Identification of factors impacting on pharmaceutical supply, and alternative approaches to human resource capacity, inventory management, quantification, and forecasting of pharmaceuticals in Timor-Leste

(A mixed methods study)

by

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SUMMARY

Timor-Leste gained independence in 2002 and faces similar challenges to other fragile states. Among the challenges is the continuous pharmaceutical stock-out in health facilities in the country. This has been the case since independence.

There are three theoretical frameworks deployed to understand the pharmaceutical stock-out phenomenon in Timor-Leste. The first is the Privett and Gonsalvez (2014) dependency model which is used to identify pharmaceutical supply chain management within the country. The second is the post-colonial and hybrid state theorem. The last is Andersen's (Andersen 1995a) behavioural model which has been used to forecast and quantify pharmaceuticals. These frameworks have guided the study, the data collection, and the analysis of the findings.
Privett and Gonsalvez's dependency model (2014) has been used to identify how the pharmaceutical supply chain process functions within the health sector in Timor-Leste. The Privett and Gonsalvez model is fundamental to uncovering the most important problems in the global pharmaceutical supply chain. It is, by itself, a theoretical framework used to collect data and present the findings logically according to well-defined levels of pharmaceutical supply chain management. The top 10 global pharmaceutical issues identified by Privett and Gonsalvez guided the development of the interviews and the document reviews during data collection and in the presentation of the findings.

The findings from the Privett and Gonsalvez model (2014) were then combined with the findings from 10 previous studies specifically conducted in the country that examined the problems with pharmaceutical stock-out in Timor-Leste. These reports identified major issues such as lack of leadership, policies and guidelines, poor human resource management, infrastructure, inventory management, and quantification; and faulty procurement strategies in the government sector. A lack of data to inform quantification and forecasting was also found to be the case in two of the development partner organisations providing healthcare in the country.

As a post-conflict country and fragile state, Timor-Leste requires slow but steady development of its systems, infrastructure, and human resource development. An innovative approach to pharmaceutical planning needs to be introduced. Andersen's behavioural model for healthcare utilisation was applied in the study specifically to the quantification and forecasting of pharmaceuticals. This was seen as a suitable approach, because the model has extensive predictors that can be applied to quantifying and forecasting of pharmaceutical needs. Andersen's model is appropriate for this purpose because it deploys extensive predictor variables that enable accurate decisions on pharmaceutical quantification. The predictors applied to the quantification approach are population predictors, socio-economic factors, the health system, education, literacy and employment rates, attitudes towards health services, and health outcomes. The outcome variables are made up of pharmaceutical consumption and expenditures during 2016. Andersen's behavioural model of healthcare utilisation guided the

cross-sectional data collection, statistical testing, and analysis of the results of the forecasting and quantification model generated for the government and development partner organisations.

The results of the statistical analysis of the quantification and forecasting provided a conclusion to the thesis by testing which forecasting model was more suitable for Timor-Leste. The recommended forecasting model would be based on the acceptance of any of the hypotheses being tested. Whether the forecasting should be based on total primary healthcare need/expenditure per health facility, per-capita, or per out-patient department visits is to be determined later. The analysis encompassed univariate analysis, T-test and multivariate analysis, and the Shapiro-Wilk's test for dichotomic variables.

Optimal statistical modelling for prediction was performed using a stepwise regression analysis to identify the significant predictors, followed by a nested stepwise regression analysis to test the changes in coefficient values and the percentage of variability of the explanatory variables to the predicted variables. Statistical tests on both linear-linear and log-linear models were determined by the best fit of the model. Overall, eight prediction models were produced. The explanatory power of the models ranged from 55% to 94%. A final prediction model with 89% explanatory power is proposed for future pharmaceutical planning.

DECLARATION

"I certify that this thesis does not incorporate without acknowledgement any material previously submitted for a degree or diploma in any university; and to the best of my knowledge and belief it does not contain any material previously published or written by another person except where due reference is made in the text"

Signed:

Date 22 June 2020

PUBLICATIONS FROM THIS THESIS

An abstract containing the qualitative section of the thesis was published in the International Journal of Health and Medical Engineering Vol. 13, No. 3, in March 2019 by the World Academy of Science, Engineering, and Technology. A presentation of the abstract was delivered at the International Seminar on Public Health and Medical Technology in Paris, France, on 28-29 March 2019.

Articles under preparation:

- Colonial legacies of human resources in Timor-Leste: A review of two colonial eras on the capacity of human resources in pharmaceutical supply chain management in the Timor-Leste health sector.
- Factors impacting on pharmaceutical stock-outs in Timor-Leste: a sector-wide qualitative study of the central services of the Ministry of Health, the Municipal Health Services, and health facilities in Aileu, Dili, Ermera, and Liquiça.
- Optimal statistical modelling for pharmaceutical quantification and forecasting in Timor-Leste: a post-conflict nation.

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ABBREVIATIONS

ACCESSWater	Access to clean and safe water
ACG	Adjusted Clinical Groups
APICS	American Production and Inventory Control Society
ASHP	American Society of Health-System Pharmacists
ANOVA	Analysis of Variance
ANC-4	Antenatal Care-4
ACT	Artemisinin-based Combine Therapy
APODETI	Associação Popular Democrática de Timórense (Timorese Popular Democratic Association)
ASDT	Associação Sosiál-Democrata Timórense (Social Association of Timorese Democratic)
AusAID	Australian Aid for International Development
RRAvail	Availability of Regional Referral Hospital
AMC	Average monthly consumption, adjusted for stock-outs (adjusted average monthly consumption)
BIOSS	Biological Signalling Studies
SMS	Central Medical Store
CEOs	Chief Executive Officers
CCT	Cliníca Café Timor
CRG	Clinical Risk Groups
CPFR	Collaborative Planning, Forecasting, and Replenishment
CoC	Combined Oral Contraceptive pill
CHCs	CHCs
CHC	Community Health Centre
CNRT	Concelho Nacional da Reconstrução de Timor-Leste (Nacional Council for the Reconstruction of Timor-Leste)
CC	Coordination Council
DELIVERYHlthProf	Delivery Assisted by Health Professionals
DV	Dependent Variable
(DPT3)	Diphtheria, Pertussis, Tetanus - 3
DC	Directive Councils
DGCS	Director General for Corporate Services
DGHSD	Director General of Health Service Delivery
DRP	Distribution Requirement Planning
DHC	District Health Councils
DHS	District Health Service
DMOs	District Malaria Officers
PhD	Doctor of Philosophy
EIS	Elderly in Institutions Survey
EDI	Electronic Data Interchange

ERP	Enterprise Resource Planning
EDL	Essential Drug List
EML	Essential Medicine List
EMLTL	Essential Medicine List for Timor-Leste
M_{OS}	Estimated number of months an item was out of stock during the review period
EPI	Expanded Program on Immunisation
FUS	Facilities Use Survey
FreeBalance	Finance Management and Accounting software
FEFO	First-Expired-First-Out
FIFO	First-In-First-Out
FDA	Food and Drug Administration
FALINTIL	Forças Armadas da Libertação Nacional de Timor-Leste, The Armed Forces for the National Liberation of East Timor
FRELIMO	Frente de Libertação de Moçambique (Liberation Front of Moçambique)
FRETILIN	Frente Revolucionario de Timor-Leste Independente (Revolution Front of Independent East Timor)
GPs	General Practitioners
GF	Global Fund
HCE	Health Care Expenditure
HFNGO	Health Facility operated by NGO
HPs	Health Posts
HAART	Highly Active Antiretroviral Therapy
HRD	Human Resource Development
HR	Human Resources
IUD	Implant and Intra-Uterine-Device
IV	Independent Variable
IMR	Infant Mortality Rates
IT	Information Technology
INS	Instituto Nacional de Saúde, National Institute of Health
ICD-9-CM	International Classification of Diseases - Ninth Revision - Clinical Modification
JSO	Judicial Service Office
JIT	Just-in-time
LABOURABSRATE	Labour Absorption Rates
LILO	Last-In-First-Out
LATCoverage	Latrine Coverage
LT	Lead Time
LnPHCPEFacility	Log-Liner of Pharmaceutical Expenditure for Primary Health Care per health facility
LnPHCPEVisit	Log-Liner of Pharmaceutical Expenditure for Primary Health Care per visit to OPD

LnPHCPECapita	Log-Liner of Primary Health Care Pharmaceutical Expenditure per capita
LnPHCPETotal	Log-Liner of Total Pharmaceutical Expenditure of Primary Health Care
LMIS	Logistic Management Information System
mSupply	Logistic Management Information system software for pharmaceuticals
MRP	Material Requirement Planning
MMR	Maternal Mortality Rates
MoH	Ministry of Health
MCH	Mother and Child Health
MHS	Municipal Health Services
NHC	National Health Council
SNIBS	National Water and Sanitation Information System
NGOs	Non-Government Organisations
D_{OS}	Number of days an item was out of stock during the review period
OHIA	Office of Health Inspectorate and Auditing
OQC	Office of Quality Control
OPV	Oral Polio Vaccine
OECD	Organisation for Economic Cooperation and Development
OPD	Outpatient Department
OPDCapita	Outpatient Department Visit per Capita
PercFem	Percentage of Female Population
PHCPECapita	Pharmaceutical expenditure for primary healthcare per capita
PHCPEFacility	Pharmaceutical expenditure for primary healthcare per health facility
PHCPEVisit+	Pharmaceutical expenditure for primary healthcare per visit to OPD-Plus
PHCPEVisit	Pharmaceutical expenditure for primary healthcare per visit to outpatient department
PHC	Primary Health Care
P-P Plot	Probability–probability plot
PP	Procurement period
POP	Progesterone Only Pill
PMU	Project Management Unit
S_S	Quantity needed for safety stock = buffer stock
Q_O	Quantity to order in basic units, before adjustment for losses or program change
R^2	R-square
RAEOA	Região Autonómo Especial Oecusse-Ambeno, Special Autonomous Region of Oecusse-Ambeno
R_M	Reviewed period in months (number of months of data reviewed for forecasting)
RuralPov	Rural Poverty

SAMES	Serviço Autónomo Medicamementos e Equipamentos de Saúde (An Autonomous Agency for Pharmaceuticals and Health Equipment) – Central Medical Store
SPOs	Standard Operating Procedures
STG)	Standard Treatment Guidelines
SPSS	Statistical Package for Social Sciences
S_I	Stock now in inventory, in basic units equal to stock on hand
S_O	Stock now on order, in basic units = stock on order/pipeline stock
TA	Technical Assistance
TOR	Terms of Reference
CSCMP	The Council of Supply Chain Management Professionals
NEML	The National Essential Medicine List
UNAMET	The United Nations Mission in East Timor
WB	The World Bank
MunCHC-2	Total CHC level-2
MunCHC-1	Total CHC level-1
C_T	Total consumption during review period, in basic units
HFGovTot	Total Government Health Facilities
HospTot	Total Hospitals
LITERATETotal	Total Literacy
MunHp	Total Municipal Health Posts
MunTop	Total Municipal Population
PHCPETotal	Total pharmaceutical expenditure for primary healthcare
UGX	Ugandan Shillings
UDT	União Democrática Timorense (Timorese Democratic Union)
UK	United Kingdom
UNFPA	United Nations Fund for Population Agency
UNICEF	United Nations International Children and Education Fund
UNTAET	United Nations Transitional Administration in East Timor
USD	United States Dollar
USA	United States of America
UrbanStat	Urbanisation status
VIF	Variable Inflation Factor
VMI	Vendor Managed Inventory
WIP	Work-in-process
WHO	World Health Organisation

DEFINITIONS

The Council of Supply Chain Management Professionals (CSCMP) defined supply chain management as:

> "Linkages that encompass the planning of all activities involved in sourcing and procurement, conversion, and all logistic management activities. It includes coordination and collaboration with channel partners, which can be suppliers, intermediaries, third party service providers, and customers. In brief, it can be said that supply chain management integrates supply and demand management within and across organizations" (Gibson, BJ, Mentzer & Cook 2005; Knemeyer 2006).

According to the American Production and Inventory Control Society (APICS), inventory management is a "branch of business management concerned with planning and controlling of inventories; and aims at maintaining a stock level of products or items" (Toomey 2000, p. 1).

Perceived health status refers to the "percentage of the population aged 15 years or more who report their health to be good or bad"(OECD 2008, p. 401).
Forecasting is a management tool that is used to estimate future uncertainty by using management experience and knowledge. It presents the analysis of predicted future trends (Dictionary 2016).

Demand is defined economically as "the aggregate quantity of a product or service estimated to be bought at a particular price. Or the total amount of funds which individuals or organizations want to commit to spending on goods or services over a specific period of time" (Dictionary 2016).

The terms 'stock-out' and 'shortages of pharmaceuticals' are used interchangeably in the industry. The World Health Organization has defined pharmaceutical stock-out as the "complete absence of a required drug at a storage point or delivery point for at least one day. Stock-outs are defined as absence of the medicines at health facility level. For those items out of stock, the duration of the stock-out in days was determined by consulting the stock card or simply the absence of the medicines at health facility level" (World Health Organization 2016a, p. 10). This definition is in line with that provided in the Business Dictionary which states that stock-out is "a situation in which the demand or requirement for an item cannot be fulfilled from the current inventory" (Business Dictionary 2019).

Health post in Timor-Leste context is a heath facility located at village level serving as the first line service provider and it is staffed with a general practitioner or a nurse, providing basic medical services and health promotion programs to communities in a village or a cluster of villages. In other health systems, for example in Indonesia it is known as village health post with the same structure and services under supervision of a community health centre (Mahendradhata et al. 2017).

CHAPTER 1. INTRODUCTION

This chapter briefly introduces the background to the research questions, the research problem, and the justification for the study, including an overview of previous reports investigating the issue, the methodology used in the study, an outline of the thesis, and the limitations and key assumptions made and their justifications.

This is a study of the problems encountered in the supply chain management of pharmaceuticals in Timor-Leste, with a specific focus on inventory and demand information management, which are the basis of quantification and forecasting. Inventory and demand information management are key parts of any supply chain management system.

The main research question for this study is: 'what factors contribute to the continuous pharmaceutical stock-out in health facilities and what alternative approaches could be applied to remedy the situation?' This question is further elaborated in the objectives which are aligned with the various stages of the study. The first stage seeks to describe and identify gaps in the existing supply chain processes, specifically:

a) How is inventory management and demand information managed?
b) How are quantification and forecasting of medicines managed?
c) What are the predictors or determinants that influence pharmaceutical forecasting?
d) Does the current forecasting model meet pharmaceutical needs given the frequent stock-outs?

The objectives of the second stage of the study are:

a) To identify the current methods used by government and the three specified development partners to quantify pharmaceuticals.
b) To examine the social, cultural, political, and managerial/educational factors that contribute to the failure of current quantification processes that lead to on-going stock-out of pharmaceuticals.
c) To apply Andersen's explanatory model for pharmaceutical expenditure for 2 groups (Antibiotics and Antipyretics) of drugs used by the three specified non-government agencies (the Global Fund, the UNFPA [United Nations Fund for Population Agency], and CCT [Cliníca Café Timor]), in order to see how they correlate with the present model used by the government for quantification and forecasting needs.
d) To replicate objective c) using the government model.
e) To draw a conclusion about the strength of Andersen's model for pharmaceutical quantification/forecasting by comparing the estimates arrived at in objectives c) and d) and the utility of the model for the Timor-Leste context.

1.1. Background to the Research

Pharmaceuticals are an essential component of any health system. Lack of medicines can have serious implications for patients, and also for overall population health. Despite this, millions of people around the world do not have access to pharmaceuticals. Pharmaceutical supply chain management in Timor-Leste is in its infancy, which has resulted in a wide range of problems. Since the restoration of the country's independence in 2002, pharmaceutical supply issues, such as stock-out of essential medicines, have been frequently experienced by health facilities every year. The country uses a proxy model (Management Sciences for Health 2012) to quantify and forecast the pharmaceuticals that will be needed across the nation. This is made up of the previous year's consumption and distribution data.
However, frequent stock-outs raise many questions about the application of the current model used to quantify pharmaceuticals, one of which is: "does the current model for quantification of pharmaceuticals used in Timor-Leste correctly forecast the required amount of medicines for the country, and what other factors should be taken into account?" While there are a number of factors influencing the performance of pharmaceutical management, three core examples are coordination, demand information, and inventory management.

Management of the pharmaceutical supply chain is an essential part of a healthcare service. A poor performing pharmaceutical supply chain means that patients' access to medicines is jeopardised, which results in the population having less confidence in the healthcare service. Lack of access to much needed pharmaceuticals is mainly related to accessibility issues (the ability to reach a health facility), availability (actual organisation and service provision), acceptability (the competence of the provider), and affordability (Anderson, S et al. 2004; Wiknera & Johansson 2015). All these problems are due to the poor organisation of the healthcare services, particularly in relation to supply chain management.

This study is mainly related to the accessibility and availability of pharmaceuticals. There are very limited studies on the supply chain management of pharmaceuticals in Timor-Leste. Issues and problems in supply chain management of pharmaceuticals have been addressed from several perspectives; however, most of the studies have been undertaken in developed and developing countries (Berling & Marklund 2013; Lemos et al. 2012; Mazibuko et al. 2014; Privett & Gonsalvez 2014; Quadri et al. 2015; Skipper, JB et al. 2008; Weraikat, Zanjani & Lehoux 2016; Wiknera & Johansson 2015). No studies have been done in newly-independent countries that are directly comparable to Timor-Leste Most supply chain management issues are associated with the capacity, or the lack thereof, of healthcare providers. Studies on the challenges facing pharmaceutical management have focused on coordination (Berling & Marklund 2013; Privett & Gonsalvez 2014; Skipper, JB et al. 2008; Weraikat, Zanjani & Lehoux 2016; Wiknera & Johansson 2015), the absence of demand information (Chen, Chen & Chen 2006; Kjos et al. 2016; Morgan, L & Eichler 2011; Privett & Gonsalvez 2014; Ryu, Tsukishima & Onari 2009; Shang, Zhou & Houtum 2010; USAID | DELIVER PROJECT Task Order 4 2014; Zhang, C & Zhang 2007), the lack of human resources in pharmaceutical management (Cometto et al. 2014; Lubinga et al. 2014; Matowe et al. 2008; Mazibuko et al. 2014; Privett & Gonsalvez 2014; Sankaranarayanan et al. 2014;

Suparan et al. 2014), and the avoidance of shortages (Fox & Tyler 2003; Lemos et al. 2012; Morrissey 2012; Privett & Gonsalvez 2014; Quadri et al. 2015; US FDA 2014).

Supply chain management, as a discipline and a science, emerged at the beginning of the 1980s. The original aim was to develop models and systems to overcome barriers to the control of the flow of goods between companies, and to integrate the management of the entire supply chain between suppliers, manufacturers, distributors, and consumers in the context of increasing globalisation (Alfalla-Luque & Medina-López 2009). There are many definitions of supply chain management according to the strategies, activities, and processes in place (Gibson, BJ, Mentzer & Cook 2005, p. 17). The Council of Supply Chain Management Professionals (CSCMP) defined supply chain management as:

> *"... linkages that encompass the planning of all activities involved in sourcing and procurement, conversion, and all logistic management activities. It includes coordination and collaboration with channel partners, which can be suppliers, intermediaries, third party service providers, and customers. In brief, it can be said that supply chain management integrates supply and demand management within and across organizations" (Gibson, BJ, Mentzer & Cook 2005; Knemeyer 2006).*

Important prerequisite components for quality supply chain services include the availability of trained staff, access to pharmaceuticals, adequate funding, appropriate policies and guidelines, and sufficient equipment and infrastructure. Hence, the stock-out of pharmaceuticals, particularly essential medicines as defined by the World Health Organization (World Health Organization 2013, pp. 9-20) within a healthcare system, is counterproductive to health service provision.

Stock-out of pharmaceuticals, particularly essential medicines in health facilities, has a negative impact on the quality of services and the safety of patients. For example, one factor found to be associated with the poor treatment of tuberculosis cases is the stock-out of pharmaceuticals (World Health Organization 2014b, p. 64). Despite the role of pharmaceuticals in the health system, stock-out of pharmaceuticals is a global issue and has a negative impact on healthcare services in many low- and middle-income countries. A report from the United Nations Millennium Development Gap Task Force reported that over the period 2007-2011, the median availability of essential pharmaceuticals that must be available in public health sector facilities in low- and middle-income countries was 51% (United Nations 2012). This appears to be in line with a longitudinal study conducted from 2011-2013 in Mozambique which concluded that the mean average stock-out of essential pharmaceuticals at district health facilities was 44% and this was strongly associated with the number of healthcare staff working in the healthcare facilities (Wagenaar et al. 2014, p. 791).

Timor-Leste has experienced various rates of stock-out since it gained independence in 2002. A number of reports and studies have been conducted in an attempt to understand the underlying problems that cause stock-outs. These reports have suggested that the main causes of stock-out are associated with the poor performance of the supply chain management system (Holloway 2016; Ministry of Health Timor-Leste 2011; The World Bank 2015 ; Yebio 2015). The factors that have contributed to the poor performance of the supply chain are lack of coordination, poor warehouse and inventory management, a lack of policy development,

erratic prescribing patterns, lack of human resources, and the overall performance of supply chain management in the health system (Ministry of Health Timor-Leste 2011). The government has responded to a number of recommendations made in these reports. Examples of these responses can be seen in policy development, guidelines and technical support, and warehouse management (The World Bank 2015); however, problems still remain.

1.2. Research Problem Propositions/Research Issues and Contributions

There have been 10 major investigations into the problem of stock-out in Timor-Leste. In 2007, the government identified problems with pharmaceutical supply chain management within its national healthcare sector strategic plan. As a consequence, various international agencies, such as the World Bank, the UNFPA, and a range of consultants were funded to investigate the issues and to develop recommendations for improvement. These consultants investigated the problem from various perspectives. A brief outline of these studies is described below.

The first report by Norris et al. in 2007 was a descriptive study that focused on the purchase, distribution, and supply of medicines, and the identification of associated challenges. The authors found a lack of trained staff, inadequate facilities, a lack of basic equipment for pharmacies, and an over-reliance on international technical support, but no recommendations were provided. However, Norris et al. noted that there has been action taken to improve the situation; for example, the establishment of a training course for pharmacy technicians (Norris et al. 2007). Lack of human resources, in terms of the number of pharmacists and the quality of their pre-service training, was also identified in another study on management and leadership skills in the healthcare sector in Timor-Leste. Norris et al. also showed that the issue of management and leadership among managers also influences the performance of health services. This was confirmed by another study completed four years later (Asante, Hall & Roberts 2011).

Following the first study by Norris et al. in 2007, the World Bank conducted a case study to analyse the challenges of establishing a pharmaceutical and medical supply system in Timor-Leste as a post-conflict country through an analysis drawing on documents, observations, and interviews. The case study examined the overall situation of the pharmaceutical supply chain, particularly the legal framework, human resources, procurement, warehouse management, prescribing patterns of doctors, and the financing of the various components of the supply system. The report found that incorrect forecasting had resulted in an over-stock of medicines costing around USD 2.6 million (Huff-Rousselle 2009, pp. 8-23), although there was little in the report on how the forecasting was carried out.
The third study (Pinto, 2012) used a quantitative approach to study 5 hospitals and 17 community health centres, focusing on access to essential medicines in Timor-Leste with attention given to availability, price, and affordability. The findings revealed that stock-out of pharmaceuticals in public health facilities in remote areas was 47.5%, meaning that less than half of the demand for essential pharmaceuticals required by the population were not met. Although pharmaceuticals are dispensed free of charge at public health facilities, the

cost in private chemists is 40 times higher than international prices. Pinto also identified a lack of human resources in terms of staffing numbers, management skills, and standard procedures. He found that staff failed to adhere to standard treatment guidelines due to lack of awareness of the existence of such guidelines. Large numbers of expired pharmaceuticals were also found in healthcare facilities. It was also found that various organisations, i.e. SAMES, the Ministry of Health, and the District Health Services, had poor coordination in the delivery of medicines. Pinto recommended the dissemination of policy/guideline documents to promote the rational use of medicines, a drug policy implementation plan, and the development and reinforcement of legal policies (Pinto 2012).

The World Health Organization (WHO) conducted an assessment in 2012 aimed at analysing the situation of pharmaceutical management in the health sector. Areas of assessment were medication supplies; the selection, consumption, and usage of medicines; medication regulation; and relevant policies. The report concluded that poor inventory control was a major issue, and that many aspects of medication policy had not been implemented, along with a lack of adherence to Standard Treatment Guidelines (STG) due to poor dissemination of information. The report also noted the limited number of staff at the Department of Pharmacy to manage the pharmaceutical supply chain, and the low number of pharmacists working in the health system. There was also no budget allocation for each individual health facility. The distribution of pharmaceuticals was not undertaken according to facility requests and available budgets, with health facilities often receiving less than requested. The quantification of medicines was based on the previous year's distribution data, rather than on the population or other factors. There was also no central allocation of budgets based on population or case-mix. The WHO recommended improvements in inventory management by standardising stock control cards, quantification, and training in inventory management. In addition, in order to ensure consistency in the procurement of the Essential Medicine List (EML), the WHO suggested adherence to the Standard Treatment Guidelines (STG), the promotion of the rational use of medicines, and the development of Standard Operating Procedures (SOP). The WHO also suggested the establishment of national statutory bodies to monitor compliance with policies and guidelines, as well as the elevation of the Department of Pharmacy to directorate level in the Ministry of Health (MoH) (Holloway 2012).

The same assessment was conducted four years later, in 2015, with the same goal (Holloway 2016). Holloway found that there were changes in the procurement system, with the central medical store no longer involved in the quantification and procurement process[1]. There was a slight improvement in the number of staff (from 6 to 10) in the Department of Pharmacy at the Ministry of Health. However, no progress was evident in record-keeping and inventory management which both remained poor. Stock-out of pharmaceuticals remained a common problem. Stock-out of essential medicines at facility level was 33.3%. The National Essential Medicine List (NEML) had been updated; however, dissemination of the list to health professionals had yet to be done. Some harmful prescribing patterns, such as the prescription

[1] However, subsequent findings suggested that the procurement function was returned to the Central Medical Store in 2016 (AD-040 2017; AG-070 2017; AH-080 2017).

of steroids for coughs and the common cold, were found. Coordination, monitoring, and supervision remained weak due to inadequate staff numbers and training. The Ministry of Health still used the proxy quantification method, based on the previous year's distribution patterns and consumption data. As well, budget allocations for pharmaceuticals were not linked to need. Finally, there had been no in-service training on the NEML, in the use of the logistic information system, or in inventory management (Holloway 2016).

An additional study (Chindove et al., 2012) that did not focused on the overall problems in the system, but rather on prescription patterns for three common diseases (acute respiratory infections, diarrhoea, and malaria) at three CHCs in three districts was conducted in Timor-Leste in 2012. Chindove, Ximenes and Martins found that there was low usage of antibiotics via injection; however, the use of antibiotics for acute respiratory diseases was high. Vitamins, analgesics, and antihistamines were commonly prescribed medicines in the health facilities (Chindove, Ximenes & Martins 2012).

A further study, conducted in 2015 by Higuchi et al, was a mixed method, cross-sectional study that focused on adherence to standard treatment guidelines by nurses for three target diseases (respiratory tract infection, malaria, and diarrhoea) at 44 Community Health Centres. The findings were similar to the previous study on prescribing patterns conducted by Chindove et al. (2012). The study found little over-prescribing and low use of penicillin injections, but vitamins were commonly prescribed. The authors also reported that clinical nurse training had a strong association with low usage of antibiotics and penicillin injections, and greater adherence to standard treatment guidelines compared to those without training (Higuchi et al. 2015).

An analysis of the security of reproductive health commodities, carried out in April 2010 by a UNFPA-funded consultant, found that document reviews and recommendations from a national workshop confirmed that there had been stock-out of reproductive health items, particularly the Progesterone Only Pill (POP), implants, and condoms, between 2006 and 2009. Reporting by users on the distribution of reproductive health items had not been done well due to a lack of understanding of the reporting forms and the technical terms involved. As well, no regular performance monitoring had been undertaken with the District Health Services. Overall, it was concluded that forecasting, procurement, and supply chain management are complex processes for a post-conflict country with limited capacity. The UNFPA offered support to strengthen the Ministry of Health (Belton 2010).

In line with the World Bank assessment of establishing pharmaceutical management in Timor-Leste, two Technical Assistants (TA) were provided to support the Ministry of Health between 2013 and 2015 (The World Bank 2015). The latest technical assistance reports identified that most of the supply chain issues ranged from coordination, utilisation of warehouse management software and associated challenges, logistics management information systems, and standard treatment guidelines. Some noted improvements were in the use of warehouse management software and the rolling out of a paper-based logistics management information system to DHS (Sustainable Solutions 2015; Yebio 2015). There

have been calls from the authors of these reports to conduct studies in the area of pharmaceutical supply chain management in Timor-Leste (Pinto 2012; Yebio 2015). These technical reports were produced with narrowly-defined terms of reference and were not necessarily broadly based in the analysis they provided.

In summary, these reports identified 10 main pharmaceutical management issues found in Timor-Leste. The issues ranged from a lack of coordination, poor inventory management, a lack of demand information, a lack of human resources, poor quality order management, a lack of shortage avoidance, poor monitoring of expiration, poor warehouse temperature control management, poor shipment visibility, and other associated issues (Democratic Republic of Timor-Leste 2011; Holloway 2012, 2016; Norris et al. 2007; Privett & Gonsalvez 2014; Yebio 2015). Each of these functions is important in supply chain management and needs to be understood through further research; however, it is impossible to remedy all of these issues at the same time.

In addition to the findings from these reports, issues such as poor inventory management, poor record keeping, frequent stock-out, and opaque quantification approaches that do not meet demand need to be considered. Therefore, this study will focus on inventory and demand information, which form the basis for quantifying and forecasting the need for pharmaceuticals.

The study will be limited to inventory management, demand information, and quantification of pharmaceuticals for primary healthcare at the municipal health service level.

1.3. Justification for the Research

As is briefly described in Section 1.2, there have been many studies on supply chain management of pharmaceuticals in both developed and developing countries (Federal Ministry of Health Nigeria 2010; Kjos et al. 2016; Management Sciences for Health 2012; Ministry of Health and Social WellfareTanzania 2008). Studies on the determinants of pharmaceutical quantification and forecasting have mostly focused on clinical settings (Fernández Liz 2008; García-Goñi & Ibern 2008; Hanley, Morgan & Reid 2010; Lenihan et al. 2016; Morgan, Cunningham & Hanley 2010; Mueller, Schur & Connell 1997; Santamargarita-Pérez et al. 2013), with few studies undertaken in post-conflict countries.
There have also been several studies conducted in Timor-Leste over the last 10 years in an attempt to understand the main problems underlying medicine stock-out. These studies have made several recommendations to the government on how to improve the supply chain, but none have directly addressed the issue of the quantification and forecasting of pharmaceuticals. Little is known about the current quantification and forecasting model in use, or the determinants that inform the model. What is also not known is whether there are more appropriate models for the Timor-Leste context.

One widely used model for predicting the determinants of expenditure for clinical care is Andersen's behavioural model for healthcare utilisation. While this model has not been

widely applied to forecasting in post-conflict countries, one study successfully applied the model in Uganda to predict pharmaceutical needs (Mujasi & Puig-Junoy 2015). Given this, it is proposed that this study will explore how the factors identified by using Andersen's behavioural model might better predict the quantification and forecasting of pharmaceuticals in Timor-Leste, and thereby, reduce the incidence of stock-out.

1.4. Methodology

This is a sequential mixed methods study in two stages where the qualitative data analysis led to the quantitative data collection and analysis where "one data set illuminates the finding from the first data set" (Grbich 2017, p.365) in two stages. Stage one is a qualitative study using interviews and document analysis to map the major problems identified by personnel along the supply chain, from senior bureaucrats to end users, doctors, and nurses. The analysis follows a critical interpretive approach to identify the major areas of stock-out. Stage two employs several variables identified by using Andersen's model to test whether this would be a more robust approach to pharmaceutical forecasting. This is done through a hierarchical regression analysis. The final outcome is used as an optional model for developing forecasting of pharmaceutical expenditures.

Qualitative Methods for Stage One

Qualitative interviews were conducted with key personnel along the pharmaceutical supply chain in order to understand the current model and how it operates in Timor-Leste. This included an investigation of the issues identified in the 10 major supply chain management studies conducted by aid agencies over the previous decade in order to identify gaps in these reports, their currency, and whether the Timor-Leste government had implemented any of the recommendations that affected supply chain management issues contributing to stock-out. Additional reports and policy documents; for example, LIMS reports and inventory data, were also collected and examined to understand the current model of quantification and forecasting.

Analysis of the qualitative data firstly describes the current supply chain management with a focus on inventory management, demand information, and quantification. Secondly, the analysis identified the factors used to quantify and forecast pharmaceuticals and pinpointed the pre-disposing and enabling factors identified through Andersen's behavioural model for healthcare utilisation that had not been taken into account in past quantification and forecasting of pharmaceuticals. For example, Andersen's model identifies population, human resources, policies, and guidelines and regulations. This enabled the identification of other factors that might contribute to more accurate demand information and quantification.

Quantitative Methods for Stage Two

Qualitative and quantitative data were collected during the second data collection stage. Interviews were conducted and documents related to supply chain management were gathered

from three non-government organisations. Data for stage two were obtained through cross-sectional data of pharmaceutical consumption provided by government services and three non-government organisations in the country for the 2016 period. Government pharmaceutical consumption was collected from 13 municipal health services. Additionally, data were retrieved from monthly and quarterly pharmaceutical consumption reports on 260 pharmaceutical items consumed during the period. The pharmaceutical items selected for analysis were based on two of the top 10 pharmaceutical items consumed during the period, Paracetamol tablets 500mg and Amoxicillin caplets 500mg. This selection only applied to the government municipal health services and the non-government organisation known as Cliníca Café Timor (CCT). In order to calculate the final estimated data for pharmaceutical consumption and expenditure, the unit cost of all pharmaceuticals purchased during the period was collected from the procurement division of the central medical store. The unit cost was then multiplied by the total pharmaceutical consumption for each pharmaceutical item. The final figure was then used as the outcome or dependent variable. The same information was also collected from the three non-government organisations. Predictor or independent variable data were collected from the Timor-Leste Statistics Office, the Health Management Information System of the Ministry of Health, the National Water and Sanitation Office, and the State Secretary for Training and Employment Timor-Leste.

Outcome variable data for the other two non-government organisations was collected from the Global Fund and the UNFPA. Pharmaceutical consumption of anti-malaria pharmaceuticals for the malaria program, which is administered by the Global Fund, only focused on Arthemether-Lumefantrine 20mg+120mg for the period of 2016. Data for the third non-government organisation, which manages a reproductive health program and pharmaceuticals was also collected, which related to family planning commodities, namely the progesterone-only pill (POP), the Depo-Provera hormonal injection, subdermal hormonal implants, and intrauterine-devices (IUDs).

The analysis of the data from pharmaceutical quantification and forecasting for the government using a multiple regression analysis was applied using SPSS-version 25. The analysis was undertaken through a univariate analysis, a T-test and multivariate analysis, and Shapiro-Wilk's test for dichotomic variables. Optimal statistical modelling for prediction was also performed. This was initiated through a stepwise regression analysis to identify the significant predictors, followed by a nested stepwise regression analysis to test the change in coefficient values and the percentage of variability of the explanatory variables to the predicted variables. Statistical tests on both linear-linear and log-linear models were determined by the best fit of the model. Overall, eight prediction models were produced. The explanatory power of the models ranged from 55% to 94%. A final prediction model with 89% explanatory power is proposed for future pharmaceutical quantification.

1.5. Outline of the thesis

The thesis is divided into 10 chapters. Chapter 1 is the introduction, providing an overview of which studies have already been undertaken in Timor-Leste as well as providing the thesis question and an exploration of various research approaches.

Chapter 2 provides the overall context of Timor-Leste as a small country that has experienced two waves of colonisation; the first from the 16th century to the 20th century under Portugal, and the second in the last half of the 20th century under Indonesia. The chapter describes:

- Colonisation under Portugal and Indonesia;
- A brief history of the post-conflict development of the country, including a description of the current healthcare system; and
- A discussion of the cultural factors that have influenced healthcare utilisation, including the relevance of post-colonial/development theory to the Timorese context.

Chapter 3 deals with the identification of pharmaceutical supply chain issues. This includes an explanation of the current pharmaceutical supply chain management problems in Timor-Leste using Privett and Gonsalvez's model to identify issues from 10 studies previously conducted in Timor-Leste as key data. These studies and Privett and Gonsalvez's dependence model are used to identify specific gaps in inventory management, demand information and quantification, and forecasting of pharmaceuticals. Additionally, other factors that influence pharmaceutical supply chain management are described in addition to a discussion of quantification and forecasting.

Chapter 4 outlines the theoretical models of quantification, including Andersen's model and a number of others. The chapter explains various models that have been used to quantify and forecast pharmaceuticals, with a focus on Andersen's behavioural model for healthcare utilisation. Included is a description of the quantification and forecasting models. The factors to be considered are the variables, the strengths and weaknesses of each model, and the use of quantification and forecasting models in developing/post-colonial contexts.

Chapter 5 outlines the methodology, and provides a detailed explanation of the data collection methods and how the data were analysed. The limitations of the research and the research setting are also discussed.

Chapter 6 presents perceptions of government officers at all management levels on pharmaceutical stock-outs, followed by a thematic and critical analysis of the interview data.

Chapter 7 presents the findings from document reviews of current pharmaceutical supply chain management, with a focus on inventory management, demand information, and quantification at government health facilities.

Chapter 8 provides a critical analysis of current supply chain management, with a focus on inventory management, demand information, and quantification for selected non-government organisations, based on Privett and Gonsalvez's dependency model.

Chapter 9 presents the approach to phase two of the study. It presents pharmaceutical quantification and forecasting models identified through components of Andersen's model of healthcare utilisation. Descriptive statistical analysis is used to determine the interaction between the factors affecting pharmaceutical quantification and forecasting.

Chapter 10 presents a discussion of the overall findings applying a number of theoretical frameworks, and a comparison with the proxy quantification method currently used in Timor-Leste. The implications for policy development in the pharmaceutical supply chain, especially in inventory management, demand information, and quantification and forecasting, is discussed. Finally, the limitations of the study and recommendations for future research in this area will be presented.

CHAPTER 2. THE CONTEXT OF PHARMACEUTICAL SUPPLY IN TIMOR-LESTE

Developing state institutions to deliver expected services to the citizens of a country is a lengthy process. Timor-Leste is in the early years of developing and strengthening its state institutions. State institutions operating in the newly independent state of Timor-Leste face a number of issues, such as developing a national identity as Timorese, while at the same time, developing social institutions and bureaucratic and management systems to deliver services. There has been steady development in the management of public institutions and organisations, and a number of milestone achievements and challenges in various areas have been met (Anderson, C 2014). The healthcare sector, despite solid institutions having been established, shares many of the challenges experienced by other sectors. One of the most prominent challenges faced is the supply chain management of pharmaceuticals, especially continuous pharmaceutical stock-out. The current challenges faced by Timor-Leste as a newly independent country, in addition to its history, raise questions that might provide an explanation for some of its difficulties. For example, does the colonial history of the country affect the overall capacity of government institutions to deliver expected services? Do the legacies of the previous colonial masters provide government institutions or agencies that can perform well post-colonisation? Finally, which theoretical arguments can help to explain the challenges facing government institutions in post-colonial countries?

In order to address these questions, this chapter presents a brief history of Timor-Leste during three periods: Portuguese colonisation, Indonesian colonisation, and the current period of independence. In the second section, the chapter explores the impact of colonisation and presents a number of theories that can help to explain the current status of Timor-Leste as a post-conflict country, with specific reference to the development of institutions within the context of state- and nation-building. The issue, and characteristics, of human resource development for the healthcare sector and for healthcare administrators are also presented in the latter part of the chapter. I argue here that the lack of expertise and experience in human resources (HR) is a major factor in pharmaceutical stock-out. The country has survived two colonial occupations, firstly by Portugal (1515 to 1975) and then by Indonesia (1975 to 1999), as well as a brief period of Japanese occupation during the Second World War. The desire for independence, national identity, and self-government has been present since the arrival of the Portuguese in the sixteenth century, with violence being a distinctive feature of these three colonial eras. Divisive policies by the colonial governments created tribal wars and were used as a basis to suppress society by increasing military control and failing to provide civil service infrastructure (Davidson 1994). It is worth noting that the colonial powers maintained their presence through a hybrid political approach whereby they shared authority with local leaders. This was quite overt during the development of the massive coffee plantation and taxation system during the Portuguese era, but also characterised the period of Indonesian rule (Davidson 1994; Gunn, GC 2013).

2.1. Colonisation Under Portugal – History

The first Portuguese to arrive in Timor-Leste came in 1515 to Lifau-Oecusse (Boletim da Agencía Geral do Ultramar 1965; Cardoso 2014; Meneses 2008b); however, this area was only officially recognised as one of Portugal's colonies in 1702 when a governor was appointed to oversee the province (Boletim da Agencía Geral do Ultramar 1965). Continuous confrontation with the Dutch naval fleets that challenged the Portuguese trade monopolies in the region of the East Lesser Sunda Islands and the Moluccas resulted in great losses to the Portuguese. In 1561, the Dutch invaded and controlled Kupang, the western part of the island of Timor. A treaty signed in 1859 between the Dutch and the Portuguese established a clear demarcation of areas, with the Dutch controlling West Timor and the Portuguese controlling the eastern part of Timor and an enclave in the west (Government of Timor-Leste 2019).

Colonisation of Timor by the Portuguese arose partly because of the high-quality sandalwood which grew naturally in abundance. This luxury item was used in burial and religious ceremonies by societies across Southeast Asia such as Java and Malacca, as well as further afield in China and India, well before the arrival of the Portuguese (Meneses 2008b). Trade was conducted through local Timorese rulers in the coastal areas. However, interest in sandalwood by these regional trading powers led to rivalry between Portuguese, and Dutch traders, the Macassar, and the powerful Timorese kingdom of Wehale in the 17th century (Gunn 2016) which disrupted the commercial links between the local rulers and their ancient traders from China and Java.

