mg	cap/tab	Antianemic preparations	Supplementary	\$0.0026

27	Gentamicin (injection)	40 mg/ml	millilitre	Antibacterials	Supplementary	\$0.0446
28	Glibenclamide	5 mg	cap/tab	Antidiabetic agentes	Global	\$0.0034
29	Hydralazine (injection)	20 mg/ml	millilitre	Antihypertensives	Supplementary	\$1.8720
30	Hydrochlorothiazide	25 mg	cap/tab	Antihypertensives	Supplementary	\$0.0037
31	Ibuprofen	400 mg	cap/tab	Non-opioid analgesics and NSAIDs	Regional	\$0.0094
32	Magnesium sulphate (injection)	500 mg/ml	millilitre	Anticonvulsants	Supplementary	\$0.0956
33	Medroxyprogesterone acetate	150 mg/ml	vial	Hormonal contraceptives	Supplementary	\$1.2297
34	Metformin	500 mg	cap/tab	Antidiabetic agentes	Regional	\$0.0105
35	Metronidazole (injection)	5 mg/ml	millilitre	Antibacterials	Supplementary	\$0.0040
36	Metronidazole (tablets)	250 mg	cap/tab	Antibacterials	Supplementary	\$0.0052
37	Misoprostol	200 mcg	cap/tab	Oxytocics (MNCH)	Supplementary	\$0.4481
38	Omeprazole	20 mg	cap/tab	Antiacids and other antiulcer medicines	Global	\$0.0300
39	Oral rehydration salts (ORS)	sachet for 1 L	sachet	Water, electrolyte and acid-base balance	Supplementary	\$0.0858
40	Oxytocin	10 IU/ml	millilitre	Oxytocics (MNCH)	Supplementary	\$0.1810
41	Paracetamol (suspension)	24 mg/ml	millilitre	Non-opioid analgesics and NSAIDs	Global	\$0.0039
42	Paracetamol (tablets)	500 mg	cap/tab	Non-opioid analgesics and NSAIDs	Supplementary	\$0.0045
43	Ranitidine	150 mg	cap/tab	Antiacids and other antiulcer medicines	Regional	\$0.0200
44	Ringer's lactate	IV solution	millilitre	Water, electrolyte and acid-base balance	Supplementary	\$0.0009
45	Salbutamol (inhaler)	100 mcg/dose	dose	Antiasthmatic and drugs for COPD	Global	\$0.0085
46	Simvastatin	20 mg	cap/tab	Lipid lowering agents	Global	\$0.0587
47	Tetanus toxoid vaccine		vial	Vaccines	Supplementary	\$0.0872
48	Vitamin A	100.000 IU (30 mg)	cap/tab	Vitamins and minerals	Supplementary	\$0.0200

APPENDIX 3. DATA COLLECTION FORM

Medicine Price Data Collection Form

Use a separate form for each medicine outlet

Date : _____ Survey area number : _____

Name of town/village/district : _____

Name of medicine outlet (optional): _____

Medicine outlet unique survey ID (mandatory): _____

Distance in km from nearest town (population >50 000): _____

Type of medicine outlet :

Public sector facility (specify level of care below):

Primary care facility

Secondary care facility

Tertiary care facility

Private sector medicine outlet

Other sector medicine outlet (please specify): _____

Type of price :

Procurement price Price the patient pays

Type of data:

Sample outlet back-up outlet validation visit

Name of manager of the medicine outlet: _____

Name of person(s) who provided information on medicine prices and availability (if different from manager): _____

Name of data collectors : _____

Verification

To be completed by the area supervisor at the end of the day, once data have been verified

Signed: _____ Date: _____

Medicine Price Data Collection Form
 Lowest priced generic equivalent product: determined at facility