Continuous harvesting of sandalwood without rejuvenation resulted in its almost complete depletion in Timor. Around 1870, the central colonial government in Portugal experienced an economic crisis and was unable to allocate resources to its colonies, forcing the colonial authority in East Timor to become self-sustaining. In order to achieve this, the colonial government introduced coffee as a cash crop along with enforcing a tax on coffee plantations; the corvée and capitação, or head-tax as it was known (Davidson 1994; Gunn, GC 2013). The *capitação* was paid to the local rulers in return for ensuring "community" security and prosperity for the colonisers (Davidson 1994, p. 11). This model, introduced by the colonial government, violated the customary ancient Timorese way of paying tribute to their local rulers (*liurai*) for religious and cosmological protection. It also enabled the colonial powers to rule with ease, although it did not completely halt the desire for an independent state. Attempts to overthrow the Portuguese colonial power occurred with the rebellion of Manufahi on 25th December 1911 (Davidson 1994, p. 1). As a result, the colonial government withdrew support for the independent authority of the Timorese elites. While initially, Portuguese colonial rule worked in tandem with the local rulers, by the 19th century, they had increased their military autocratic power, reducing recognition of indigenous rights and increasing economic exploitation under colonial civil law (Davidson 1994).

Further efforts to break down Timorese loyalty and to increase colonial control, particularly for administrative purposes, were enacted in early 1860. The then governor, Afonso de Castro, divided the Timor-Leste kingdoms into 11 districts headed by military commanders (Davidson 1994, p. 148). By 1866, Timor lost its status as a province and was integrated into the province of Macau as a result of continuous clashes between local rulers and the ruling military governments. The

situation of the colony became almost unmanageable when the treasury in Portugal refused to provide funds for wars against local rulers, as no aid was provided by Lisbon or Macau. Lack of resources resulted in the governor's plan to raise funds by increasing commercial crops. A report by the governor in 1870 noted, "… I have always lacked the means to pay the public servants and staff … but I am not giving up all to pay the fees of their salaries on time" (Davidson 1994; Governo da Provincia da Macau e Timor 1870, p. 184).

2.1.1 Resistance and the elites under Portuguese colonisation

Traditional ancient Timorese society was organised around clusters of households based on clans or kin groups. A cluster of hamlets was headed by a village or *suco* authority, known as *chefe-de-suco,* elected through acclamation by the elders in the community. A number of villages formed a kingdom with a *liurai* as its minor king. Warriors came from the clans, but were independent. They would go to war when requested by the *liurai* if the risk was minimal and the gains significant (Gunn, GC 2013, p. 11). No centralised state system existed prior to colonisation. The disruption of this customary way of life of the Timorese, the lack of civil rights, the rigid military rule, exploitation of the economy, forced labour, and the lack of economic benefit to the people of Timor were the initial catalysts for rebellion and independent struggle. The Portuguese era of colonisation was marked by continuous wars and violence. This was exacerbated by the fact that the Portuguese had a monopoly on trade with Timor's ancient trading partners, which lead to resentment within the local population. Examples of this included the war with Ulmera and Laclo in 1861, and with Laga in 1863/1864. Another revolt against increases in taxes and tributes came from the Kingdom of Manufahi in 1895, and another major war with the same kingdom occurred a decade later (Davidson 1994, p. 224; Districto Autonomo de Timor 1902a, p. 202; Meneses 2008b, p. 20). The Laleia (Manatuto) War took place between 1878 and 1879. Further revolts against Portuguese colonial power occurred in 1911-1912 in Manufahi, which had remained independent from Portugal up to that time. Despite most of the rebellions being supressed by the Portuguese colonial powers, the desire to be free from foreign control grew into a nationalist movement. This resistance was expressed in a refusal to accept the colonial trade monopoly and to pay taxes.

By the mid to late 20th century, the independence movement was further fuelled by the global movement of liberalisation, secularisation, and shifts in the clerical structures and the internal political system in Portugal. The Carnation Revolution of April 1974 restored democracy in Portugal, and with it came respect for the right to self-determination for the Portuguese colonies. This had an impact on the movement for liberation in Timor-Leste. The Portuguese government established a commission for self-determination in Dili on the 13th of May 1974, allowing for the establishment of political parties. Three main parties with different aims were created, the UDT (União Democrática Timorense) which sought to integrate Timor-Leste with Portuguese-speaking countries; the ASDT (Associação Sosiál-Democrata Timórense), which later transformed itself into FRETILIN (Frente Revolucionario de Timor-Leste Independente) and aimed for independence; and APODETI (Associação Popular Democrática de Timórense) which wanted integration with Indonesia (Government of Timor-Leste 2019; Meneses 2008b). The president of APODETI was Arnaldo dos Reis Araujo, (deceased) (Adiguna 2018; Kamah 2019), and the secretary-general was Jose Fernando Osorio Soares (deceased), assisted by Guilherme Maria Goncalves and

Hermenegildo Martins (deceased). Their mission was continued by Joao Tavares (deceased), Francisco Lopez da Cruz, and other figures who were pro-Jakarta and who currently reside in Indonesia (Government of Timor-Leste 2019; Meneses 2008b). On the 28th of November 1975, FRETILIN proclaimed independence for Timor-Leste unilaterally. Indonesia invaded Timor-Leste on the pretext that FRETILIN had connections to The Mozambique Liberation Front (FRELIMO) and wished to establish a Marxist government. Timor-Leste became the 27th province of Indonesia. Indonesia occupied the country for the next 24 years (Government of Timor-Leste 2019; Hicks 2015).

Meanwhile, the ASDT continued to defend the right of independence. The president of the party was Francisco do Amaral, who later became the president of the Democratic Republic of Timor-Leste when it was proclaimed on the 28th of November 1975 (he died in 2014), with an indigenous person as vice-president of the party, Nicolao Lobato (died in battle in 1979). Other senior FRETILIN officials were Alarico Fernandes (died while fighting the Indonesians), Marie Alkatiri, secretary for political affairs, and Ramos Horta, secretary for foreign affairs. Marie Alkatiri is the current secretary-general of FRETILIN, and the current authority of special economic and social markets, and the first prime minister after independence. Ramos Horta was the minister of foreign affairs under the United Nations Transitional Administration and later became the second president of Timor-Leste (2007-2012). Horta is still politically active in the country. Within FRETILIN, a number of FALINTIL generals led the guerrilla wars against the Indonesian forces, including Xanana Gusmão, Taur Matan Ruak, and Lu-Olo. Xanana is the current president of the CNRT – (the National Council for the Reconstruction of Timor-Leste), and the current principal negotiator of maritime boundaries. He was the supreme commander of FALINTIL and, after independence, served as the first president and the second prime minister of Timor-Leste. Taur Matan Ruak is the current prime minister of Timor-Leste (2017-current). During the Indonesian occupation, he was the chief of staff of FALINTIL (1992-1999), and after independence, held the position of supreme commander of the armed forces and became the third president (2012-2017). Lu-Olo is the current president (2017-curent), and was the first speaker of the National Parliament of Timor-Leste between 2002-2007. Other important senior party officers were Abilio Araujo, Rogerio Tiago Lobato, and Jose Luis Guterres (Fernandes 2011; Meneses 2008a).

2.1.2 Development of the education system under Portuguese Rule

Education for the indigenous population under Portuguese rule was minimal and focused on colonial control. For example, in 1897, Jose Celestino da Silva, the governor of Timor, shifted responsibility for education to the Catholic missionaries in an attempt to resist dissent, while all public schools were closed. The governor expected that the church would take an assimilationist approach and, by doing so, would undermine the local culture and authority (Davidson 1994). Portuguese-ation was decreed in 1902, and all children of the local elites aged between 7-15 were required to be sent to Portuguese schools in Dili, Lahane, Manatuto, or Soibada. There was no publicly-funded, planned education system for the indigenous population (Davidson 1994, p. 224; Districto Autonomo de Timor 1902a, p. 202; Meneses 2008b, p. 20); however, this approach failed. Schools became breeding grounds for a national movement for independence, with many political

elites graduating from these secondary schools. The church also established seminary schools to educate future priests for its mission. Many past and current influential political activists are descendants of the local elites who graduated from the Catholic seminary schools in Dili, Soibada, and Manatuto (Meneses 2008a).

Only three primary schools were established, one each in Dili, Manatuto, and Batugade, in the early part of the century. The formal delegation of the management of the education system by the Catholic missions was only ratified through Law no. 110 on the 8th of November 1927. However, by the end of the 1940s, there were 1,000 registered primary school students in Timor-Leste (Meneses 2008b). The education system was improved by the acknowledgement of indigenous rights in 1958, which resulted in a dramatic increase in school attendance to over 11,000 primary school children. Schools for teachers and 31 primary schools were established across Dili, Baucau, Lospalos, Bobonaro, Pante Macassar (Oecusse), and Maubisse, with 325 teaching staff in Timor-Leste (Meneses 2008b, pp. 28-34). Finally, a number of secondary schools were opened in the 1960s. In summary, it was not until the 1960s that the colonial government established a free and obligatory education system for the majority of the Timorese population. By 1974, the number of primary school students had reached 60,000, with 456 teachers across 31 government primary schools, as well as 17 Chinese schools, an Arab school, and 7 preparatory schools. There was also one secondary school, one Primary Magisterium, 1 Catholic school for catechists, and 2 technical schools, one for healthcare services and one of letters. Despite this increase, only one quarter of primary school aged children attended school, with 78% of the population remaining illiterate at the end of 1974 (Meneses 2008b, p. 39). The language of instruction was Portuguese, with no education offered in the local language. The top government education level available in the country at the time of the proclamation of independence in 1975 was senior high school (the equivalent of Year 12 in Australia), and could only be accessed by the children of the local rulers and only a limited number of the rest of the population.

2.1.3 The Timor health system under Portuguese rule

Prior to the 1850s, the supreme authority in Portuguese Timor was the governor in Macau. Timor was one district of the province of Macau and Timor (Governo da Provincia da Macau e Timor 1870, p. 185); however, this was later changed in 1870. The governor was assisted by a council composed of representatives from the clergy, the finance system, the armed forces, and the public health, education, and justice sector (Davidson 1994, p. 41). As a result, public health was under the direction of a higher authority in the colonial government system. However, almost every management position in the council delegates, including in public health, was assumed by lower ranked military officers, and the number of personnel overall was limited to “only sixty-eight officers” (Davidson 1994, p. 43). Some of these military officers were sent to Timor as punishment due to their behaviour, so they were not necessarily competent or disposed towards taking up their public sector duties (Davidson 1994, p. 42). The second issue was funding. A report from the governor of Macao and Timor on public health activity following an outbreak of cholera and smallpox in 1870 noted that he could not deal with the issues without funding (Davidson 1994, p. 43).

The dominant public health issues in the 1800s were malaria, smallpox, and cholera (Davidson 1994, p. 44; Governo da Provincia da Macau e Timor 1870). There is no clear information on who suffered from these diseases, although it would most likely have included Europeans and many members of the Timorese elites and their families within the colony, as noted by an English visitor to the colony in 1882 (Davidson 1994, p. 79). Programs to combat malaria by draining the swamps around Dili were successful, but little effort was made to train medical personnel or to improve the supply of medicines. A military hospital was opened in 1906 with only one medical doctor to treat the colonial officers, but not the colonised population. In 1947, a school of nursing and a nurse-assistant school were opened at the central hospital in Dili, and later in 1964, the status of these schools was upgraded to technical schools of health and social services, with the same courses then being conducted over two years. The nursing graduates were prepared to work at health posts (Meneses 2008a). A health post is the lowest health facility located at village level, serving a population of up to 1500. Other technical schools were also opened in the following years, such as elementary schools for agriculture, industry, and commerce, and technical schools for telecommunications and postal services.

The 1906 annual report noted that at the military hospital in Dili, of the 57 registered deaths, 24% of primary cause of death was due to anaemia, and 19% respiratory infection (Districto Autonomo de Timor 1902b, pp. 2-4). These cases were all foreigners working in the country. By 1975, there were 17 doctors working in Dili and regional clinics (Fernandes 2011, p. 38). The focus of the health services was only for Europeans during the 18th century, and this only changed in 1959 when the indigenous population were granted civil rights by the Portuguese colonial administration. The health system also suffered from a lack of resources, such as not enough health professionals and pharmaceuticals. As for public health programs, these included the construction and installation of clean water supplies, public sanitation facilities, and CHCsin the 1960s. These developments also came with road networks and telephones linking municipalities with the sub-districts. The focus was more on security to enable trade, and less on social and institutional development (Boletim da Agencía Geral do Ultramar 1965).

2.2. Colonisation of Timor under Indonesian rule

Indonesia had long engaged both directly and indirectly in the process of integrating Timor-Leste into its territory. This was marked by the involvement of 14 Indonesian exiles in Timor in the Viqueque rebellion in 1959 (Chamberlain 2010; Gunn 2015; Madjiah 2002; Subroto 1997; Sukandar, Wijayanto & Manggo 2000). Indonesia provided subtle financial and intelligence support, with its military disguising themselves as “volunteers”, and conducting training with the APOTETI members at Batugade, on the border of Timor-Leste and Indonesia (Fernandes 2011; Hicks 2015). Following the dissolution of the Portuguese Metropole Government, the decolonisation process in 1975, and the increase in the liberation movement within Timor through the establishment of political parties, political tension between the three major parties increased. As noted above, the UDT planned a coup d’état, but failed. As well, the APODETI leaders were captured and detained. The Portuguese governor could not control the situation and fled the country. The FRETILIN party leaders organised themselves and launched a reprisal, which led to a unilateral declaration of independence of the country on the 28th of November 1975 (Subroto 1997). The

conflict between the major political parties not only brought internal chaos, but also a foreign invasion from the neighbouring country, Indonesia.

The APODETI and UDT leaders were forced to seek sanctuary in West Timor-Indonesia, with the tensions resulting in an influx of refugees into Indonesian territory (Subroto 1997). After this, APODETI declared integration with Indonesia. Tempted by the pretext of a communist government headed by FRETILIN, and the determination of the Indonesian army to incorporate the country into its own territory, Indonesia invaded Timor on the 7th of December 1975, and made it one of its provinces (Majelis Permusyawaratan Rakyat Republik Indonesia 1978). This second period of recolonisation was also characterised by violence, and lasted for 24 years (Hicks 2015). During this time, the military regime controlled the entire province, and the Timorese were treated as second-class citizens of Indonesia (Madjiah 2002).

2.2.1 Resistance and the elites

During the Indonesian occupation, FRETILIN continued to consolidate the resistance movement through diplomatic methods overseas and through guerrilla warfare conducted by its armed forces, FALINTIL, and the National Liberation Forces of East Timor lead by Xanana Gusmão, within Timor itself. Apart from leading the armed struggle, Xanana also unified all political factions under a single umbrella organisation, the CNRT (the National Council of Timorese Resistance), which culminated in a consultation led by the United Nations in August 1999 (Fonseca & Almeida 2015; Government of Timor-Leste 2019). This consultation resulted in a vote, with 78.5% of the Timorese favouring independence from Indonesia, rather than autonomy as proposed by Indonesia. Indonesia had to hand over the country to the United Nations Transition Administration, which then prepared the country for full independence between 1999 and 2002. The country restored its sovereignty on the 20th of May 2002 (Government of Timor-Leste 2019; Leach 2016).

2.2.2 Health systems and pharmaceuticals under Indonesia

The basic principles of the national Indonesian health system are humanity, empowerment, autonomy, justice, and equity, and pro-poor policies intended to reduce poverty (Republik Indonesia 1960, 1982). The provision of health services is built upon the principles of sustainability, quality, safety, justice, accessibility, and equity, is needs-based and non-discriminatory, and is based on effective and efficient teamwork, and appropriate health technology. Management of the pharmaceutical supply chain is one among the six sub-systems of the Indonesian national health system (Republik Indonesia 1982). Indonesia has acknowledged that the implementation and roll-out of the national essential medicine list was ineffective in Timor (Departemen Kesehatan R.I. 2009, pp. 10, 7, 25, 32). As a province of Indonesia, the health system in Timor-Leste was similar to other Indonesian provinces. Under the Indonesian occupation, the health system in Timor was organised according to the Indonesian National Health System of 1960, 1982, and 1992 (Indonesia 1960; Presiden Republik Indonesia 1992; Republik Indonesia 1960). Access to healthcare was free of charge to the public. Health insurance was introduced for public servants and police and military officers (Thabrany 2008; World Health Organization 2016b). There is no evidence to suggest that there was a separate healthcare system designed for the Indonesian colonies, such as Timor-Leste.

The health system was designed around five levels of government: the central government, the provinces, districts, sub-districts, and villages (Presiden Republik Indonesia 1982, 2012). The development of governance and healthcare facilities followed these same levels of government. In terms of structure, the health sector was managed by the Ministry of Health within its central structures. At the provincial level, there was a regional office representing the Ministry of Health headed by a regional director responsible for overseeing a general hospital, and pre-service and in-service training institutions. At the provincial level, there was a Provincial Health Services Office responsible to the governor to oversee the implementation of health services at the provincial, district, sub-district, and village levels (Fonseca & Almeida 2015; Presiden Republik Indonesia 1976). This office was responsible for the management and implementation of health policies developed centrally at the provincial level.

The provincial health management system consisted of a provincial office and District Health Service offices. It had district hospitals, CHCs at the sub-district level, a number of health posts and village delivery houses[2], with the number of health facilities based on population need (World Health Organization - Regional Office for South-East-Asia 2017, pp. 19-20). Under the Indonesian government, there were improvements in the health status of the population, but it was noted that there were challenges in the distribution of healthcare facilities and accessibility. The distribution of health professionals remained problematic with significant geographical discrepancies. Health information systems were further weakened by the decentralisation of health service functions to provincial and district governments (Calundu 2018, p. 18; Presiden Republik Indonesia 2012, pp. 10-4; World Health Organization - Regional Office for South-East-Asia 2017).

During the Indonesian occupation, many healthcare facilities at the district level suffered from a lack of resources, especially core health professional staff such as doctors, nurses, and midwives, and a lack of funding for equipment. The services offered to the Timorese people stemmed from the concept of the Primary Health Centre known in Indonesia as *Puskesmas* which was established in 1958 (Suryanto, Plummer & Boyle 2017; World Health Organization - Regional Office for South-East-Asia 2017, pp. 22-3). Steady progress in health system development can be seen from reports on the Indonesian profile in 1993 and the provincial report in 1997. There were 13 pharmaceutical stores in 13 districts that served 69 Community Health Centres, 211 health posts, 926 community outreach posts[3], 10 district hospitals, and 1 regional hospital in Dili (Pusat Data Kesehatan Departemen Kesehatan RI 1993). By 1997, there was a noted increase in healthcare facilities, with 305 health posts, 22 chemists, and 1,152 outreach posts (Badan Pusat Statistik Propinsi Timor Timur 1997, p. 95). Funding for pharmaceuticals increased from Rp. 387,277 in 1988/9 to Rp. 557,368 in the 1993/4 fiscal year (Badan Perencanaan National (Bappenas) Indonesia 1995). In terms of the numbers of healthcare professionals, there was a total of 18 pharmacists, 19 assistant pharmacists, 930 nurses, and 439 midwives. Out of the total number of nurses working in the territory at that time, 862 had graduated from local nursing schools in Timor-Leste (Badan Pusat

[2] Village delivery house is a maternity house managed by a midwife with special focus on assisting pregnant mothers undergo antenatal care and delivery.

[3] Community outreach posts are mobile clinics that provided services to population that are not reached by health post services and is conducted once a month

Statistik Propinsi Timor Timur 1997, p. 87). In terms of physicians, there were 7 specialist doctors, 151 general practitioners, and 36 dentists. Of the 151 general practitioners 40% were working at the Community Health Centres, 34% in the hospitals and the remaining 26% in management positions (Pusat Data Kesehatan Departemen Kesehatan RI 1993, pp. 263, 8, 71, 77, 84, 99). With these resources, the healthcare system also reached a number of milestones in this period. About 63% of pregnant women attended antenatal care, with numbers more than three times this level in the Community Health Centres. Eighty-five per cent of children under one year of age were vaccinated against measles and average life expectancy reached 61 (Badan Perencanaan National (Bappenas) Indonesia 1995; Pusat Data Kesehatan Departemen Kesehatan RI 1993, pp. 82,5).

2.2.3 The education system and achievements under Indonesian rule

Data on the success of Indonesia in building the Timor-Leste education system comes primarily from the Indonesian National Planning Agency and the Provincial Statistics Agency of East Timor (Badan Perencanaan National (Bappenas) Indonesia 1995; Badan Pusat Statistik Propinsi Timor Timur 1997; Madjiah 2002). In comparison to the Portuguese era, there were considerable gains under Indonesian occupation. With a total population of 880,600, 64 kindergartens with 4,502 registered students were built, and between 1991– and 1997, children were able to progress from primary school to junior high school, and finally, to high school. By the mid 1990s there were 59,352 graduates from 766 primary schools, 47,379 graduates from 114 junior high schools, and 30,837 graduates from 60 high schools. Tertiary education included two nursing schools, one polytechnic, two higher education institutions for catechists, and one university (Badan Pusat Statistik Propinsi Timor Timur 1997, pp. 64-96; Madjiah 2002). The total number of university students at the local university, the Universitas Timor-Timur, in 1997 was 2,221 across three faculties: Agriculture, Political and Social Sciences, and Education and Training (Badan Pusat Statistik Propinsi Timor Timur 1997, p. 93). The language of instruction was Indonesian.

The preamble to the Indonesian Constitution acknowledges the right to self-determination for every nation. However, global geopolitics and territorial expansion blinded the Indonesian government, which initiated the colonisation of Timor-Leste in 1975 (Madjiah 2002; Subroto 1997; Sukandar, Wijayanto & Manggo 2000). This ended with a period of brutal violence in 1999 (Sukandar, Wijayanto & Manggo 2000). The Indonesian media, *Antara,* portrayed the situation in Timor-Leste in 1974 and 1975 as a disastrous civil war with Timorese people fighting each other, widespread looting, assaults, and murder. This was used to justify the Indonesian invasion under the pretext of ensuring humanitarian and regional peace (Hicks 2015). While there was considerable development of healthcare infrastructure during the 24 years that Indonesia occupied Timor-Leste, commentators have suggested that the management of the healthcare system was characterised by widespread corruption, nepotism, and collusion among the Indonesian and Timorese elites (Fonseca & Almeida 2015; Madjiah 2002; Sukandar, Wijayanto & Manggo 2000). The achievements in building the education and healthcare systems, particularly the facilities, were destroyed when the Indonesian military and officials left the country post-referendum.

2.3 Timor since independence

The independence of Timor-Leste was marked by the popular consultation in August 1999, in which 78% of the population rejected the special autonomous state proposal offered by Indonesia (BBB News Services 2018). The vote was administered by the United Nations Mission in East-Timor (UNAMET), which later became the United Nations Transitional Administration in East Timor (UNTAET), in preparation for full nation-state on the 20th of May 2002. During the transition, the UNTAET was expected to prepare the emerging state institutions for independent operation within the context of a full sovereign democratic country through peace-building initiatives. This approach proved to be insufficient as evidenced by the outbreak of internal conflict in the early years of independence. This conflict was due to a power struggle between various members of the elites within the national security forces. The promotion of army officers within the armed forces also caused fatal clashes between the army and the police, in addition to civilian conflict erupting in 2006. At this time, the country was heading towards a fragile and potentially failed state.

2.3.1. The post-independence organisation of the health system.

The health system of Timor-Leste was established under Parliament Law No. 10 in 2004, with the following general principles:

(a) The protection of health is the right of all individuals and is a joint responsibility of citizens, society, and the state;
(b) The provision of healthcare, and the promotion and defence of public health are carried out by the state, other public entities, and non-government organisations;
(c) Health service provision is inclusive in nature (Parlamento Nacional 2004, p. 21).

The health system is composed of national central services and District Health Services. The central services consist of the office of the Minister and the Vice-Minister for Health, the Office of the Health Inspector, the Office of the General Director, and three national directorates covering service delivery, health policy and planning, administration, finance, logistics, and procurement. There are also four autonomous agencies: the National Hospital, the Institute of Health Sciences, the Central Medical Store known as SAMES, and the National Laboratory. The DHS are composed of the office of the DHS which oversees activities and health facilities at this and the sub-district level. The health system is also equipped with collective bodies such as directive councils, coordination councils, and District Health Councils (República Democrática de Timor-Leste 2003). The Timor-Leste health system also has 1 national hospital, 5 regional hospitals, 65 Community Health Centres, 198 health posts, and 442 integrated community outreach programs to villages, known as SISCa.

2.3.2. Post-independence progress

Since independence, there has been much progress made in the healthcare sector, including improvements in access to healthcare services and sanitation, the number of trained health

professionals, reductions in infant and maternal mortality rates, and the elimination of malaria in the country. The details of these successes are presented in the following sub-sections.

One of the major successes has been the increased supply of health professionals and their equitable distribution across the territory. The number of medical doctors working in health posts has increased. For example, there were 18 doctors in Timor-Leste in 1975, all of whom were expats (Fernandes 2011). At the beginning of 1997, the number had increased to 158 (Badan Pusat Statistik Propinsi Timor Timur 1997), with a further 157 working in hospitals and CHCs in the territory. At the end of 1999, only 30[4] Timorese general practitioners (GPs) and general surgeons remained. Eighty per cent of the GPs and senior administrators who were Indonesian left the country after the popular consultation (or 'referendum') (Anderson, C 2014; Hoda 2012; Rosser & Bremner 2015; World Health Organization (East Timor) 2000). By the end of 2017, there were more than 1,000 doctors in Timor-Leste. Of these, 627 were working in 442 villages and 69 CHCs (Departamentu Estatistica e Informação de Saúde 2017, p. 52), with the remaining working in hospitals or in healthcare services management. This improvement in the ratio of doctors to the population occurred as a result of a program that saw over 1,000 doctors trained in Cuba. In addition, there were 438 midwives and 561 nurses working in CHCs across the 13 municipalities of the country (Departamentu Estatistica e Informação de Saúde 2017, p. 52).

Improvements have also been recorded in household access to sanitation facilities. In 2009, 65 per cent of urban households, and 34 per cent of rural households, had access to improved toilet facilities. In 2009, 64 per cent of the population surveyed had access to sustainable water sources (Nationa Statistic Directorate Ministry of Finance and ICF Macro 2010, p. 22). By 2014, 50 per cent of the 52,472 households in all urban areas had access to a secure water source while, within the rural areas, 64 per cent of the population had access to safe water (Direcção Nacional dos Serviços de Agua 2015, pp. 4-5; National Water and Sanitation Information System - SNIBS 2015).

These improvements in access to public health services and access to healthcare, including health promotion programs, have had a positive impact on the infant mortality rate (IMR) and the maternal mortality rate (MMR) (Anderson 2018; General Directorate of Statistics, Ministry of Health & ICF 2018; Nationa Statistic Directorate Ministry of Finance and ICF Macro 2010). A clear improvement in maternal healthcare has been achieved since independence. In 2010, the maternal mortality rate was 557 per 100,000 live births (Nationa Statistic Directorate Ministry of Finance and ICF Macro 2010, p. 111). This number was dramatically reduced to 195 per 100,000 live births in 2016 (Chabal 1981; General Directorate of Statistics, Ministry of Health & ICF 2018, pp. 263-7). The same positive trend can be seen in the infant mortality rate. The infant mortality rate in 2009 was 45 deaths per 1,000 live births compared to the same demographic health survey conducted in 2003, where the IMR was 60 deaths per 1,000 live births. This represents a 23 per cent improvement in infant survival. A 50 per cent decline in the infant mortality rate was noted five years later (Nationa Statistic Directorate Ministry of Finance and ICF Macro 2010, pp. vii, 100-1, 17-18).

[4] My own count in 1999 indicated that there were 44 Timorese nationals in the Interim Health Authority who were doctors, with none having had experience in health management. My position was Manager and Consultant for the Expanded Program of Immunization at the time.

One of the leading causes of death in Timor-Leste in the past has been malaria, which was endemic to the country. With support from the Global Fund, the country has achieved success in rolling back malaria, with a decrease in the incidence of the disease since 2006. There were 223,002 cases in 2006, but only 95 cases in 2016, or less than 1 case per 1,000 people (General Directorate of Statistics, Ministry of Health & ICF 2018, pp. 210-7). The country is now in the elimination phase, and it is predicted that malaria will be eliminated by 2021 (ABU-460 2018; General Directorate of Statistics, Ministry of Health & ICF 2018). The main factors contributing to the elimination of malaria in Timor-Leste have been increased health promotion, increased ownership and use of insecticide-treated bed nets, and case management of malaria (General Directorate of Statistics, Ministry of Health & ICF 2018; Nationa Statistic Directorate Ministry of Finance and ICF Macro 2010).

2.3.3. Major post-independence issues and problems: Critical commentary

Timor-Leste has operated under a policy of free healthcare for all. To effectively and efficiently deliver these free services to the population, access to essential medicines is pivotal. Accessibility and availability can only be guaranteed if supply chain management of medicines is effectively implemented. Important factors that influence effective supply chain management of pharmaceuticals are the selection, procurement, distribution, and use of medicines, and inventory management at all levels of the services. Following the 1999 upheaval, Timor's health system and the supply chain management of pharmaceuticals completely collapsed. The system was restored under the Interim Health Authority chaired by the World Health Organization (WHO) and UNICEF. A healthcare system with an Autonomous Agency for Medicines and Medical Equipment (AAMME) was re-established in 2000 by UNICEF, and the management of warehousing was contracted out to an international non-government organisation (NGO) from Ireland, known as GOAL. Under the management of GOAL, a Warehouse Management System (WMS) software package was introduced. In addition, when the AAMME known as SAMES (Serviço Autonomous Medicamentos é Equipamentos de Saúde) was established in 2014, the responsibility for pharmaceutical supply chain management was transferred to them (Norris et al. 2007; Republica Democratica de Timor-Leste 2009).

Since the restoration of independence on the 20th of May 2002, there have been significant changes in the supply of pharmaceuticals to the country. In the earlier years of full independence, the supply of pharmaceuticals was managed by GOAL (an international NGO). In addition, United Nations (UN) agencies provided medicines for their specific programs. UNICEF supplied vaccines for the EPI (Expanded Program on Immunization), the WHO provided medicines for the leprosy program, and the UNFPA provided contraceptive products for family planning programs. NGOs also supplied some pharmaceuticals for their clinics. A World Bank Project Management Unit (PMU) attached to the Ministry of Health conducted their procurement of pharmaceuticals, while UN agencies conducted procurement based on their internal systems. SAMES performed all functions of pharmaceutical supply chain management, but only took up procurement after 2009 (Republica Democratica de Timor-Leste 2009).

Fifteen years after independence, the difficulty in accessing medical supplies still plagues some health facilities in the remote areas of the country. Complaints from health facilities in Timor-Leste about the on-time delivery of medicines remain common. Road conditions are cited as a major obstacle to the delivery of medicine supplies. A sophisticated pharmaceutical management system, known as mSupply, has been implemented at SAMES and at pilot sites at the National Hospital Guido Valadares, and in the Baucau and Dili DHS (The World Bank 2015), although there has not been any evaluation of the success of the system. A technical report on the implementation of the mSupply system pointed out that there were well-documented medical supply chain issues that have not yet been addressed. These problems are associated with the ongoing procurement issues, such as inaccurate quantification, the high price of medicines, and long lead-times (Sustainable Solutions 2015).

The situation of medical supply chain management in Timor-Leste is typical of that of other post-conflict countries (Huff-Rousselle 2009, p. 8; Norris et al. 2007). The country shares similar weaknesses with other developing countries, such as a lack of coordination between interdependent functions and components. Many technical weaknesses have been addressed, but not necessarily human resource issues (Spisak et al. 2016). Similar problems, such as inadequate performance in procurement, logistics management, and storage of pharmaceuticals are found in Chile, throughout Africa, and in some Southeast Asian countries. In Timor-Leste, shortcomings in the government's central medical stores are found in human resource management, as well as in a range of technical issues (Huff-Rousselle 2009; USAID Deliver Project 2013, p. 19).

2.4. The Impact of Colonialism on the State of Timor-Leste

2.4.1. Challenges of language, culture, and national identity

During the occupation by Indonesia, there was an obligatory six years of schooling, and many people had access to high school and university education. The national language was Bahasa Indonesian, which was spoken throughout the entire Indonesian archipelago and also in Timor-Leste. As a consequence, those growing up during the Indonesian occupation only learned Bahasa Indonesian and not Portuguese. However, the independent leaders who were educated during the period of Portuguese colonisation had been educated in Portuguese. Portuguese was also the formal language of communication among the guerrilla fighters and diplomatic wing personnel living in exile. In such situations, Portuguese was used partly to avoid quick interpretation by Indonesian officials. In the 2002a Article 13 of the Timor-Leste proclamation, it was stated that Tetun and Portuguese were the official languages of the country (Republica Democratica de Timor-Leste 2002, p. 11), thereby creating a two-language state.

Hybridisation of the two languages has not worked well. Institutionalisation of the two languages has not reached maturity, and at times, this causes problems within the political system and in government structures. As one of the official languages, Tetun has not been well developed, although it is used in government and parliamentary legal documents. In the early years of independence, this created resistance from some of Timor-Leste's senior- and middle-level

officials, as well as lower-level government staff who were trained under the Indonesian system and had built their identity around the Tetun language (Makoni & Severo 2015), while older members of the elite and FRETILIN preferred to use Portuguese. Portuguese is effectively used by senior government officials and older politicians. All the laws are proclaimed in Portuguese and translated into Tetun. Technical advisors assisting senior government officials use either Portuguese or English. However, while documents produced by advisers are translated into Tetun, the meaning is sometimes lost during translation, causing delays in understanding of how to action official policies and jeopardising coherence between official documents and the implementation of policies. In addition, the elites speak Portuguese and lower-ranked government officials and the general population speak Tetun and their local dialects. It will take at least two to three decades for the entire population to speak Portuguese. These complex language arrangements, inherited from the two colonial periods, further complicate communication within the country. The languages used during schooling are also complicated; throughout Years 1-3, the local dialect is used as the language of instruction, in Years 4-6, Tetun and Portuguese are the languages of instruction, in Years 10-12, Portuguese is the language of instruction, and at university, Indonesian and Tetun are still used, as students have not yet fully grasped Portuguese at the tertiary level.

Traditional beliefs in healthcare still exist in Timor-Leste, and this has had a negative impact on the use of healthcare facilities (General Directorate of Statistics, Ministry of Health & ICF 2018; Nationa Statistic Directorate Ministry of Finance and ICF Macro 2010). The use of traditional medicines has strong roots within the pre-colonial culture of Timor-Leste. Traditional healers used herbal formulae and psycho-spiritual powers in their approach to disease. A traditional healer in Timor-Leste is known as *"matandok",* simply meaning a person who can see far away (The International Bank for Reconstruction and Development/The World Bank 2008). There is no special training for the *matandok*; the position comes with seniority. Traditional healers co-exist alongside Western bio-medical approaches due to cultural beliefs, and because during the colonial period, many people lacked access to bio-medical treatment. A study on the treatment of childhood illnesses in 2005 indicated that parents still sought out traditional healers either before or after seeing a doctor/nurse, especially where the signs and symptoms of the disease remained. In such cases, it is thought that the disease may have been caused by supernatural beings. The use of traditional healers is more prevalent in rural than urban areas. There is a serious lack of research on traditional medicines in Timor-Leste which makes it difficult to predict the level of education of traditional healers, or how widely they are accessed for healthcare (Rogers 2005). However, their continued use suggests that some people still adhere to traditional cultural understandings or might not be able to adequately access Western medical care.

The Catholic church is another cultural influence from the Portuguese colonial period. The church was tasked by the Portuguese colonial government to educate and "civilise" the Timorese, including providing positive support during this period of colonisation by educating both past and current political elites. The role of the church in civilising the Timorese people resulted in the loss of much of the traditional culture. During the Indonesian occupation, the Catholic church provided refuge for those who were tortured, and a voice for the independence struggle.

Timor-Leste's history has been marked by continuous violence during its nearly 500 years of occupation. After independence, the country experienced a period of civil national violence, known

as the 2006 crisis, that almost led the country to collapse. While the 2006 crisis arose from discontent within the military wing of FRETILIN, it also had its origins in the difficulties of establishing a national identity, and the lack of educational infrastructure which left the country unable to provide personnel to adequately staff state institutions. The complexity around language use also made the work of the government difficult.

Another impact of the prolonged period of colonisation has been the lack of a strategic approach to human resource development for healthcare, especially healthcare administration. The development of an indigenous administrator class has been directly affected by the capacity to manage major infrastructure and processes, including the supply chain, in post-independence Timor-Leste.

2.5. Human Resource Development in Fragile and Post-Conflict States

Human resource development is a critical aspect of quality public administration. Well-developed and capable human resources are an essential component of modern healthcare service management in stable countries. This is also an important pillar in the development of healthcare services in post-conflict and fragile states (Fujita et al. 2011; Hewitt 2015; World Health Organization 2005). However, as an important pillar, it also presents a number of challenges. These range from a lack of qualified health professionals and the lack of technical expertise of health administrators, to poor governance due to failure to establish robust managerial systems (Mustafa, Berisha & Lenjani 2014; Sami et al. 2018). In addition, there has also been an imbalance of health professionals in terms of quantity and gender. This is certainly the case in Timor-Leste. Similar situations have been found in Afghanistan, Cambodia, and the Democratic Republic of Congo (Fujita et al. 2011; Leather et al. 2006; Sami et al. 2018; Varpilah et al. 2011; World Health Organization 2005). In terms of human resource development in post-conflict countries, one of the dangers has been the overproduction of key healthcare professionals such as nurses, midwives, and physicians (Bertone et al. 2018; Varpilah et al. 2011), while training of healthcare administrators has been neglected. For example, Timor-Leste has focused its energies on training a thousand physicians in Cuba, to be distributed in all villages and health facilities throughout the country upon their return. This has resulted in an oversupply of doctors, but contrary to the situation in other fragile states, lower numbers of nurses, midwives, and allied health professionals as well as managers and administrators (Hewitt 2015).

In an ideal situation, a healthcare system will achieve its goals by being led by competent health administrators who have technical expertise, experience, awareness of local situations, and dedication. These are the people who translate political goals into actions, and eloquently lead the available human resources to success at every level of management (Department of Health Policy Development and Services (Health System and Services) - WHO Geneva 2007; Iglehart 2003). However, having only these managerial personal qualities is not enough. At a systemic level, a strategic management system must be developed to enable continuous improvement and quality management which can be achieved through pre-service and in-service training, and executive networking (Harris 2005; Loh 2015; Skipper, CO & Bell 2011; World Health Organization 2005). The situation in post-conflict countries such as Timor Leste is the opposite. There are difficulties in establishing and reforming the healthcare system. These range from the lack of technical expertise of health professionals, managers, and administrative staff, to a lack of funding (Bertone et al. 2018;

Callander 2005; Fujita et al. 2011; Gholipour et al. 2018; Khurshid 2010; Macrae, Zwi & Gilson 1996; Muchekeza et al. 2012; Mustafa, Berisha & Lenjani 2014; Roome, Raven & Martineau 2014; Sami et al. 2018; Shah 2012; World Health Organization 2005). This is especially so if there has been a long period of colonisation prior to conflict that has hampered the development of a managerial class.

Disorganised and non-strategic approaches to the training of health management executives is seen in a number of emerging countries. A reactive approach to training health managers may achieve short-term objectives, but not strategic outcomes. For example, there was short-term in-service training for District Health Service managers between 2001 and 2002 under the United Nations Transitional Administration for East Timor-Leste (Witter et al. 2015). Higher quality management and leadership training was organised by the Institute of Health Sciences Timor-Leste during the period of 2005 and 2008. There have been efforts made by the Ministry of Education Timor-Leste to reform the curriculum in the schools and universities; however, there is nothing currently available in terms of training managers in the education and health sectors (Shah 2012). The Timor-Leste government has acknowledged the inadequacy of human resources in the health sector as part of its strategic plan. There was no specific statement about the capacity of health administrators; however, one of the key indicators identified the need to develop curricula for health sciences and healthcare leadership and management (Ministry of Health Timor-Leste 2011, pp. 66-9). To date, no action has been taken on this matter.

Understanding human resources development needs in post-conflict countries is vital for creating a balance between healthcare needs and access to healthcare services during the reconstruction phase and beyond. Investment in management and leadership, and attention to background factors such as language and other cross-cutting issues (i.e. succession planning and donor support), are also required.

2.5.1. Language as a factor in human resource development

As noted above another challenge to the development of human resource capacity building in fragile states, including in health administration, is language. Language plays an important role in national identity. However, this presents challenges in networking with other countries or overseas institutions. The challenges of using more than one official language is part of the problem for Timor-Leste. This challenge contributes to limitations to the number of capable officers who could attend training overseas to improve their managerial capacity (Leather et al. 2006; Taylor-Leech 2008). This is exacerbated by the small number of staff with fluency in the official languages. This small number makes it difficult for managers to obtain in-country experience and overseas training. Only a small number of senior managers can speak foreign languages, which limits their opportunities to benefit from international technical support, participate in meetings, and undertake fellowships. Similar situations are also found in Cambodia and Afghanistan (World Health Organization 2005, pp. 23-7).

2.5.2. The role of donors in rebuilding healthcare systems in post-conflict countries

The development of healthcare systems in many post-conflict countries cannot be separated from the support of international donors. Most of the support from donors is based on baseline assessments of the situation in the recipient countries or on past studies conducted by overseas researchers (Bertone et al. 2018; Callander 2005; Development-OECD 2009; Díaz-Monsalve 2004; Fujita et al. 2011; Gholipour et al. 2018; Hewitt 2015; Khurshid 2010; Leather et al. 2006; Legnini 1994; Macrae, Zwi & Gilson 1996; Muchekeza et al. 2012; Mustafa, Berisha & Lenjani 2014; Roome, Raven & Martineau 2014; Sami et al. 2018; Shah 2012; United Nations Development Programme 2018; Varpilah et al. 2011; Witter et al. 2015; World Health Organization 2005). There are two points to be made about this situation. Firstly, HR problems are seen by other people from a fresh and often different perspective, which can be valuable. Secondly, the results of the research conducted (outlined earlier in this paragraph) is often used by donors to plan a quick fix to the problems faced in post-conflict countries (Fujita et al. 2011; Khurshid 2010; Muchekeza et al. 2012; Shah 2012; Taylor-Leech 2008; World Health Organization 2005). The consequences of this can be both positive and negative. The positives are that this information can be used as the basis for more strategic approaches in developing qualified human resource workers and healthcare administrators within the health sector. The negative aspect is that the information gathered from the studies and assessments are only intended to meet the goals of the studies and not necessarily the broader needs of the country.

POST-COLONIAL THEORIES

2.6. The Concepts of Post-Colonialism, Hybrid Political Orders, Emerging, and Fragile States

Theories exploring the impacts of colonialism or internal conflict and war on newly-formed states include concepts such as failed states, hybrid political orders, emerging states, fragile states, and post-colonial and institutions theory (Grawert 2012; Karkov 2012; Lange 2004; Lepsius 2017; Lynn 2008; Yahiaoui 2015). These theories go some way towards explaining the difficulties facing newly-formed nations. The concepts of emerging and fragile states, the hybrid state, and institutional theory can be used to explain the current progress of development within Timor. In this thesis, I argue that pharmaceutical stock-out can be explained by the fact that Timor-Leste, at this point in time, has many characteristics of an emerging and fragile state. One of the explanations for this is the issue of national identity and language, and the underdevelopment of state institutions. Understanding how newly-formed states with histories similar to that of Timor-Leste transfer knowledge and skills in management to build strong state institutions is a highly complex process. It is not clear whether attention should be given to socio-political or cultural factors, or which factors are more influential in the successful transfer of skills and practices. What is clear is that Timor-Leste lacks a managerial and administrative class. I argue that much of this is a result of the country's colonial legacy. Secondly, I argue that the definition of a fragile state is very narrow because it measures the fragility of the state based on security measures (Boege, Brown & Clements 2009; Call 2016; Kraushaar & Lambach 2009). The current stage of development in Timor-Leste indicates that the country is not fragile, but instead, is weak in its institutional capacities, especially in public administration, as a result of its colonial legacy. Timor-Leste is not a failed state, but a weak state that has not had the opportunity over the past 500 years to build its state institutions.

2.6.1. Post-colonial theory and failed states

Following the period of decolonisation in the 20th century, many social commentators provided accounts outlining the dangers of new forms of imperialism and colonialism (Grawert 2012; Karkov 2012; Lange 2004; Lepsius 2017; Lynn 2008; Yahiaoui 2015). This led to the term post-colonialism in academic and public discourse, which describes the emergence of new forms of colonialism within newly independent states or among newly enfranchised citizens. The terms can be traced back to the 1950s, but became fully entrenched in academic circles in the 1990s (Al-Saidi 2014) as a means of giving a voice to poor and voiceless communities across the globe. Examples include the voice of the oppressed, as identified by Frantz Fanon in his writing on the "dichotomy (coloniser/colonised) as a product of a "Manichaeism Delirium"[5], and Claude Levi Strauss and Roland Barthes with the concept of "binary opposition" (Al-Saidi 2014, p. 98).

Post-colonial theory refers to a discourse of resistance to colonialism at any time from countries that are being colonised, are colonised, or that have achieved their independence but still retain remnants of the colonial mind-set. Robert Young defined post-colonial as "a political experience in the period or aftermath of the colonial" (Young 2016, p. 57). The term refers to the fact that those groups colonised by Western nations up to the mid-20th century underwent a form of cultural domination whereby their identities were defined in binary forms such as coloniser or colonised, civilised or uncivilised, master or slave, and modern or primitive. This politics of inclusivity/exclusivity resulted in injustice and systems of hierarchical, political, and economic power for the colonisers. Academically, the aim of post-colonial discourse is to create universal ideas for social justice and modernity, but also to be alert to the ways in which the colonial mind-set prevails, even following independence, in the minds of those who were once colonised, as well as in the minds of the colonisers.

The impact of colonialism on the national identity, politics, and socio-economic freedom of the colonised, even after independence, is evident. The coloniser's knowledge, and their political, social, and economic beliefs are imposed on the colonised to meet the interests of the colonisers, while the rich culture and identity of the colonised is supressed through either violence or subtle coercive actions (Hook 2004). A marked example in Timor was use of Portuguese and Indonesian as the official languages of education and governance. Another residue of this following independence is the mystification of the Western approaches to state affairs, management practices, quality of institutions and goods (Hook 2014, p. 1686) that the locals see as superior to their own. A further development within post-colonialism is hybridization. This occurs when the "the post-colonial culture deriving from the confrontation between the colonial and the colonized cultures led to a reconstruction of the colonized culture and results in a new hybrid culture". Examples of this legacy of hybridisation to governance is evident in Timor-Leste. For example, the older generation of leaders educated during the Portuguese occupation

[5] Fanon's concept of the Manichaeism Delirium refers to the idea that many heroes of the anti-colonial movement become themselves new colonisers (Fanon 1974)

prefer the systems that were in place at the time, including the use of Portuguese as the major language of bureaucratic communication, while the younger generation, educated under the Indonesian rule, prefer more modern approaches.

Post-colonialism also plays out in decisions about striking a balance between the adoption of Western practices of governance and institutional practices, and the need for high standards and adaptation to local conditions and culture. There are many adopted and adapted administrative practices instituted in post-colonial countries, and Timor-Leste is no exception. One example of this is the use of international advisers to provide technical support to the Timor-Leste healthcare sector, supported by international donor organisations such as the World Bank (The World Bank 2004, 2015, 2015). Another example is the institutionalisation of antenatal care programs. The Timor-Leste program "Liga Inan", or "connecting mothers", was adapted from a similar program in Rwanda which connected pregnant mothers via phone calls and messages. This Rwandan program is a success story of adaptation that has yielded excellent results in improving the delivery of antenatal care (Health Alliance International 2013). Similarly, it has been a success in Timor.

Timor-Leste has both directly and indirectly used the discourse of post-colonialism in its struggle for independence. This discourse is tied to raising awareness of a national identity separate to that of the colonisers, and is played out in issues over language. During the resistance against the Indonesian occupation, the languages used for clandestine activities were Portuguese and Tetun. When Portuguese was established as the official language, it sparked discontent from the younger generation[6], who did not see Portuguese as part of their identity, but rather as a colonial language. However, both generations maintain aspects of the traditional culture of *maun and alin* – big brother and young brother, which reflects a strong emotional relationship. In traditional Timorese culture, there has been an expectation that powerful clan leaders would protect people who supported them. This was a relationship of reciprocity. The success of the elites in the resistance that led to full independence commanded a sense of trust in these people. After independence, FRETILIN remained an important party, along with Xanana Gusmao's CNRT. Both drew upon a large membership as well as the surviving militants. The concept of *maun and alin* draws on this history and is reflected in political appointments to administrative positions. It can be defined as a subtle form of nepotism; however, given Timor's history, it is difficult to avoid. There is some indication that this traditional form of nepotism has remained pervasive in Timor-Leste over the 15 years following the gaining of independence (Guterres 2018; Reed 2017). Ngugi wa Thiong'o, a world-renowned Kenyan writer and commentator on post-colonialism, stated that the effort of trying to align oneself to one or another culture will continue to be a subject of cultural and economic colonisation of the mind (Hook 2004, p. 99).

Another potential indirect cause of state fragility and failure, apart from poverty, is nepotism, which in some instances is related to traditional clan systems. In Timor-Leste, as noted above, this is manifested in political appointments based on affiliation to a ruling political party rather than on merit and competence. In some instances, such appointments might also be related to political authorship and clandestine relationships developed during the struggle for

[6] The 'young generation' refers to those who were born after 1975 and raised under the Indonesian education system.

independence. The result is that the newly-appointed elites are required to pay back those who supported the struggle for independence. State-building and nation-building is aligned to a dominant group and those within the party, rather than to the citizens of the country. This situation may also influence policy direction in the process of state-building, including the development of state institutions and their role of delivering expected functions. Two features of this practice are, first, the political appointment of senior government officials is more likely to have strong affiliations with the ruling power, and second, they are appointed not on merit and capacity, but according to their relationship to the ruling party as a consequence of needing to maintain reciprocal relationships or to pay back former debts. One consequence of this is that the capacity to think administratively and technically may be lacking. In such situations, improvements in state- and nation-building are jeopardised, especially when the same senior government officials are rotated to take the same or similar roles in other sectors, and their family members are often appointed to positions within the sector (Guterres 2018).

The concept of a failed state is associated with sustained violence in the country, and issues such as malnutrition, high mortality rates, and lack of services. However, in the case of Timor-Leste, the country is not characterised by violence or instability, but by bureaucratic systems that cannot function adequately. This is clearly captured by Anderson who stated that "Timor-Leste's problems are bureaucratic, … the insular centre lacks understanding about the remote areas, and not geographic" (Anderson 2018, p. 2). The attention of external observers has constantly been on what happens in the capital city of the country rather than on the situation in the rural areas. Timor-Leste was not in a position to implement an independent bureaucratic system until it gained independence in 2002. Prior to this, the Portuguese and the Indonesian colonial powers-maintained control over the system of governance. Control was maintained through violence, with the education of the Timorese being limited to the elites. Because the country had never built it owns institutions, there was no experience of how this might be done. The leadership was expected to create functioning state institutions, without a tradition of doing so, and without an educated managerial and administrative class. Since independence, there have been efforts made to educate doctors and nurses, but the same effort has not gone into educating administrators.

2.6.2. The fragile state and hybrid political orders

The concept of a hybrid state has been applied not only in political contexts, but also in a business context in newly formed nations following decolonisation. This concept suggests that organisations and institutions, including indigenous commercial companies, draw on ideas from both their colonial past as well as their indigenous culture. For example, a study on hybridisation in corporate management was conducted on the subsidiary offices of a French multinational corporation operating in Tunisia (Yahiaoui 2015). The focus of the study was on the hybridisation of human resource management practices and how they differed from the parent company in France. The study concluded that "institutional factors have less impact on the transfer of human resource management practices in ex-colonised countries than cultural factors" (Yahiaoui 2015, p. 1687). For example, Tunisian firms have a family-oriented culture in employment. Relations between superiors and subordinates are seen as a 'father and son' relationship. This means that lower-level

staff respect senior staff and obey their instructions, but it also means that superiors have obligations to take care of the welfare of their subordinates and their families. This paternalistic culture and emotional style of relationship was seen to result in positions in a company being reserved for candidates with personal links to senior staff (Yahiaoui 2015).

The concept of the hybrid state suggests that there is a need to take into account the local culture when transferring practices from developed countries into states where the newly independent population have not been part of Western forms of management under colonial rule. However, it is also possible that new or hybrid forms of governance might emerge. A distinction is made here between adaptation and diffusion. In the case of management practices, diffusion is related to the transfer of knowledge and practices to a recipient; whereas adaptation is the process by which the knowledge and practices are adjusted to suit the local institutional context (Hook 2004, p. 1666; Yahiaoui 2015). For example, the hybridisation of human resource management processes and practices using the "father and son" approach is similar to the application of *maun-alin* in Timor-Leste. The process of hybridisation of the pharmaceutical supply chain could be implemented by considering isomorphic[7] factors such as diffusion, the stakeholders, relational contexts, and adoption and reinvention of management practices. This might reduce resistance to change from current managers and technical staff and could possibly make an institution stronger. Hybridisation could be encouraged, but to date, efforts at improvement have been driven by donor agencies rather than by local entities.

This leads to questions about whether or not Timor-Leste's pharmaceutical supply chain management could be hybridised. This phenomenon has been misunderstood by external transnational and international actors who have tended to overlay their programs without appropriately considering local culture, dynamics, and capacities. The mystification of international capacities is a pretext for international actors to "romanticise their superior capacities" (Richmond 2011, p. 116). One key example is the pharmaceutical supply chain software known as mSupply, developed by Sustainable Solutions New Zealand. The software produced in English, was pilot-tested in a few sites and later expanded to all Community Health Centres. Lack of political commitment from the central office of the Ministry of Health, and inadequate attention to isomorphic factors, led to the cancellation of the software contract at the end of 2017 (AD-040 2017; AH-080 2017). One of the major obvious issues here is the fact that Indonesia was the language of education during the recent 24 years of occupation rather than English.

2.6.3. Institutional development and institutional theory

Institutional theory deals with the process in which law, order, and management practices are introduced into a state institution or a professional organisation. The standard reference is to the concept of the neo-Weberian state. These theories explain the processes of establishing state or professional institutions that perform their functions as expected by the public. A weak state is characterised as having a lack of institutional development and weak institutionalisation of law,

[7] Hawley (1968), in DiMaggio & Powell 1983, p.149, defined isomorphism as "a constraining process that forces one unit in a population to resemble other units that face the same set of environmental conditions".

order, policies, norms, guidelines, ways of life, or expected ethical behaviours of an institution (Di John 2010; March & Olsen 1998).

Any investigation on the functions of an institution would not be complete without an understanding of the meaning of the term 'institution'. There are many definitions of an institution. Jepperson (1991, pp. 5, 7, 143, in Lepsius 2017, p. 3) defined an institution as a set of "organised, established procedures and as the property of an order" (Lepsius 2017, p. 3). How individual institutions behave depends on the category of the institution and the political culture of a country. According to Lepsius, there are three streams of institutional theory, rational choice institutionalism, sociological institutionalism, and historical institutionalism. Each of these has its own characteristics and guiding principles. In the context of historical institutionalism, institutional organisations determine rules and processes that shape the behaviour of individuals and outcomes. Rational choice institutionalism is guided by economic principles that focus on functions and benefits; for example, property rights, rent-seeking, and transaction costs. This tradition is found in both state and professional institutions. In contrast to these two streams is sociological institutionalism, in which the stewardship of an institution is guided by unquestioned routines, cognitive scripts, and moral values. According to Lieberman, "sociological institutionalism seems to almost exclusively follow the culture approach" (Lepsius 2017, p. 7). The Timor-Leste situation most closely represents the characteristics of historical and sociological institutionalism. The institutions of government are new, but they are also influenced by traditional institutions that govern the family, clan leadership, and the church, all of which play an important role in social cohesion. Institutions that have been established to perform state roles have had to deal with the issue of the social cohesion of the population, which draws on clandestine connections developed during the struggle for independence.

As there was no centralised unified state in the history of Timor-Leste prior to colonisation, there are uncertainties about what and how state institutions should be formed, and the functions they should perform. The public administrative system is characterised by a lack of legal mechanisms and trained, experienced administrators to run state institutions and organisations. The immediate alternative is isomorphism, or to take on administrative practices from outside. State institutions have been forced by international standard practices to implement public administration systems without necessarily taking into account local traditions and history.

Understanding institutional theory and the context in which state institutions operate provides insight into how to introduce new approaches or to model and/or adapt practices that exist elsewhere in the world for a newly independent state. Isomorphic mechanisms can be applied to achieve the goals of state institutions to achieve efficiency and efficacy in public administration, including in pharmaceutical supply chain management. As Timor-Leste is currently isolated and weak, the use of a mimetic mechanism supported by donors, is the immediate approach that could be taken while preparing qualified administrators through formal education programs.

2.7. Conclusion

The legacy of more than 450 years of Portuguese colonisation and 24 years of Indonesian rule have contributed to the weakness of all sectors in Timor-Leste. The desire of the Timorese to gain self-

rule nevertheless remained constant during these colonial periods, culminating in the proclamation of independence in 1975 and the restoration of independence on the 20th of May 2002. As a newly independent country, Timor-Leste is expected to establish institutions that will maintain a state presence across the entire country and provide expected services. While state administration is steadily improving, it remains weak in comparison to the ideal Weberian-state model. Nevertheless, progress has been noted in many sectors; for example, in the healthcare, social services, and central banking sectors (Anderson 2018; Guterres 2018; Reed 2017). In the healthcare sector, there has been noted progresses especially in the reduction of infant mortality rates and maternal mortality rates. The ratio of healthcare professionals to the overall population has also increased. The population now has better access to healthcare services; however, training and experience in the management of healthcare services remains inadequate, with too few professionals trained for these roles. Healthcare professionals and healthcare facilities are available; however, pharmaceutical stock management is not satisfactory. Continuous stock-out of pharmaceuticals throughout the year means that patients do not receive adequate healthcare service.

States that fail to deliver services fall into the category of either a fragile or a failed state. However, Timor-Leste is not a fragile or a failed state. Rather, it is a weak state. The main weaknesses comes from the country's colonial history, because neither the Portuguese nor the Indonesians developed an indigenous managerial class during their occupation. The status of healthcare administrators' abilities is typical of post-conflict countries. Timor-Leste has training facilities for healthcare professionals such as doctors, but it has yet to create facilities to focus on the education of managers and administrators of healthcare services. There are traditional cultural factors that were reinforced during the fight for independence that lead to a form of maun-alin/nepotism that continues to weaken current state institutions (Bartram et al. 2007). The situation in Timor-Leste is typical of other post-conflict countries. There is no strategic approach to human resource development for healthcare. The situation in post-conflict countries is marked by a lack of human resource capacity, oversupply of certain types of health professionals, lack of competent healthcare administrators, and reactive approaches to the training of healthcare administrators. Donor support could be better harnessed to improve overall human resource development, especially for healthcare administrator training in Timor-Leste. Apart from the lack of a systematic approach to the capabilities of healthcare administrators, the opportunities for improvement through engagement with overseas resources have been hindered by a lack of proficiency in international languages.

CHAPTER 3. PRIVETT AND GONSALVEZ'S MODEL AND IDENTIFICATION OF ISSUES

The pharmaceutical supply chain issues in Timor-Leste are very complex. These issues affect healthcare service delivery to the nation's people. The human resource requirements for adequate management of the supply chain are poorly understood. On the one hand, there is an oversupply of core healthcare professionals, and on the other, there is lack of healthcare administrators. The assignment of staff to managerial positions has not been based on the appropriate knowledge, skills, and experience required to successfully manage the system. The country inherited a colonial legacy of weak state institutions and a lack of managerial and technical staff in pharmaceutical supply chain management. While there has been progress achieved in the healthcare sector, pharmaceutical stock-out continues to be a problem.

This chapter does not focus on presenting the complexity of human resource issues in the health system, but instead, details the organisational side of the pharmaceutical supply chain across the entire healthcare system in Timor-Leste. Apart from examining the human resources, the chapter also investigates the non-human resource factors that contribute to pharmaceutical stock-out. The Privett and Gonsalvez dependency model is used as a guide to report on the problems identified in 10 studies of pharmaceutical supply chain management conducted in Timor-Leste, as previously introduced in Chapter One. These studies are listed in Table 3.1 below. The 10 studies revealed information about supply chain management of pharmaceuticals in the healthcare sector, prescription patterns in primary healthcare facilities, and adherence to standard treatment guidelines. In providing a description of the problems with pharmaceutical stock-out in Timor-Leste, I draw on these studies as a form of data. This will be supplemented by data from other developing countries. However, firstly, the chapter describes the Privett and Gonsalvez model, after which the supply chain issues are categorised according to this model, along with other factors not captured by the 10 previous studies on Timor-Leste. Secondly, the chapter will describe the situation of supply chain management in regard to the top 10 issues in the Privett and Gonsalvez model. Technical and management capacity of human resources at the system, facility, and item levels of pharmaceutical supply chain management and other associated factors are tabled in this chapter.

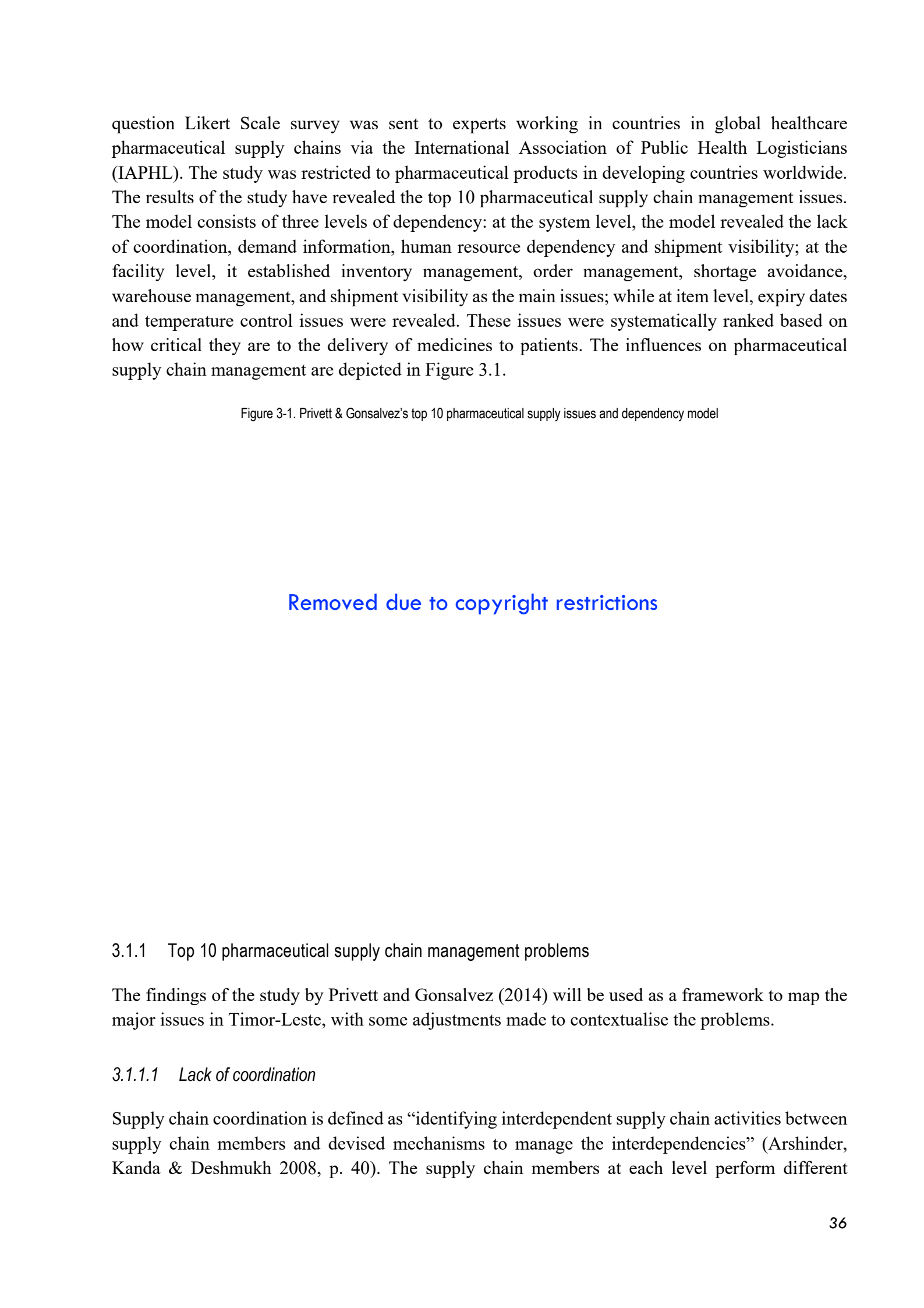
3.1 Privett and Gonsalvez

Natalia Privett and David Gonsalvez developed a dependency model to determine the underlying influences on global pharmaceutical supply chains in the healthcare sector, e.g. the supply of medical devices or pharmaceuticals. They developed their model in 2014 through qualitative interviews with experts in pharmaceutical supply chain management and a survey questionnaire[8]. Their conclusions were drawn from interviews with 22 experts in global healthcare and supply chain management working in pharmaceutical manufacturing and healthcare facilities. A seventeen (17)

[8] *Please note that the exact figure for the number of participants in the survey could not be verified at this stage. Email confirmation has been sent to the authors for clarification, but response is yet to be obtained.*

question Likert Scale survey was sent to experts working in countries in global healthcare pharmaceutical supply chains via the International Association of Public Health Logisticians (IAPHL). The study was restricted to pharmaceutical products in developing countries worldwide. The results of the study have revealed the top 10 pharmaceutical supply chain management issues. The model consists of three levels of dependency: at the system level, the model revealed the lack of coordination, demand information, human resource dependency and shipment visibility; at the facility level, it established inventory management, order management, shortage avoidance, warehouse management, and shipment visibility as the main issues; while at item level, expiry dates and temperature control issues were revealed. These issues were systematically ranked based on how critical they are to the delivery of medicines to patients. The influences on pharmaceutical supply chain management are depicted in Figure 3.1.

Figure 3-1. Privett & Gonsalvez's top 10 pharmaceutical supply issues and dependency model



3.1.1 Top 10 pharmaceutical supply chain management problems

The findings of the study by Privett and Gonsalvez (2014) will be used as a framework to map the major issues in Timor-Leste, with some adjustments made to contextualise the problems.

3.1.1.1 Lack of coordination

Supply chain coordination is defined as "identifying interdependent supply chain activities between supply chain members and devised mechanisms to manage the interdependencies" (Arshinder, Kanda & Deshmukh 2008, p. 40). The supply chain members at each level perform different

functions such as temperature control, inventory management, forecasting, and distribution of goods, information, and finance. Coordination can take place at different function points such as during inventory, ordering, and transportation, and in a range of processes such as during procurement, production, and distribution. A supply chain is complicated and involves relationships with many partners within an organisation, across organisations and service providers, and across countries (Skipper, JB et al. 2008).(Skipper, JB et al. 2008). According to Beier (1995, in Mustaffa and Potter (2009, p. 234), "supply chain in healthcare is unique from other industries because it requires adequate and accurate medical supplies to meet patients' needs" and this impacts on people's health.

Apart from the complexity of supply chains, there are major market forces that also influence how to manage them. Major driving forces in the supply chain are the product life-cycle, profit margins, forecasting of demand, the expectations of customers, just-in-time (JIT) manufacturing, and globalisation (Lewis & Talalayevsky 1997; Mustaffa & Potter 2009). Another factor that needs consideration is that typically, supply chains deal with human systems and can create other challenges and difficulties caused by different individual interests and the opportunistic behaviour of stakeholders (Stank, Crum & Arango 1999, p. 43).

Relationships with partners/participants within an organisation and with other organisations in the supply chain pose substantial risks, challenges, and disruption. Supply chain coordination is one available effective way to overcome risks related to the flow of goods, money, and information. The main risks associated with supply chain coordination are transaction costs, supply lead-time, price uncertainty, orders split between different suppliers, contract management, and stock maintenance (Arshinder, Kanda & Deshmukh 2008; Lewis & Talalayevsky 1997; Skipper, JB et al. 2008). Effective coordination of the supply chain involves accurate and efficient communication between stakeholders and rigorous monitoring of performance. The benefits of effective coordination lead to performance improvement in inventory levels, stock management, transportation costs, ordering costs, timely delivery, and faster response rates (Lee, CH 2007; Stank, Crum & Arango 1999). Arshinder et al (2008) indicated that comparative studies on information policies that promote full sharing show improvements in inventory reduction and cost saving, and increases in efficiency in supply chain management (Pawlewski 2015).

Privett and Gonsalvez's survey (2014) revealed that supply chain coordination in developing countries remains problematic. This is due to fragmented and uncoordinated supply of medicines due to product type, project, and funding entities. When and where to send an order depends on the funder, the product, and the project (Privett & Gonsalvez 2014). Attention to market forces, relationship within and with other organizations, type of pharmaceutical products and funding are essential in achieving an effective supply chain coordination , There are three efficient supply chain coordination models, the stockless model, Vendor Manager Inventory (VMI), and single period inventory. These are explained below.

Models of coordination

The first efficient coordination model is the stockless approach, in which a customer procures medicines and medical products in large volumes to avoid stock-out. Using this method, the customer assumes responsibility for inventory management and decisions regarding stock replenishment. This model often requires improvements in information and communication technology to be successful (Pawlewski 2015; Sajadieh & Bolooriarabani 2011; Simatupang, Wright & Sridharan 2002; Stank, Crum & Arango 1999).

The second coordination model is Vender Managed Inventory (VMI) and Collaborative Planning and Forecasting and Replenishment (CPFR). Vendor Managed Inventory (VMI) is applied in Malaysia and Australia (Darwish, Odah & Goyal 2012; Mustaffa & Potter 2009; Wang & Xu 2014). Under the VMI model, a supplier assumes full responsibility for inventory management and the customer makes decisions on stock replenishment. For this model to function well, there is a need to provide accurate information at the inventory level and consumption data through reliable information technology networks. Another factor that enables the success of this approach is the trust between the supplier and their customers.

The third recommended model is the single period inventory model, where a mutual contract is made between a manufacturer/seller and a retailer/buyer to order goods in significant amounts to avoid the risk of understocking. This model could be applied in a situation where there is uncertainty in production, orders, and demand (Arshinder et al. 2008, p. 49). Both the manufacturer and the buyer agree on a range of conditions such as return policies, sales rebates, and price discounts (Arshinder, Kanda & Deshmukh 2008). Another way to improve coordination in the supply chain is through the implementation of joint production delivery policies, with common cycle approaches, identical replenishment cycles, and joint lot scheduling mechanisms (Yang & Wee 2002; Kim et al. 2006, in Arshinder et al. 2008).

Traditional coordination techniques include face-to-face meetings, letters, and modern coordination approaches using information technology. Each of these coordination methods has advantages and disadvantages and must be tailored to the environment in which it is in place. In today's globalised world, the use of information technology (IT) in the supply chain is the preferred choice. It has proven to be time-effective and cost-efficient in coordinating supply chain activities. It has also contributed to better coordination between organisations (Lewis & Talalayevsky 1997). However, in many developing countries, the information technology infrastructure is not reliable or available.

3.1.1.2 Inventory Management

According to the American Production and Inventory Control Society (APICS), inventory management is a "branch of business management concerned with planning and controlling of inventories; and aims at maintaining a stock level of products or items". The primary function of inventory management is to serve customers (Toomey 2000, p. 1). According to Wee (2011), inventories are "stocks on hand at a given time which are idle or incomplete resources that possess

economic value waiting for sale or use". In pharmacy operations, inventory is referred to as the stock of pharmaceuticals retained to meet future demand (Ali 2011).

In the past, the focus of inventory management was on "lot sizing, safety stock, forecasting methods and ordering techniques" (Toomey 2000, p. 1), along with balancing ordering costs against the cost of carrying the inventory (Buxey 2006, p. 996). However, in today's competitive business environment, inventory management has evolved and new systems have been introduced to improve existing inventory practice.

There are a number of ways to classify inventories, depending on the type of operation, the function, and the goals being sought. From an operational perspective, particularly in manufacturing, inventories are classified into five categories, "supplies, raw materials, work-in-process (WIP), final products and deteriorating materials" (Wee 2011, p. 4). However, another way of classifying inventories is based on their functions. According to function, inventories are classified into six categories:

- Working stock. This is an inventory in which materials are ordered in lot sizes to meet future requirements.
- Safety stock. The function of this stock is to protect an organisation against the uncertainty of demand and supply (Mahendrawathi, Nurul Laili & Kusumawardani 2011). This is aimed at meeting customers' requirements or lead-time uncertainty (Wee 2011, p. 5).
- Anticipation stock. This is an inventory that is built up to cope with peak seasonal demand of any given product. According to demand patterns, demand can be divided into dependent demand, where an item is required based on demand of other items from suppliers. Hence, it is known as a manufacturing inventory or an independent demand which does not need other supplies or parts, but can be simply delivered to the customer (Toomey 2000, pp. 79-80).
- Pipeline stock. This is transit stock or a working process. This deals with the lead-time of delivery from one place to another. The amount of stock will increase because the distance of delivery from one place to another increases. Stock is an inventory that accumulates due to dependency on other activities.
- Psychic stock. This is a display inventory that is carried out by retailers to attract demand. It acts as a 'silent salesperson'.

Inventory systems are classified into goal, function, and demand for a product. Material Requirement Planning (MRP) systems and Distribution Requirement Planning (DRP) are inventory systems that are better suited to the supply of raw materials for manufacturing purposes. However, Just-In-Time (JIT) inventory systems are more efficient inventory management systems. An Enterprise Resource Planning (ERP) system is an inventory system that aims at linking supply and demand information received from the entire network. This system applies information communication methods such as Electronic Data Interchange (EDI) to network companies. For small businesses, a simple re-order point system is preferable (Toomey 2000).

Methods of Inventory Cost Control and Cost Accounting

Generally, methods used in inventory cost control and cost accounting are First-In-First-Out, Last-In-First-Out, average cost, and accurate cost (Wee 2011). In the health sector, the primary consideration of inventory control lies in the life-cycle of an item, and cost comes later.

Inventory Monitoring

Wee (2011, pp. 19-20) identified three categories of inventory monitoring. These are: (a) periodical physical inventory, where movement of items is recorded as they occur, but inventory is not updated immediately. Physical stock-take is done at the end of the year; (b) continuous physical inventory. In this system, continual physical counts of stock quantity are recorded as they occur to show the amount of stock on-hand at all times. A separate ledger for each item is maintained. The inventory is updated whenever an input or output of items happens; and (c) combination physical inventory is a combination of (a) and (b) above.

Application of Inventory Management to the Healthcare Sector

Due to the nature of the healthcare industry, healthcare system inventory is unique compared to other industries. Traditionally, healthcare systems have applied the ABC[9] method based on annual requirements or a combination of ABC and Fuzzy Classification (Mahendrawathi, Nurul Laili & Kusumawardani 2011). Using this combination, inventory systems are classified according to criticality: vital, essential, or non-essential. The main consideration of ABC-Fuzzy Classification is the criticality of a service to patients. Stock-out of essential items may have a detrimental effect on patients. Other factors that require consideration are the financial impacts of stock-out and the holding costs (Mahendrawathi, Nurul Laili & Kusumawardani 2011). In addition to the ABC Classification method, another way of managing an inventory is by considering the flow of inventory and inventory costing methods. Accordingly, the storage of items in healthcare system inventories is based on FIFO – First-in-First-Out. The adaptation of this general principle is applied by giving attention to the life-cycle or expiration of an item (Wee 2011).

Inventory Organisation and Storage Patterns

The primary goal of storage organisation is that "inventory is managed logically, neatly and in an organized fashion" (Sheldon 2014, p. 85). This helps to ascertain the correct location, and improves accuracy in inventory counting. It is a good practice for a manufacturer or distribution company to update its inventory system every 24 hours by item location and quantity. This can be achieved by developing a checklist for inventory monitoring (Pearson 2013). Monitoring is directed to housekeeping organisation (organising items neatly in a designated place, good aisle alignment, and

[9] *ABC is an inventory classification technique. Where class "A (high value) items" have very tight control and accurate records, "B (low value) items" have less tight control and good records, and "C (intermediary) items" with simple control. Available (online) at: http://www.materialsmanagement.info/inventory/abc-inventory-analysis.htm*

labels on racks), sufficient lighting, properly sized locations, clearly marked drop areas, paper counting tools/methods (such as scales), logical sized or configured packaging, and standardised layering. Inventory monitoring can also take into account required component protection, material handling equipment, accessible materials, limited access, specific and unique location identification, adequate availability of system tools, storage patterns, specific and unique location identification, carousels for storage, and location systems (Sheldon 2014).

Methods of Inventory Management

In pharmacy, there are three methods used to manage inventory, the visual method, the periodic method, and the perpetual method. In the visual method, warehouse personnel visually compare the stock on hand with the listing of products that should be carried. Purchasing orders must be placed when stock levels reach a minimum threshold. The periodic method refers to the action of regular counting of stock and compares it with a desired minimum inventory level at a predetermined time. Purchasing orders must be in place when the stock level reaches a minimum threshold. In the perpetual inventory management method, a computerised system monitors the inventory at all times on a continuous, systematic basis. This is a common method used in industrialised countries (Ali 2011). Studies indicate that the perpetual method is more efficient than other methods (Ali 2011).

3.1.1.3 Demand Information

Information sharing between members from various levels of an organisation is an important aspect of coordinating actions in a supply chain. This enables improvements in the flow of information to all parties in both directions, improves efficiency, reduces uncertainty, and provides a more profitable supply chain (Fiala 2005; Ryu, Tsukishima & Onari 2009). In a multi-level supply chain with a general demand process environment, an increased level of demand information sharing among supply chain networks is effective in reducing manufacturing and distribution costs (Shang, Zhou & Houtum 2010; Wu & Edwin Cheng 2008).

Demand information on medicines is often absent in health systems in developing countries. Consumption data is often kept at healthcare facilities, is paper-based, and is shared with management at higher levels. Management at the national level receive orders only every 60 to 90 days (Privett & Gonsalvez 2014). Quantification of medicines is based on mathematical estimations. This situation jeopardises procurement and management decisions because the amount of medicines that need to be procured is not based on real need (Federal Ministry of Health Nigeria 2010; Ministry of Health and Social WellfareTanzania 2008).

3.1.1.4 Human Resource Dependency

Universal health coverage and equitable access to medicines can only be achieved with well-trained and qualified health workers (Brown & Gilbert 2014; Richey et al. 2011; Sankaranarayanan et al. 2014). This can be accomplished by hiring and maintaining staff through training and teamwork within and between organisations (Lengnick-Hall, Lengnick-Hall & Rigsbee 2013; Menon 2012).

Human resource limitations in developing countries is recognised as one among many factors that result in the poor performance of the healthcare sector and all aspects of supply chain management (Privett & Gonsalvez 2014). This means a few qualified professionals and unqualified staff or medical professionals must assume heavy workloads. Lack of qualified professionals affects supply chain performance due to poor management of warehouse inventory and poor decision-making. The result is that supply chain activities are compromised (Cometto et al. 2014; Privett & Gonsalvez 2014). Human resource dependency is only one component of overall pharmaceutical supply management in the healthcare sector.

3.1.1.5 Order Management

One of the most important parts of supply chain management is order management. It is highly complex but plays an important role in inventory management to meet demand from customers. In today's global market, proper order management can benefit a company by reducing inventory costs and maintaining safety stock and customer satisfaction. Order management refers to all activities required to convert a customer order into a payment. These include order taking, scheduling, allocating resources, invoicing, and payment collection (Kay 1995). Electronic-order management can help companies to cut costs, eliminate redundant procedures, and shrink inventory. Improvements in order management depend on the capabilities of the organisation. Three capabilities are needed to succeed in modern order management, better demand management, global order promising, and global distribution orchestration (Maha Muzumdar & Anijay Zinzuwadia, 2015).

Traditionally, order management has been closely linked to lot size and order quantity. There are two choices here, large lot sizes and economic lot sizes. When the lot size is larger, the ordering cost is low, but the inventory carrying cost is high. If the lot size is small, the order cost is high, but inventory carrying costs can be minimised (Kay 1995; Thomas, DJ & Tyworth 2006). Marketing and production companies prefer large lot size ordering. The perception is that with this ordering mode, the risk of running out of stock can be avoided and higher customer service satisfaction can be met. Demand and large inventory carrying costs are therefore not considered (Toomey 2000).

3.1.1.6 Shortage avoidance

The Food and Drug Administration (FDA) of the United States defines a medicine shortage as "a situation in which the total supply of all clinically interchangeable version of and FDA-regulated medicine is inadequate to meet the current or projected demand at the user level" (Ramanan & Grampp 2014, p. 151). The American Society of Health-system Pharmacists (ASHP) defines a shortage as "a supply issue that affects how the pharmacy prepares or dispenses a drug product or influences patient care when prescribers must use an alternative agent" (Fox et al. 2009, p. 1400). Supply shortages in ordinary non-medical goods do not have a severe impact compared to medicine shortages. Shortages of medicines are an increasing concern in many countries. Shortages began to appear in private pharmacies and in public health system pharmacies in the USA and Canada and in developing countries in the 1990s (Fox & Tyler 2003; Lemos et al. 2012; Poston, Woodend & Weir 2005).

Shortages of medicines, particularly essential medicines in healthcare settings poses severe consequences for patient safety (Lemos et al. 2012; Morrissey 2012; Poston, Woodend & Weir 2005). A study on drug shortages in the USA from 1996 to 2013 revealed that cardiovascular medicine were ranked among the top five classes of medicines with ongoing shortages nationally in this period (Wiggins et al. 2014). The trend of medicine shortages in healthcare facilities, particularly in hospitals, has been on the increase (Lemos et al. 2012; Quadri et al. 2015). Fox et al. (2009) predicted that shortages of medicines are likely to continue.

There are multiple causes of these shortages and these can be classified into supply or demand issues. Supply shortage factors are related to manufacturing, communication, and regulatory issues (Poston, Woodend & Weir 2005), an uneven supply and demand equation, natural disasters, and poor inventory practices (Fox et al. 2009; Lemos et al. 2012; Wiggins et al. 2014). Health professionals are challenged to come up with alternative approaches when experiencing shortages. One example is the shortage of Alemtuzumab, an anti-neoplastic agent used in North America. Physicians have had to use this product after the manufacturer's expiry date to treat patients (Lemos et al. 2012), or have had to substitute medicines with similar therapeutic effects (Lemos et al. 2012).

Strategic approaches have been taken at the healthcare facility level to avoid shortages of medicines through fostering coordination, the centralisation of pharmacies and hospitals, and routine monitoring of inventory. Improved coordination and communication with medical teams (physicians, pharmacists, and nurses) to prioritise how medicines are used (oral or injections) is required. A multiple-hospital system might be able to centralise pharmacy functions to enable the sharing of information and medicines among facilities. Continuous monitoring can be undertaken daily or weekly by assigning medicine shortage coordinators (Lemos et al. 2012, pp. 49-50).

3.1.1.7 Expiration of pharmaceuticals

Expiration is one of the key forms of item/resource wastage in business, resulting in significant economic consequences such as financial loss, safety disposal efforts, and stock shortages (Privett & Gonsalvez 2014). In the healthcare sector, the causes of expiration are poor management and selection of medicines, lack of demand quantification, procurement issues, inventory and warehouse management, and lack of training for employees (Privett & Gonsalvez 2014).

A study of the expiry of medicines in 19 public medicine outlets, 16 hospital stores, 123 private wholesale pharmacies, and 173 pharmacy retailers in Uganda indicated that products prone to expiration come from donated medicines, medicines used in vertical programs, and slow-turnover medicines. Most donated medicines have a short life. Lack of attention to slow turn-over medicine leads to expiration (Nakyanzi et al. 2010). Expiration results in serious threats to patient safety and services, and contributes to stock shortages in healthcare systems in both developed and developing countries (Nakyanzi et al. 2010). It also harms people's health and increases disposal costs (Lemos et al. 2012).

There are two approaches that could be taken to address the issue of expiration issues, the management of medicine expiry dates, and the improvement of information. The management of

products/medicines with expiry dates takes place at the facility and management levels. At the management level, one approach is to establish government policy on the return of expired products, recycling, and disposal (Huang et al. 2015). The approach at this level should be strengthened by sound coordination between national medical stores and pharmacy retailers with healthcare facilities, and between government and vertical programs and donors (Nakyanzi et al. 2010). Improvements to real-time information between supply chain partners is also required (Le et al. 2011; Morrissey 2012). At the facility level, training in warehouse and inventory management, and continuous monitoring and evaluation of practices and procedures is necessary (Nakyanzi et al. 2010).