A	B	C	D	E	F	G	H	I	J
Generic name, dosage form, strength	Medicine Type	Brand or product name(s)	Manufacturer	Available yes/no	Pack size recommended	Pack size found	Price of pack found	Unit price (4 decimal places)	Comments
Acetylsalicylic acid 300 mg cap/tab	Originator brand	Aspirin	Bayer		10			per cap/tab	
	Lowest-priced generic				10			per cap/tab	
Amitriptyline 25 mg cap/tab	Originator brand	Tryptizol	MSD		100			per cap/tab	
	Lowest-priced generic				100			per cap/tab	
Amoxicillin 500 mg cap/tab	Originator brand	Amoxil	GSK		21			per cap/tab	
	Lowest-priced generic				21			per cap/tab	
Ampicillin injection 1 g/vial vial	Originator brand	Penbritin	GSK		1			per vial	
	Lowest-priced generic				1			per vial	
Artemether/lumefantrine 20+120 mg cap/tab	Originator brand	Coartem	Novartis		24			per cap/tab	
	Lowest-priced generic				24			per cap/tab	
Artesunate 50 mg cap/tab	Originator brand	Arsumax	Sanofi-Aventis		12			per cap/tab	
	Lowest-priced generic				12			per cap/tab	
Atenolol 50 mg cap/tab	Originator brand	Tenormin	AstraZeneca		60			per cap/tab	
	Lowest-priced generic				60			per cap/tab	
Beclomethasone inhaler 250 mcg/dose dose	Originator brand	Becotide	GSK		200			per dose	
	Lowest-priced generic				200			per dose	
Benzathine benzylpenicillin injection 2.4 MIU vial	Originator brand	Bicillin L-A	Wyeth		1			per vial	
	Lowest-priced generic				1			per vial	
Calcium gluconate injection 100 mg/ml millilitre	Originator brand				10			per millilitre	no originator brand
	Lowest-priced generic				10			per millilitre	
Captopril 25 mg cap/tab	Originator brand	Capoten	BMS		60			per cap/tab	
	Lowest-priced generic				60			per cap/tab	
Cefixime 400 mg cap/tab	Originator brand	Suprax	Lupin		1			per cap/tab	
	Lowest-priced generic				1			per cap/tab	

Generic name, dosage form, strength	Medicine Type	Brand or product name(s)	Manufacturer	Available yes/no	Pack size recommended	Pack size found	Price of pack found	Unit price (4 decimal places)	Comments
Ceftriaxone injection 1 g/vial vial	Originator brand	Rocephin	Roche		1			per vial	
	Lowest-priced generic				1			per vial	
Chloramphenicol injection 1 g/vial vial	Originator brand	Chloromycetin	Park Davis		1			per vial	
	Lowest-priced generic				1			per vial	
Chloramphenicol tablets 250 mg cap/tab	Originator brand	Chloromycetin	Park Davis		10			per cap/tab	
	Lowest-priced generic				10			per cap/tab	
Ciprofloxacin 500 mg cap/tab	Originator brand	Ciproxin	Bayer		10			per cap/tab	
	Lowest-priced generic				10			per cap/tab	
Clotrimazole topical cream 1% gram	Originator brand	Canesten	Bayer		20			per gram	
	Lowest-priced generic				20			per gram	
Co-trimoxazole suspension 8+40 mg/ml millilitre	Originator brand	Bactrim	Roche		60			per millilitre	
	Lowest-priced generic				60			per millilitre	
Co-trimoxazole tablets 480 mg cap/tab	Originator brand	Bactrim	Roche		10			per cap/tab	
	Lowest-priced generic				10			per cap/tab	
Diazepam 5 mg cap/tab	Originator brand	Valium	Roche		100			per cap/tab	
	Lowest-priced generic				100			per cap/tab	
Diclofenac 50 mg cap/tab	Originator brand	Voltaren	Novartis		100			per cap/tab	
	Lowest-priced generic				100			per cap/tab	
Doxycycline 100 mg cap/tab	Originator brand	Vibramycin	Pfizer		10			per cap/tab	
	Lowest-priced generic				10			per cap/tab	
Enalapril 5 mg cap/tab	Originator brand	Renitec	MSD		10			per cap/tab	
	Lowest-priced generic				10			per cap/tab	
Ethinylestradiol/levonorgestrel (COC) 30+150 mcg cycle	Originator brand	Mycrogynon	Bayer		1			per cycle	
	Lowest-priced generic				1			per cycle	
Ferrum sulphate 60 mg Fe eq cap/tab	Originator brand				100			per cap/tab	no originator brand
	Lowest-priced generic				100			per cap/tab	