3.1.1.8 Warehouse management

Warehouse management refers to the process of operating warehouse and distribution systems efficiently (Hompel & Schmidt 2007; Warehouse Logistics 2016). It deals with the flow of goods through storage and distribution. This involves methods and means to perform the work efficiently. Warehouse management systems are comprised of a combination of technology and hardware usage, ranging from simple software programs which track inventories, receiving, shipping, and pallets, to complex automated storage and retrieval systems according to the principle functions of a warehouse (Hompel & Schmidt 2007; Wilson 2006). The principle functions of a warehouse are goods acceptance, receipts and inspections, storage, inventory control, retrieval, consolidation of goods, order picking and packing, staging, and shipping/loading/delivery (Hompel & Schmidt 2007; O'Hearn et al. 2005). Another important function is controlling system records and monitoring inventory levels and overall performance. It is expected that a warehouse management system is designed to achieve its tasks and make significant economies in operations, improve service quality and accuracy, and reduce cost and inventory (Nolen, Herman C. & Maynard, Harold H. 1941; Wilson 2006).

Approaches to warehouse management also include the more traditional methods of manual inventory, shipping, and receiving management. These tasks require a combination of technologies such as forklifts, truck radio frequency data, and hand-held barcode readers. Any well-designed warehouse and distribution centre will consist of hardware and equipment such as a racking system, forklifts, cranes, pallet accumulators, and conveyors (Hompel & Schmidt 2007; Wilson 2006).

Adequate warehouse layout planning is an essential part of overall management of the store to improve convenience and traffic movement. The objectives of the layout of the medical store are to use space efficiently, promote the efficient handling of commodities, provide economical storage, and provide flexibility to meet changing warehousing requirements (Nolen, Herman C. & Maynard, Harorld H. 1941; O'Hearn et al. 2005). The underlying problem that is typically faced by warehouse arrangements is that of increasing store traffic. To overcome this, attention to the factors that influence storage mechanisms is critical. These are convenience of movement, store operating expenses, and store protection (Nolen, Herman C. & Maynard, Harorld H. 1941). Traffic convenience can be achieved through dividing departments into aisles to allow for rapid movement. In a retail activity, the aisles expose items to be easily identified. Narrow, zig-zag, and crooked aisles should be avoided. The arrangement of items according to certain classifications or

departments is desirable. Protection and store arrangement are other important factors to be considered. This is important for medicines/goods and equipment, and the prevention of personal injuries (Nolen, Herman C. & Maynard, Harold H. 1941).

Medium and Small Size Medical Store Routines and Housekeeping

Every warehouse has regular tasks/activities to be undertaken, regardless of size. General procedures are assigned to personnel in charge of particular departments. Their duties may range from inventory, stock replenishment, and other monitoring tasks of receiving and marking medical items. The procedure for receiving goods is to firstly receive them, then to examine them, and sign the delivery consignment. Once the products have been accepted, marking is done, and an update of the inventory records is conducted (Nolen, Herman C. & Maynard, Harorld H. 1941). It is also important to keep the medical store's goods, floor, interior, and exterior clean. Temperature should be maintained according to the defined standards for each department. Regular checks on the air-conditioning and ventilation are necessary. All of these procedures are essential, but also labour-intensive.

Today, these traditional systems do not appear to be sufficient to cope with the changes in the global market and the resulting customer expectations. Optimisation is required to be able to meet the demands of the flow of goods and economic efficiency. Optimisation of the traditional approaches through applying information technology to the monitoring and control systems is the answer. All of these forms of optimisation are necessary for drug stores and district health service drug stores. The same approach must be applied to a public sector national medical store, which also functions as a distributor.

From a practical perspective, there are four critical areas in the warehousing of healthcare commodities, human resources, layout, racking systems and material handling equipment, and warehouse management systems (O'Hearn et al. 2005). These areas are all interlinked. To achieve efficiency in healthcare warehouse management, careful planning of these four elements is essential. The requirements for human resources should be established according to the core functions of warehouse management. The layout of the warehouse should be designed according to the principal functions of a warehouse. A racking system should be planned and operated according to the description manual and the general category of the commodities. Material handling equipment should be scheduled according to need and proper maintenance principles. Warehouse management systems require technologies that integrate software bar coding equipment and radio frequency communication to provide computerised inventory management and distribution (O'Hearn et al. 2005). The key advantages of a well-designed warehouse management system are zero information errors, reduced information lead-time, improved storage capacity, and increased productivity.

3.1.1.9 Temperature control

Temperature control is considered an important aspect of supply chain management where the quality of products needs to be maintained from manufacturing to the hands of the end-user. The main focus is on the stability of perishable products such as most food items, and especially, medicines (Bogataj, Bogataj & Vodopivec 2005). Any change in temperature during travel time will alter the quality of the product and will result in economic loss due to waste (Privett & Gonsalvez 2014). The focus of this section is on the temperature control of perishable medicines such as vaccines and biological agents.

Temperature control within the supply chain is called cold chain management, which is the "supply and distribution chain for products that must be kept within a particular temperature range" (Castiaux 2010, p. 20). Biological agents and medicines are subject to changes to storage and temperature; therefore, a standard temperature for perishable medicines must be maintained (Castiaux 2010; Ramanan & Grampp 2014). The standard temperature for each vaccine is also different. For example, Measles, Mumps, and Rubella (MMR) vaccines should be refrigerated or frozen at a temperature between -58ºF and 35º to 46ºF; while the Human Papilloma Virus (HPV) and Pneumococcal vaccines such as PPC13 and PPSV23 should not be frozen, but kept between 35º to 46ºF (Williams 2015). Failure to manage medicines at the right temperature will result in loss of stability, efficacy, and potency. They can also become threatening to patients' health and can cause substantial economic loss.

In 2005, the WHO reported that vaccine wastage around the world was at 50 per cent. This is hugely significant as the loss of 1 per cent of vaccines due to exposure to hot or freezing temperatures can result in millions of dollars lost annually (Department of Immunizations Vaccine and Biologicals of WHO 2005). The latest survey on pharmaceutical supply chain management reported that temperature control of vaccines during shipment and transit is difficult to monitor. The application of monitoring technologies such as Vaccine Vial Monitors (VVM) and FreezeWatch^{TM} tags have been difficult to achieve due to a lack of human resources and limitations in the training provided for using these technologies effectively. No regular temperature control and a lack of temperature history charting in drug stores were also identified as issues by Privett and Gonsalvez (Privett & Gonsalvez 2014).

3.1.1.10 Shipment visibility

Shipment visibility is the capability of efficient sharing of timely and accurate information between all parties on demand, inventory location, delivery cost, and other activities in the supply chain (Barratt & Oke 2007, p. 1218; Yu & Goh 2014, p. 125). The process involves identifying reasonable inventory levels to meet customer demand (Ding, Guo & Liu 2011; Zhang, AN, Goh & Meng 2011). Tracing the movement of shipments is required to maintain quality products according to customer orders. Missing information on a shipment means that a product may be lost or the authenticity of the product may be questionable. Quality customer service and consumer protection are the ultimate goals of a supply chain.

McCrea formulated eight steps to enhance shipment visibility (McCrea 2011, p. 36). The first step is to assess the logistics strategy correctly through reflection on current supply chain operations, and to consider improving it internally or externally. The second step is to determine ownership via early establishment of tracking processes, alerts, and decision-makers. The third step is to integrate with trading partners by maximising the sharing of data and information through any possible means of communication, such as EDI (Electronic Data Interchange), manual email systems, or via fax (Barratt & Oke 2007, p. 1217; Ding, Guo & Liu 2011). The fourth step is to rethink lean inventory strategies. This can be addressed by keeping reasonable amounts of products on-hand to meet supply chain demand through instant and routine updates of the inventory. The fifth step is to open lines of communication with customers, which must then be maintained by involving them in the monitoring of the location of shipments. The sixth step is to go beyond simply taking orders, as understanding exactly the movement of freight is essential to the tracking task. The seventh step is to think globally. This deals with linking with freight forwarders, ocean carriers, and other provider network shippers who conduct instant monitoring of shipments, and then acting immediately if there are problems. The eighth and final step is to use the information wisely. Optimal shipment visibility is only possible when logistics professionals are equipped with technology and the drive to do the job (McCrea 2011, p. 36).

In the healthcare industry, the concern over potential counterfeit medicines being shipped to drug stores and dispensing pharmacies is increasing (Durdu 2011). Medicine manufacturers have used automatic shipment verifications solution technology, such as Zetes[10], to ensure that medicines are shipped according to customer orders, to improve the accuracy of shipped pallets (Durdu 2011).

3.2 Other Factors Contributing to the Pharmaceutical Supply Chain

Other factors which directly or indirectly contribute to overall pharmaceutical supply chain issues stated in the top 10 global issues, are management roles at each level of management; the distribution of medicines and supply chain management of medicines; sources of funding for pharmaceuticals; pharmaceutical selection and procurement; the import and quality of pharmaceuticals; policies and regulation; prescribing patterns; and control of pharmaceutical expenditure.

3.2.1 Roles of each management level in pharmaceutical supply management

The study by Privett and Gonsalvez (2014) on the top 10 pharmaceutical supply chain management issues will be used in the next section as a framework to map the major issues in Timor-Leste. This will be achieved by working from the Community Healthcare Centre level, to the District Health Services, hospitals, the National Directorate of Pharmacy, and SAMES (the Central Medical Store) of Timor-Leste. The issues of supply chain management are examined at the item, facility, and system levels. The literature and data used for this analysis is based on 10 research papers, technical assistance reports, field visits to health facilities, and project reports that have been conducted by

[10] Zetes is an effective and efficient logistical software package that can track the accuracy of deliveries and pick-ups, loadings, and estimated time of arrival.

various consultants and agencies in Timor-Leste since independence. Despite these reports, little appears to have occurred in the way of implementing the recommendations. The studies are listed in Table 3.1.

Table 3.1 List of studies/reports that deal with pharmaceutical supply at the district level

No	Author(s)	Year	Title of study/report
1	Pauline Norris, Raul B dos Santos, David Woods, and Wale Tobata	2007	Delivering medicines in a challenging environment: the pharmaceutical sector in East Timor (a descriptive study).
2	Mariana Reis Pinto	2012	Access to essential medicine in Timor-Leste: availability, prices and affordability.
3	Kathleen Holloway	2012	Pharmaceuticals in healthcare delivery - Timor-Leste (mission report).
4	Stanley Chindove, Antonio Ximenes, and Nelson Martins	2012	Medicine prescription pattern for the treatment of common disease at CHCsin three districts of Timor-Leste.
5	Michiyo Higuchi, Junko Okumura, Atsuko Aoyama, Sri Suryawati, and John Porter	2015	Use of medicines and adherence to STG in rural CHCsin Timor-Leste.
6	Kathleen Holloway	2015	Medicines in Healthcare Delivery: Situational Analysis-Timor-Leste.
7	Sustainable Solution, New Zealand	2015	SAMES mSupply Review and Support Project (final report).
8	Embaye Andom Yebio	2015	End of Assignment Report (Pharmacy Specialist).
9	The World Bank	2015	National Health Sector Strategic Plan: Support Project (completions results).
10	The World Bank	2015	Timor-Leste: Better management of medical supply improves lives.

3.2.1.1 CHCs

Community Health Centres (CHCs) are responsible for providing technical and managerial support to communities in their catchment area and to healthcare posts in the sub-districts (Ministry of Health Timor-Leste 2007). A core component of health services delivery is the availability of medicines. The availability of medicines depends on the management of the medicine inventory and accessibility of medicines (World Health Organization 2004). The role of CHCs in the management of medicines ranges from recording epidemiological data on the incidence of disease, to consumption data, inventory management, and the implementation of pharmacy policies, regulations, and guidelines. To achieve these roles and tasks, the management and staff of a CHC must be well-equipped with skills and knowledge in the selection, quantification, distribution, use, and inventory management of medicines (World Health Organization 2004). Routine standard processes required for the management of medicines are the consolidation of consumption data, requesting and reporting of the consumption of medicines, and submitting the gathered data to the District Health Service office every month (Holloway 2016).

However, access to medicines in CHCs and in healthcare posts in Timor-Leste remains a problem. Various studies, reports, and field visits identify a range of challenges faced by CHCs at the item and facility levels. These can be categorised into five major issues: i) inventory management, ii) order management, iii) warehouse management, iv) shortage avoidance, and v) shipment visibility. Research by Norris et al indicated that consumption and inventory data were unavailable (Norris et al. 2007). In a study undertaken in 2012, Holloway supported Norris et al.'s findings, reporting that

stock management, record-keeping of medicines, and requesting of medicines was not based on consumption data (Holloway 2012, 2016; Norris et al. 2007). The outcome of these deficits is frequent stock-outs of medicines (Holloway 2012, 2016; Norris et al. 2007; Yebio 2015). In the second quarter of 2015, stock-outs amounted to 33.3% of essential medicines. Yebio and Sustainable Solutions reported the difficulty in calculating inventory at hand, and the poor quality of record-keeping for the return of expired medicines (Sustainable Solutions 2015; Yebio 2015).

In terms of order management, requests for medicines are based on inaccurate consumption data, and there is no accurate dispensing documentation. This could be related to a lack of information and knowledge of the Essential Medicine List – Timor-Leste. This has resulted in harmful prescribing practices such as over-prescribing of systemic steroids at the health post level (Holloway 2012, 2016; Norris et al. 2007). Most pharmacies at the health centres are staffed by pharmacy assistants, nurses, or staff without adequate on-the-job training in pharmaceutical supply (Norris et al. 2007). There has been low utilisation of the essential medicine list and the Standard Treatment Guidelines (2010, 2015) due to poor introduction for users (Holloway 2012, 2016). In 2012, a study of 20 CHCs on prescribing patterns and adherence to the Standard Treatment Guidelines concluded that there has been excessive use of antibiotics in the healthcare centres for the treatment of acute respiratory tract infections (77% of 404 cases), and diarrhoea (94% of 360 cases) (Chindove, Ximenes & Martins 2012).

3.2.1.2 District Health Service

The role of DHS(DHS) management is to plan, coordinate, supervise, monitor, evaluate, and report all healthcare service activities at the district level (Ministry of Health Timor-Leste 2007; Republica Democratice de Timor-Leste 2003). Each DHS is responsible for financial support and the provision of medicines and medical equipment to between 3 and 7 CHCs and associated health posts. Some DHS have a small warehouse where medicines can be stored. Those without a warehouse must dispose of expired medicines as soon as possible. A major issue found at the item level at the DHS was the compromised quality of medicines in relation to temperature control and expiry dates. At the facility level, the issues found were in warehouse management, inventory management, demand information based on epidemiological data, the quantification of medicines based on requests from CHCs and health posts, monitoring and supervision of warehouse inventory control (World Health Organization 2004), and shipment visibility linked to transport and road conditions (The World Bank 2015). At the system level, problems included accurate demand information and HR issues such as a lack of qualified staff.

The key issues faced by the DHS were shared in common with those experienced by the CHCs, i.e. frequent stock-out of essential medicines (Holloway 2012, 2016; Norris et al. 2007; Pinto 2012). The causes of frequent stock-out were due to the challenges faced by DHS identified at all levels of the supply chain, ranging from limited human resources to temperature control. The key issues can be categorised into four main factors. The first factor is the lack of availability of a warehouse management system or a logistic management information system to enable standardised warehouse management practice and reliable data (Norris et al. 2007; Yebio 2015). According to Holloway, the consequences of this are poor inventory and storage management systems/practices in all district

warehouses, CHCs, and Health Posts (HPs). Storage of medicines also varied between facility pharmacies and no labelling was noted. Poor record-keeping is another common problem, with stock cards missing or not being updated, and a lack of standardised inventory forms in use. There was also no clear list of the most consumed medicines; hence, it was difficult to compare items that were fast or slow moving (Holloway 2012, 2016).

The second factor that contributed to the frequent stock-out of medicines was the lack of human resources in terms of both numbers and quality. Holloway found that DHS offices had two pharmacy technicians, but were unable to monitor or supervise medicine consumption in their territory. Medicine management at the health posts was managed by either a nurse or a midwife who had inadequate knowledge of, and skills in, pharmaceutical inventory management systems, and therefore, could not report the details to district staff (Holloway 2016). Between 2012 and 2015, a warehouse management system was piloted, but a lack of basic numeracy skills was identified as a barrier to full implementation. A level of success was nevertheless achieved at SAMES; however, a lack of staff commitment to use the warehouse management system and unreliable Internet connectivity contributed to the unsuccessful implementation of the online customer modules of the mSupply system at the district level. The appointment of untrained staff to replace trained staff has been noted as an inefficient human resource management strategy. Lack of knowledge in warehouse management systems at the DHS was also noted. Lack of supervision and support from SAMES and the Directorate of Pharmacy was experienced at two pilot sites, the Referral Hospital Baucau and at the DHS (Sustainable Solutions 2015).

The third factor that contributes to frequent stock-out of medicines is the lack of training on the Essential Medicine List for Timor-Leste (EMLTL) and the Standard Treatment Guidelines (STG) for healthcare professionals (Holloway 2016). When the EMLTL and STG were implemented, there was no training plan to improve staff capacity to engage in supply chain management of medicines, STG, and the ELMTL (Holloway 2012). There was also no supervision of inventory management provided by the Ministry of Health because the Directorate of Pharmacy did not have adequate human resource capacity to conduct integrated supervision with the DHS, the CHCs, and the hospitals (Holloway 2012, 2016; Yebio 2015).

The fourth factor, which was exacerbated by the other three factors, was the poor quantification of medicines required to be delivered to the health services. This was due to there being no adequate medicine consumption data at the health facilities. Inventory record-keeping was also poor, as there was no standardised formula for medicine quantification that could have been used at the health facilities (Holloway 2016). Requests for medicines were drawn up from consumption data and reporting from CHCs. However, in many DHS and CHCs, staff tended to avoid shortages of medicines by doubling the quantity of medicines requested for each quarter (Holloway 2012, 2016).

In reference to Privett and Gonsalvez's top 10 issues in pharmaceutical supply chain management, it is clear that the DHS experienced almost all these issues at all levels, i.e., at the system, facility, and item levels. At the system level, there was only limited capable human resources. At the facility level DHS faced the challenge of a lack of capacity in inventory, warehousing, and order

management. At the item level, they faced issues in relation to the lack of record-keeping, temperature control, and recording of expiry date of medicines.

The DHS are positioned between the Ministry of Health and the CHCs, and the health posts, so it inherits all the challenges experienced at the system, facility, and item levels. The various reports captured the majority of issues at district level, as this was the primary focus of their studies (Chindove, Ximenes & Martins 2012; Holloway 2011, 2012, 2016; Norris et al. 2007; Pinto 2012; Sustainable Solutions 2015, 2017; The World Bank 2015, 2015 ; United Nations Fund for Population Agency (UNFPA) Timor-Leste 2017; Yebio 2015). Importantly, there is an expectation that at district level, the DHS provide assistance to the CHCs and the health posts by way of supervision and monitoring of medicines, and the identification of the need for education and training. However, this tended to be beyond their capacity.

3.2.1.3 Pharmaceutical supply in the hospitals

In Timor-Leste's Basic Service Package released in 2007, it was stated that the primary role of hospitals was to offer a comprehensive level of care to patients referred from lower-level healthcare facilities (Ministry of Health Timor-Leste 2007). Access to, and availability of, medicines is an essential part of delivering hospital healthcare. This means that every pharmacy in a hospital must be equipped with qualified health professionals with adequate pharmaceutical and management skills to perform pharmaceutical supply chain management tasks ranging from warehouse management, quantification, and inventory management to distribution to patients. Hospitals make monthly requests for medicines to SAMES. This is based on consumption data; however, there is little research on how quantification is undertaken (Holloway 2016).

Pharmaceutical supply chain problems identified at the hospital level ranged from systemic issues to facility and item level issues. At the system level, Holloway reported that there was no functional hospital drug and therapeutic committees at any of the hospitals. At the facility level, all the hospitals shared the same issues in warehouse and inventory management. Inventory record-keeping was poor, and there was no consumption or inventory data. There was also no standard formula for medicine quantification that could be used at this level (Holloway 2012, 2016). Hospitals are allowed to procure emergency or extra medicines based on a government-allocated budget. According to Holloway, medicines identified for emergencies purchased during the first quarter of 2015 should have been anticipated during the quantification phase (Holloway 2016). However, there was no demand information at the hospital level, which accounted for the high cost of medicines procured during emergencies.

A report on the pilot of the mSupply system that was designed, in part, to capture hospital data and report it to SAMES, concluded that there was a lack of staff commitment to the use of the warehouse management system, and lack of Internet reliability contributed towards the unsuccessful implementation of the online customer modules of the mSupply system. There was also a lack of follow-up support on training from SAMES and the Pharmacy Directorate to the two pilot sites (the Referral Hospital at Baucau and the DHS) (Sustainable Solutions 2015).

With only limited research available at the hospital level, it is difficult to draw conclusions about overall pharmacy supply chain issues. Further investigation is required to thoroughly understand the problems in detail. The various research and consultancy reports do not capture the HR issues at the hospital system level, nor do they address issues related to the item level, such as expiry dates and temperature control.

3.2.1.4 The National Directorate of Pharmacy at the MoH

The role of the National Directorate of Pharmacy at the Ministry of Health (MoH) is to define pharmaceutical policies and pharmaceutical law, develop technical guidelines for pharmacy management for hospitals and clinics, to put plans in place, to acquire medicines, to maintain data on pharmaceutical activities for public and private vendors, and to conduct supervision and monitoring at all levels of the health facilities.

Since independence, the directorate has developed a Medicine Act and National Medicine Policy, and has developed and updated the Essential Medicines Lists (EML) and the Standard Treatment Guidelines (STG). It has also developed and rolled out a paper-based Logistic Management Information System (LMIS) and updated related policies (Holloway 2012). The department also established and now maintains the Committee for the Selection of Medicines, Products and Medical Equipment, known as the Commição de Selecção Medicamentos, Produtos e Equipamentos Médicos (CSMPEM), and the National Drug and Therapeutic Committee (Yebio 2015).

When the Ministry of Health was established in 2002, the strategic management of medicines in Timor-Leste was undertaken through the Pharmacy Department established under the National Directorate of Health Services (Republica Democratice de Timor-Leste 2003). In exercising its roles and responsibilities, the department faced barriers in negotiating with the government and aid agencies. In 2015, the department was elevated to directorate level, becoming the National Directorate (Republica Democratica de Timor-Leste 2015b) with the authority to deal directly with senior management in healthcare, politicians, and aid agencies (Holloway 2012).

The management of pharmaceutical activities has not been an easy task under the Pharmacy Department, as the top organisation in the Ministry of Health that oversees the management of medicines. The department is tasked to deal with all of this with very limited human resources. The pharmaceutical supply chain unit within the directorate has only two staff members (Yebio 2015). This is inadequate for managing the supply chain, monitoring, advising, and supervising of inventory management in all healthcare facilities, given the lengthy bureaucratic processes involved (Holloway 2016; Yebio 2015). The findings from previous studies and reports have documented the issues associated with these human resource inadequacies, such as the low number of pharmacists, and the lack of training and capacity in leadership and strategic management for pharmaceutical supply chain management (Higuchi et al. 2015; Holloway 2012; Norris et al. 2007). The impact of this is that there is a lack of monitoring and supervision mechanisms in place, or where they are in place, low staff numbers make these mechanisms difficult to maintain (Holloway 2016).

The issues identified above have been further jeopardised by the claim that the establishment of the Department of Pharmacy has not been well designed to cope with its role. The decree law No. 12/2004 does not accommodate the fragmentation of authority and coordinated delegation (Yebio 2015). Many regulatory functions cannot be implemented. One example is the delay in promulgation of the Drug Act 2010 by the National Parliament and the drug regulatory authority. In this case, there was only limited coordination and no coordinating mechanism. For example, there were too few meetings between SAMEs and the Department of Pharmacy or with the DHS and the various facilities to enable information to be disseminated (Holloway 2012, 2016).

The lack of a coordinating mechanism has resulted in a lack of engagement between the Department of Pharmacy and SAMES in managing vital and essential medicines and the use of warehouse management system data. This has had a serious effect on the implementation of the online customer modules of the mSupply system installed in the private clinics due to delays in approval. There has been no response to a recommendation to appoint an mSupply mobile supply management data analyst at the Directorate of Pharmacy (Sustainable Solutions 2015).

The lack of coordination has not only been observed in engagement, but also in the introduction and distribution of regulations, policies, and guidelines. An example of this relates to the introduction of STG and EMLTL through in-service training, but not at the pre-service training level for health professionals. There has also been no follow-up after training or regular supervision. This approach results in the change strategy having a low impact. Higuchi et al and Pinto reported non-adherence to the guidelines and to the Standard Treatment Guidelines for Timor-Leste by health professionals (Higuchi et al. 2015; Pinto 2012). There has been no pre-service or in-service training conducted on the updated EMLTL or STGs from 2015 (Holloway 2012, 2016). Another example of a lack of coordination was noted in the fragmented and ad-hoc training for LMIS provided by the United Nations Population Fund (UNFPA) for reproductive health programs (Bismark & Cruz 2008).

The lack of adequately trained staff in logistic management information systems is a further difficulty. The trained human resource in this case is the pharmacists or other health professionals involved in pharmaceutical supply chain management. This has contributed to poor inventory record-keeping and stock-out of medicines. The effect is that there has been no consumption or inventory data at the health facility level. There is no standard formula for medicine quantification that can be used at health facilities (Holloway 2012, 2016; Pinto 2012). The development of the Logistic Management Information System (LMIS) has also not been successful. Paper-based LMIS tools developed for DHS have been delayed which has contributed to the continuous poor supply of medicines (The World Bank 2015).

Lack of regulation, and lack of inspection and monitoring according to the existing regulations has been reported as one of the principal causes of the challenges faced by the health sector in medicine management (Pinto 2012). There is no quality testing of medical products and no replacement of any product found to be faulty when a contract with a supplier expires. The recall system for faulty medicines is not effective at all (Holloway 2016).

3.2.1.5 Central Medical Store, SAMES

SAMES is the only autonomous state enterprise that performs the full cycle of pharmaceutical supply chain management in Timor-Leste based on revolving drug funds (Cross et al. 1986; Huff-Rousselle 2009; República Democratica de Timor-Leste 2015a). Article 5 of Government Decree No. 18/2015, stated that SAMES is a public business entity that has a well-defined role in the production, importation, storage, and distribution of medicines and medical products for Timor-Leste (Holloway 2016; Norris et al. 2007; Republica Democratica de Timor-Leste 2015a). SAMES does not produce medicines, but procures them from overseas manufacturers, inspects their quality, manages storage at SAMES's warehouse, and distributes them to healthcare facilities. Regular distribution of medicines and medical products to hospitals is made on a monthly basis, and to DHS on a quarterly basis (Holloway 2016; Norris et al. 2007).

Since its enactment in 2004, and during the implementation of its functions, SAMES has faced many challenges. The following are the recorded findings on issues faced by the agency. Norris et al. maintained that there have been inefficiencies in warehouse management at SAMES. Inventory records have been kept on paper and on computer. Often, SAMES cannot deliver medicines to healthcare facilities if its trucks have broken down, and it lacks the funds to maintain the vehicles (Norris et al. 2007). Stock shortages, expired stock, and stock receipt and distribution are issues that prevent SAMES from being an effective supply chain service entity (Sustainable Solutions 2015).

Other issues include critical shortages of vital and essential medicines (33% for vital medicines and 55% for essential medicines), with stock availability of less than six months (Sustainable Solutions 2015). According to the World Bank, delays in procurement and poor quantification are other causes of the poor supply chain management of medicines, and stock-out of tracer essential medicines at SAMES and in the healthcare facilities were 20% and 43% respectively (The World Bank 2015).

There have also been discrepancies found between stock on hand and the system supply balance due to errors in stocktaking and checking of quality and expiry dates. There was no regular stock check, with poor practices and unknown causes. The lack of reliable Internet connectivity and services was also noted as another main issue within the healthcare system. There was significant waste found due to expiry or overstock of vital and essential medicines (Sustainable Solutions 2015). Overall, there were found to be three fundamental causes of the inefficiencies at SAMES: human resources, procurement, and coordination.

Lack of training for human resources is another challenge that affects almost all business operations in warehouse management and procurement at SAMES. Norris, et al. (2007) found that there were inadequate numbers of skilled staff available to operate and fix warehouse management database problems. At the item level, it was reported that most temperature control units at the SAMES warehouse were broken, while some medicines were stored in containers outside the Central Medical Store under tropical heat conditions. There was also some evidence to suggest that when SAMES ran out of medicines, it would send substitute products or lower amounts than requested to the various facilities (Norris et al. 2007).

In addition to the lack of skills and knowledge, according to the Sustainable Solutions report, there was also a lack of motivation and commitment by staff. Staff members refused to follow agreed standard operation procedures (Spisak et al. 2016; Sustainable Solutions 2015). Another HR challenge found was in relation to staff retention. Management would transfer skilled staff members to other functions and roles that were unrelated to their previous developed competencies and experience. This meant that it was difficult for competent staff to implement effective systems. The lack of skilled people to operate computers and to procure medicines at SAMES has been cited as a major reason why they have not carried out their procurement role satisfactorily (Norris et al. 2007; Pinto 2012). In addition, poor Internet connection was an infrastructure issue that hindered the implementation of the medical supply system (Sustainable Solutions 2015; USAID Deliver Project 2013).

The quality and safety of medicines has long been compromised due to a lack of functioning laboratory testing equipment. According to Holloway, SAMES has a clear stock record in electronic and paper form; however, there has been no in-depth study on the effectiveness of the inventory management system (Holloway 2016). Interestingly, there has not been any stock-out of the medicines procured by United Nations agencies for their vertical programs (Norris et al. 2007) due to their centralised procurement system and flexible funding model. Nevertheless, the lack of timely procurement and associated procurement problems such as inaccurate quantification, the high price of medicines, and long lead times remain an issue for SAMES.

The second underlying cause of the inefficiency of SAMES was the lack of capacity to carry out the procurement of medicines. Procurement was based on SAMES distribution data because there was no accurate consumption data from the health facilities (Holloway 2016; Sustainable Solutions 2015). There was also no immediate plan to address these issues; reports had been written and recommendations made, but no action had been taken. Hence, timely procurement has not yet been achieved (Sustainable Solutions 2015).

The third primary cause of inefficiency was lack of coordination. The Pharmacy Department of the Ministry of Health is the main strategic partner of SAMES. Reports indicated that there had been a lack of engagement between SAMES and the Department of Pharmacy across almost the entire supply chain process. For example, between 2012 and 2015, the role of procurement was transferred from SAMES to the Ministry of Health under the control of the National Directorate of Finance and Procurement. During this time, there was only limited engagement between the two entities. This resulted in slow approval processes for the implementation of the mSupply online customer modules in the pilot healthcare facilities, and for the supply of medicines requested by the DHSs (Sustainable Solutions 2015). This lack of engagement has been cited as causing a bottleneck in the supply of medicines (Holloway 2016). In 2015, Government Decree No. 18/2015 restored full functions to SAMES. Clearly, it will take some time to judge how effectively SAMES will perform.

It is important to note that SAMES also stores and distributes medicines and medical products procured independently by UNICEF, the WHO, and the Global Fund for their vertical programs (Holloway 2016); however, these agencies use their own procurement systems. Because SAMES

was not responsible for the procurement of medicines between 2012-2015, they have lost an opportunity to enhance these functions.

An important action taken by the Ministry of Health, with support from the World Bank to address bottlenecks in the pharmaceutical supply chain at SAMES, was the installation of a warehouse management software system known as mSupply, followed by training in the system for staff at SAMES and a few pilot health facilities. The mSupply warehouse management system was successfully implemented at SAMES and in the other pilot sites. At SAMES, there is one officer who is proficient in most aspects of system administration, but not in inventory management (Sustainable Solutions 2015). There was an expectation that the successful implementation of mSupply and the recently developed paper-based LMIS by the Pharmacy Department and the Ministry of Health would improve the underlying factors that lead to stock-out in the country. However, a report by the World Bank found that the rollout of the paper-based LMIS tools developed DHS was delayed. This has contributed to the continuing poor supply of medicines (The World Bank 2015).

A number of studies and monitoring visits to healthcare facilities in 2007 found that there was no pharmaceutical management system in place. Storage facilities were sub-standard, small, dark, and had no ventilation (Norris et al. 2007). Despite the development of a logistic management information system (LMIS), poor distribution results in continued stock-out of certain essential medicines (The World Bank 2015).

In terms of shipment visibility, bad road conditions are a major cause of delay in the delivery of medicines, and therefore, of frequent stock-out of medicines in health facilities in remote areas (The World Bank 2015). CHCs do not undertake the procurement of medicines. This is conducted centrally at SAMES or by the Ministry of Health. When there is a stock-out of a medicine, the item is transferred from other facilities, or a notification is sent to SAMES.

3.2.2 Distribution and supply chain management of medicines

Frequent stock-out of medicines and medical consumables in most healthcare facilities in Timor-Leste is a common problem that has been apparent since independence. From 2011 to 2015, this became a national issue forcing many healthcare facilities to make emergency orders, with hospitals and CHCs operating without the availability of essential medicines (Fabricant 2014; Ministry of Health Timor-Leste 2015). Lack of availability of essential medicines became an important issue in the National Health Sector Strategic Plan for 2011-2030, and strategies have been devised to address this issue. The strategic plan identified that the main root causes of the problem were related to inefficiencies in the pharmaceutical supply chain management system, particularly inappropriate item selection, irrational use of medicines, and poor distribution systems for pharmaceuticals (Ministry of Health Timor-Leste 2011).

In 2012, the piloting of the mSupply software was carried out at SAMES and in the National Hospital Guido Valadares, Municipal Health Services of Dili, and the Referral Hospital of Baucau. The result of the pilot of the mSupply system indicated that some improvements could be achieved

as long as dedicated staff were employed to implement the software (Sustainable Solutions (NZ) 2015). The mSupply system was later introduced to all 12 municipalities; however, due to unclear political decisions by the government, it was withdrawn in December 2018.

The Ministry of Health (MoH) took steps in 2014 to rectify the issue by directly managing the procurement of pharmaceuticals centrally at the Central Service Offices of the MoH, a role previously assumed by SAMES (Ministry of Health Timor-Leste 2015). As previously noted the procurement functions were then returned to SAMES in 2016 (AH-080 2017).

Apart from some minor changes in the administration of the management of pharmaceuticals, frequent stock-out remains a chronic problem at the healthcare facility level. During 2014, 33% of CHCs experienced stock-out of essential medicines. A study completed in 2006 recorded the incidence of stock-out of medicines in health facilities, although there was no exact figure presented in the study, only a general description of the situation. The study was descriptive and based on observations, but was not supported by reliable figures (Bravo & de Carvalho 2013).

Poor management was not the only factor that contributed to frequent stock-out of medicines in the country. Other factors that may have contributed to frequent stock-out were the failure to use the Standard Treatment Guidelines (STG) and the Essential Medicines List (EML) to guide the procurement of medicines. An EML for Timor-Leste only became available in 2010 (Committee for Selection of Medicines Product and Medical Equipment Timor-Leste 2015). How this contributes to the frequent stock-out of medicines will require further investigation.

The problem of stock-out has also been partially caused by inappropriate prescribing of medicines to patients, according to Timor-Leste's Standard Treatment Guidelines. This has been confirmed by a retrospective cross-sectional study conducted in 2011 on the use of medicines for three categories of diseases: acute respiratory infections, diarrhoea, and malaria cases in eight CHCs in three districts in Timor-Leste. This study indicated that the average stock-out of medicines was 50% in all target facilities. The study did not classify the stock-out medicines according to the categories in the List of Essential Medicines (Chindove, Ximenes & Martins 2012). The study used the terms 'drug availability' instead of stock-out of medicines, and further clarification of the findings is required, as the low availability of selected medicines may not mean stock-out of medicines.

3.2.3 Sources of funding and pharmaceuticals

Timor-Leste does not have local pharmaceutical manufacturers; therefore, it is entirely reliant on importing medicines from overseas. In 2014, 18 per cent of the health sector budget (US$ 67 million) was allocated to the supply of pharmaceuticals. The health sector budget was 5.21 per cent of the total Government State Budget (US$1.27 billion) (Ministry of Health Timor-Leste 2015). This means that US$5 per capita was spent on drugs and medical supplies (Fabricant 2014, p. 23). Over the past five years (see Table 3.2), there has been a sharp decline in overall government expenditure for the health sector; however, expenditure per capita for pharmaceuticals has increased over the same period, with the exception of 2016. The figures in Table 3.1 do not include funding

from donors for medicines and medical consumables, or from vertical programs such as those for Expanded Program for Immunisation (EPI), leprosy, and reproductive health commodities from UN (United Nations) agencies.

Table 3.2 MoH budget allocation for medicines and medical supplies

Fiscal year	Health Sector Budget (in millions)	Medicines are included in goods and services (in millions)	Medicines and medical supplies only (in millions)	Health expenditure per capita
2012	46.50	18.20	Unknown	42
2013	61.50	21.08	Unknown	55
2014	67.22	28.85	1.20 (18%)	61
2015	69.90	30.01	5.00 (13%)	62
2016	42.38	10.05 [11]	1.05	38

Adapted from Fabricant 2014, p.28 (República Democrática de Timor-Leste 2016 p. 283)

Funding for vertical programs comes from each agency that oversees its own programs[12]. The supply of pharmaceuticals is based on estimated data agreed to by the Ministry of Health. Based on the figures, the agencies then independently procure and ship medicines to the country; and store them at SAMES. SAMES manages the national inventory and distributes medicines and medical products according to requests from the various healthcare facilities. At this stage, there has not been any cost-sharing agreements between the government and the agencies overseeing vertical programs, such as the Global Fund and the World Food Program.

3.2.4 Control of pharmaceutical expenditures

There is a significant difference in the price of medicines between private chemists, and consumers are not aware of these differences. Even if prices are regulated, little can be done to control the price of medicines in private chemists. As every single medicine and medical product is imported, and the size of the pharmaceutical market is small, regulating the price of pharmaceuticals in the country is difficult.

The government of Timor-Leste is not in a situation to control the price of pharmaceuticals on the market. However, there are ways that the government could control pharmaceutical expenditure. For example, drug policies could be developed that lead to cost containment through de-listing medicines that are considered non-essential, and controlling the influx of new medicines that are less efficient than existing ones. Enforcing the use of the EML would be one strategy for future improvement, while another would be to consider approaches from other countries. Experience from a range of European countries has shown that there is a correlation between pharmaceutical expenditure and price control. Price control policies can effectively curtail increases in the price of prescribed medicines (Andersson 1992; Brekke, Grasdal & Holmås 2009; Håkonsen, Horn & Toverud 2009; Kaiser et al. 2014; Lambrelli & O'Donnell 2011; Puig-Junoy 2010; Vogel 2004).

Norway is one European country that has succeeded in keeping the price of medicines and consumption levels at the lower end. This has been achieved by establishing regulatory and cost-

[11] *A confirmation for the 2016 figure is expected from the National Directorate of Finance Management and Procurement of MoH Timor-Leste*

[12] *Email confirmation from National Directorate of Pharmacy and UNFPA Timor-Leste*

containment policies. Strategies introduced included the procurement of medicines based on defined population needs, and the establishment of a monopoly on the wholesale distribution of medicines. Another successful strategy in controlling pharmaceutical expenditures has been the implementation of the reference price system in Denmark. Both Norway and Denmark use a co-payment system (Andersson 1992; Brekke, Grasdal & Holmås 2009; Kaiser et al. 2014).

A study by Hsiao et al. (Hsiao, Tsai & Huang 2010) indicated that the factors affecting the increased cost of pharmaceuticals are the price of medicines, volume, and therapeutic choice. However, reviews by Hsiao et al. noted that there was a significant correlation between price regulation and escalating pharmaceutical expenditure (Hsiao, Tsai & Huang 2010). The findings from a longitudinal study on non-steroidal anti-inflammatory drugs in Taiwan supports this view; however, suggested price regulation has confounding effects on cost containment (Hsiao, Tsai & Huang 2010, p. 2; Maynard & Bloor 2003).

3.2.5 Pharmaceutical Supply and Selections

The Department of Pharmacy at the Ministry of Health is responsible for the management of pharmacies at the district and health facility levels, as well as the quantification of medicines. The low position of the department in the Ministry of Health poses another challenge. Being a department means it has no authoritative capacity to make a deal with a directorate, especially the Director of Health Services and other directorates in the health sector such as SAMES and other health agencies. This lack of authority and administrative power has resulted in ineffective coordination. This has been addressed by elevating the department to a national directorate, which has equal power with semi-autonomous agencies in the healthcare system (República Democratica de Timor-Leste 2015b). Regardless of the administrative power bestowed on the Directorate of Pharmacy, and changes in executive power and authority without sufficient human resources to run the organisation, it will take some time to achieve the effectiveness required of the organisation, and to resolve the lack of coordination in the supply of medicines.

3.3 Conclusion

The literature referred to in this chapter strongly indicates that Timor-Leste shares the ten most significant global supply chain management issues based on Privett and Gonsalvez's dependency model. The nation faces issues at all levels of pharmaceutical management. At the item level, there are issues with temperature control. At the facility and system levels, there is a lack of coordination, demand information, human resources, warehouse and inventory management, order management, and shortage avoidance. Other noted factors that contributed directly or indirectly to the pharmaceutical supply chain management problems are lack of awareness of pharmaceutical management roles and responsibilities at all management levels, pharmaceutical selection and procurement, distribution of pharmaceuticals, sources of funding for pharmaceuticals, development and implementation of pharmaceutical policies and regulations, prescribing patterns, and pharmaceutical expenditure controls. Furthermore, the legal separation of functions between the

Pharmaceutical Division and SAMES, and the implementation of related polices and guidelines, has also caused chaos in pharmaceutical supply chain management.

Of all the top 10 pharmaceutical supply chain management issues identified above, lack of capacity of human resource management at the technical and managerial levels is evident, along with deficits in infrastructure, financial sources, and continuous changes in managers in pharmaceutical supply chain management. The lack of development of human resources includes deficits in initial training, lack of in-service training, inadequate staff supervision, and poor understanding of what is required to maintain a robust supply chain. Poor technical and managerial capacity have a direct impact on pharmaceutical supply chain management at all levels. Clearly, there is a serious lack of strategic and technical capacity related to addressing the complexity of the issues in the healthcare system. All these complex issues call for the deployment of a quantification and forecasting approach that is more appropriate to the local context in Timor-Leste. Where econometric forecasting models cannot be fully operational due to the enormous challenges faced, the social-behavioural model developed by Andersen is a model that might meet the needs of a post-conflict country such as Timor-Leste.

CHAPTER 4. PHARMACEUTICAL QUANTIFICATION MODELS

4.1 Introduction

The magnitude of pharmaceutical supply chain management issues in Timor-Leste cannot be fully understood through a single theoretical framework. As noted in previous chapters, there is a failure in human resource capacity as a result of the history and political context of Timor-Leste, which is one of violence, and the negative impact of the nation's colonial past. The backbone of the current human resources in the healthcare sector is almost entirely limited to clinical staff who have had little exposure to management roles. This is reflected in the various studies of pharmaceutical supply chain management conducted during the 18 years post-independence.

The 10 studies explored in the previous chapter revealed the root causes behind pharmaceutical stock-out; however, they did not provide an understanding of the full picture. Another way to examine current pharmaceutical stock-out in Timor-Leste is to analyse how pharmaceutical provision is calculated to meet current pharmaceutical needs. This raises the following question: 'what is the demand information and which determinants are deployed to meet pharmaceutical needs?' Understanding how these demands and determinants or predictors are used to quantify pharmaceuticals is essential. The root of demand information is inventory management, from which logistics management information systems generate detailed information. This is an important component of the pharmaceutical supply chain system that details stock levels and the flow of pharmaceuticals along with morbidity information. All of these provide the basis on which to quantify and forecast pharmaceutical needs in a health system. This chapter provides a description of Andersen's behavioural model of healthcare utilisation, in addition to other quantification models.

4.2 Pharmaceutical Quantification Models for Primary Healthcare

A number of models that have been used to quantify pharmaceuticals requirements for healthcare services that may be useful for Timor-Leste are outlined below. The baseline of these groupings for pharmaceutical quantification are derived from the WHO guidelines. These can be divided into econometric and social or behavioural models. The econometric models discussed here are: Adjusted Clinical Groups (Orueta et al. 2006); Clinical Risk Groups (Vivas-Consuelo et al. 2014); the Charlson Comorbidity Index (Charlson et al. 1987); and the World Health Organization's Quantification Model (Management Sciences for Health 2012; World Health Organization 1991, 1995).

4.2.1 Econometric models for pharmaceutical quantification

Many healthcare systems, both public and private, use econometric models to quantify pharmaceuticals needed for primary healthcare at community healthcare centres and hospitals. This section provides a snapshot of well-known econometric models used in healthcare studies.
One of the factors that have an impact on econometric models of healthcare utilisation is how the healthcare system in a particular country is funded, whether it be a public system funded through general taxation or some form of compulsory insurance, or a private for-profit system requiring citizens to take out individual insurance (Willis & Krassnitzer 2016) In systems where citizens must take out insurance, institutional aspects have important implications in modelling the relationship between health insurance plans and healthcare utilisation. One factor that determines this relationship is the type of insurance plan; for example, whether it is a basic insurance plan or a supplemental health insurance plan, i.e. private or semi-private. These factors influence access to services such as seeing a doctor or other allied health professional or accessing surgical services. For example, econometric models may assume that a patient only seeks to use a healthcare service when they are ill, and what care they receive depends on the form of health insurance plan purchased. Hence, a key determinant will be income. Other determinant factors that influence healthcare utilisation that can be measured are age, gender, income, education, physical activity, socio-economic status, number of hours worked per week, illness symptoms, living alone or with family, tobacco consumption, geography (urban/rural), and body mass index. The insurer may limit the cover that can be purchased based on these factors (Holly et al. 1998). In Timor-Leste, the government provides free universal healthcare, so while many of the determinants listed above are relevant, the cost to the consumer at the point of care should not be an issue.

4.2.1.1 Adjusted Clinical Groups

The Adjusted Clinical Group is an instrument that classifies patients into categories based on diagnostic codes, age, and sex within a one-year period. These factors are used to adjust payment rates for service fees, the profile of the physician, morbidity adjustment methods for healthcare utilisation, and description of the burden of disease. The system quantifies morbidity by grouping individuals based on patients' demographic characteristics and their known diagnoses.

Vivas-Consuelo et al. conducted a study in 2014 to validate the capacity of the Adjusted Clinical Groups to explain the variance in primary care settings in Spain (Vivas-Consuelo et al. 2014). The source of data for the study came from patient's medical records, with patient's health problems organised into healthcare episodes for those hospitalised for more than 24 hours. The investigation of diagnoses based on an established coding system and prescriptions were undertaken. Observation of the patients' coding systems were also conducted, and advice based on the International Classification of Diseases-Ninth Revision-Clinical Modification (ICD-9-CM) was given to physicians for coding errors. Patient and other variables for the study were age, sex, established diagnoses, and the use of primary care resources such as the number of visits to physicians, requests for laboratory tests, radiography tests, referral to specialised services, and the cost of prescriptions. Scenarios were then developed to increase data validity. The quantification of morbidity based on

gender and medical diagnosis were established. The diagnoses were then clustered into manageable categories. To test the capacity of the system to explain variations in the use of primary healthcare services, adjusted R^2 multiple regression models were performed. In evaluating the approach, Vivas-Consuelo et al concluded that the system explained more than 50% variance in visits to primary care physicians and 25-40% of prescription costs (Vivas-Consuelo et al. 2014).

In the clinical setting, Adjusted Clinical Groups (ACG) have stronger predictive power for pharmaceutical use and expenditure than age, sex, and Charlson Index of comorbidity. The research suggests that there have not been many studies on the predictability of pharmaceutical expenditure (Hanley, Morgan & Reid 2010; Morgan, Cunningham & Hanley 2010). Past studies have found that demographic and geographic determinants alone have very low predictive power. Health status information gathered through the utilisation of diagnostic cost group has been used to conduct studies using ACG. Limitations in the use of linear regression to explain and predict pharmaceutical expenditures show that ACG does not predict well. This is due to the fact that healthcare costs are rarely normally distributed. The small percentage of high-cost cases results in a right-skewed tail. No previous studies were found to validate modelling techniques to address this issue. Generalised linear models can overcome the above issues and better predict pharmaceutical expenditures (Hanley, Morgan & Reid 2010) which may be suitable for patients with chronic conditions (Vivas et al. 2011).

In critiquing this approach, Orueta et al (2006) and Vivas-Consuelo et al (2014) both concluded that a lack of administrative databases, particularly those involving medical records, was the main challenge for ACG model (Orueta et al. 2006; Vivas-Consuelo et al. 2014). This system has been implemented in a number of European Union countries, Canada, and the United States where there are rigorously-monitored medical records, but has been difficult to implement in developing and emerging countries which tend to lack adequate medical record systems.

4.2.1.2 Clinical Risk Groups

Clinical Risk Groups (CRG) is an extension of the Adjusted Clinical Groups approach, with some modifications that researchers claim assist in the quantification of pharmaceuticals. It uses administrative and clinical data to stratify a population according to morbidity at the individual patient level. The morbidity of patients is adjusted by chronic conditions according to CRG classifications. Once again, data validity from reliable comprehensive electronic medical records is paramount. Vivas-Consuelo et al. claimed that the CRG system is statistically significant and better predicts patients' pharmaceutical costs in primary healthcare services (Vivas-Consuelo et al. 2014).

4.2.1.3 Charlson Comorbidity Index

The Charlson Comorbidity Index was developed and published in 1987 by Mary E. Charlson, a distinguished Professor in Medicine from the Weill Cornel Medical College. This approach takes account of comorbidities. Comorbidity is a situation in which other diseases occur at the same time as the primary disease. For example, a patient with a cardiovascular disease may also have diabetes mellitus. The effect from the other disease on the primary disease in terms of risks to mortality is

measured. The index predicts one-year mortality from the comorbidity condition of a patient from 18 defined comorbidity conditions. Each condition is assigned a score of 1 to 6, based on the severity of the disorder. The scores are then calculated to produce a total score that predicts mortality (Charlson et al. 1987). The index has been used extensively in clinical studies. The Charlson Index has been used to predict the cost of pharmaceuticals for chronic conditions for patients (Charlson et al. 2008) in countries such as the USA, the UK, and Ireland. It does not appear to have been used in developing countries or in post-conflict situations.

4.2.1.4 World Health Organization forecasting models

There are quantification guidelines for healthcare utilisation provided by the World Health Organization (WHO). For programmatic purposes, i.e. tuberculosis and HIV/AIDS, the guidelines are based on a quantification formula and set of tools (i.e. QuanTB or Excel templates) provided to support managers in pharmaceutical quantification and forecasting. The formula for the total drug requirements for a program is made up by having the consumption of health resources required by new patients added to the consumption of ongoing patients and then subtracting the stock on hand. Information required for this forecasting includes the number of new patients enrolled, treatment regimens being used, average daily dose per medicine, and the percentage of utilisation of each medicine (World Health Organization 2014b). There are four quantification methods formulated by the WHO: (a) morbidity, (b) the consumption method, (c) the proxy consumption method, and (d) the service-level projection of budget requirement method (Management Sciences for Health 2012; World Health Organization 1991).

The morbidity method estimates pharmaceutical needs based on standard drug treatment schedules for quantifying requirements based on average doses. Information on morbidity data, essential drug list packages and prices, the pharmaceutical budget, and standard treatments are required for this calculation (Management Sciences for Health 2012; World Health Organization 1995). The consumption method calculates the pharmaceutical needs for each item according to a list of all pharmaceuticals eligible for procurement and accurate inventory of the previous consumption period (six or twelve months). Average monthly consumption is calculated over a set period to adjust for stock-out. A percentage increase for monthly use is added to the average monthly consumption to come up with the final figure (Management Sciences for Health 2012; World Health Organization 1995). The proxy method is used to quantify the pharmaceuticals when neither consumption nor morbidity data are available. This is undertaken by estimating pharmaceuticals using consumption data from a region or country that shares similar characteristics to the situation at hand. It can be based on a region with a similar population or on specific medicines (Management Sciences for Health 2012). The service-level projection of the budget requirement method is used to estimate the financial requirement for pharmaceutical procurement based on cost per patient treated at all health facility levels. It does not forecast pharmaceuticals for one specific medicine, but has a clear political justification as it is based on cost per patient per healthcare facility (Management Sciences for Health 2012).

The econometric models are mostly applied in clinical settings in developed countries where clinical data availability and reliability are at a high level. In addition, the WHO methods for pharmaceutical

quantification and forecasting mostly require epidemiological and population data. It is assumed that to implement these models, there needs to be healthcare personnel with the knowledge and skills to provide the necessary data. These models assume that accurate quantification and forecasting of medical and health services can be achieved through rational calculations based on epidemiological and demographic data. However, they do not take into account cultural, political, social, or managerial issues that may confound these quantitative approaches.

Understanding the cultural, social, and political factors that have an impact on the pharmaceutical quantification and forecasting required to meet the demand is crucial. None of the previous studies examining pharmaceutical stock-out in Timor-Leste have considered the political, social, and cultural issues that may confound current supply chain processes, nor do they identify what method of quantification is used in Timor-Leste, or what demographic or epidemiological data informs prediction and forecasting. Andersen's behavioural model of healthcare utilisation is a social model that takes account of environmental factors that can accommodate the social, political, and cultural situation of a country, as well as the demographic and epidemiological factors. The model accommodates these issues in its enabling factors which are briefly outlined in the next sub-section.

4.3 Andersen's Behavioural Model of Healthcare Utilisation

There are many methodologies used to quantify and forecast pharmaceutical needs in a healthcare system, including approaches developed by the WHO (World Health Organization 1991, 1995, 2014a, 2014b). Each of the quantification methods requires a different set of data applied to different scenarios in program or clinical settings. Andersen's behavioural model (Andersen 1995a) for healthcare utilisation offers an alternative perspective for quantification and forecasting of pharmaceutical need in both hospital and clinical settings as well as in primary healthcare settings.

Andersen's model was first developed in the 1960s by Ronald M. Andersen, a Professor in Health Service Management at the University of California, Los Angeles (Andersen & Aday 1974). The model has been updated four times, with the latest phase (Phase 4) occurring in the 1990s. Since then, the model has been used as a conceptual framework by researchers to predict and understand the utilisation of healthcare resources in clinical and management settings (Andersen 1995a). The model consists of four primary components: the environment, population characteristics, health behaviours, and outcomes. Each of these components has a number of factors that influence individual use of a healthcare service. Interactions between these factors determine health outcomes.

The **environmental factors** in the model include the healthcare system and the external environment. The external environment includes the health status of the physical environment, as well as the political, cultural, social, and economic situations. The influencing input factors in a healthcare system are its healthcare policies, resources, and the organisation of the system, such as whether or not it is a universal healthcare service or if it is one requiring patient payment. All these factors determine whether or not a population will use the service.

The environmental factors identified in Andersen's model can be extended to incorporate the effects of the colonial legacy of both the Portuguese and the Indonesians on people's behaviour, and the political, cultural, and social aspects of Timor-Leste society. For example, the healthcare system is still greatly influenced by the legacies of colonialism given that, over the past three centuries, the health system has been managed by the colonial powers, while at the same time, the struggle for independence has been part of East Timor's history (Hägerdal 2006, 2012; Kammen 2010, 2015; Van Klinken 2016). Postcolonial theory allows the researcher to ask questions about what it means for a country to manage its own affairs independently in the shadow of the cultural identities and knowledge left by the colonisers. This legacy often includes a high dependency on expatriate experts in policy development, resulting in the emerging nation being susceptible to neo-colonialism and neo-imperialism. As already noted, due to lack of capacity, most peace-building activities have been undertaken by foreign experts.

External control and economic exploitation of native people and their lands tend to have both positive and negative human consequences. This depends on whether or not a colony has been directly or indirectly ruled (Lange 2004). One example of the positive consequences is rapid economic growth and development, such as improved sanitation and public health (Aginam 2003). The negative consequences include powerlessness, knowledge dependency (Go 2013), loss of culture and language, racism, discrimination, lack of capacity (Browne & Fiske 2001), and resistance and rebellion (Bell 2010; Hägerdal 2006, 2012; Kammen 2015). For many newly independent countries, these negative factors often mean that the indigenous population have not been adequately equipped to operate and manage services.

The fact that many health policies in pharmaceutical management are developed by foreign consultants reflects a neo-colonial approach. The development of the national essential medicine list and the standard treatment guidelines, and supply chain management approaches (Nelakurthi 2015; Norris et al. 2007; Sustainable Solutions 2015; Yebio 2015) are examples of Timor-Leste taking on ideas from more powerful countries and agencies. Many of the guidelines and standard operating procedures developed in the past have not resulted in improvements to healthcare service management or services.

Many questions can be asked in relation to the post-colonial legacy. Is there any resistance to organisational change from local healthcare managers? If so, what are the reasons for resisting change in management practices? To what extent does the colonial legacy in healthcare governance enable or disable health service management in postcolonial Timor-Leste? These questions allow for an analysis based on postcolonial (Go 2013; Karkov 2012) and resource dependency approaches (Balcilar, Kutan & Yaya 2017; Palat 2014; Tileagă 2012; Yeager et al. 2015; Yeager, Zhang & Diana 2015).

Population characteristics identified in Andersen's (1975) model involve the specific demographic and epidemiological factors that have an impact on an individual's health, along with enabling factors and the need for healthcare. These predisposing characteristics include age, gender, geographic location, education, and socio-economic status. Enabling resources include the healthcare system, relevant policies, infrastructure, road networks and transport, and healthcare

facilities. These also include input factors such as health beliefs and practices that influence how a person uses the healthcare service. Specific factors in the healthcare system in relation to the provision of pharmaceuticals include sound policies in pharmaceutical supply chain management. The need predictors of a population are expressed through their perceived health status. This is linked to population characteristics, particularly literacy (including health literacy), and policies that might induce demand for services. One example of such a healthcare policy would be mandatory child immunisation.

Health behaviours are an individual's personal healthcare beliefs and practices. These may be linked to their cultural beliefs (such as beliefs about child immunisation), and/or their socio-economic status. For example, beliefs about appropriate food may depend on socio-economic status or cultural understandings. These two factors (cultural beliefs and/or socio-economic status) will have an impact on how people use healthcare services.

Health outcomes are determined by how individuals perceive their health, but also by the level of health coverage of the population for services such as immunisation, ante-natal care, and other preventative services (OECD 2008, p. 401). Health outcomes are also dependent on consumer satisfaction with these services. Both health outcomes and health behaviours are heavily influenced by predisposing, enabling, and need factors which form part of the population characteristics. In fact, all four components interact. Factors from each of the sub-components are essential inputs that are helpful in understanding healthcare service utilisation. Andersen's model is outlined in Figure 4.1 below (Andersen 1995a).

Figure 4-1 Andersen's emerging behavioural model for healthcare utilisation

4.3.1 Four components of Andersen's model to predict utilisation and need for healthcare

In order to begin to predict healthcare service utilisation, such as the need for pharmaceuticals, population predictors such as age, gender, and socio-economic status need to be considered. For example, the number of children under five will be a predictor of the provision of vaccines. The number of women of reproductive age, or who are pregnant, will determine the pharmaceutical needs required during pregnancy, such as folic acid. However, predicting the requirements for many

diseases also requires an understanding of factors for both the population characteristics and the external environmental components. For example, malaria and tuberculosis are closely associated with socio-economic factors, but also with environmental factors such as climate, living conditions, and health beliefs about prevention. The use of healthcare services will also depend on cost. Where healthcare services are free, or there is adequate insurance, low socio-economic populations will be more likely to seek out services. Again, this health-seeking behaviour will be dependent on the availability of the services, the location of the healthcare facilities, trust in the healthcare professionals, and personal cultural beliefs about illness causation. In brief, Andersen's model is a detailed model that depicts how interactions between four components, the environment, population characteristics, health behaviours, and health outcomes, might predict pharmaceutical use.

4.3.2 Measuring the four components of Andersen's behavioural model for healthcare utilisation

The relationship between the determinants of health behaviour and the utilisation of (and requirement for) pharmaceuticals and pharmaceutical management can be explained by looking at factors within the four components that can be measured. For example, one way of taking account of forecasting pharmaceutical needs for a population would be to measure factors such as total population, gender, age, geographical location, literacy rates, poverty levels, employment, accessibility to healthcare facilities, and transport availability.

In terms of the healthcare system, policies that establish healthcare facilities that are accessible to the population based on a defined distance that can be reached on foot or by a motor vehicle are determinants that can also be measured. In addition to the healthcare system, the number and skill level of human resources assigned to each healthcare facility can be used to calculate pharmaceutical expenditures. A healthcare facility staffed with the right healthcare professionals, according to the service level, will ensure that the population has confidence to use the healthcare services. Increased confidence to use healthcare services is associated with the right provision of required pharmaceuticals and correct management of pharmaceuticals. In addition, specific factors in the healthcare system in relation to pharmaceutical provision are related to sound policies in the management of the supply chain.

4.3.3 Application of Andersen's behavioural model of healthcare utilisation in clinical settings

Andersen's behavioural model has been used in a number of studies to understand the predictors for healthcare utilisation expenditure in a variety of healthcare settings in both developed and developing countries. In developed countries, the model has been used to answer questions dealing with equitable access to healthcare (Andersen et al. 2000; Farley, Harley & Devine 2006), treatment and use of medication among different ethnic groups (Thind & Andersen 2003; Vyas et al. 2012), healthcare/ pharmaceutical expenditure (Agarwal & Sambamoorthi 2015; Payne 2010; Payne et al. 2009), and the effects of supply on regional inequalities (Heider et al. 2014; Ozegowski & Sundmacher 2014). Details on which programs, what has been measured, and the methodologies and findings are provided below.

The first group that applied Andersen's model are studies related to equitable access to healthcare for specific populations, such as low socio-economic, or specific ethnic, groups. For example, Andersen at al. (2000) deployed the model in a survey to examine the predisposing, enabling, and need factors that have an impact on equitable access to HAART (Highly Active Antiretroviral Therapy) for HIV-positive populations in the USA. The study used baseline data and six-monthly follow-up surveys. The data collection method was a computer-assisted personal interview.

Following a multi-stage logit regression, they concluded that the HIV-positive groups with the greatest need were the most likely to have access to early HAART. However, there was evidence of inequality of access for some groups such as African-Americans, injecting drug users, and low-income groups (Andersen et al. 2000). Similarly, in a study conducted by Farley et al., the predisposing factors predicting the use of antiresorptive medications among women over the age of 45 were examined. The findings revealed that there was an association between ethnicity and race and the use of the antiresorptive[13] medication. The data for the study was taken from the 2000 Medical Expenditure Panel Survey and was analysed using hierarchical multivariate logistic regression. The results suggested that ethnicity (which is a predisposing characteristic) was a significant predictor for the use of hormone therapy and antiresorptive medicine (Farley, Harley & Devine 2006). Similar findings come from a study conducted by Gimeno-Feliu et al. (2016) who applied Andersen's model to evaluate equity of access to pharmaceuticals between two immigrant groups and native-born people in Norway and Spain. This cross-sectional study drew on data related to pharmaceutical purchases of 5 million native-born and nearly 100,000 immigrants over the space of one year. Despite the fact that there were significant differences in the health systems of Spain and Norway, overall the study reported that immigrants in both countries purchased fewer medicines compared to native-born Spanish and Norwegian people, except for those from Morocco who had higher rates of use of antidepressants and pain killers (Gimeno-Feliu et al. 2016).

The second group of studies that applied Andersen's model in relation to access to treatment and the use of medications were conducted by Thind and Andersen (2003) and Vyas et al (2012) who explored predisposing/demographic factors. For example, in Thind and Anderson's study, they examined predictors for the use of public and private healthcare for respiratory illnesses in children under five years of age in the Dominican Republic. They used the 1991 DHS-2 dataset to perform logistic regression analyses and found that gender, insurance coverage, and location were factors that influenced the decision to seek care for this group of children. The use of a public or private healthcare service provider was determined by location and insurance coverage (Thind & Andersen 2003). Vyas, et al. (2012) used Andersen's model to evaluate predisposing factors such as patient demographics, enabling factors such as access to care, need factors such as self and family medical histories of women 40 years of age and self-reported adherence to mammographic screening. They expanded Andersen's model by adding a number of psychosocial factors (such as perceived five-year risk, knowledge about mammography, and views on mammography) to the existing predisposition, enabling, and need factors. Vyas et al. (2012) used a cross-sectional study to collect data from 686 women who used mobile mammographic services between 2009 and 2011. The

[13] *Therapies that are used to increase bone strength in individuals with osteoporosis which include five principal classes of agents: bisphosphonates, estrogens, selective estrogen receptor modulators (SERMs), calcitonin, and monoclonal antibodies such as denosumab.*

results from the bivariate data analysis showed that the predisposing factors were older age and unemployment status, while the enabling factor was visits to an obstetrician/gynaecologist in the past year. Need-related factors such as family history of breast cancer and having had breast problems in the past were significant predictors of self-reported adherence to mammography (Vyas et al. 2012).

The third approach to the use of Andersen's model examined the predictors of healthcare expenditure. Payne (2010) used Andersen's model to explore the relationship between age, individual healthcare utilisation expenditure, and mortality over a one-year period in British Columbia. The study used secondary data from The British Columbia Linked Health Database such as individual-level utilisation records for hospital and physicians' services, prescription medications, and home and facility-based continuing care. Results from the analysis showed that the costs for those who died rose, while the cost for survivors fell during the study period, particularly in relation to continuing care (Payne 2010). These researchers used Andersen's model to measure changes over time in healthcare expenditures for individuals who died in a given year and aged-matched survivors in Canada, once again illustrating that costs for survivors were lower (Payne et al. 2009). In another study exploring total healthcare expenditure associated with depression among individuals with osteoarthritis, 1,881 people with osteoarthritis were identified using the 2010 Medical Expenditure Panel Survey. Differences in healthcare expenditure between individuals with osteoarthritis who had depression were analysed, with depression being seen as a predisposing factor that had an impact on healthcare needs, and hence, on costs. The authors concluded that excess healthcare costs associated with depression among individuals with coexisting osteoarthritis and depression was related to comorbidities of anxiety, chronic conditions, and poor health status (Agarwal & Sambamoorthi 2015).

A macroeconomic study extended Andersen's behavioural model to measure the impact of aging on healthcare expenditure for acute and long-term care services (Meijer 2012). Data for the study were collected from two cross-sectional surveys, the Facilities Use Survey (FUS) (2003) and the Elderly in Institutions Survey (EIS) (2004). The results concluded that healthcare expenditure (HCE) will continue to rise in coming decades. Age as such is a limited driver of HCE. Notwithstanding this, most determinants of HCE are directly or indirectly age-related. The odds that the larger part of the increase in future expenditures will go to the elderly are very high. If increases in HCE reflect an increasing willingness to pay for healthcare, HCE growth in itself would not be a problem. However, the large extent to which HCE will be used by the elderly in combination with a financing system that distributes costs over the entire population could lead to strain between age groups. Therefore, although put in perspective, the relationship between age and HCE is still a factor of great importance (Meijer 2012).

Finally, a study on the effect of supply-side determinants on healthcare utilisation conducted by Ozegowski and Sundmacher (2014) used Andersen's model as a framework for analysis in Germany. The study found that supply-side factors accounted for half of the model's coverage of regional inequities. The remaining regional variance explained by the model was attributed to socioeconomic and (socio-)geographic determinants, as well as price effects. The study also highlighted the importance of differentiating between need, demand, and utilisation of healthcare

services in order to understand the root causes of inequities (Ozegowski & Sundmacher 2014). Heider et al. (2014) used the predisposing and the need factors from the model to study healthcare costs among elderly populations in Germany. This cross-sectional study analysed expenditure data of 3,124 participants aged 57-84, following up within 8 years of the ESTHER cohort study. This was then followed by a retrospective assessment of healthcare utilisation over a 3-month period through interviews in the participants' homes. The results showed that the need factors of multi-morbidity and mental health were the dominant predictors of healthcare cost compared to the predisposing and enabling factors (Heider et al. 2014).

4.3.4 Pharmaceutical quantification and expenditure in developed and developing countries

There has been very limited application of Andersen's model in estimating pharmaceutical utilisation in developing countries. One study that used the model in this context in order to understand the predictors for pharmaceutical expenditure at district public healthcare facilities was conducted by Mujasi and Puig-Junoy (2015) in Uganda. A brief overview of the study follows.
Mujasi and Puig-Junoy (2015) set out to identify the potential predictors of primary healthcare pharmaceutical expenditure at the district healthcare service level. They developed an explanatory model that enabled predictions for the required budgeting for, and allocation of, pharmaceuticals for each district. This was achieved through a cross-sectional, retrospective observational study using data from 87 randomly selected DHS (from a total of 112). Drawing on Andersen's conceptual model of predictors drawn from the four components of the environment, population characteristics, health behaviour, and health outcomes, they demonstrated that it was possible to cost and quantify the pharmaceuticals required for a region.

Mujasi and Puig-Junoy (2015) modified Andersen's model, drawing on limited datasets from the four components mentioned above. For example, for the predisposing factors, they limited the data to district population and gender. For the enabling factors, they used only data on district poverty levels, urbanisation levels, literacy rates, measures of human development, and employment levels. These factors were then operationalised into independent variables with pharmaceutical expenditures at district healthcare facilities as the dependent variables. Data on current expenditure of pharmaceuticals using Ugandan Shillings (UGX) for the fiscal year July 2011 to June 2012 were collected. In estimating expenditure, four dependent variables were employed, total pharmaceutical expenditure, pharmaceutical expenditure per capita, pharmaceutical expenditure per visit, and pharmaceutical expenditure per health facility. The data collected for the dependent variables was in UGX. The data for the independent variables, which are the explanatory variables, were collected according to defined measurements. Statistical analysis using regression analysis procedures were conducted. Firstly, minimum, maximum, and mean values, and standard deviation for the sample districts, were conducted. Then, the correlation coefficient between the dependent and the independent variables was calculated. Comparison of the mean indicators for pharmaceutical expenditures for dichotomic[14] variables, such as relevant human resources, newly created healthcare facilities, hard to reach districts, and availability, were presented. The final linear logarithm from the regression analysis resulted in eight multiple regression models that explained pharmaceutical

[14] *Dichotomy variable is a variable with two responses: Yes or No*

expenditure with a range of explanatory power based on level of statistical significance. The results indicated that the explanatory power of the regression models ranged from 51 to 82 per cent. The proposed models for predicting primary healthcare pharmaceutical expenditures for districts in Uganda are best explained by total Outpatient Department (OPD) visits, Diphtheria, Pertussis, and Tetanus 3 (DPT3) cover, urbanization, total government healthcare facilities in a district, and community health facility level II.

Studies in other developing or middle-range countries have also used Andersen's model. For example, a study in Bogota (Colombia) found that socio-demographic variables such as age and sex and co-payment methods were valid determinants of pharmaceutical expenditure at CHCs at the district level (Huber et al. 2013; Santamargarita-Pérez et al. 2013). The predictive power of socio-demographic variables has been recorded in other studies. This is supported by a study on outpatient visits during one year (September 2009 – August 2010) in Valencia (in the eastern part of Spain) to CHCs at the district level, which found that variables based on socio-demographic determinants such as pharmacy status, age, and sex were strong predictors, representing 34 per cent of pharmaceutical expenditure at district and CHCs. Aging was another important predictor for pharmaceutical expenditures. Variables within the health system such as pharmacy dispensing, prescriptions, and level of CHCs are other predictors of pharmaceutical expenditures.

Adjustment of the variables by adding diagnosis variables (using clinical risk groups, diagnostic cost groups, and adjusted clinical groups methods) also provides significant predictive power to overall pharmaceutical expenditure (Vivas-Consuelo et al. 2014). Improvements in predictive accuracy and risk adjustment models have been recommended by Lin (2008) who found from previous studies that predictors such as demographic characteristics and health status were useful in pharmaceutical predictions. Demographic prediction increased reliability by 5 per cent, and when adding health status, it increased the measures of the adjusted R^2 to 10-20 per cent (Lin 2008). There are other possibilities for pharmaceutical forecasting that focus only on the other predictors. The latest research indicates that the main factors contributing to estimating pharmaceutical expenditure are price, demand, and the introduction of new drugs into a healthcare system (Mousnad, Ahafie & Ibrahim 2014).

Another important factor is the provision of primary healthcare services and pharmaceutical expenditure, particularly of the distribution of healthcare professionals. A study of 412 districts in Germany indicated that it was essential to differentiate causes of healthcare utilisation from three perspectives, need, demand, and utilisation. Strengthening the role of physicians by countering poor distribution of healthcare professionals is an important determinant in primary healthcare services (Ozegowski & Sundmacher 2014). While not based on a developing country, this study did highlight the issue of predictors.

Access to primary healthcare becomes a fundamental right of a population, regardless of economic status. In emerging and developing countries, access to certain medicines for the treatment of certain diseases such malaria, HIV/AIDS, and tuberculosis has been provided through bilateral and multi-lateral partnerships. For example, Andersen's model, especially in relation to the inherent need factors, has been used to examine policies to improve access to medications through the

development of global health partnerships in African countries (Ngoasong 2009). Partnerships in funding healthcare have also realised other improvements, with health insurance and private-public partnerships aimed at providing healthcare access through health facility improvements (Thind & Andersen 2003).

Andersen's approach has also been used to examine stock-out of pharmaceuticals by examining demographic factors at district and facility level. The factors identified by Wagenaar et al. were distance of health facilities to a distribution point in kilometres, number of technical staff, number of pharmacy staff, number of provincial and district supervisory visits, ratio of technical to 10,000 visits, proportion of clinics that are urban/rural, frequency of meetings (weekly, monthly or quarterly), and number of OPD visits (Wagenaar et al. 2014, pp. 793-8). In addition, Mujasi and Puig-Junoy found in their study in Uganda, that total population, percentage of female population, number of staff in a health facility, the literacy rate, and the level of healthcare facilities are determining factors in healthcare service utilisation (Mujasi & Puig-Junoy 2015).

Overall, the application of Andersen's model to examine pharmaceutical expenditure has been used extensively in many developed and developing countries. Most of the studies have used statistical regression analysis to predict and forecast pharmaceutical needs and costs. However, there appears to be very little validation of the statistical analysis used, with the exception of the study by Hanley, Steve, Morgan, and Reid in 2010. There have been limited studies which have examined the influence of external factors on the provision of healthcare and pharmaceutical expenditures in post-conflict countries.

4.4 Conclusion

Econometric and social and behavioural models have been applied extensively in healthcare settings to address healthcare and pharmaceutical expenditure. Both types of model use similar determinant variables to predict and forecast pharmaceutical expenditure, such as demographic and epidemiological predictors. The pivotal factor in determining healthcare and pharmaceutical expenditure lies in data reliability. Most of the research on pharmaceutical expenditure using econometric models occurs in developed countries. Andersen's model of healthcare utilisation is a prominent framework that has been used to a limited extent to quantify and forecast pharmaceutical needs in primary healthcare in developing and emerging nations. There has been limited research on pharmaceutical expenditure in developing countries (Mujasi & Puig-Junoy 2015). Hence, Andersen's model might prove to be useful in validating pharmaceutical expenditure in developing countries. In the case of Timor-Leste, the model could be used to validate whether or not the current quantification model has addressed the pharmaceutical needs of the country. Data on quantification and forecasting are readily available from the Ministry of Health, the National Statistics Office, and other related offices in Timor-Leste. Through the availability of this data, it is possible to run statistical tests to validate the predictive powers of Andersen's model, which would build on the way the model was used in the Ugandan study. This would meet calls from the various authors of the 10 studies explored in Chapter 3 for improvements in the quantification of medicines, overall

pharmaceutical management, and to test the determinant factors in pharmaceutical quantification and forecasting and to conduct detailed studies on inventory management.

The review of past studies on pharmaceutical supply chain management in Timor-Leste presented some background information. However, neither the accuracy of the findings from the 10 studies is known, nor is it clear which model of pharmaceutical quantification and forecasting is used in the country, as none of the research noted this. In order to more fully understand the pharmaceutical supply issues in Timor-Leste, there is a need to establish the accuracy of the pharmaceutical supply chain management issues at all levels within government and non-government organisations, and to investigate the existing pharmaceutical quantification and forecasting processes. This will be undertaken in Chapters 6 and 7 using Privett & Gonsalvez's dependency model and Andersen's behavioural model for health utilisation as frameworks for understanding pharmaceutical stock-out. Details of the research methodology will be presented in Chapter 5.

CHAPTER 5. RESEARCH METHODOLOGY

5.1 Introduction

This chapter outlines the mixed methods used for the data collection. Data were collected in two stages. The first stage was initiated using a conceptual framework based on Privett and Gonsalvez's dependency model and Andersen's model of healthcare utilisation, both of which can be applied to pharmaceutical supply chain management. Stage one is presented as a qualitative exploration as part of a mixed method study that aims to understand pharmaceutical stock-out in Timor-Leste. Mixed methods research has increasingly gained credibility as a research methodology in business management and healthcare (Azizi, Kapak & Tarhandeh 2014; Barlow et al. 2018; Beal, Stewart & Fielding 2013; Gibson, CB 2017; Kahraman & Topcu 2018; Kovács, Spens & Moshtari 2018; Lauckner, Paterson & Krupa 2012; Madondo & Phiri 2018; McGloin 2008; Miller & Cameron 2011; Na-Nan, Chaiprasit & Pukkeeree 2017; Von Geibler et al. 2016).

A case study is an intensive description and analysis of a single instance (Eisenhardt, Kathleen M & Graebner 2007). Case studies are "bounded by time, phenomenon or social unit that may employ both qualitative and quantitative approaches" (Harrison et al. 2017, p. 4). This definition is in line with other prominent case study researchers (Eisenhardt, Kathleen M & Graebner 2007; Hesse-Biber 2010; Taylor & Thomas-Gregory 2015). Thomas (in Taylor & Tomas-Gregory 2015) noted that a case study concentrates on one issue, looking at it in detail and not seeking to generalise, while Baxter and Jack (2008) added that qualitative case study design can be used to investigate a complex phenomenon within a particular context, such as stock-out in Timor-Leste. Building upon this understanding, a mixed methods exploratory sequential study using both qualitative and quantitative approaches has been applied in this study to understand the phenomenon of pharmaceutical stock-out in Timor-Leste. Consequently, while this research draws on similar studies in other developing countries, it is recognised that many of the findings may not be generalisable. What the case study approach does provide is the opportunity to describe and analyse the pharmaceutical stock-out issues, the context, and the real organisational experiences of the situation in one post-conflict country.

An exploratory approach also allows for a deeper cross-cultural understanding of the issues and is less likely to suffer from cultural bias and ethnocentric assumptions because it allows for the capture of the social, cultural, and political factors that might have an impact on pharmaceutical quantification – thus enhancing the case study (Creswell 2013; Eisenhardt, Kathleen M. 1989; Grbich 1999; Marshall 1999; Neale 2016; Taylor-Powel & Renner 2003; Thomas, DR 2006). This approach also allows for understanding beyond the measurement of observable behaviour to messy issues that are typical in international management research (Marschan-Piekkari & Welch 2004). Given that Timor-Leste has emerged from a long period of colonisation, it was considered important to examine the cultural and social factors that might have an impact on a well-functioning pharmaceutical supply chain system from the perspective of postcolonial and dependency theory. Consequently, Phase 1 investigated the phenomenon of pharmaceutical stock-out from various

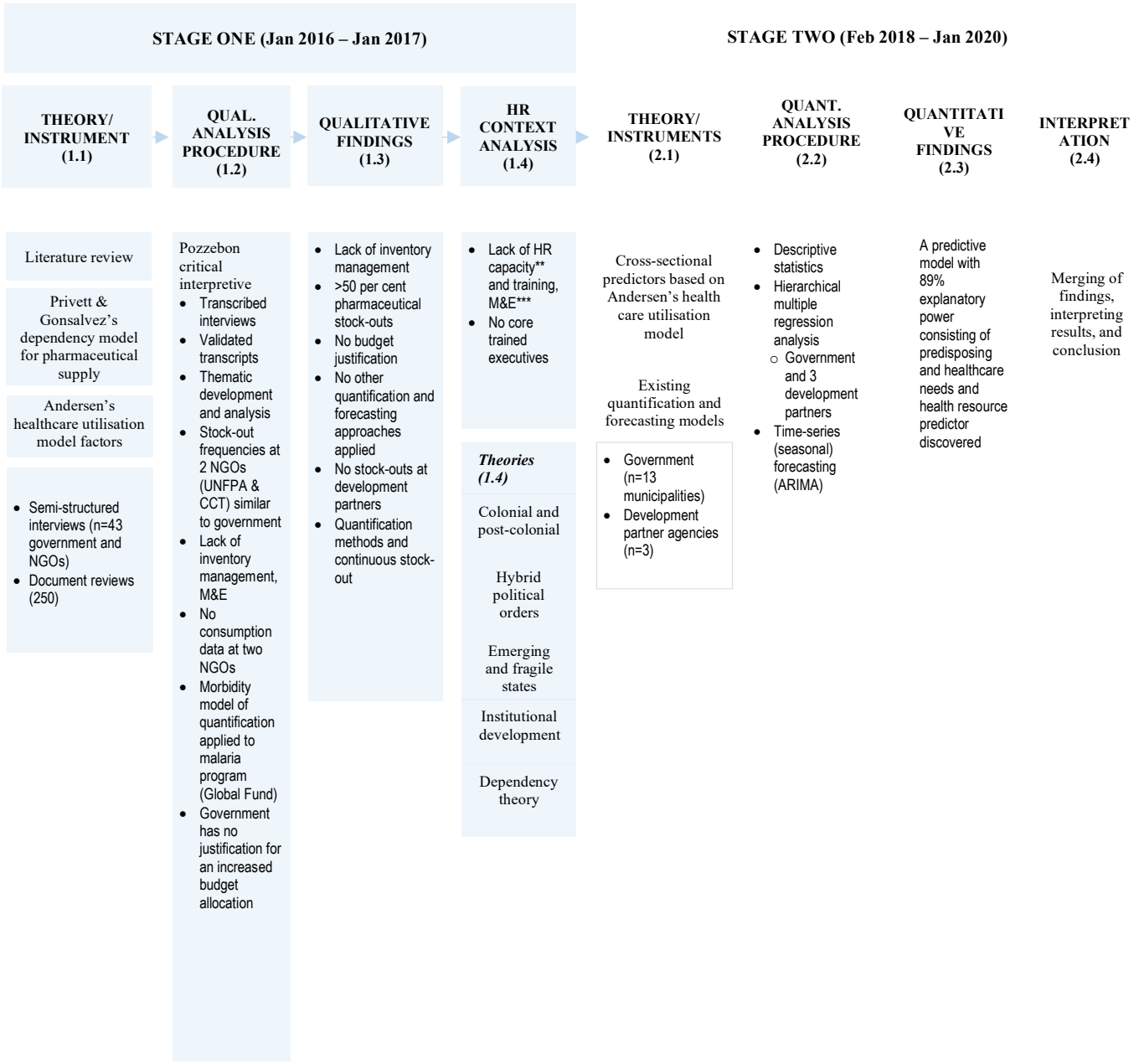
participants' points of view within a range of healthcare organisations, from the central pharmacy in Dili to the Municipal Health Services, through to doctors, nurses, and midwives in local healthcare posts, and finally to senior officers of non-government organisations who deal with stock-out on a day-to-day basis.

Qualitative methods involving interviews and document analysis (Baxter & Jack 2008 ; Taylor-Powel & Renner 2003; Thomas, DR 2006) have been used to map the pharmaceutical supply chain processes (warehouse and inventory management, logistic management information systems, and quantification model/s in use). In summary, the aims of the study are to:

- Identify and examine the current methods used to quantify pharmaceuticals in Timor-Leste;
- Identify the social, cultural, political, and managerial/educational factors that might contribute to the failure of the current quantification approaches that lead to ongoing stock-out of pharmaceuticals; and
- Compare Andersen's model to the current model in use with a view to establishing if it would improve the quantification of pharmaceuticals.

In order to respond to the three aims of the study, the research design was divided into two phases requiring ethics applications for both phases of the study. The overall design of the study for each of the two phases is outlined in Figure 5-1. Detailed information on each phase of the study is described in the following section which addresses the conceptual framework of the study.