Generic name, dosage form, strength	Medicine Type	Brand or product name(s)	Manufacturer	Available yes/no	Pack size recommended	Pack size found	Price of pack found	Unit price (4 decimal places)	Comments
Folic acid + ferrum sulphate 400 mcg + 60 mg cap/tab	Originator brand				100			per cap/tab	no originator brand
	Lowest-priced generic				100			per cap/tab	
Gentamicin injection 40 mg/ml millilitre	Originator brand	Gentalline	Schering-Plough		2			per millilitre	
	Lowest-priced generic				2			per millilitre	
Glibenclamide 5 mg cap/tab	Originator brand	Daonil	Sanofi-Aventis		60			per cap/tab	
	Lowest-priced generic				60			per cap/tab	
Hydralazine 20 mg/ml millilitre	Originator brand	Apresoline	Ciba-Geigy		1			per millilitre	
	Lowest-priced generic				1			per millilitre	
Hydrochlorothiazide 25 mg cap/tab	Originator brand	Dichlotride	MSD		100			per cap/tab	
	Lowest-priced generic				100			per cap/tab	
Ibuprofen 400 mg cap/tab	Originator brand	Brufen	Knoll		30			per cap/tab	
	Lowest-priced generic				30			per cap/tab	
Magnesium sulphate injection 500 mg/ml millilitre	Originator brand				20			per millilitre	no originator brand
	Lowest-priced generic				20			per millilitre	
Medroxyprogesterone acetate injection 150 mg/ml vial	Originator brand	Depo-Provera	Up,John		1			per vial	
	Lowest-priced generic				1			per vial	
Metformin 500 mg cap/tab	Originator brand	Glucophage	BMS		100			per cap/tab	
	Lowest-priced generic				100			per cap/tab	
Metronidazole injection 5 mg/ml millilitre	Originator brand	Flagyl	Sanofi-Aventis		100			per millilitre	
	Lowest-priced generic				100			per millilitre	
Metronidazole tablets 250 mg cap/tab	Originator brand	Flagyl	Sanofi-Aventis		10			per cap/tab	
	Lowest-priced generic				10			per cap/tab	
Misoprostol 200 mcg cap/tab	Originator brand	Cytotec	Searle		120			per cap/tab	
	Lowest-priced generic				120			per cap/tab	
Omeprazole 20 mg cap/tab	Originator brand	Losec	AstraZeneca		30			per cap/tab	
	Lowest-priced generic				30			per cap/tab	

Generic name, dosage form, strength	Medicine Type	Brand or product name(s)	Manufacturer	Available yes/no	Pack size recommended	Pack size found	Price of pack found	Unit price (4 decimal places)	Comments
Oral rehydration salts (ORS) sachet for 1 L pack	Originator brand				1			per pack	no originator brand
	Lowest-priced generic				1			per pack	
Oxytocin injection 10 IU/ml millilitre	Originator brand	Syntocinon	Novartis		1			per millilitre	
	Lowest-priced generic				1			per millilitre	
Paracetamol suspension 24 mg/ml millilitre	Originator brand	Panadol	GSK		60			per millilitre	
	Lowest-priced generic				60			per millilitre	
Paracetamol tablets 500 mg cap/tab	Originator brand	Panadol	GSK		10			per cap/tab	
	Lowest-priced generic				10			per cap/tab	
Ranitidine 150 mg cap/tab	Originator brand	Zantac	GSK		60			per cap/tab	
	Lowest-priced generic				60			per cap/tab	
Ringer's lactate IV solution millilitre	Originator brand				1000			per millilitre	no originator brand
	Lowest-priced generic				1000			per millilitre	
Salbutamol inhaler 100 mcg/dose dose	Originator brand	Ventoline	GSK		200			per dose	
	Lowest-priced generic				200			per dose	
Simvastatin 20 mg cap/tab	Originator brand	Zocor	MSD		30			per cap/tab	
	Lowest-priced generic				30			per cap/tab	
Tetanus toxoid vaccine vial	Originator brand				1			per vial	no originator brand
	Lowest-priced generic				1			per vial	
Vitamin A 100,000 IU (30 mg) cap/tab	Originator brand				100			per cap/tab	no originator brand
	Lowest-priced generic				100			per cap/tab	

Before leaving the facility :

Data collectors should check that the data collection form is legible, accurate and complete before leaving the facility and returning completed forms to the area supervisor. They should report any problems as soon as possible. They should also check to see whether at least half of the survey medicines were available, to determine whether a visit to a back-up facility is required.

APPENDIX 4. MEDICINES PER THERAPEUTIC GROUP

Table 4. Medicines, per therapeutic group and WHO/HAI list (availability analysis).