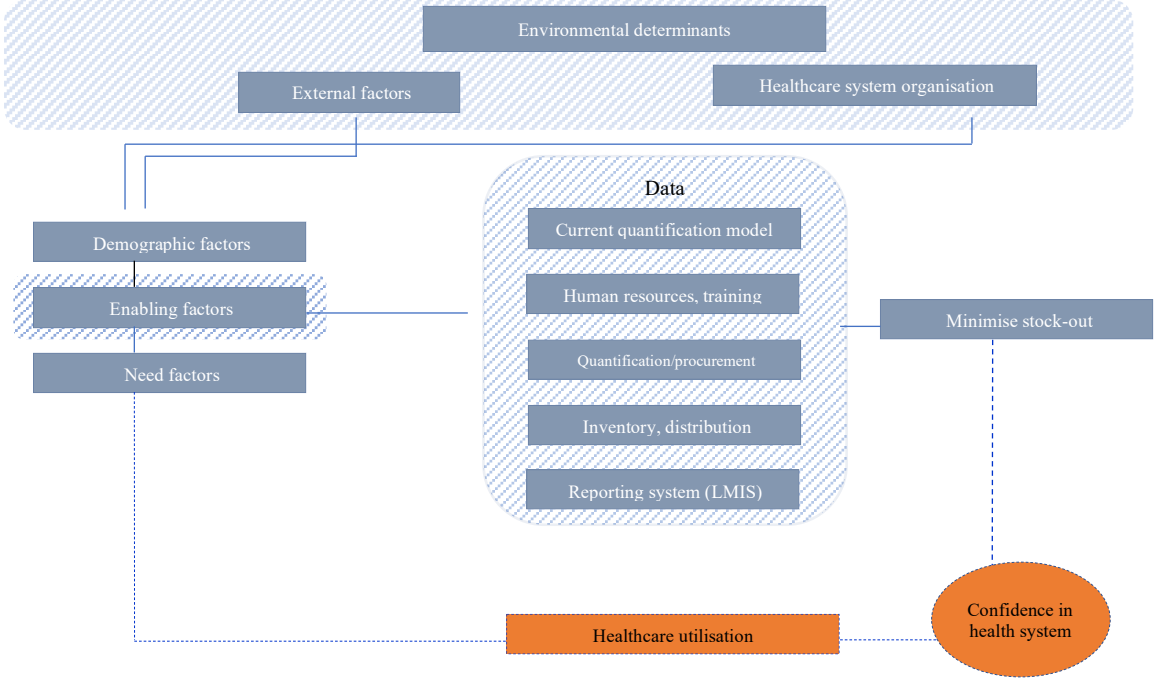
Figure 5-1. Study design of the two-stage study



5.2 Conceptual Framework of the Study

The framework for Phase One of this study drew on Privett and Gonsalvez's dependency model (Privett & Gonsalvez 2014) and Andersen's behavioural model of healthcare utilisation (Andersen 1995a).The study built its technical questions and document reviews on Privett and Gonsalvez's model to identify the pharmaceutical issues and other information not pertaining to the model, such as budget allocation, related policies, and regulations. The interview questions investigated the pharmaceutical supply chain management at the item, facility, and system levels. At the item level, the study investigated how the temperature of the storerooms, pharmaceuticals, and expiration of pharmaceuticals are managed. At the facility level, the investigation focused on warehouse and inventory management, order management, and shipment visibility. At the system level, the aim was to discover policy development in coordination, demand information management, and shipment visibility at the national level. The model can be seen Figure 3-1. Privett and Gonsalvez's (2014) dependency model does not cover the predictors of pharmaceutical quantification. Pivotal information on pharmaceutical quantification and predictors can only be explored through Andersen's (1995a) model of healthcare utilisation. In this model, information on the predictors used to quantify medicines are assembled. The principal information collected in Phase One of the study related to the external environment, the healthcare system, and the interactions with predictors of healthcare utilisation in the population characteristics of predisposing, enabling, and needs factors. Information gathered on the external environmental factors included the physical environment, and political, social, cultural, and economic information about the country. This proposed focus of stage one data collection is presented Figure 5-4 below.

Figure 5-2 The conceptual framework of the study



Through examining the healthcare system, information was gathered which dealt with questions to do with how the system is designed to respond to the need for services in the country. The specific

healthcare system information that was collected were the current pharmaceutical quantification models, human resources and training in pharmaceutical supply chain management, pharmaceutical quantification, inventory, and the logistics management information systems.

The study questions asked the participants to comment on which support systems in the overall healthcare system were designed to meet healthcare facilities' pharmaceutical needs. The interviews and document analysis explored how healthcare policies were framed to meet the needs of existing predisposing factors such as demographics, geographical location, and the socioeconomic and cultural aspects of the population. The study then investigated how the organisation of the healthcare system was designed to meet the needs of the population aimed at improving healthcare utilisation by defining organisational structures such as healthcare facilities, healthcare professionals' characteristics, and support systems to promote efficiency, efficacy, and equity within the health system organisation. The function and roles of each service in the supply chain, such as the Central Medical Store, the Directorate of Pharmacy, the National Directorate of Finance and Procurement, the District Health Services, and the CHCs were examined. The study did not address issues related to healthcare utilisation, or how confident the population were in using the health system (the dotted lines in the orange shapes in Figure 5-43).
In summary, Phase One of the study set out to answer the following questions:

- What are the current models of quantification?
- How are inventory management and demand information systems managed by the Directorate of Pharmacy, the Central Medical Store (SAMES), and non-government organisations (NGOs)?
- How are quantification and forecasting of medicines at the Directorate of Pharmacy, the Ministry of Health for Municipal Health services, and NGOs managed?
- Do political, social, and cultural factors influence pharmaceutical quantification?
- Do the current quantification models of government and NGOs meet pharmaceutical needs given frequent stock-out?

5.3 The Research Processes

5.3.1 Phase One data collection in Timor-Leste

Common qualitative data collection strategies applied in case studies are formal and informal interviews, transcribing, analysis of interviews and the researcher's diary, and review of documents relevant to the study objectives. Interviews with key personnel who work in the field being investigated in the case study is an effective data collection method for gathering information and documenting the participants' perspectives, feelings, opinions, values, attitudes, and beliefs about the research question and the wider social world (Cruz & Higginbottom 2013; Knoblauch 2005; Marshall 1999; Saldaña 2011; Taylor & Thomas-Gregory 2015). According to Marschan-Piekkary and Welch 2004), there is no satisfactory substitute for data than that obtained through interviews. For Phase One, this study employed interviews, the researcher's diary notes, and document analysis.

5.3.1.1 Gaining ethics approval

Ethics approval was granted for Phase One of the study by the Flinders University Social and Behavioural Ethics Committee and the Timor-Leste Health and Medical Research Ethics Committee (HMREC) on arrival in the country for the first phase in July 2017. The first activity upon arrival in Timor-Leste was to present the research proposal in person to the national HMREC, which had previously been submitted a month earlier to the committee via email. The research proposal was written in Tetun to enable the ethics committee to reach a faster decision. While waiting for the approval letter from the ethics committee, advice was also sought from the National Directorate of Pharmacy and the Central Medical Store, SAMES. The objectives of these visits were to present myself to the committee and to obtain their input and advice on which Municipal Health Services[15] with high or low pharmaceutical stock-out should be included in the study, as well as to set times for the interviews. Data collection for the study in Timor-Leste started when the Health and Medical Research ethics committee approved the proposal on the 24th of July 2017. Information about direct visits and letters of introduction with the information sheet were distributed to the target interviewees at the Central Services of the Ministry of Health in the capital city, as well as in the Municipal Health Services included in the study.

5.3.1.2 Entering the field

5.3.1.3 Participant selection, location, and data management

Purposive sampling was used to select the interviewees/participants. Approximately 40 participants were targeted for the interviews. These were the Chief Executive Officers (CEOs) and senior managers at the Ministry of Health, the Central Medical Store, the National Institute of Health, the Municipal Health Services (MHS), and doctors and nurses who worked in the health posts. The interviews with the managers at the Central Services Offices of the Ministry of Health was initiated with the distribution of the letter of introduction and information sheet and a telephone follow-up to determine interview times and venues. Nine interviews were conducted between the 24th of July and the 11th of August 2017, and a number of policy and report documents were collected at central services of Ministry of Health; for example, the Standard Treatment Guidelines, the Essential Drug List, quantification guidelines, and other related documents.

During this period, a decision on which municipal health services to include in the study was also obtained, and introductory letters were sent to potential interviewees. Some of the early interviews were transcribed, which enabled preliminary analysis and identification of specific issues to follow-up in the subsequent interviews. Letters of introduction were personally delivered to the offices of all the potential interviewees in their municipalities, as the postal service is not reliable in Timor-Leste. The responses varied as sometimes, an immediate decision on the time and the venue for the interviews was made at the initial visits, while at other times, there were long delays on making these decisions.

[15] *With the decentralisation of power and administrative functions to municipalities, the name of the District Health Services has been replaced by the Municipal Health Services.*

At the Municipal Health Service level, interviews were conducted with the director of District Health Services, the District Program Officer for Pharmaceuticals and the heads of the Community Health Centres. Medical doctors and clinical nurses who worked at selected CHCs and health posts also participated in the study. The selection of doctors and nurses was determined after discussion with the CEO of the Central Medical Store and the National Director of Pharmacy. This is discussed in detail below. I approached the potential participants directly through face-to-face meetings or via telephone to request an interview and to establish a suitable time and venue. Most of the interviews took place at the interviewees' workplaces, except one which had to be conducted at the interviewee's home.

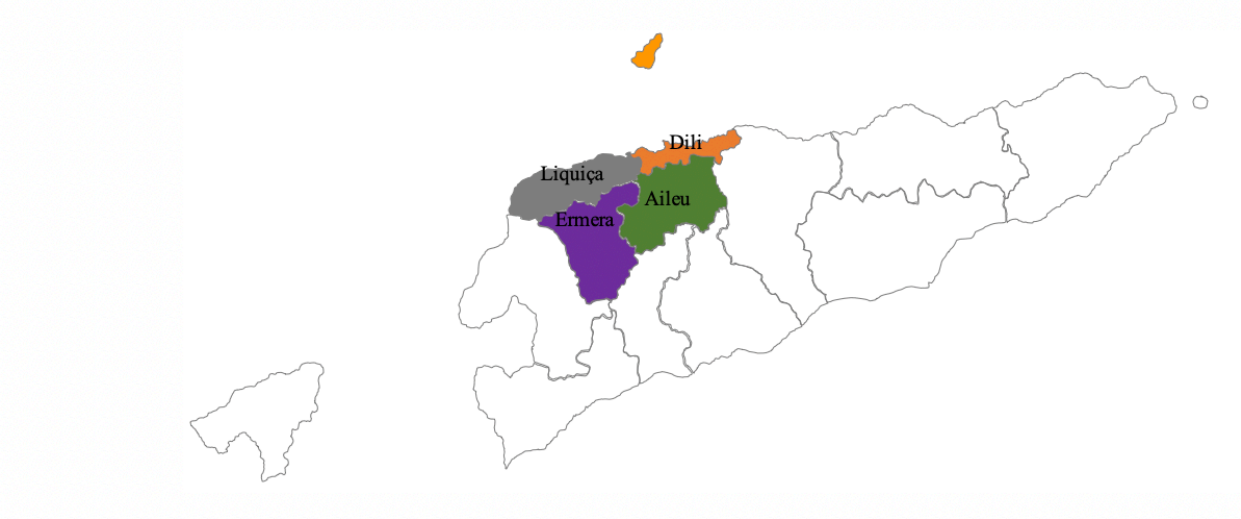


Figure 5-3 Map of Timor-Leste and target municipalities in Phase One of the data collection

Local public transport operated by private owners in Timor-Leste is not reliable. The public buses do not operate on fixed timetables and only when the vehicle is full do they proceed to their destination. Public buses only travel to the capitals of the municipalities and sub-districts; consequently, for this study, it was difficult to reach the isolated health posts. Road conditions were very bad, so a motorbike was purchased to enable easier access to the health facilities in three municipalities. Among the four municipalities selected for the study, one was in the capital, Dili. The other three were in nearby municipalities. Two of the municipalities were located along the north coast (Dili and Liquiça) and the other two were located in the mountains. The capital of Aileu is located 67 kilometres south of the border of Dili with four sub-districts. Ermera is located 62 kilometres south-west of Dili, and Liquiça is approximately 36 kilometres west of Dili (see Figure 5-5).

Overall, there were 43 recorded interviews and three non-recorded interviews conducted between the 26th of July and the 14th of October 2017. A number of policy documents, guidelines, quantification and procurement reports, and stock reports for the period between January and June for both 2016 and 2017 were collected. Interviews with senior personnel in Dili were conducted first. The sequence of interviews is detailed in Table 5-1. During this time, I visited the National Statistics Office to gather demographic and other data related to the predictors identified in

Andersen's behavioural model. Health statistics data were also obtained from the Department of Health Management Information Systems at the Ministry of Health.

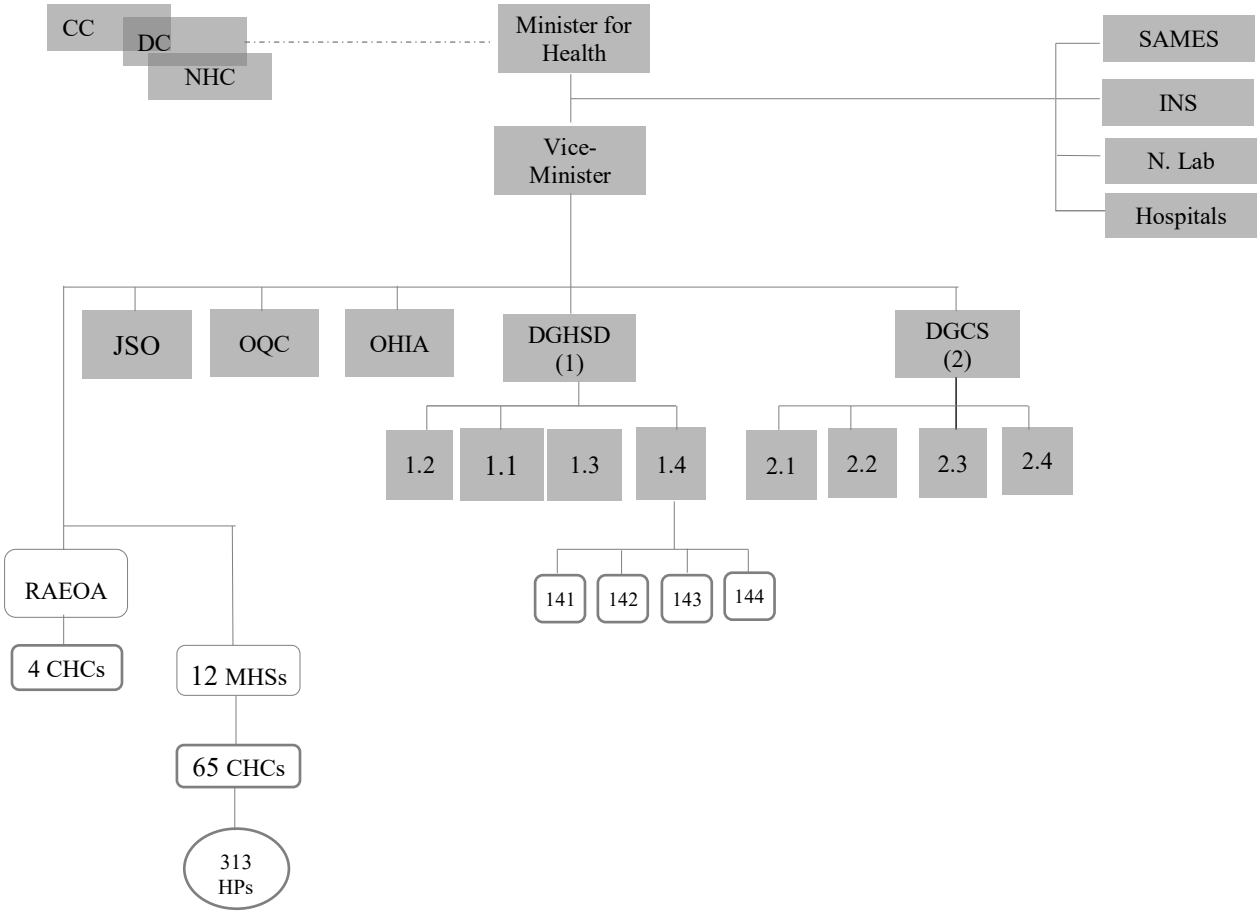
Table 5-1 Summary of government participants interviewed between July-October 2017

Interviewees	Interviewed	Interview Sequential number	Interviews not recorded	Declined interviews
Executive Directors	2	8, 42	0	2
National Directors	6	3, 4, 5, 7, 9, 41, 43	0	0
Municipal Health Services (MHS) Directors	2	10, 40	0	2
Heads of Departments	4	1, 2, 3, 6	0	0
Heads of Community Health Centres	10	11, 14, 16, 18, 21, 24, 27, 34, 35, 38	0	2
Pharmacists at MHS and CHCs	9	12, 13, 19, 23, 25, 29, 36, 37, 39	3	1
Nurses	2	17, 33	1	0
Midwives	1	20	7	0
Physicians	7	15, 18, 22, 26, 28, 31, 32	0	1
Total	43		11	8

The two Executive Directors interviewed are the most senior managers in their organisations who directly oversee pharmaceutical supply chain management for the Ministry of Health. I interviewed interviewee No 8 and 42, both were Executive Directors. Most of the time, the position of Executive Director is linked to political affiliation, but the position can also be filled by independent people. These two Executive Directors were trained professionals with postgraduate trainings.

I then interviewed six national directors. These senior managers have the authority to plan and execute strategic plans. They were members of the Ministry of Health Directive Council which engages in all decision-making at the ministerial level. Most of these directors have postgraduate qualifications in economics, management, and public health. Most have been in their positions for more than two years and had held other senior positions within the Ministry of Health in the past. Figure 5-6 provides an overview of the Ministry of Health.

Figure 5-4. Organogram of MoH Timor-Leste (Decree Law 21/2015)



Four heads of department at the Central Services of the Ministry of Health under the National Directorate of Pharmacy were also interviewed. These are the heads of the departments of Regulation and Licencing of Pharmaceutical Activities, Pharmaceutical Vigilance and Control, Authorisation and Introduction of Pharmaceutical Marketing, and Pharmaceutical Planning and Acquisition. These department heads have limited authority in decision-making. The agencies deal with technical design, implementation, and monitoring of the efficacy of policies and guidelines across the pharmaceutical supply chain. Heads of departments report to the National Directors. National Directors are appointed to the position for two years with the possibility of an extension based on performance evaluation. When a new government is sworn-in, all Executive Directors and National Directors are replaced regardless of performance.

Municipal Health Services are led by directors who represent the Ministry of Health at the municipal level. Of the four directors interviewed, two were pharmacists, one was a trained physician with one year of experience in the role, and the other was a trained midwife who has held the position for four years (see Figure 5-6. Organogram of MoH Timor-Leste (Decree Law 21/2015).

CHCs are located at each sub-municipal level, with health posts in their catchment areas. The head of these 69 CHCs are the technical managers responsible for the implementation of the Ministry of Health service delivery programs in their areas. Most of them were nurses and midwives with health service management training although one acting head of a CHC was a physician. The 11 managers

interviewed had been in these positions for between 2 and 17 years. They also oversee 313 health posts operating in their area.

5.3.1.4 Municipal Health Services included in the study

The decision on which Municipal Health Services should be included in the study was initially based on the level of stock-out experienced by each municipal health service over the 24 months prior to data collection. However, stock-out data for this period was not readily available from the National Directorate of Pharmacy and the Central Medical Store. The mSupply warehouse management system had only just been installed; therefore, data on stock-out at the national level could not be provided. There was a comprehensive stock progress report for SAMES for 'vital', 'essential', and 'necessary' pharmaceutical items. The system is well established at the Central Medical Store, SAMES, the Municipal Health Service of Dili, and in the referral hospitals; however, this was not the case for the Municipal Health Services. The system was not completed until June 2017. The use of mSupply in the health facilities was in trial mode; hence, data quality could not be guaranteed. This was due to the fact that mSupply is an Internet-based warehouse management software program and is entirely reliant on Internet connectivity, which is unfortunately, unstable. It takes considerable time to download the data, and consequently, a considerable amount of information was missing. In addition to this, there is no recurrent cost allocated to the Municipal Health Services for Internet services for all healthcare facilities.

The data used to decide which Municipal Health Services to include in the study were the monthly pharmaceutical requests from healthcare facilities and the distribution data. According to SAMES, request data is related to stock-out at health facilities. This data were used to identify which health facilities had high levels of stock-out and which rarely experienced it. In addition, the volume of pharmaceuticals requested was also used to guide the decision on which municipalities to select. However, one important point to take into account is that a request does not always mean that there is stock-out at a local health clinic. A request may in fact represent shortage avoidance.

Table 5-2 Pharmaceutical items requested from health facilities in Timor-Leste to SAMES, Timor-Leste, period January - June 2017

Facility	Jan	Feb	Mar	Apr	May	Jun	Total items requested	Average items requested monthly	Rank of facilities according to monthly drug requests
SSM* Dili	325	374	336	191	82	27	1,335	223	1
Hospital Nacional Guido Valadares	286	209	193	194	193	170	1,245	208	2
HR** Covalima	113	74	66	113	111	32	509	85	3
HR Maliana	96	56	71	72	71	70	436	73	4
HOREX Baucau	75	74	38	97	41	44	369	62	5
HR Maubisse	76	69	43	65	44	56	353	59	6
HR RAEOA ***	11	69	0	53	104	94	331	55	7
SSM Covalima	100	13	29	91	58	2	293	49	8
SSM Liquiça	79	39	6	73	41	21	259	43	9
SSM Ermera	22	82	38	64	12	28	246	41	10
SSM Viqueque	24	93	8	19	83	14	241	40	11
SSM Lautem	3	69	17	10	98	31	228	38	12
SSM Bobonaro	63	16	14	89	16	23	221	37	13
SSM RAEOA **	41	29	40	49	11	51	221	37	14
SSM Ainaro	62	10	10	94	25	12	213	36	15
SSM Manufahi	33	3	66	14	13	84	213	36	16
SSM Baucau	103	3	6	90	3	7	212	35	17
SSM Manatuto	52	18	1	68	65	8	212	35	18
SSM Aileu	49	11	18	65	6	8	157	26	19
Laboratory Nacional	52	0	0	51	0	0	103	17	20
Marie Stopes TL	2	2	0	0	0	0	4	1	21

* Serviço Saúde Municipio or Municipal Health Services
** Hospital Referencia or Referral Hospital

*** Região Autonomo Especial Oecússe-Ambeno, Special Autonomous Region of Oecússe-Ambeno

SAMES provided an Excel spreadsheet with pharmaceutical request information from 21 health facilities (see Table 5-2). Only one international Non-Government Organisation was included in the list of facilities which had mSupply[16] installed. The information was reorganised to show the total number of requests processed during the period January to June 2017, after which the average monthly information was added. Based on the average monthly processed requests, the healthcare facilities were ranked from the highest to the lowest number of requests. This information was shared with SAMES and the Directorate of Pharmacy, and a final decision on which Municipal Health Services to include in the study was made. The Municipal Health Services of Dili was the highest on the list, followed by Covalima, Liquiça, and Ermera. The Municipal Health Service with the lowest number of pharmaceutical requests was Aileu, followed by Manatuto and Baucau. A final decision was made to include four Municipal Health Services in the study, Aileu, Dili, Ermera, and Liquiça.

Interviews and data collection at these Municipal Health Services were conducted from the 25th of August to the 22nd of September 2017, followed by data collection at the Central Service Offices of the Ministry of Health and the National Statistics Office at the Ministry of Finance.

5.3.1.5 Interview approach

The interviews were semi-structured, audio-recorded, and on average, lasted for one hour. The participants were interviewed in person at their offices. The interviews focused on their understanding of the current pharmaceutical supply chain, especially pharmaceutical quantification, and which quantification model was in use. Questions relating to inventory management as the basis of the quantification data at the Central Medical Store and the DHS were also asked. The interviews targeted the use of information to plan pharmaceutical needs, recording and reporting, and processes and procedures in inventory management. The participants were also asked about the external factors that influenced quantification. All pharmaceutical supply chain-related documents such as stock reports for the period of January to June for 2016-7 were scanned with a mobile phone directly into PDF format and transferred immediately to a computer.

5.3.1.6 Document reviews

Documents related to inventory management and logistic management information system processes in selected warehouses at health facilities and the Central Medical Store were collected. Specific information for quantification was gathered in order to understand what data is used, how calculations are undertaken, how decisions are made, and how requests from District Health Centres are managed. This was narrowed down to the top four districts with the highest stock-out between January and June 2017 based on negotiations with the National Directorate of Pharmacy and the Central Medical Store, SAMES. The flow of information from the health facilities to the Central Medical Store (SAMES), the delivery of medicines to the health facilities, and how this information was used in procurement plans for pharmaceuticals was obtained and recorded. As

[16] *mSupply is an inventory management software*

well, the supply chain participants were asked to provide copies of relevant de-identified government documents relating to pharmaceutical inventory management, such as bin cards, stock cards, and reporting templates or notes. Scanning of filled bin cards, inventory cards, etc. were photographed with an iPhone as access to scanning machines and photocopiers was not reliable or not available. No photographs of the participants were taken, and all forms were de-identified. A review of government policies, guidelines, procedures, and reports to identify the basis of pharmaceutical management, human resources, training plans, regular monitoring, evaluation, and budget allocation for pharmaceuticals and quantification was performed at the three leading organisations, the National Directorate of Pharmacy, the National Directorate for Finance and Procurement, and the Central Medical Store, SAMES. This was limited to documents dating from 2002 to 2016. Table 5-3 summarises the data-gathering techniques used in this phase of the study and how they were used to address all relevant identified aspects of the supply chain management and stock-out issues.

Data obtained through recorded interviews was transcribed from Tetun into English, coded, and then organised into themes. Analysis was undertaken using an iterative process of moving between noting and coding, field notes, interview transcripts, and reviews of documents. These were then organised into emerging themes. A critical interpretive approach was used to analyse the data (Pozzebon 2004). This involved examining the dynamic relationship between the social, political, cultural, and organisational factors.

At the first level, the data from the interviews with the senior officers and managers in the healthcare sector, and the document reviews, were analysed to capture views on the pharmaceutical stock-out phenomenon. Data management at this stage followed a standard qualitative data management protocol (Baxter & Jack 2008 ; Burnard 1991; Grbich 1999; Luck, Jackson & Usher 2006). At this level, the interviews were fully translated and transcribed. Text cleaning was undertaken and dross[17] removed. Once this was done, the meaning unit, which is a discrete phrase, sentence, or series that conveys an idea, was developed (Burnard 1991). Chapter 6 provides analysis at this level.

[17] Materials in a transcript that do not related to the topic being investigated and which are repetitive (Burnard 1991, p. 112).

Table 5-3 Data and data collection methods

Data	Method of data collection
Politics, and social and cultural factors within the organisation	• Interviews • Government policies and directives, and procedure reviews
Current pharmaceutical quantification model	• Interviews • Document reviews (epidemiological data)
Human resources, training, and education	• Interviews • Document reviews (records of training, qualifications of people in positions)
Quantification/procurement	• Interviews • Document reviews on the process • Data recording on type of data used to calculate pharmaceutical needs and analysis of the quantification method (i.e. distribution data, consumption data, budget allocations, demographic and epidemiological data)
Inventory management and distribution	• Interviews • Document reviews, especially process documents
Reporting system	• Interviews • Document reviews on LMIS guidelines, training and monitoring, and evaluation
Predisposing factors	• Collection of demographics (total population and proportion of population based on gender from National Statistics Office based on latest census and household survey (2015)
Enabling factors	• Interviews • Collection of demographic data (total literacy rate, and male and female literacy rates); geographic data (district accessibility, and districts considered to be urban); and socioeconomic data (district population who live under poverty line, human poverty index, and human development index) from the National Statistics Office based on latest census and household survey (2015)
Needs factors (includes policy factors, healthcare resources)	• Interviews • Data collection on vaccination coverage for children under five, antenatal care coverage for pregnant mothers, and outpatient department visits from the Department of Monitoring and Evaluation of the Ministry of Health
Policy factors	Data collection on: • Availability and awareness of standard treatment guidelines, staff trained in pharmaceutical supply chain management, percentage of realised planned supervision and monitoring conducted from the Ministry of Health • The percentage of population with access to safe drinking water and latrines from the Ministry of Health and State Secretary for Water and Sanitation
Healthcare resources	• Interviews • Data on total government and non-government healthcare facilities at district-level, percentage of CHCs with or without inpatient clinics, percentage of staff positions filled, and access to health facilities from the Ministry of Health

5.3.1.7 Qualitative data analysis: critical interpretive

Data analysis for Phase One was undertaken based on Pozzebon's critical interpretative approach. This approach involves interaction with empirical materials, interpretation, critical interpretation, and reflection (Pozzebon 2004, pp. 278-9). The analysis is initiated by observation and talking to people who create their own picture of an empirical phenomenon based on reality in the field. There are four levels of interpretation and analysis in this thesis. At the first level of interpretation of the empirical material, the focus of the research is on making accounts from the interviews, observations, and findings from the empirical materials. At the level of interpretation, the focus is on identifying the underlying meaning of these accounts. At level three, which is the critical interpretation, the focus of the analysis is on identifying ideology, power, and social production embedded in the accounts. At the final level, reflection on text production and language use, the focus is on the texts, claims to authority, and selectivity of the voices represented in the text (Pozzebon 2004, p. 279). In addition to Pozzebon's approach, according to Carpenter, the role of participants and the research in qualitative studies are crucial to determine the credibility of the research process (Carpenter 2017, P.165). As a senior and an experience health services management, my accumulated knowledge and management practice in Timor-Leste is assumed as a knowledge and expertise in the field, hence I commanded trust from the research participants. The accumulated knowledge and length of experiences assisted me in exercising continuous reflection during the research process"

Chapters 6 and 7 present the second and third levels of the analysis. The second level involves writing up the interpretations guided by the selected theoretical frameworks. Meanings emanating from the interview materials were critically analysed using the concept of pharmaceutical supply chain management, quantification of pharmaceuticals, Privett and Gonsalvez's interdependent model, predictive factors from Andersen's behavioural model, post-colonial theory, and previous studies on pharmaceutical supply chain management in Timor-Leste. The third level of analysis is a critical interpretation (Marschan-Piekkari & Welch 2004, p. 11) through which the underlying meanings of the phenomenon based on ideologies, power, and cultural and social construction of the phenomenon are explored. To achieve this, a continuous review of empirical and non-empirical articles and national leading newspaper articles was also conducted. The last level of analysis activity is a reflection on how the findings were shaped through the specific interviews undertaken, the theoretical lenses applied, and the motivations of the researcher to provide practical solutions to the issue of stock out in Timor-Leste. The discussion and limitations section in Chapter 10 include reflection on how the research deliberately seeks to provide an authoritative voice on how to address a complex logistical and socio-political issue. Whilst it is acknowledged that other voices could have been included in the study, the discussion demonstrates that the selectivity of voices and data sources presented in this thesis assist in putting forward pragmatic responses to the research questions posed.

5.3.1.8 Questions on reliability and validity

Since most of the interviews were conducted in Tetun (one of the official languages of Timor-Leste), and then translated into English, there were challenges in maintaining the authenticity of the meanings attributed to each interview participant. These types of challenges are acknowledged by researchers in international business research who suggest that it is essential to validate translations (Marschan-Piekkari & Welch 2004, pp. 225-41). In this study, validation was achieved by initially cross-checking the interviews with the respondents by returning their transcripts to them for review and editing. The second validity check was certification of the translated interview transcripts. Translation certification was sought from a local senior researcher in Timor-Leste, who checked a random selection of interviews that had been translated from Tetun to English, focusing on the accuracy of the translations. This required him to sign a confidentiality agreement to ensure that the study remained ethical. The third validity check was undertaken by experts in the areas of the pharmaceutical supply chain, health sociology, cross-cultural research, and international business management on the categorisation of the themes. These experts have also supervised this thesis.

5.3.1.9 Pharmaceutical inventory of NGOs

Critical interpretation of the interviews and documents in the first phase indicated that there were stock-outs in government healthcare facilities during 2016 and 2017. However, no information surfaced in the local media on pharmaceutical stock-out in the government's development partners which, in this case, will for the purposes of this thesis be named as non-government organisations operating in the health sectors. This led to further data collection on pharmaceutical supply chain management and pharmaceutical quantification at the NGOs. A second visit to Timor-Leste was required. NGOs were approached in order to gain approval of access to conduct the interviews and to undertake the document reviews. Three NGOs agreed to participate in the study, the United Nations Fund for Population Agency (UNFPA), the Global Fund, and Cliníca Café Timor (CCT). Interviews with six senior officers were conducted during the second stage of data collection. Access to policies and guidelines, operation manuals, inventory data, and quantification and procurement data was granted, and data collection carried out.

5.3.1.10 Second stage of ethics approval

Target organisations were extended to government development partner agencies, so a modification to the ethics approval was necessary. The modification of the ethics approval from the Flinders University Social and Behavioural Ethics Committee was granted on the 24th of July 2018, and by the Timor-Leste Health and Medical Research Ethics Committee on the 16 of August 2018.

5.3.2 Phase two (cross-sectional quantitative data collection)

5.3.2.1 Phase Two data collection – second visit to Timor-Leste

The second phase of the data collection focused on cross-sectional data collection for the pharmaceutical consumption and forecasting by government and the three partner agencies. The objectives of the data collection were: to compare the models used by the three non-government agencies with the government model; to use Andersen's explanatory model for pharmaceutical expenditure for two drug items used by these three development partners in order to see how effective their quantification and forecasting models in meeting pharmaceuticals needs in their programs and services; to repeat the first and second of these objectives using the government model; and finally, to draw conclusions about the statistical strength of this approach. Data on the predictors for pharmaceutical quantification and forecasting were obtained from a range of government institutions and agencies. Additional interviews with managers or senior officers responsible for pharmaceutical supply were also conducted with the three NGOs.

These research objectives were grouped into two main aims of the phase two data collection. Further detailed descriptions of the objectives, the sources of the data, data collection, and data analysis are presented in the next sub-sections.

The first aim of this second phase of the study was to identify the quantification and forecasting models used by the UN agencies, the international multi-lateral organisations, and NGOs (the UNFPA, the Global Fund, and Cliníca Café Timor).
The investigation of the quantification and forecasting by the government development partners was built on understanding the process and the data. The following primary research questions were asked of the respondents:

- What is the current quantification and forecasting process in place?
- What are the steps involved in the process?
- What quantification and forecasting model is used?
- What data is used for pharmaceutical quantification and forecasting?
- How is the quantification and forecasting process managed?

The second aim of the study was to establish an explanatory model for pharmaceutical expenditure that reflects both estimated pharmaceutical needs and pharmaceutical expenditure for the municipalities.

The achievement of the second aim of the study was initiated by the identification and examination of both the external environment and healthcare system characteristics (i.e., policies, strategic plans, staffing levels, and epidemiological data), and relevant population characteristics (i.e., predisposing factors, enabling factors, and the need for healthcare) (Andersen 1995a) for factors that could be quantified. These factors have been used in the previous research using Andersen's approach (Andersen 1995a; Mujasi, PN & Puig-Junoy, J 2015). The outcome/dependent variable data was the annual pharmaceutical distribution and expenditure data for 2017 for the 12 municipal health services. This was obtained from the Ministry of Health and the Central Medical Store, Timor-

Leste. This data was held centrally and was not dependent on data collection at the community or health post levels. Pharmaceutical expenditures from vertical programs for HIV-AIDS, tuberculosis, malaria, and reproductive health programs were excluded from the explanatory model.

Table 5-4. Monthly Pharmaceutical Consumption Reports for 2016, Submitted by Municipal Health Services

Municipal Health Services	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	% Reports received
Aileu	0	0	0	0	0	0	0	0	0	0	0	0	0
Ainaro	0	1	1	1	1	1	1	1	1	1	0	0	75
Baucau	0	0	0	1	1	1	1	1	1	1	1	0	67
Bobonaro	0	1	0	0	0	1	0	0	1	0	1	0	33
Covalima	1	1	1	1	1	1	0	0	0	0	0	0	50
Dili	1	1	1	1	1	1	1	1	1	1	1	1	100
Ermera	0	0	0	0	0	0	0	0	0	0	0	0	0
Lautem	1	1	1	1	1	1	1	0	1	0	0	0	67
Liquica	0	0	0	0	0	0	0	0	1	1	1	0	25
Manatuto	1	1	1	1	1	1	1	0	1	0	0	0	67
Manufahi	0	0	0	0	0	0	0	0	0	0	0	0	0
Oecusse	0	1	1	1	1	0	1	1	1	1	1	0	75
Viqueque	0	1	1	1	0	0	0	0	1	1	1	0	50
Total reports	4	8	7	8	7	7	6	4	9	6	6	1	

Pharmaceutical consumption and expenditure were the predictor or dependent variables. These were identified from the External and Demographic Characteristics components in Andersen's (1995a) behavioural model for healthcare utilisation. Details of the predictor variables can be seen in Table 5.5: Description of independent variables and availability in Timor-Leste (adapted from Mujasi 2014). These identified predictor variables consisted of three dichotomised variables (availability of regional referral hospital, hard to reach municipalities, and the availability of technical advisers for pharmaceutical management) and 25 continuous variables.

Consumption data from non-government organisations were not available, except from the Global Fund. Therefore, more effort was concentrated on government consumption and expenditures. Government pharmaceutical distribution, consumption, and expenditure data were made available through the mSupply software at the Central Medical Store and the National Directorate of Pharmacy, but only for the period of 2017. Aggregated consumption data for 2016 was incomplete (see Table 5-4) (Direção Nacional de Farmacia 2017; Direcção Nacional da Farmacia e Medicamentos 2016, 2016 2017a, 2017b; Division of Warehousing and Distribution 2016a, 2016b; Procurement Division of SAMES Timor-Leste 2016, 2017). Consumption data was obtained from the National Directorate of Pharmacy at the Ministry of Health (Direcção Nacional da Farmacia e Medicamentos 2016 2017b; Dirrecção Nacional Farmacia e Medicamentos 2017).

Predictor data based on demographic and socio-economic factors were collected from the National Statistical Office, the State Secretary for Training and Employment, and the Water and Environmental Services at the Ministry of Public Work. Data on enabling factors, healthcare policies, and needs predictors were obtained from the Department of Health Management Information System of the Ministry of Health and the General Directorate of Statistics Office Timor-Leste. This covered predictor data for ante-natal care, vaccination coverage, human resources, and healthcare facilities (Departamentu Estatistica e Informação de Saúde 2017;

Department of Partnership and Cooperation 2018; Department of Personnel Management 2017). See the details of the type of variable, measurement, and sources in Table 5-5.

Table 5-5. Description of independent variables and availability in Timor-Leste (adapted from Mujasi 2014)

Type of variable	Variable		Description	Measurement	Data sources
Predisposing factors	1.	MUNTOP	Total population of municipality	Total population municipality population, 2015	National Directorate of Statistics Timor-Leste (NDSTL)
	2.	PercFem	Municipality female population	Percentage of municipal female population, 2015	National Directorate of Statistics Timor-Leste (NDSTL)
Enabling factors	3.	RuralPov	Rural poverty	Percentage of rural population below poverty line, 2015	National Directorate of Statistics Timor-Leste (NDSTL)
	4.	URBANISATION	Urbanisation level	Percentage of municipality considered to be urban	National Directorate of Statistics Timor-Leste (NDSTL)
	5.	LABOURABSRATE	Labour absorption rate	Percentage of population of working age (15-65) who are employed	National Directorate of Statistics Timor-Leste (NDSTL); State Secretary for Employment and Vocational Training
	6.	LITERATETotal	Total literacy rate	Percentage of the population aged 15 and above who can, with understanding, read and write short, simple statements about their everyday life	National Directorate of Statistics Timor-Leste (NDSTL): Census 2015 and Household Survey 2015
	7.	LITERATEFemale	Female literacy rate	Percentage of the female population aged 15 and above who can, with understanding, read and write short, simple statements about their everyday life	
	8.	LITERATEMale	Male literacy rate	Percentage of the male population aged 15 and above who can, with understanding, read and write short, simple statements about their everyday life	
	9.	MUNAccess	Municipality accessibility	Whether or not MoH considers the municipality difficult to reach. =1 if Yes, and =0 if No	National Directorate of Statistics Timor-Leste (NDSTL) and MoH
Need for healthcare	10.	BCGCover	Immunisation coverage for tuberculosis	Percentage of children under one fully immunised against tuberculosis	Department of Health Management Information System (HMIS) MoH Timor-Leste 2017
	11.	OPV3	Immunisation coverage for poliomyelitis	Percentage of children under five fully immunised against poliomyelitis	Department of Health Management Information System (HMIS) MoH Timor-Leste 2017
	12.	ANC4	Coverage of ante-natal care	Percentage of pregnant women who had four ante-natal care visits	Department of Health Management Information System (HMIS) MoH Timor-Leste 2017
	13.	DELIVERYHllthProf	Deliveries assisted by health professionals	Percentage of deliveries at home or in health facilities assisted by health professionals	Department of Health Management Information System (HMIS) MoH Timor-Leste 2017
	14.	OPDCapita	Outpatient visits	Outpatient visits per capita	Department of Health Management Information System (HMIS) MoH Timor-Leste 2017
	15.	ACCESSWater	Access to drinking water	Percentage of population with access to safe drinking water	National Directorate of Statistics Timor-Leste (NDSTL): Census 2015; MoH and Timor-Leste Demographic and Health Survey 2016 (General Directorate of Statistics (DGS) Ministry of Health and ICF 2018)
	16.	LATCoverage		Percentage of population with latrine access	National Directorate of Statistics Timor-Leste (NDSTL): Census 2015; and TL Household Survey 2015

Type of variable	Variable	Description	Measurement	Data sources
				and Environmental Health Department of MoH
Health Care Resources	17. HFGovTot	Government healthcare facilities	Total number of government healthcare facilities in the municipality (excluding hospitals)	Office of Quality Control and HMIS MoH Timor-Leste
	18. HospTot	Government hospital services	Total number of general hospitals, both government and private, in the municipality	Office of Quality Control and HMIS MoH Timor-Leste
	19. HFNGO	Non-government healthcare facilities	Total number of non-government organisation (NGO) healthcare facilities in the municipality	Office of Quality Control and HMIS MoH Timor-Leste
	20. RRHAvail	Referral hospital services	Availability of regional referral hospital in the municipality; Yes =1, No=0	Office of Quality Control and HMIS MoH Timor-Leste
	21. MunCHC1	Health facility I	Number of government facilities that are CHCs at the municipal level	Office of Quality Control and HMIS MoH Timor-Leste
	22. MunCHC2	Health facility II	Number of government facilities that are CHCs at the sub-district level	Office of Quality Control and HMIS MoH Timor-Leste
	23. MunHp	Health facility III	Number of health posts in the municipality	Office of Quality Control and HMIS MoH Timor-Leste
	24. STAFFSTRENGTH	Staff strength	Number of staff posts filled	National Directorate of Human Resources and HMIS MoH Timor-Leste
	25. StaffStrengthPhy	Staff strength =physicians	Number of medical officer positions filled	National Directorate of Human Resources and HMIS MoH Timor-Leste

5.3.2.2 Sampling

The current study drew on the population data from 13 municipalities. Data on pharmaceutical need/ expenditure was obtained from the central services of the Ministry of Health Timor-Leste and the Central Medical Store. An attempt was made to calculate the sample size using the sample calculator from the Australian Bureau of Statistics[18], but it did not reflect the population at hand. The following basic measurements were entered into the calculation. Standard error 0.016, population size of 13, 0.75 proportion of the population, and 95 per cent level of confidence, which returned a sample size of 12. Hence, the analysis was conducted cross-sectionally. As there are 13 municipalities in the country, it was decided that the sampling would be conducted on the whole population rather than only on selected municipalities.

5.3.2.3 Predictor variables

Predictor or independent variables are factors that influence the pharmaceutical need and pharmaceutical expenditures identified from the external and demographic components of Andersen's behavioural model for healthcare utilisation. Details of the predictor variables can be seen in Table 5-5. Data for the variables from the predisposing and enabling factors were collected from the National Directorate of Statistics, Ministry of Finance. This data is available from the latest population census, the demographic health survey, and the household expenditure survey[19].

[18] The Australian Bureau of Statistics sample size calculator was used to calculate the sample size for data collection, (Online). https://www.abs.gov.au/websitedbs/D3310114.nsf/home/Methods,+Classifications,+Concepts+&+Standards?opendocument

[19] The household survey is a survey on the household size, income, and expenditure conducted by ICF-Macro and the Ministry of Finance for the Government of Timor-Leste.

Employment data were also obtained from the State Secretary for Training and Employment. Variables for policy and healthcare resources, training, and need factors were collected from the Ministry of Health.

5.3.2.4 Outcome variables

The outcome variables data is the annual pharmaceutical expenditure for two of the top 10 pharmaceuticals (items most consumed during the fiscal year of 2017). This data was obtained from the Ministry of Health and the Central Medical Store, Timor-Leste. The selection of the outcome variables was guided by Andersen's behavioural model (Andersen 1995a) and the Ugandan study on predictors of pharmaceutical expenditure for primary healthcare (Mujasi, PN & Puig-Junoy, J 2015). Pharmaceutical consumption was transformed into American Dollar values for all municipal healthcare services for fiscal year 2017. Consumption data was collected from the National Directorate of Pharmacy of the Ministry of Health/ Central Medical Store to Municipal Health Services and healthcare facilities. Where there was no immediate pharmaceutical expenditure data available for collection, pharmaceutical data was obtained from the total cost of pharmaceuticals supplied by SAMES (the Central Medical Store) to the Municipal Health Services and each health facility during 2017. The total quantity for each pharmaceutical item was calculated based on procurement figures from SAMES. An Excel spreadsheet table to capture the details pharmaceuticals for each municipality was prepared. Table 5-6, 5-7, 5-8 and 5-9 consisted of the pharmaceutical items, total American Dollar values of total pharmaceutical quantities for the 2 pharmaceutical items supplied within a year and total American Dollar values for each municipality. The pharmaceutical expenditure data is the source of information for outcome (dependent) variables.

Table 5-6. Top ten pharmaceutical consumption in Timor-Leste during the period of 2017

1	Paracetamol Double Scored 500mg
2	Amoxicillin 500mg tabs
3	Cotrimoxazole (Sulfamethoxazole+Trimethoprim) 400mg+80mg tabs
4	Ferrous Sulphate/Folic Acid 200mg/0.4mg tabs
5	Ranitidine HCl 150mg tabs
6	Ibuprofen Scored 400mg tabs
7	Cloxacillin Sodium 250mg caps
8	Ferrous Sulphate 200mg (60mg Iron) tabs
9	Dexamethasone Sodium Phosphate 4mg tabs
10	Folic Acid 5mg tabs

5.3.2.5 Estimation of the pharmaceutical expenditure for the outcome variables

The value of the outcome variables was obtained through the following process. The total primary healthcare pharmaceutical expenditure data was obtained through the collection of data on total expenditure by obtaining information on total pharmaceuticals supplied to healthcare facilities in each municipal health service during 2017 and 2018 from SAMES, the Central Medical Store. The pharmaceutical expenditure items were generated by having the total annual pharmaceutical items supplied to health facilities converted into US dollars based on the unit cost of each pharmaceutical item. The total value of pharmaceutical expenditure per capita was obtained from the average value of pharmaceutical expenditure in US dollars supplied by SAMES to healthcare facilities during one

financial year based on the projected population for 2017 and 2018 for each municipality. The final dependent variable, the pharmaceutical expenditure per visit per healthcare facility, was obtained by calculating the average value in US dollars of pharmaceuticals supplied by SAMES to healthcare facilities in each municipality in one financial year for all reported outpatient department (OPD) visits to PHC facilities in a municipality. Primary healthcare pharmaceutical expenditure per PHC facility was obtained by calculating the average value in US dollars of pharmaceuticals supplied by SAMES and the National Directorate of Finance Management to healthcare facilities in each municipality in one financial year per reported number of total PHC healthcare facilities in two periods, 2016 and 2017 (Mujasi, PN & Puig-Junoy, J 2015).

5.3.2.6 Hypothesis

There are five hypotheses pertaining to the differences in pharmaceutical expenditure based on the following observed variables.

- There is no difference in the **pharmaceutical needs/expenditure** between groups of municipalities
- There is no difference in **total primary healthcare** pharmaceutical needs/expenditure among municipalities
- There is no difference in primary healthcare pharmaceutical need/expenditure **per health facility** between municipalities
- There is no difference in primary healthcare pharmaceutical needs/expenditure **per OPD (Outpatient Department) visit** between municipalities
- There is no difference in pharmaceutical needs/expenditures **per capita** between municipalities

5.3.2.7 Data analysis

The SPSS-25 program was used to undertake the analysis of the data. The study has 4 outcome variables and 25 variables. The outcome variables are total pharmaceutical expenditure for primary healthcare (PHCPETotal), pharmaceutical expenditure for primary healthcare per capita (PHCPECapita), pharmaceutical expenditure for primary healthcare per visit to outpatient department (PHCPEVisit), and pharmaceutical expenditure for primary healthcare per health facility (PHCPEFacility). There are 22 continuous variables and three explanatory dichotomic variables. The dichotomic variables are accessibility to a municipality (MunAccess), urbanisation status (UrbanStat), and the availability of a regional referral hospital (RRHAvail). Each of these explanatory variables has two grouping variables: *Yes = 2 or No = 1.*

Univariate analysis was undertaken to determine data distribution and identification of outliers. Bivariate analysis was undertaken to determine the association between the predictor variables and the outcome variables in order to determine the mean differences between municipal health services. The equality of the means was then tested through Pearson correlation coefficients for continuous independent variables and the outcome variables. This was intended to be followed by the testing of independent sample t-tests for the mean values of the dichotomic variables. However, due to the small sample size, Shapiro-Wilk's tests were undertaken instead.

Optimal statistical modelling for prediction was performed. Stepwise regression analysis was used to identify the significant predictors, followed by a nested stepwise regression analysis to test the change in coefficient values and the percentage of variability of the explanatory variables to the predicted variables. Statistical tests on both the linear-linear and log-linear models were determined by the best fit of the model.

5.4 Detailed report of the findings

Detailed reports on the qualitative findings are presented in Chapters 6 and 7. The results of the analysis of the cross-sectional quantitative data are then presented in Chapter 8.

Table 5-7. Pharmaceutical expenditure (outcome variable data) by Municipality in Timor-Leste 2017

Observations	Municipality	Amoxicillin 500mg tab (A)*	Paracetamol 500mg tab (P**)	Expenditures in USD – AP***	PHCPETotal (AP)	PHPCECapita (AP)	PHCPEVisit (AP)	PHCPEFacility (AP)
1	Aileu	6,711	828	14,250	0.29	0.92	3,562	14,250
2	Ainaro	16,299	1,293	33,890	0.54	0.72	2,607	33,890
3	Baucau	23,932	1,811	49,675	0.40	0.65	12,419	49,675
4	Bobonaro	19,701	1,559	40,961	0.42	0.87	5,120	40,961
5	Covalima	21,824	2,632	46,280	0.71	1.51	7,713	46,280
6	Dili	63,582	4,979	132,143	0.48	0.84	16,518	132,143
7	Ermera	18,630	1,522	38,782	0.31	0.84	4,848	38,782
8	Lautem	17,112	1,580	35,804	0.55	0.95	5,967	35,804
9	Liquica	13,342	1,037	27,721	0.39	1.86	5,544	27,721
10	Manatuto	15,569	882	32,020	0.69	1.40	10,673	32,020
11	Manufahi	13,199	1,251	27,648	0.51	1.94	4,608	27,648
12	Oecusse	13,278	1,667	28,223	0.41	0.76	7,056	28,223
13	Viqueque	22,965	1,818	47,748	0.63	1.93	11,937	47,748
	Timor-Leste	266,144	22,858	48,586	4.47	1.07	7,934	48,586

*A= Amoxicillin tablet
**P= Paracetamol tablet
***Amoxicillin & Paracetamol tablets

Table 5-8. Predictor data for pharmaceutical prediction by municipality in Timor-Leste

Municipality	TotPop*	PercFem	RuralPov	Urban	AlbAbsRt	LitTotal	LitFem	LitMale	MunAcces	BCGCover	OPV3	ANC4	DeliverP	OPDCap	AccesWat	LatCover	HFGovTot	HospTot*	HFNGO*	RRHAvail	MunCHC1	MunCHC2	MunHp	StafStrg	Phys
Aileu	48,837	48	47	No	53.31	54.5	35.75	40.27	1	64	75	42	48	3.2	75	37	8	0	2	0	1	3	12	40	13
Ainaro	63,136	50	47	No	56.82	44.7	26.85	29.99	1	66	65	38	51	1.3	54	58	7	1	1	1	1	12	12	66	30
Baucau	123,203	50	47	Yes	48.11	53.8	33.85	37.68	1	76	73	54	79	1.6	56	38	27	1	2	1	1	3	18	235	81
Bobonaro	97,762	50	47	Yes	55.02	45.7	27.34	31.84	1	80	81	48	73	2.1	68	54	22	1	2	1	1	7	25	136	49
Covalima	65,301	48	47	Yes	54.36	55.2	35.89	40.58	1	87	89	64	84	2.1	63	52	21	1	2	1	1	5	136	148	41
Dili	277,279	49	47	Yes	35.82	73.8	55.93	58.04	1	106	91	54	81	1.8	32	93	12	1	12	1	1	7	13	331	111
Ermera	125,702	51	47	No	52.44	41.3	24.33	29.86	1	77	77	53	50	2.7	72	47	14	0	9	0	2	6	16	124	51
Lautem	65,240	49	47	No	43.23	51.8	32.11	37.08	1	74	80	41	47	1.7	58	54	11	0	2	0	1	5	30	146	59
Liquica	71,927	49	47	No	49.91	47.6	30.88	36.35	1	81	96	80	71	4.8	83	56	8	0	3	0	1	4	24	132	50
Manatuto	46,619	48	47	No	49.48	51.1	32.95	36.91	1	70	69	45	49	2.0	76	69	12	0	0	0	1	2	22	87	32
Manufahi	53,691	50	47	No	53.94	55.4	35.52	40.10	1	76	73	49	49	3.8	61	51	5	0	2	0	1	5	24	92	22
Oecusse	68,913	50	47	Yes	60.47	36.6	22.76	27.70	1	71	62	47	48	1.9	86	42	9	1	0	1	1	3	19	84	34
Viqueque	76,033	50	47	No	52.79	49.5	30.60	34.58	1	84	84	58	60	3.1	72	36	12	0	2	0	1	3	17	141	54
Timor-Leste	1,183,643	49.4	47.1		51.20757	51	33	37	1	77.89	78.01	51.81	60.68	2.47	65.93	52.86	168	6	39	6	14	65	368	1762	627

Source: *National Directorate of Statistics, Ministry of Finance 2015, Timor-Leste in Figures (6th Edition)

Table 5-9. Amoxicillin 500mg tab consumption and total expenditure per municipality in Timor-Leste 2017

Amox. 500mg tablet	2017												Timor-Leste	Expenditure (USD)
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec		
Aileu	-	-	-	-	70,000	-	10,000	-	-	55,300	-	-	135,300	6,710.88
Ainaro	28,000	63,500	7,000	65,000	5,100	15,000	-	5,000	20,000	110,000	10,000	-	328,600	16,298.56
Baucau	70,000	11,500	-	90,000	-	20,000	151,000	60,000	-	20,000	60,000	-	482,500	23,932.00
Bobonaro	-	60,000	35,700	76,500	-	20,000	105,000	10,000	20,000	10,000	30,000	30,000	397,200	19,701.12
Covalima	47,000	8,000	29,000	100,000	56,900	6,100	105,000	20,000	8,000	10,000	50,000	-	440,000	21,824.00
Dili	453,200	75,500	97,500	43,200	76,500	101,500	92,000	50,000	92,000	95,000	54,500	51,000	1,281,900	63,582.24
Ermera	-	75,000	-	81,600	-	25,000	-	105,000	40,000	49,000	-	-	375,600	18,629.76
Lautem	-	80,000	-	-	120,000	-	-	137,000	-	-	-	8,000	345,000	17,112.00
Liquica	45,000	-	-	70,000	-	-	20,000	19,000	70,000	-	25,000	20,000	269,000	13,342.40
Manatuto	70,000	-	-	40,000	30,000	-	40,000	20	113,880	20,000	-	-	313,900	15,569.44
Manufahi	-	-	100,000	-	-	93,100	-	-	73,000	-	-	-	266,100	13,198.56
Oecusse	25,000	30,000	-	21,000	10,700	71,000	-	-	15,000	80,000	-	15,000	267,700	13,277.92
Viqueque	-	-	100,000	-	100,000	-	-	100,000	-	-	163,000	-	463,000	2,2964.80
Timor-Leste	738,200	403,500	269,200	587,300	369,200	351,700	523,000	406,020	451,880	449,300	229,500	124,000	5,365,800	266,143.68

Table 5-10. Paracetamol 500mg tab consumption and total expenditure by municipality in Timor-Leste 2017

Paracetamol 500mg tablet	2017												Timor-Leste	Expenditure (USD)
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec		
Aileu	-	5,000	-	40,000	35,000	-	50,000	-	-	100,000	-	-	230,000	828.00
Ainaro	3,100	5,000	33,000	80,000	-	5,000	20,000	3,000	10,000	50,000	10,000	140,000	359,100	1,292.76
Baucau	-	5,000	20,000	130,000	26,000	20,000	151,000	-	60,000	71,000	20,000	-	503,000	1,810.80
Bobonaro	-	-	50,000	88,000	100	20,000	105,000	20,000	20,000	-	70,000	60,000	433,100	1,559.16
Covalima	-	5,000	15,000	115,000	61,000	5,000	405,000	20,000	20,000	20,000	65,000	-	731,000	2,631.60
Dili	464,600	1,000	154,500	116,000	95,000	69,000	117,000	60,000	79,000	111,000	35,000	81,000	1,383,100	4,979.16
Ermera	-	5,000	20,000	90,000	-	20,000	-	177,800	10,000	100,000	-	-	422,800	1,522.08
Lautem	-	5,000	30,000	37,000	50,000	80,000	-	17,000	120,000	-	-	100,000	439,000	1,580.40
Liquica	3,000	5,000	-	55,000	30,000	-	20,000	20,000	85,000	-	50,000	20,000	288,000	1,036.80
Manatuto	-	5,000	-	40,000	40,000	-	20,000	-	100,000	40,000	-	-	245,000	882.00
Manufahi	-	6,400	100,000	-	-	100,000	-	-	101,000	-	40,000	-	347,400	1,250.64
Oecusse	-	-	100,000	-	100,000	-	-	100,000	-	-	163,000	-	463,000	1,666.80
Viqueque	-	-	5,000	25,000	125,000	-	-	115,000	-	25,000	170,000	40,000	505,000	1,818.00
Timor-Leste	470,700	47,400	527,500	816,000	562,100	319,000	888,000	532,800	605,000	517,000	623,000	441,000	6,349,500	22,858.20

CHAPTER 6. PERCEPTIONS OF DIRECTORS, MANAGERS, MUNICIPAL HEALTH SERVICES, AND CLINICIANS ON PHARMACEUTICAL STOCK-OUTS

The first stage of this study has used a qualitative approach (Baxter & Jack 2008 ; Taylor-Powel & Renner 2003; Thomas, DR 2006) to develop an in-depth understanding of pharmaceutical supply chain management in Timor-Leste from the point of view of those upon which it has an impact. The aim of mapping the supply chain processes of the inventory management of pharmaceuticals in Timor-Leste are to:

- Identify and examine the current methods used to quantify pharmaceuticals in Timor-Leste;
- Identify the social, cultural, political, and managerial/educational factors that contribute to the failure of the current quantification that leads to ongoing stock-out of pharmaceuticals; and
- Compare Andersen's health utilisation model to the current model in use with a view to establishing if it would improve the quantification of pharmaceuticals.

This chapter provides a first level analysis of pharmaceutical stock out in Timor-Leste. The data has been taken from interviews with senior personnel across the country, directors, managers, and municipal healthcare service staff (doctors, nurses, midwives, and pharmacists). The chapter is organised into three sections to illustrate how individuals at various levels within the government healthcare services understand stock-out. The first section explores what senior bureaucrats within SAMES[20] and the Ministry of Health identify as the major issues drawing on their responses to the seven questions in the interview schedule; section two details the views of managers at the Municipal Health Service level; and section three outlines the responses of clinicians in the field. The bureaucrats involved are those who hold management positions, ranging from Executive Directors, Directors at all administration levels, heads of departments, and heads of the Community Health Centres. The practitioners are made up of physicians, nurses, and midwives who work at the Community Health Centres and health posts as clinicians. Questions for the bureaucrats and the practitioners were different (see Appendix 3 for a list of questions for each category of participant).

6.1 Perceptions of central bureaucrats at the Ministry of Health in relation to pharmaceutical stock-out

Interviews were conducted with 12 senior bureaucrats from the Central Services of the Ministry of Health, two Executive Directors, six National Directors, and four Heads of Departments. In their view, the major predictors contributing to continued pharmaceutical stock-out were found in the development and implementation of policies, regulations, and guidelines, in monitoring and evaluation, and in the organisational culture, specifically in relation to issues of leadership, management, human resources, and coordination. Their responses were classified according to six

[20] *SAMES, Serviço Autonomo Medicamentos e Equipamento de Saúde or Autonomous Agency for Drugs and Medical Equipment*

themes: pharmaceutical management, quantification, and stock-out; the current strategy to improve pharmaceutical supply chain management; essential issues impinging on the current pharmaceutical supply chain; the usefulness and what is lacking in the previous studies and reports on pharmaceutical management; the work culture and work ethic within organisations that have an impact on the effectiveness of supply chain management; and funding issues that have an impact on pharmaceutical stock-out. Before describing the respondents' understandings of the causes of stock-out, an overview of their definitions of stock-out is provided.

6.1.1 What is Meant by Pharmaceutical Stock-out?

There were different understandings among the senior managers on the definition of pharmaceutical stock-out. There were no guidelines on standard minimum requirements, or the level of stock that would be tolerated in the country. Stock-out means an item is not available at any point in time within a health facility. This means that a health facility is not able to provide this item. There were varying responses from the interviewees (ABP-410 2017a; AC-030 2017; AF-060 2017; Department of Personnel Management of Ministry of Health Timor-Leste 2017; Department of Pharmacy 2015; Pharmacy Department 2015) at the National Directorate of Pharmacy of the Ministry of Health that illustrated this lack of shared understanding. Interviewee No. 03, claimed that:

> *... pharmaceutical stock-out is a problem which we face as a newly independent country. It's permitted percentage is five per cent, according to our standards. If it goes beyond that, we can say that there is a failure in the supply chain (AC-030 2017).*

Interviewee No. 06, contradicted this by stating:

> *According to our regulation, minimum pharmaceutical stock-out for the whole country is fifteen per cent. This is the minimum condition. However, we have seen that many times stock-out exceeds this standard. Perhaps it could be due to a failure in quantification and there is no maximum control of the data (AF-060 2017).*

Another respondent, Interviewee No. 01 stated that it was 10 per cent (AA-010 2017).

When requests from healthcare facilities cannot be fully met because the item is not available at SAMES, this is most often due to stock-out at SAMES. Many healthcare facilities claimed that most of the time, pharmaceuticals delivered to them did not match the quantities requested. SAMES agreed with this, stating:

> *... right. Many times, requested pharmaceuticals are not available. SAMES manages to reduce the quantities. Sometimes health facilities request a small amount, SAMES provides more ... In the past, SAMES always consulted us by asking us to make the decision on how much should be provided, however we do not know real [inventory] situation at SAMES (AC-030 2017).*

Because the definition of stock-out is not clear among bureaucrats, it is also not clear for the health facilities. This leads to misleading assumptions about stock-out. An observation from Interviewee

No. 04 provided another interpretation of how stock-out is understood by healthcare bureaucrats, practitioners, and the public in general.

> *According to my understanding, an emergency request is launched when the stock reaches a minimum level. When an emergency order is not addressed, a patient may die. However, our friends at the hospital classify an emergency request when an item is not available. They do not anticipate the pharmaceutical needs. The right thing is when a pharmaceutical item reaches a threshold, for example 45%, a request must be lodged to maintain that item availability. For example, they classify a consumable item as emergency request (AD-040 2017).*

6.1.2 Pharmaceutical management, quantification, and stock-out

All 12 interviewees understood that pharmaceutical quantification is essential to pharmaceutical supply chain management. They saw that a well-established mechanism in pharmaceutical quantification had many advantages. When it was done well, it became the basis for justifying accurate budget allocations and procurement. Furthermore, service delivery could be guaranteed because the pharmaceutical needs of the population were being met.

The first factor identified as problematic and a major contributor to pharmaceutical stock-out noted by these senior managers was a lack of supply chain management in almost all the processes, from the selection of medicines, through to quantification, procurement, distribution, and pharmaceutical use (ABP-410 2017a; ABR-430 2017; AC-030 2017). Interviewee No. 41, stated that:

> *Stock-out happens because the supply chain management is weak throughout the whole supply chain management: from selection, quantification, procurement, storage, distribution, and users. Physicians still prescribe pharmaceuticals not listed in the Essential Drug List (ABP-410 2017a).*

Any quantification method used for pharmaceutical planning and procurement depends on data quality and confidence in the data. The National Directorate of Pharmacy was the only division that had confidence in its data. For the other divisions, the challenge was data quality. Both the pharmaceutical division and the central medical store reported that they did not have confidence in the consumption data for a range of reasons, including the incompleteness of reports (AH-080 2017) and incorrect data submissions from healthcare facilities for pharmaceutical quantification (ABP-410 2017a; AG-070 2017). As one interviewee (No. 41) noted, distribution levels have become the proxy formula:

> *Consumption method is used to quantify pharmaceutical needs, but the data is not trusted. Municipal health services send to DoP(Directorate of Pharmacy) distribution data, but not consumption data for quantification due to lack of understanding about the two. Many times, when analysed, the pattern of the data is questionable and more likely they are made up. In the absence or non-confidence of consumption data, the DoP has used distribution data as a proxy consumption method for pharmaceutical quantification (ABP-410 2017a).*

This lack of confidence in the pharmaceutical consumption data spills over to the National Directorate of Finance Management of the Ministry of Health. The pharmaceutical procurement process was previously managed by the National Directorate of the Ministry of Health; however, in 2016, it was handed over to the Central Medical Store, SAMES, who have since been using

consumption data for quantification. As the comment below reveals, while consumption data has been used since 2016, there is no formula for monitoring either distribution or consumption.

> *In the past, distribution data from SAMES was used for pharmaceutical quantification. However, in the following years such as 2016, we started using consumption data for quantification. There is great difference between distribution and consumption data. This makes it difficult for those who do the quantification to know what quantification model to use, because there is nobody telling them about this and they do not have the capacity to do that … there is no quantification formulae that can be used (ABR-430 2017).*

Other participants stated that the pharmaceutical quantification team had always used the consumption method for all health facilities and did not use quantification methods. When asked about quantification, most bureaucrat interviewees mentioned the consumption method, noting that it was not the method used to calculate requirements that was at fault, but the accuracy of the data. Interviewee No.03 noted:

> *"I do not have doubts about the method [quantification]. We can use any quantification method. The important factor is the quality of the data. We are really concerned with the data. We do not know if LMIS is used well or not. I think from our side, it may be due to our weakness in controlling. Maybe … instead of limiting supervision to Municipal health services office, we must go to health facilities, and then down to health posts (AC-030 2017).*

The second factor contributing to pharmaceutical stock-out according to senior bureaucrats was the lengthy quantification process. There were two issues that deterred staff from speeding up the procurement process. One was that quantification could not be completed if there was no data from the health facilities which, in their view, was often the case. Secondly, they suggested that staff were afraid to take responsibility if the quantification was higher or lower than expected needs. These two issues culminated in a delay in sending the quantified pharmaceutical needs to the procurement division to initiate the long standard advertising period of 120 days from mid-year required for the purchase of medicines and other medical devices (ABR-430 2017; AC-030 2017; AG-070 2017). A contract can only be awarded after this required lengthy period. For example, interviewee No. 43 provided an account of the process and its challenges:

> *It is difficult to make procurement decisions based on distribution and consumption data. The decision on the quantities to procure has legal implications. Over-procuring also brings problems, however, if we procure less quantities this means we would be questioned by authorities. This dilemma makes people afraid. The quantification documents can also be received late. For example, the quantified pharmaceuticals are normally received late in May or June every year. The procurement process then needs three to four months to advertise … before we are can finalise it, we are at the end of the year. So, all we do is respond to emergencies requests. There is no real pharmaceutical availability. The budget is always been used to do emergency procurement … (ABR-430 2017).*

However, there are difficulties with by-passing the tendering process. The main reason was the fear of the risk of prosecution if a wrong decision is made. In recent years, a number of ministers and top managers in Timor-Leste have gone to prison for making wrong purchasing decisions. This made others hesitant to make innovative decisions. For example, when asked, interviewee No. 07 cited the example of a minister who inadvertently gave a contract to a distant relative and was jailed for procuring beds for the national hospital.

> *If we would like to address the pharmaceutical stock-out, we must have direct contract agreement in our procurement. However, the decision must be justified according to procurement law. Frankly, I would not like to take the risk. It is good we can go procure pharmaceutical very quickly to respond to the need. However, in the future, when we are audited, the auditors do not want to know that. We can see the example of direct contract to quickly procure beds for National Hospital Guido Valadares to help patients. What happens next is that people do not see the good will, and the law could not protect us (AG-070 2017).*

The third factor is the lack of warehouse management. Because there is no integrated inventory management system in place, stock is not correctly registered, and the records of all items are not recorded at the Central Medical Store or in the healthcare facilities. Staff tend to use any record system at their own discretion (AG-070 2017; AH-080 2017). Interviewee No. 08, stated that:

> *People are welcome to make their pharmaceuticals requests, and pick-up their pharmaceuticals, however, the pharmaceutical items picked-up are not registered. Hence there is no baseline data, or a database for the management of supply. There was no correct registration of pharmaceuticals that we can use to inform our leaders to procure pharmaceutical. When we came into the Central Medical Store in 2012, the was no proper registration of pharmaceuticals in the warehouse. The application of FIFO-FEFO is simply a slogan, but nobody does it at the Central Medical Store. There was no unified registration system. Some staff in the warehouse use the WMS system, some use mSupply, some manually record, and others prefer to record information in Excel spreadsheet. There is no leadership. Discrepancy between printed data and physical data are so high and this has impacted on pharmaceutical quantification and procurement … When there is a discrepancy in pharmaceutical quantity, this automatically impacts on monetary value" (AH-080 2017).*

Similar comments on the data quality also came from other senior managers in the Ministry of Health and the Central Medical Store. They noted that the quantification of pharmaceuticals had always been based on consumption data; however, they also doubted the accuracy of the data and the way it was prepared (ABP-410 2017a; ABR-430 2017; AH-080 2017). This is supported by Interviewee No. 08 who stated that:

> *We quantify pharmaceuticals based on consumption. Now when we say that the quantification has been based on consumption, we add a percentage for buffer stock or safety stock. However, this has proven insufficient for procurement. Hence we said to ourselves, there is something that we need to correct. However, pharmaceuticals quantification is the responsibility of the National Directorate of Pharmacy. Interpretation of our advisors on the procurement law concluded that SAMES can conduct pharmaceutical quantification when is has its own budget, which is not the case at the moment" (AH-080 2017).*

Interviewee No. 43 voiced similar concerns on the consumption data, stating that:

> *Our biggest problem in pharmaceutical supply chain management is lack of quality data to calculate the pharmaceutical needs. It is because health facilities do not consider the importance of data in pharmaceutical management. In addition to that, health facilities assume that pharmaceutical supply chain is not an important aspect of their work, because they do not have sufficient knowledge on how to manage it (ABR-430 2017).*

According to most of the senior bureaucrats at the central services of the Ministry of Health, the major factor influencing pharmaceutical stock-out is quantifying the need. For example, interviewee No. 08 said that, "the issue of stock-out is mostly related to quantification". This was reported by the Honorary Minister for Health in response to questions from the Parliament on the issue of why

pharmaceutical stock-out continues to happen? The Minister stated that "our quantification is problematic" (AH-080 2017).

Improvements in pharmaceutical quantification were occurring, but it is considered a lengthy process conducted by a team led by the National Directorate of Pharmacy. They were accessing consumption data from health facilities and the National Essential Medicines List (NEML). The process was described by interviewee No. 03.

> *The quantification process has started by National Directorate of Pharmacy with the pharmaceutical selection process based on items used at health facilities and NEML. The monthly consumption data from all health facilties is analysed. Other factors are the buffer-stock to compensate for a long procurement process. The buffer stock is normally set for three or six months. Final quantification is then sent to the Procurement Department for further processing (AC-030 2017).*

However, as already noted, a number of these senior personnel had little faith in the consumption data sent in from the healthcare facilities. The Logistic Management Information System (LMIS) is designed for management decision-making, and records and reports pharmaceutical inventory needs at all levels. In Timor-Leste, the system is semi-automated. At the warehouse level, inventory requirements were initiated by recording of stock levels on stock cards which are updated when any pharmaceutical item is distributed to service delivery points such as small internal chemists, outpatient departments, and maternity houses. At the service points, the dispensed pharmaceuticals were recorded daily in tally sheets. Registration of total daily consumption, requests, and monitoring of the pharmaceutical request was done through newly installed inventory management software called mSupply. Implementing the Logistic Management Information System (LMIS) is not obligatory for every healthcare facility. Interviewee No. 03 explained:

> *We have distributed the LMIS to health facilities and have had induction sessions with the Pharmacy Coordinators at municipal health services, with the expectation that they will then disseminate information to community health centres and health posts. We see that some health facilities have used the LMIS tools, but others health facilities have not (AC-030 2017).*

Data from the healthcare facilities was not considered reliable. When ordering pharmaceuticals, local facilities do not place the items in order, and stock cards are not used or updated. Hence, it is difficult to locate a pharmaceutical item, even if the item is available. Interviewee no. 2 noted:

The final factor in this section on quantification is lack of supervision, monitoring, and evaluation of the pharmaceutical supply chain management process, particularly the use of LMIS tools that record and report the data. Most interviewees at the central services of the Ministry of Health, in the Municipal Health Services, staff at health facilities, and clinicians thought that the major factor impacting on stock-out was lack of human resources (AA-010 2017; AF-060 2017; AG-070 2017; AI-090 2017) and inadequate training in using the tools. The National Directorate had made some effort to train pharmacy coordinators at the Municipal Healthcare Services; however, there has been no follow-up to see how well the LMIS tools are used. This lack of training evaluation is summarised by the statement of a senior government interviewee. He said that

There were two training session for all staffs responsible for pharmaceutical supply at Municipal Health Services. However, whether or not the people who were trained have provided further trainings to staff at health facilities is not known (AC-030 2017).

Interviewee No. 01, the Acting Head of the Department for the Planning and Quantification of Pharmaceuticals, and a pharmacist who had only been in the post for one year, had more accurate information about the training provided. They said that, "there was one training session in 2015 and another one in 2016 and none in 2017" (AA-010 2017).

Failure to use the LMIS systems goes beyond a lack of training. It is also the result of local clinicians claiming they do not have time to fill in the forms. Anecdotal information indicates that the LMIS tools are not implemented well at healthcare facilities. A central senior government officer revealed how LMIS tools are used at district level health facilities in the following comments. According to the officer,

many do not implement the LMIS tools because they have not been given the information. Others say that they have not seen the forms yet. They do not do the registration because they do not know how to do it. In the field, especially General Practitioners (GPs) do not fill in the forms. They say that they are preoccupied with their job and they are busy and cannot fill the forms or this form. When we asked, how do you do your requests … they say that they estimate their pharmaceutical requests. This affects data accuracy and pharmaceutical quantification (AB-020 2017).

In summary, these bureaucrats at the central services of the Ministry of Health and the Central Medical Store suggested that poor pharmaceutical management was due to an inability to quantify need, and to ensure that the tools needed to do this quantification were being used across the sector. As a result, they had little faith in the quality of the data and felt that there had not been enough in-service training.

6.1.3 Current strategies for improving management of the pharmaceutical supply chain

In 2016, a national strategy was put in place to improve the management of the pharmaceutical supply chain. This was done by re-instating the role of the Central Medical Store which had been dissolved as a public enterprise into a public institution. There were two sub-strategies implemented. The first was in relation to improvements in warehouse management, and the second was improvements in inventory management through the introduction of inventory management software to all health facilities. However, there is no concrete evidence available to date that this strategy remedied the problems. The Central Medical Store has attempted to improve the work culture and implement warehouse improvement through maximising external support from development partners, e.g., UNICEF, the Global Fund, AusAID, and the European Union. Interviewee No. 08, an Executive Director stated that in order to influence the work culture, a policy of registering the movement of every pharmaceutical item in the warehouse was introduced at the Central Medical Store:

Our staff used to register delivered pharmaceuticals on a piece of paper and did not archived it, so there was no unified registration system. What we did was to introduce policy to register pharmaceuticals and provide minimum adjustment for missing pharmaceuticals. We talked to our staff and explain our ideas.

For improvements in management, especially warehouse management, the Central Medical Store maximises support from its development partners, welcoming support from the World Bank, the Global Fund, AusAID, and the World Food Program. Each of these agencies played an important role in strengthening the capacity of warehouse management and technical support in inventory management. For example, the World Bank provided technical support for the introduction and piloting of the software for inventory management known as mSupply at SAMES, the National Hospital Guido Valadares, the Referral Hospital of Baucau, and the Municipal Health Service in Dili.

However, a further problematic issue with the warehouse was its limited storage capacity, as SAMES has only limited physical space to accommodate stock for the entire year.

> *SAMES, according to my observation can only accommodate pharmaceutical stock up to six months … (ABQ-420 2017). We also need to assess how much the small warehouses at each Community Health Centres can accommodate for their population? This would enable distribution of pharmaceuticals to health facilities and not just store them at SAMES (ABR-430 2017).*

Another endeavour taken to improve pharmaceutical supply chain management was to cut down the lead time for ordering new medicines by relaxing the fiscal regulations for SAMES. Normally, the procurement process starts when the annual State Budget is promulgated by the President in the middle of the year. FreeBalance, a financial management system, can only be accessed by SAMES once the President has released the annual budget. However, the law has changed to allow SAMES to commence procurement processes immediately once the budget has been released. Interviewee No. 08 stated that:

> *The Prime Minister has issued a decree to enable earlier access to the FreeBalance system as soon as the President promulgates the annual state budget.*

However, this has not been implemented to its full capacity. Interviewee No. 43, stated that:

> *The procurement law provides an exception for SAMES to initiate any procurement even without a government budget commitment approval. However, SAMES has not executed this law. It needs a person with the courage, brave enough to implement such procurement law (ABR-430 2017).*

An additional strategy to the above change in the law has been the introduction of a standing offer agreement in the procurement system. This enables SAMES to directly access the distributors for emergency supplies of pharmaceuticals. This new approach was only introduced in 2017, as noted in the summary quote by interviewees No. 07, 41, and 43.

> *There has been a standing offer agreement reached with local importers to address the continuous stock-out with a limited budget. However, this only began in August 2017 (ABP-410 2017a; ABR-430 2017; AG-070 2017).*

It was also hoped to improve the efficiency and prevent further stock-out by cutting down the time between requests to tender through the online notification system and to procure supplies in bulk (AH-080 2017).

One technical approach that has led to improvements in warehouse management is the employment of pharmacists to oversee warehouse management. These well-trained pharmacists understand pharmaceuticals and warehouse management principles and have implemented the technical changes required. Interviewee No. 04, made note of the improvements in processing requests:

> *Before the arrival of the additional four pharmacists, we used to process normal requests within four to seven days. Now, the whole process from picking up, verifying and packing of pharmaceuticals only takes three days (AD-040 2017).*

Closely aligned with the technical improvements in the central warehouse has been a proposal to build regional warehouses. The aim would be to enable timely delivery of pharmaceuticals to healthcare facilities, cutting down the transport and delivery time. As noted,

> *They have a plan to build three regional warehouses in Baucau, Ainaro and Maliana. However, this is not the only solution. We need to consider also small warehouses at Community Health Centres. A configuration study is required to fully understand the situation (ABR-430 2017).*

A fourth improvement has been the introduction of an online inventory management software program known as mSupply. This software is effective for recording and monitoring inventory levels and online requests, as well as following up requests. The software has been installed in all municipal healthcare services and some healthcare facilities, but not at the health posts, with final installation completed in August 2017 (AD-040 2017). However, full implementation of this software has been a challenge due to poor Internet speeds and the lack of funding to operate it. As a result, the system has not been fully functional.

There have also been a number of organisational changes within the Ministry of Health to reflect the need for improved coordination and management, including the continuous problem of pharmaceutical stock-out. For example, the pharmacy department has been elevated to the level of a directorate (AA-010 2017; AB-020 2017; ABP-410 2017a). This has been done to improve the power imbalance between the Department Heads and the Directors. In addition, SAMES has been elevated to a public institution with full functions. SAMES is now responsible for procurement, which had previously been undertaken by the Ministry of Health (ABR-430 2017).

Interviewee No. 42, who is another Chief Executive Officer, stated that:

> *Now we discuss pharmaceuticals which is also a determinant in the service delivery, especially lately there has been many critics and questions from the population on the pharmaceutical stock-out. The Ministry of Health is aware of that. However, I would like to inform you that in 2016, the General Division of Service Delivery has a new structure in which the Pharmacy Department has been elevated to a National Directorate level (ABQ-420 2017).*

Within the healthcare system in Timor-Leste, departments are managed by the Directorates. All planning and decision-making is made by the directorate in which it is situated. Elevation of the status to directorate level means power, decision-making, and a reduction in bureaucratic steps. It improves efficiency and effectiveness. However, it is not clear if this policy is working.

Another conventional approach is the provision of pre-service training scholarships to pharmacists to study within the country or overseas. Timor-Leste sends its pharmacy students to Indonesia. However, an undergraduate program is about to be opened in 2017 at the National University of Timor-Leste (AF-060 2017; AI-090 2017). As noted,

> *The Ministry of Health sent 40 students to Indonesia to study Diploma III. This cohort has returned and will be distributed within the health facilities (AF-060 2017).*

While these improvements have occurred across the Central Medical Store and the Human Resource Directorate of the Ministry of Health, the approaches remain fragmented and there is no integrated national strategy to improve the process of every component of supply chain management within the healthcare sector.

6.1.4 Essential issues impinging on the current supply chain of pharmaceuticals

Dissemination of regulation, policies, guidelines, and protocols to Municipal Health Services and healthcare facilities is inadequate. The reasons for this are a lack of human resources and funding for these activities. Engagement with Municipal Health Services when new policies, guidelines, and protocols are introduced is very low. For example, Interviewee No. 02, who is a pharmacist and Head of the Department of Pharmaceutical Regulation, Licencing, and Activities, stated that:

> *We introduced training and policy development activities on pharmaceutical regulation, policies and guidelines before the Department of Pharmacy was elevated to a directorate level in 2016. We introduce the Standard Treatment Guidelines and Essential Drug List in 2010, 2015 and conducted another one in 2016. Materials introduced were the Decree Law, the Standard Treatment Guidelines and the Essential Drug List. The same thing was done for the revised EDL in 2015 and then distributed to all health facilities (AB-020 2017).*

The important factors that affect current supply chain management are leadership, coordination, warehouse management, and funding. Interviewee No. 08 indicated that:

> *Coordination between National Directorate of Pharmacy, SAMES, and health facilities does not go well. For example, late submission and incompleteness of reports from health facilities (AH-080 2017).*

Other components also lacking in the coordination process (ABQ-420 2017; AC-030 2017) were the supervision, monitoring, and evaluation of pharmaceutical supply chain management (AB-020 2017; ABP-410 2017a). Interviewee No. 08 (AF-060 2017) continued by suggesting that:

> *Due to lack of human resources, the National Directorate of Pharmacy never goes to health facilities to directly see how the small warehouses at health facilities are managed? Who can tell that pharmaceuticals that are placed on top of pallets maybe damaged due to humidity and thrown away? (AH-080 2017).*

This claim is supported by interviewees No's. 04, 09, and 41 (ABP-410 2017a; AD-040 2017; AI-090 2017), who stated that the National Directorate of Pharmacy simply could not provide

supervision, monitoring, and evaluation of staff due to a lack of human resources in terms of both the quantity and quality of training. As a division responsible for pharmaceutical supply chain management, the Directorate is severely under-staffed; therefore, it cannot cope with all the required functions. As noted, there is a:

> *Lack of supportive supervision or monitoring and evaluation due to limited staff at the National Directorate of Pharmacy. With current limited human resources, the Directorate cannot perform its other functions to develop guidelines and standard operating procedures (ABP-410 2017a; AG-070 2017).*

This is supported by interviewee No. 04 as follows:

> *We all, including you, are acquainted with progress in our country since we got independence ... the big challenge faced by the Ministry of Health and down to SAMES is human resources. In her address to the National Parliament, the Minister for Health stated that the "Ministry of Health has a huge crisis in human resources". Most of the pharmacists employed in the country are basically diploma level with one-year pre-service training (AD-040 2017).*

According to interviewee No. 04, there are seven pharmacists in the country, two with Bachelor degrees, three with a Diploma III, and two with a Diploma I in Pharmacy who were successfully appointed to work at SAMES in July 2017. Prior to this, "the warehouse was served by two pharmacists with a Diploma I in Pharmacy and two laboratory technicians" (AD-040 2017).