Therapeutic group	Medicine	Therapeutic group	Medicine
Oral antibiotics	Amoxicillin	Cardiovascular disease (oral therapy)	Acetylsalicylic acid
	Cefixime		Atenolol
	Chloramphenicol tablets		Captopril
	Ciprofloxacin		Enalapril
	Co-trimoxazole tablets		Hydrochlorothiazide
	Co-trimoxazole susp.		Simvastatin
	Doxycycline		
	Metronidazole tablets	Regional SEAR (WHO/HAI)	Beclometasone inhaler
MNCH	Ampicilin injection		Clotrimazole topical cream
	Artesunate		Doxycycline
	Benz. benzylpenicillin injection		Ibuprofen
	Calcium gluconate injection		Metformin
	Cefixime		Ranitidine
	Ethinylloestradiol/levonorgestrel		Glibenclamide
	Gentamicin injection	Hydralazine	
	Magnesium sulphate injection	Global (WHO/HAI)	Amitriptyline
	Medroxyprogesterone injection		Amoxicillin
	Metronidazole injection		Atenolol
	Misoprostol		Captopril
	Oral rehydration salts (ORS)		Ceftriaxone injection
	Oxytocin injection		Ciprofloxacin
Ringer's lactate	Co-trimoxazole susp.		
NSAIDs	Diclofenac	Diazepam	
	Ibuprofen	Diclofenac	
	Paracetamol susp.	Glibenclamide	
	Paracetamol tablets	Omeprazole	
	Diclofenac	Paracetamol tablets	
		Salbutamol inhaler	
		Simvastatin	

MNCH: maternal, newborn and child health; NSAIDs: non-steroid anti-inflammatory drugs

APPENDIX 5. RESULTS FROM OTHER SURVEYS

Table 5. Public procurement prices in Timor-Leste and other low- and lower-middle-income countries recently surveyed.

Country	Median Price Ratio – Public sector procurement prices (LPG)				
	Orders	Medicines	Median MPR	Min MPR	Max MPR
Timor-Leste	1	18	1.06	0.47	3.65
India (NCT state) (2011)	5	44	0.59	0.08	3.44
Indonesia (2010)	22	36	1.34	0.37	8.67
Philippines (2008)	19	39	2.93	0.87	40.79
Burkina Faso (2009)	1	44	1.13	0.27	4.90
S. Tomé and Príncipe (2008)	1	45	1.02	0.14	10.42
Nicaragua (2008)	1	36	0.95	0.15	20.52

Table 6. Affordability of treatments for some common conditions in Timor-Leste and other low- and lower-middle-income countries, recently surveyed.

Condition	Medicine	Timor-Leste	India (NCT state)	Indonesia	Burkina Faso	São Tomé and Príncipe	Haiti	Guatemala	Bolivia	Nicaragua
Asthma	Salbutamol 100mcg inhaler	2.0	–	–	1.2	–	0.8	1.3	1.6	1.8
Diabetes	Glibenclamide 5mg tab	1.6	–	0.2	0.6	6.6	0.8	–	1.1	0.8
Diabetes	Metformin 500mg tab	2.9	0.4	0.5	–	–	–	–	–	–
Hypertension	Atenolol 50mg tab	2.7	0.4	–	2.5	4.1	0.9	–	1.1	0.6
Hypertension	Captopril 50mg tab	1.8	1.1	0.3	4.5	9.9	1.5	–	–	1.5
Hypercholesterolemia	Simvastatin 20mg tab	2.3	0.6	0.6	9.7	–	2.1	–	–	5.9
Adult resp. infection	Ciprofloxacin 500mg tab	0.5	0.3	0.2	0.7	38.6	0.4	–	0.7	1.2
Adult resp. infection	Amoxicillin 500mg tab	0.5	0.8	0.3	1.0	2.3	0.5	–	0.8	0.7
Paediatric resp. infection	Co-trimoxazole 8+40mg/ml susp	0.3	0.1	0.1	0.6	1.9	0.3	0.8	0.4	0.4
Arthritis	Diclofenac 50mg tab	2.3	0.4	0.5	0.7	19.8	1.3	–	0.8	1.0
Pain/inflammation	Paracetamol 24mg/ml susp	0.2	0.1	0.1	0.2	2.0	0.2	0.5	0.4	0.2
Ulcer/dyspepsia	Omeprazol 20mg cap	2.0	0.5	0.5	1.4	41.3	0.8	–	1.6	–
Ulcer/dyspepsia	Ranitidine 150mg tab	2.3	–	0.4	–	–	–	–	–	2.7

Note: numbers in bold represent unaffordable courses of treatment (i.e. ≥ 1 day's wages of the lowest paid unskilled government worker).