The lack of trained pharmaceutical staff had a domino effect on the implementation of the logistics management information system, which is the primary recording system for pharmaceutical distribution, requests, recording of consumption data, and reports. Interviewee No. 41 acknowledged that:

> *There has been a rollout of LMIS tools with support from NHSSP-SP and adjustment to stock-report card and re-training program with support from WHO. However, some pharmacy coordinators still felt that they need more training, especially those without a pharmacy background (ABP-410 2017a).*

Adherence to the National Essential Medicine List (NEM (ABP-410 2017a) was also noted as one of the reasons why stock-out of pharmaceuticals continues to be problematic. Some physicians did not prescribe, or request pharmaceuticals listed in the NEML. It was difficult to cope with various ad-hoc requests of pharmaceuticals not included in the national medicine list. In their account, interviewee No. 41, stated that:

> *"Lack of adherence to Essential Drug List. Physicians prescribe medicines outside the National List of Medicines and many times this is considered stock-out by the public, which it is not. There has not been any submission for consideration to include new medicines in the EDL or submit justifications for proposals for new medicines"(ABP-410 2017b).*

Another issue that impinges on pharmaceutical supply chain management was the unaccounted adjustments of pharmaceuticals from the Municipal Health Services due to unjustified reasons and weak monitoring and evaluation. This is voiced by a senior manager at Ministry of Health who stated that

There is a big adjustment of the pharmaceuticals from municipal regular monthly reports. It is not known if it is related to damage, expired or missing medicines. There has even been a case of missing Insulin, which was found in a distribution list, but the stock card had not been updated. The percentage of spillage could not be established. It is really difficult to distinguish between Government drugs and private sector because they look the same (ABP-410 2017a).

6.1.5 Lessons learnt from studies and reports on pharmaceutical management

Studies and reports conducted by various international development agencies are a source of evidence for improving the planning of pharmaceutical supply chain management. However, most of the interviewees had not read or made use of the recommendations of the 10 reports conducted over the last 10 years, which are outlined in Chapter Two. For example, in responding to the question of the usefulness of these reports and the limitations of such studies, the Executive Director of the Central Medical Store stated that:

I have not read the details of these studies. Most of the studies are linked to their research objectives. These studies stated that our supply chain management is uncoordinated … Yes. Dispersed in supply chain … With this situation, your coordination and collaboration should be strong to maintain the functioning of the chain. When one part of the chain, breaks down, you are paralysed (AH-080 2017).

This has been supported by other senior management officers at the Ministry of Health who admitted that the recommendations provided in the studies and reports could be a valuable source of information for the Ministry of Health, but they have not been used effectively in planning and decision-making. Interviewee No. 42, for example, stated:

Yes ... reports from development partners also become information to Ministry of Health. However, I have not looked at them in detail. I would like to say that many times, these studies are superficial. They do not go far enough. For example, quantification conducted by Directorate itself and hospitals (ABQ-420 2017).

6.1.6 Work culture and its impact on the effectiveness of supply chain management

Work culture and work ethics in an organisation is important, and both have an impact on efficacy and efficiency. However, achieving an ideal work ethic and culture depends very much on leadership. Improvements have been made in warehouse management and attitude changes of staff members. Interviewee No. 08, who was an Executive Director, said that: said that:

When I came to the Central Medical Store in 2012, there was no leadership in the organization. There was no proper registration of pharmaceuticals in the warehouse. The application of FIFO-FEFO is simply a slogan, but nobody does it at the Central Medical Store. There was no unified registration system. Some staff in the warehouse were using WMS system, some using mSupply, manual recording and others preferred to record information in Excel spreadsheet. There was no leadership" This culminated in the discrepancies between electronic data and physical data of pharmaceuticals (AH-080 2017).

They continued to say that working independently was not part of the culture, and continuous support and supervision is required. “A culture of working with a distant expert is not the Timorese way of doing business. The team needs some one to keep an eye and to push the implementation of the software, mSupply”(ABR-430 2017). The senior personnel did not think there was a collaborative culture where staff shared the same goals, nor was there a link between staff performance and organisational performance indicators. This is described by interviewee No. 43:

> *We do not have an organizational culture that forces people to perform. This means that pharmaceutical stock-out becomes an indicator that needs to be considered ... and the indicator is linked to performance of every staff. At the moment, people’s performance is based on good will. Without that, people do not do it, because they are not obliged to do so. We have clear policies ... however there is no mechanism to link these policies to actions/performance ... and no functioning of the pharmaceutical supply chain at facility level (ABR-430 2017).*

Another aspect that is missing from the organisational culture is a lack of leadership from the Ministry of Health. It was thought that most Directors and Heads of Departments do not exert their authority to lead and manage. When this is lacking, it is difficult for subordinates to act. Interviewee No. 43, an experienced senior government officer, described the situation as follows:

> *We need good leadership in the Ministry of Health. This does not mean that General Directors, Directors do not have capacity to lead. What we need is to develop leadership capacity in our hearts. When we have the leadership, this means we have authority to make planning decisions and supervise our areas. This does not work at the time being (ABR-430 2017).*

There was also an issue of dependency in the organisation in terms of policy development, planning, action, monitoring, and evaluation. This was summed up by interviewee No. 43, who said:

> *This dependency is called post-conflict dependency societies. In this context, dependency behaviour is very high. It takes time to eliminate this behaviour. This can be resolved with the right organizational culture which depends on a strong leadership in the organization (ABR-430 2017).*

Another component that influences pharmaceutical supply chain management was the accountability and responsibility to learn and improve. According to these respondents, this was a missing part of the puzzle in the organisational culture. An observation from interviewee No. 43 reflected on this situation:

> *Another big problem that we face is that people do not have accountability or take responsibility. When a manager has accountability and responsibility, he or she will seek to know and build a culture of accountability and learn other skills required to perform his or her functions (ABR-430 2017).*

Leadership in developing the expected work attitudes and culture in staff, especially in relation to the habit of registering medicines, was seen as deficient among managers. Interviewee No. 42 stated that, as a manager:

> *Knowing one’s staffs and their behaviour is important in creating a bond between leaders and staff. Without that there is no feeling of ownership. All these can be done through regular meeting with staff and introduction*

of a conducive working environment. There is no regular supervision to staff, no internal communication between departments; no good coordination; no professional ethics; no regular registration for pharmaceutical use for unacceptable reasons. Copy-paste reports from the previous month were submitted. There is poor attitude and low level of ownership of the health services. Health professionals and managers felt that dirty floors, lack of bedcovers, and no pharmaceuticals availability are not their problems. It is the Government (ABQ-420 2017).

A missing essential factor in supportive supervision for the districts was a lack of supervision guidelines. Even if they existed, training of staff would be required. This would assist them to supervise, monitor, and evaluate effectively at the CHCs and health posts. For example, interviewee No. 03 said:

check-list for supportive supervision is available. I think there are reports for that. I'm supportive of supervision mmmm … many times it is conducted by Department for Pharmaceutical Planning and Acquisition (AC-030 2017).

Further to this, feedback and follow-up supervision was not available. The Department of Pharmaceutical Planning and Acquisition conducts supportive supervision and provides feedback, but they do not do follow-up to see if staff had implemented the recommendations or requirements. Interviewee No. 03 stated:

I read supervision reports and feedbacks and we report the situation to the Executive Director of Service Delivery. However, we do not have the opportunity to conduct follow-up on the implementation of feedbacks to municipal health services … this is due to lack of personnel in the Pharmacy Division (AC-030 2017).

There was also no job enrichment for pharmacists in the health system. This was related to low pre-service training qualifications, and low salaries. Given this, there was some evidence that small-scale moonlighting took place in the capital of Timor-Leste. An example can be seen from a department in the Ministry of Health from the following quote. Interviewee No. 06 stated that:

… for example, in our department we have four staff, with level-3 salary, one hundred dollars a month. That is why it is difficult to add more tasks in their job. These staff said please do not give us tasks beyond our salary level (AF-060 2017).

Frequent replacement and appointment of new managers is also problematic and has an impact on organisational culture and staff motivation. In addition, it also effects institutional memory. The problem is that replacement staff and new appointments are not necessarily based on merit, but instead, are political appointments. An example can be seen with the status of SAMES. The institution was established in 2004 as a public enterprise and dissolved in 2012. In 2015, the organisation was reinstated as a public institution with the same functions restored in 2016 (AE-050 2017; AG-070 2017).

6.1.7 Funding issues and pharmaceutical stock-out

Issues with budget allocations for pharmaceutical procurement also contributed to pharmaceutical stock-out. In Timor-Leste's case, the problem does not appear to be a funding deficit, but the need to justify an increased budget allocation (ABR-430 2017; AG-070 2017; AH-080 2017). This was

because quantification had not been done correctly either by the health facilities or others. There had been no identification of demand and needs, and hence, there was no evidence to justify an increase in the budget. For example,

> *... when we are about to procure some pharmaceutical, some health facilities come to us and say that they need this pharmaceutical item and that item. They do not have their pharmaceutical needs accommodated in their quantified need in the period under review at the National Directorate of Pharmacy. They will come to us at a later stage in the procurement process and asked that their need be accommodated. Their pharmaceutical planning is not accurate, but we try to support them (AH-080 2017).*

There are always reductions in the budget allocation, hence, adjustments for pharmaceutical quantities cannot be avoided. In the end, quantification is a waste of time because amendments that are made should be based on a pre-determined allocated budget. One interviewee's account indicated this:

> *I myself made the pharmaceutical quantification in 2013. At the end of the day, I had to adjust it according to the earmarked state budget for pharmaceuticals. We had to reduce the quantity of pharmaceuticals or excluded some items. This is another problem that contributes to pharmaceutical stock-out (AC-030 2017).*

One reason for the lack of budget allocation is that there was no confidence in the data that feeds pharmaceutical quantification. The Central Medical Store does not trust the consumption data when it has to defend its earmarked budget for pharmaceuticals in the National Parliament, as can be seen in the following quote:

> *There is no confidence in justification and defending the quantification and budget proposal for pharmaceuticals from SAMES. Hence no budget proposal for pharmaceutical has been approved according to requests, but historically it is based on the budget allocation and execution. Funding it not the issue, however, weak justification of funding proposal is (ABP-410 2017a).*

The lack of pharmaceuticals and pharmaceutical stock-out in many countries is linked to a lack of funding; however, at this stage, this does not seem to be the only explanation for stock-outs in Timor-Leste. Regardless of the amount of funding allocated for pharmaceuticals, there is always stock-outs. This raises the question of what is going wrong. Complaints from the Central Medical Store and the National Directorate of Pharmacy that less funding is allocated for pharmaceuticals are not in line with the issue and neither have an exact answer to the question, but the National Directorate of Finance Management has a position that should be considered. Interviewee No. 43 said that, less funding allocation

> *is not related to budget availability. A closer look at the history of budget allocation for 2013, 2014, and 2015, show that the budget allocated to pharmaceutical was huge. However, budget spending only reached seventy per cent. What does this mean? The budget is available, but absorption rate is low. Then in 2016 and 2017, the Government reduced the budget allocation for pharmaceuticals. Government need justification for the pharmaceutical needed and ordered The Government does not want politicians to shout that there are no pharmaceuticals. However, even though budget is increased, stock-out remains (ABR-430 2017).*

The lack of data to justify a pharmaceutical budget proposal also comes from the managers responsible for procurement. Without valid data on which to base a justification, a budget proposal

could not withstand scrutiny for approval and would risk being cut (AE-050 2017; AG-070 2017). Interviewee No. 07, observed that:

> *people must not say that the pharmaceutical budget is small or big, but when they do the quantification, it should be based on reliable data … without that, it will not be approved. Low budget contributes to stock-out (AG-070 2017).*

The allocation for pharmaceuticals has been steadily reduced over the years. This forces SAMES, as the main body responsible for pharmaceutical procurement, to seek additional funding elsewhere to secure pharmaceutical needs, given the limited budget allocated to the Ministry of Health. An example of this can be found in an extract from interviewee No. 05:

> *… in the allocation of funding, the Government does not decide straight away how much is for pharmaceuticals health facilities, but a fiscal package only. SAMES, the Central Medical Store then breakdown the allocation for pharmaceuticals. The best way is each facility quantifies its needs and presents this to the National Directorate of Pharmacy. In the last two years, the reduction in fiscal package fell from five points four million in 2016 to four points three million in 2017. From this total amount, five percent is allocated for emergency procurement (AE-050 2017).*

According to Interviewee No. 04 (AE-050 2017), one of the issues in pharmaceutical stock-out is with the fiscal package, particularly justifying the budget allocation. He indicated that:

> *there are two factors. The first is availability of consumption data. If we do not have data for this, we can use data from the previous two years as bases to justify to our authorities. The second factor is the selection of a proper procurement approach, for example pre-qualification approach (AE-050 2017).*

6.2 What Do Managers Identify as the Major Issues in Pharmaceutical Stock-out?

Interviews were conducted with a further 12 senior personnel who were heads of Community Health Centres, as outlined in Chapter 5. This group identified several factors that contribute to pharmaceutical stock-out in Timor-Leste, including funding and budget allocation deficits, distribution problems, procurement and inventory management at the health facility level; human resource deficits; and difficulties with quantification, supervision, monitoring, and evaluation of pharmaceutical supply chain management. These can be summarised as budget and planning problems. As will become clear, a number of these issues were repeated by clinicians in the field.

6.2.1 Pharmaceutical stock-out as a result of funding and budget allocation deficits

The major problem identified by a number of senior personnel was funding allocation for pharmaceutical procurement. In all four municipalities, two municipal health service directors, nine pharmaceutical coordinators, and ten health facility managers mentioned this as a fundamental

problem. The following interview transcript quotes from an interview with one of the Municipal Health Directors, who summarised the problem as outlined below:

> *We see that stock-out is also happening in Dili and it is not decreasing but increasing. We at Municipality only send pharmaceutical reports and requests according to our needs. With stock-out, delivery of pharmaceutical has not met our requests … responding to continuous stock-out we have done some investigation. I and my fellow Pharmacists made contact with the Central Pharmacy and Central Medical Store, SAMES. Information obtained was that the pharmaceuticals available at the SAMES warehouse come from centralised quantification directly prepared by national Directorate of Pharmacy. When asked why they do not provide us with the pharmaceuticals we need? They responded that there is no budget allocation for each municipal health services, but one funding package for health pharmaceuticals (ABO-400 2017).*

This comment identifies the problem as both a lack of funds and a failure to allocate the existing budget across the various health services. Secondly, the budget is not allocated according to need. Based on the experience and observation of one of the interviewees, it was noted that:

> *Our problem in the past when we did our quantification and sent it to SAMES, SAMES was not able to allocate the funding according to requested due to budget insufficiency. This is one factor that I observed during my term as head of department. This has affected pharmaceutical for mental health treatment, Epilepsy and chronic diseases, hypertension, diabetes etc. Based on my own identification, budget allocation has never been done according the burden of diseases (AJ-100 2017).*

This problem is compounded by a failure to base procurement of pharamceuticals on sound epidemiological data that should come from all Municipal Health Services. The epidemiological data varies from one season to another. For example, one respondent noted that:

> *There are many skin diseases cases in Ermera, but skin disease related pharmaceuticals are not available or only in small quantities at a time (AJ-100 2017).*

This same concern was also raised by Interviewee No's. 19, 20, 26, and 28 (ABC-280 2017; AS-190 2017; AT-200 2017; AZ-260 2017).

As well, the distribution of pharmceuticals does not take into account the size of the population. Twelve interviewees reported that populous districts were provided with fewer pharmaceuticals, but the opposite happened to districts with smaller populations. Many directors voiced concern about this situation, which resulted in an over-stock in some districts with lower population numbers. For example, Interviewee No. 41 noted an over-stock of Ibuprofen in one municipality:

> *Good ... how can I express it? There is no balance. SAMES distributes to us in Dili smaller quantities of pharmaceuticals, but bigger quantities are provided to districts with smaller populations. As a result, there is over-stock in some districts, but not for districts that deserve it. For example here in DIli we run out a particualr pharmaceuticals items, but the same medicine would be amply available at Liquica and Aileu (ABO-400 2017).*

In summary, it would appear that the budget allocated for pharmaceuticals is insufficient, and is not evenly distributed across the various districts, nor is it allocated according to the burden of disease. This suggests poor planning, a second factor identified by senior personnel which will be explored next.

6.2.2 Pharmaceutical stock-out is the result of poor planning

The second factor that affects stock-out of pharmaceuticals is procurement time, also known as lead time. The long lead time from identifying the medicines required for the country, through to placing the order with various multinational pharmaceutical companies, through to its arrival and distribution influences the arrival of medicines at the healthcare facilities. As Interviewee No. 10 noted:

> *The procurement process is so long; it takes more than six months to complete and that delays the arrival of pharmaceuticals in the country. Hence there were some months, when we really need pharmaceuticals; we must wait because pharmaceuticals have not arrived in the country (AJ-100 2017).*

He further noted that there was a lack of registration of pharmaceutical consumption at healthcare facilities which added to the difficulties associated with the long lead-times. Overall, recording and reporting did not fully capture pharmaceutical consumption. A senior officer at Ministry of Health accounted that:

> *The third factor is related to the reports which are sent from Municipal Health Services to the National level, they do not represent pharmaceutical consumption. Many times more pharmaceuticals are dispensed, than the reported number of patients which is less than the dispensed medicines (AJ-100 2017).*

Another factor contributing to pharmaceutical stock-out was a push-based supply chain model. In this model, SAMES distributes pharmaceuticals based on its own discretion of what is available, rather than on requests from the health facilities. The quantitites may be less or more than what is needed and, as a number of participants stated, the medicines may go out-of-date before they can be used. For example, 12 interviewees reported that:

> *SAMES distributed some pharmaceuticals in a large amount that were due to expire within one month. For example, fifteen thousand bottles of Dephendryl[21] syrup were sent to all Municipal Health services at the beginning of July expired at the end of September 2017 (ABD-290 2017; ABE-300 2017; ABH-330 2017; ABJ-350 2017; ABK-360 2017; ABM-380 2017; ABO-400 2017; AJ-100 2017; AL-120 2017; AM-130 2017; AP-160 2017; AR-180 2017; AX-240 2017).*

Eighteen participants noted that stock-out at the Central Medical Store results in stock-out across the nation. Participants described how nationwide stock-out was immediately apparent due to so many requests being sent to the Central Medical Store and subsequently certain types of pharamceuticals not being (ABA-270 2017; ABD-290 2017; ABI-340 2017; ABJ-350 2017; ABK-360 2017; ABL-370 2017 ; ABM-380 2017; ABN-390 2017; ABO-400 2017; AK-110 2017; AL-120 2017; AM-130 2017; AN-140 2017; AP-160 2017; AS-190 2017; AT-200 2017; AW-230 2017; AY-250 2017).

[21] *A cough syrup*

Further to this, these senior bureaucrats had little confidence in the quanitification figures gathered at the centralised level, believing that the figures did not represent the needs of the healthcare facilities. This was due to the fact that some healthcare facilities register their pharmaceutical requirements; however, many do not. As interviewee No. 41 noted:

> *I have no faith in the consumption data used by the National Directorate of Pharmacy to quantify pharmaceuticals needs for the country. I am preocupied with this issue. Why not have each Municipal Health Services quantify its pharmaceutical needs with the aim of knowing exactly the need in that area? This would make each municipality responsible for its own inventory (ABO-400 2017).*

One strategy for improving the quality of the data would be to implement a recording and reporting system for pharmaceuticals at the Municipal Health Service level. While instructions have been given by the Vice-Minister to improve the documentation of daily pharmaceutical use by registering the pharmaceuticals that have been dispensed and handing these documents over to staff, it would appear that this practice is not strictly adhered to. Staff members were instructed to do a tally sheet that would include daily, weekly, monthly, and quarterly registration, but the system does not appear to be working, as reported below:

> *I have instructed to all my pharmacists to have regular daily tallysheet, daily registration to know quantity of pharmacuticals used in a day and also to know how many pharmaceuticals are received or distributed to the emergency unit, maternity or OPD, SISCa and mobile clinics activities. They must register to know how many pharmaceuticals are dispensed daily, weekly, monthly and quarterly. We have been doing this for three months. I can see improvements. The Minister for Health uses our methods to capture information to be used in all municipalities. We have not get any response for our work from National Division of Pharmacy to date (ABO-400 2017).*

Why local health facilities do not comply with this request appears to be due to a lack of knowledge of how to proceed. In August 2017, all Municipal Health Services were requested to initiate meetings with municipal authorities and health facilities to start pharmaceutical quantification for their area (ABO-400 2017; AJ-100 2017). This was done by sending out a letter to all parties that had no quantification guidelines. The situation is summarised by interviewee No. 41, and demonstrates why stock-out will continue:

> *We have been requested to make our own pharmaceutical quantification. Our team prepared one and sent it to National Pharmacy Directorate. However, I see that our quantification reports seem to get lost, there is no feedback at all. I said to them that you must support us on how to do it. We have to provide data to be used in the calculation, however, we need your support. There has not been any further information about quantification to us. All Municipal Health Services have given up trying to prepare their quantifiaction needs for 2018. This means that stock-out will continue to happen next year (ABO-400 2017).*

The difficulties go beyond a lack of understanding of how to fill out the required forms, extending to not receiving essential information. For example, eight senior staff noted that the distribution of essential documents relating to pharmaceutical utilisation did not reach every manager or pharmaceutical coordinator. These documents were the Standard Treatment Guidelines (STG) and the National List of Medicines. Most Community Health Centres, pharmaceutical coordinators, and clinicians were not aware of the existence of these documents when shown a sample of them (ABA-

270 2017; ABE-300 2017; ABF-310 2017; ABN-390 2017; AK-110 2017; AP-160 2017; AY-250 2017).

6.2.3 Pharmaceutical stock-out is a result of human resource deficits, including training

Human resource capacity remains an issue, despite 91 per cent of the 216 pharmacy technician postions being filled across the country. However, the majority of these 216 positions in the National Health Sector Strategic Plan are only for Community Health Centres and hospitals (Ministry of Health Timor-Leste 2011, pp. 127-131). This leaves the work of pharmaceutical supply chain management to physicians, nurses, and midwives at the health post level. Quantification could be undertaken at the health facility level, but this would require pharmacists to be available in all health facilities with knowledge and skills on supply chain management. Without this, it would be almost impossible to perform this task. In addition, there has been little training in pharmaceutical management for pharmacists (ABP-410 2017a). Many physicians, nurses, and midwives lack the capacity to manage pharmaceuticals, hence training is needed (ABO-400 2017; ABP-410 2017a). A District Health Service Director who has been working in the position for more than five years expressed the reality that there is a serious lack of training for pharmaceutical supply chain management. She said that

> *I assumed my position as Director of Municipal Health Services four years and six months ago. I expected that there would be training for pharmacist coming from the National Directorate of Pharmacy, however, none took place. There were workshops on STG and EDL , but these were not trainings (ABO-400 2017).*

Another difficulty is what was referred to as spillage of pharmaceuticals across the health posts. This refers to clinical staff taking small quantities of medicines for their own personal use. This was noted by managers and pharmacists at 11 healthcare facilities. When this happened only on a small scale, healthcare professionals do not register this. If it was widespread, it was considered worth preventing or recording. Actions taken to improve the registration of pharmaceutical consumption for personal use is required. Almost all the participants acknowledged this as a problem (ABA-270 2017; ABE-300 2017; ABI-340 2017; ABJ-350 2017; ABK-360 2017; ABO-400 2017; AJ-100 2017; AN-140 2017; AP-160 2017; AW-230 2017; AX-240 2017). The following statement from Interviewee No. 40 summarises the difficuties associated with this issue:

> *Prior to 2016, there were so many mistakes. We cannot deny this. A firm message has been sent out to all health facilities emphasising that, they can obtain pharmaceutical, but they have to register their use. This is to help us monitor what quantities of pharmaceutical are received and dispensed. This still exist, but I guarantee that we can achieve ninety five per cent compliance (ABO-400 2017).*

Decentralisation of some functions of the Central Services of the Ministry of Health to the Municipal Health Services has also created problems in the provision of pharmaceuticals. The Municipal Health Services do not have the funds for emergency procurement of pharmaceuticals. This is because this procurement activity is centralised in the Ministry of Health. There are no other funds from the municipality to support this approach (ABA-270 2017; ABE-300 2017; ABO-400 2017; AJ-100 2017; AX-240 2017).

Eight participants offered a number of possible solutions to the issue of stock-out. One standard action that could be taken at the Municipal Health Service level would be to intensify the monitoring of stock levels at all health facilities on weekends. This would be done to ascertain what type of pharmaceuticals were about to run out or were not available at health facilities. The information could be used to transfer pharmaceuticals from one health facility to another. Another recommendation was to use second option pharmaceuticals (generics) that would have the same therapeutic effects (ABC-280 2017; ABD-290 2017; ABE-300 2017; ABJ-350 2017; ABO-400 2017; AL-120 2017; AU-210 2017; AX-240 2017). Three interviewees suggested that technical interventions could be made to improve recording and reporting in pharmaceutical supply chain management by revisiting the LMIS (Logistic Management Information System) tools in the Municipal Health Services, and instigating regular evaluation meetings to improve monitoring and evaluation at health facilties. In certain municipalities, a triple recording mechanism is used (ABO-400 2017; AJ-100 2017; AX-240 2017). For example, Inteviewee No.10 said:

> *... we used the supportive supervision tools distributed by Central Services of Ministry of Health which have been completed with questions and how to monitor the use of LMIS tools and supervision. We encouerge our Pharmacists to have regular and surprise supervision visits by allocating supervision budgets. The objectives are to to evaluate and support health facilities to use LMIS correctly (AJ-100 2017).*

Most heads of the CHCs stated that when they have stock-out, their obligations were to submit pharmaceutical requests to the Municipal Health Services (ABA-270 2017; ABE-300 2017; ABI-340 2017; ABJ-350 2017; AK-110 2017; AN-140 2017; AP-160 2017; AR-180 2017; AX-240 2017) They did not deal with the quantification of pharmaceuticals at all. For example, interviewee No. 11 stated that:

> *Our job is to make sure that there are pharmaceuticals available for services. When there is a stock-out our obligation is to send requests to Municipal Health Services. SAMES is the organization that will respond to requests. When they deliver pharmaceuticals and the remaining pharmaceutical items requested are not delivered, this means there is stock-out. It is Central Services that knows more about it, we at district, only need to make requests to Municipal, and they take the request to central (AK-110 2017)*

6.2.4 Managing pharmaceutical stock-out

The participants reported that there were five interventions taken by healthcare facilities when there was a stock-out. First, they repeatedly send pharmaceutical requests to the Municipal Health Services office. The second approach is to contact other health facilities that might have the needed pharmaceutical and organise a transfer (ABA-270 2017; ABD-290 2017; ABE-300 2017; ABH-330 2017; ABL-370 2017 ; ABN-390 2017; AM-130 2017; AS-190 2017; AT-200 2017; AW-230 2017; AX-240 2017). The third approach is cross-institutional coordination with private clinics to organise an exchange of pharmaceuticals or to barter for the required medicine. The last avenue available to them is to provide counselling to the patients and suggest they buy the pharmaceuticals at a kiosk or a private chemist in their area (ABE-300 2017; ABH-330 2017; ABL-370 2017 ; ABN-390 2017). Interviewee No. 12, a pharmacist, shared his approach to stock-out:

> *We provide routine information to Physicians about prescribed medicines that are out of stock. We suggest coordination with private clinics (particularly the Church) to exchange pharmaceuticals. For example, if the Church clinic has SF, we barter that with Paracetamol or Cloxacilline. Coordination is also normally done*

with the Referral Hospital at Maubisse. For example, we will exchange Ringer Lactate with SF or Vaginal Cotrimoxasole or Ceftriaxone injection (AL-120 2017).

In conclusion, directors, pharmaceuical coordinators, and managers at healthcare facilities and in the municipalities identified the following factors as contributing to poor pharmaceutical management: budget allocation deficits, the lengthy procurement process, poor inventory management at the health facilty level involving a lack of human resources and training, centralised quantification and supervision, and the poor monitoring and evaluation of the pharmaceutical supply chain management process.

6.3 What do Clinicians Identify as the Impact of, and Contributing Factors to, Pharmaceutical Stock-out?

6.3.1 The impact of pharmaceutical stock-out on clinics and patients

Pharmaceutical stock-out has a negative impact on the work of clinicians. Clinicians in this case study were comprised of physicians, nurses, and midwives working in Community Health Centres, maternity houses, and health posts within the targeted Municipal Health Services. There were seven physicians, two clinical nurses, and one midwife interviewed for this study. Their views and experiences on stock-out, how it affects their work, and what actions they take as a result are captured in this section, along with their use of the STG, LMIS, and ENM guidelines.

The number of pharmaceutical items available at a health post was around 30 to 40 at any given time. Most clinicians know what is in their pharmaceutical room. Most of them did not use the LMIS tools created and supplied by the National Directorate of Pharmacy, but instead, rely on the patient consultation register book, which also contains information about pharmaceutical consumption. The consultation register is used as a tally sheet (ABC-280 2017; ABH-330 2017). Other nurses and doctors have excellent manual pharmaceutical records which provide clear information about inventory levels and expiry dates for pharmaceuticals (ABH-330 2017).

There was a range of responses provided to questions about the experience of stock-out. All the clinicians had come across pharmaceutical stock-out in their clinical practice. Examples of this can be seen in the response from interviewee No. 33, a clinical nurse with the following account,

> *We started experiencing stock-out around 2015. Medicines used to be available at Community Health Centre when the health post was running out of pharmaceuticals and pharmaceuticals were requested quarterly and delivered according to requests. According to the head of the HP, the main factor of stock-out is delivery of pharmaceuticals to health facilities that are not the same as that requested. Health facilities normally receive less than requested. Mostly half or less than half of requested quantities. Pharmaceuticals items that are frequently not available are Antibiotics (Amoxicillin, Metronidazole and erythromycin) and SF. The quarterly request does not work, so health post tend to have monthly requests instead (ABH-330 2017).*

The impact of pharmaceutical stock-out is significant. Rationing of pharmaceuticals becomes a normal practice. Most clinicians deal with stock-out by reducing the number of doses in order to be

able to sustain the treatment regimen or to distribute pharmaceuticals fairly to patients coming to a health facility on any given day. The expectation or hope in taking such action is that by doing so, replenishment of stock will arrive before the patient returns to complete the remaining dose. For example, interviewee No. 33 noted that they took the following action:

> *Instead of giving full dose of one tablet taken three times a day for five days; it turns out to be one tablet taken twice a day for the duration of five days. The practice has many effects. It impacted on consumption and request. Municipal Health Service office will only deliver pharmaceuticals when the request is in line with the past month's consumption. It may also create drug resistance. We are aware of this but could not do anything else (ABH-330 2017).*

Where there is pharmaceutical stock-out that continues for some time, an honest explanation is given to the patient. Clinicians indicated that they provide counselling and suggest alternative herbal medicines that could be taken. In many cases, patients are advised to buy the medicine at a kiosk or at the market. The main pharmaceutical suggested by clinicians for patients are analgesics-antipyretics (ABH-330 2017). In terms of family reproductive health products, such as reagents or pregnancy test kits, midwives indicated they asked couples to buy the product in the capital and bring it to the midwife to perform the test (AT-200 2017). Interviewee No. 20, an experienced midwife, described the situation at her clinic, thus:

> *Reagents for pregnancy test also have been out of stock for a long time. When a mother comes to us and say that I have not got my period, we do not have any mean to test this. What we can do is to provide a Depoprovera injection or implant insertion. Four or five months later, that mother might return to us five months pregnant! Now we would ask a pregnant mother to buy the pregnancy test. That test is not available locally and they have to buy it in Dili. However, the difficulty is that most of the time non-health professionals cannot buy it at a chemist. For those who cannot afford to buy the pregnancy test this means that they will have an unplanned pregnancy (AT-200 2017).*

Pharmaceutical stock-out also has an impact on how clinicians perform emergency procedures. These are often performed without pre-medicated intervention. For example, stitching of an injury is often done without local anaesthesia (AO-150 2017; AV-220 2017; AZ-260 2017). Interviewee No. 22, a physician at a Community Health Centre, stated that one impact of pharmaceutical stock-out was the following:

> *For emergency pharmaceuticals such as anaesthesia, Lidocaine it depends on the needs. Because Lidocaine stock is always limited, many creative approaches are normally taken. In my personal experience, when my stock is at a minimum, and an accident occurs that required one or two stitching, I would not apply local anaesthesia especially for adult patients. However, I will use local anaesthesia for children. I will refer the patient with an injury that requires more than four stitching to a Community Health Centre (AV-220 2017).*

It was a different story for interviewee No. 20, a midwife, who explained the impact of stock-out of local anaesthetic medication, which is essential for certain interventions in family planning programs:

> *Pharmaceutical stock-out also impacts on family planning services, especially local anaesthesia such as Lidocaine. Without this means no insertion of Implant for mothers is possible. They need to wait and return to the health centre without certainty for those services to take place. Sometimes we have to beg NGOs who provide the same family planning services to give us some local anaesthesia. They might give us four to five*

ampoules of Lidocaine, a local anaesthesia. We dilute it to one ml of Lidocaine with one ml Aquadest, a type of distilled water for one implant insertion procedure. We used to use the whole two ml Lidocaine for one procedure in the past. This turn out to bring better results. When we used two ml of Lidocaine in the past, the skin where the implants were inserted became black (AT-200 2017).

Standard interventions employed to address pharmaceutical stock-out were the use of generics, transferring pharmaceuticals from other government public health facilities, cross-institutional collaboration with private organisations to barter for pharmaceuticals, frequent submission of pharmaceutical requests to Municipal Health Services, reducing the dose in treatment regimens, and providing counselling to patients in the use of traditional herbal medicines from their villages. As noted earlier in this last option, asking patients to buy certain pharmaceuticals from a kiosk, the market, or a private chemist, is taken when all of the above options have been exhausted.

6.3.2 Clinicians' knowledge of the STG and EML guidelines

Distribution of the Standard Treatment Guidelines (STG) and Essential Medicine List (EML) guidelines often do not reach all clinicians at the Municipal Health Services and in other health facilities. Most clinicians interviewed had not seen the Standard Treatment Guidelines document. Some remembered the Essential Medicine List document when its colour was described (ABC-280 2017; ABG-320 2017; ABH-330 2017; AO-150 2017; AR-180 2017; AT-200 2017; AV-220 2017). An example of this can be seen from interviewee No. 22 who, when asked about these documents, said:

I ... the small booklet eh ...? I do not know yet, because I have only been in the Community Health Centre for one month by now and I have not been given these booklets. My colleagues may have them, but not me (AV-220 2017).

There are two implications of this lack of awareness of the STG and EML documents. Not accessing the STG means that these health professionals do not have a baseline for their treatment interventions. Instead, the treatment interventions are based on knowledge acquired during their pre-service training done in Cuba. As a consequence, the over-prescription of certain medicines occurs, which immediately leads to stock-out of pharmaceuticals. The second implication is that health professionals do not know the exact number of pharmaceuticals that are available where they are working. Knowing which pharmaceuticals are listed in the Essential Medicine List enables the health professional to use easily supplied pharmaceuticals and to provide effective recommendations on the most (and least) needed pharmaceuticals. This would contribute to the evaluation of the accuracy of the required pharmaceuticals in the healthcare system. In addition to knowing the EML, valuable input from the healthcare facilities would enable efficiency and effectiveness in pharmaceutical quantification and procurement.

6.3.3 Clinicians' understandings of the factors that contribute to stock-out

According to the interviewees, one factor affecting stock-out in their facilities is unfair pharmaceutical distribution across the various districts. Since 2015, the health facilities have only received between 25 and 50 per cent of requested pharmaceuticals. An analysis of the pharmaceutical request and distribution data provided by the Central Medical Store for January-June 2017 reinforced this claim. On average, all healthcare facilities received only 52 per cent of their pharmaceutical requests (Serviço Autonomo Medicamentos e Equipamentos Saúde 2017).

6.4 Conclusion

To conclude, frequent pharmaceutical stock-out affects the clinical practice of physicians, nurses, and midwives at health facilities in the Municipal Health Services of Aileu, Dili, Ermera, and Liquiça. These clinicians manage between 30 and 40 pharmaceutical items in their health facilities at any given time. Most do not use the LMIS tools developed by the National Directorate of Pharmacy at the Ministry of Health for recording and reporting purposes. Clinicians deal with recording and reporting if there are sufficient pharmacists to manage the pharmaceutical supply chain. However, such multi-tasking has led to inadequate attention to detail and low-quality data which, in turn, has affected the overall picture of pharmaceutical consumption. In addition, not all of the health professionals have access to the Standard Treatment Guidelines and the National Essential Medicines List.

CHAPTER 7. FINDINGS - GOVERNMENT DOCUMENT ANALYSIS

7.1 Document Analysis

This chapter provides the second and third levels of analysis (Pozzebon 2004), which is a critical interpretation drawing on a number of documents gathered while in the field. Documents related to inventory management and the logistics management information system (LMIS) processes in selected warehouses at health facilities and the Central Medical Store were collected. Specific information for quantification was gathered in order to understand what data is used, how the calculations are done, how decisions are made, and how requests from the Municipal Health Services are managed.

The flow of information from healthcare facilities to the Central Medical Store (SAMES), the delivery of medicines to healthcare facilities, and how this information is used in procurement plans for pharmaceuticals were obtained and recorded. In addition, participants along the supply chain were asked to provide copies of relevant de-identified government documents relating to pharmaceutical inventory management, such as bin cards, stock cards, and reporting templates or notes. Scanning of filled-in bin cards using an iPhone, inventory cards, etc. was done, because access to scanning machines and photocopiers was not reliable or not available. The timeframe for the collection of the logistic management information system (LMIS) documents was limited to between 2002 and 2016, except for policies, laws, and regulations.

More than 250 documents were collected from the Ministry of Health, the Central Medical Store, the Municipal Health Services, and various other health facilities. These documents were grouped into four categories: legal and policy documents, pharmaceutical quantification, pharmaceutical reports and requests, and the use of the LMIS. The legal and policy documents consisted of decree laws, a ministerial diploma about the classification of pharmaceuticals (República Democrática de Timor-Leste 2004), strategic plans, guidelines, pharmaceutical quantification reports, and pharmaceutical requests and approval letters. Most of the documents were approved, but there were also a number of draft documents which were ready for approval. There were eight decree laws and one ministerial diploma. These legal documents were related to decree laws on pharmaceutical activities and procurement related laws. The dates of these documents ranged from 2004 to 2010 (Democratic Republic of Timor-Leste 2004, 2005a, 2005b, 2005c, 2008, 2010a, 2010b, 2010c).

There were twelve policy documents related to pharmaceutical supply chain management. The policy documents obtained were the National Drug Policy dated 2010, the Standard Treatment Guidelines (2004 and 2010 versions), and the Essential Medicines List (Department of Pharmacy 2015; Ministry of Health -Timor-Leste 2004a, 2004b, 2004c, 2010a, 2010b, 2010c, 2010d, 2010e; National Directorate of Pharmacy - Ministry of Health Timor-Leste 2010). Also collected were lists of pharmacy personnel employed by the Ministry of Health, the draft roll-out plan for the LMIS,

and printed forms and a job guide for the LMIS tools for Timor-Leste (Department of Personnel Management of Ministry of Health Timor-Leste 2017; Department of Pharmacy 2015; Pharmacy Department 2015). There were also two draft documents, a draft pharmaceutical sector strategic plan, and standard treatment guidelines for primary healthcare (Ministério da Saúde 2017; National Directorate of Pharmacy 2015).

All documents related to pharmaceutical quantification and requests for approval of pharmaceuticals were provided by the Department of Pharmaceutical Planning and Acquisition. Four documents on inventory progress reports and management of requests and distribution of pharmaceuticals from healthcare facilities for 2017 from the Central Medical Store (SAMES) were collected (Direção Gestão de Armazenamento e Distribuiçao de Medicamentos 2017a; Serviço Autonomo Medicamentos e Equipamentos de Saúde - SAMES 2017; Serviço Autonomo Medicamentos e Equipamentos de Saúde-SAMES 2017; Serviço Autónomo Medicamentos e Equipamentos Saúde 2017a, 2017b). A total of 123 documents collected from CHCs were reviewed.

Where information was duplicated across all health facilities, the relevant data were not collected again. The pharmaceutical inventory was compared across each month to ascertain pharmaceutical availability in the health facilities. For example, monthly pharmaceutical consumption reports had only been collected for the period of January to June (2016 and 2017). However, the first step in recording pharmaceutical consumption is the tally sheet and daily pharmaceutical registration for every health facility. These were collected across all health facilities. When a monthly report was missing, the information could not be collected. Stock-card rates were randomly collected for pharmaceutical items with the aim of capturing frequency and regular updates on pharmaceuticals. While collecting the stock-cards, the condition of each warehouse was observed, and its capacity and equipment were noted.

7.1.1 Human Resources (HR) and projected HR needs

There were 216 pharmacy positions for health facilities projected in the National Health Sector Strategic Plan to be achieved by 2017 (Ministry of Health Timor-Leste 2011, pp. 127-31); however, by October 2017, only 91 per cent (197) of these positions had been filled, comprised of 146 pharmacists at 67 Community Health Centres, 30 at the district hospitals (Maliana, Oecusse, and Suai), 24 at the referral hospitals (Dili, Baucau, and Maubisse), and 16 at the national hospital. In total, 24 of the public servant pharmacists were working as managers, with 9 of these having assumed management roles at the National Directorate of Pharmacy in the Ministry of Health. Another 5 were working at the Central Medical Store (SAMES), while the remainder were working in the hospitals and the Municipal Health Services offices.

Sixty of these pharmacists had a Diploma III in Pharmacy, 102 a Diploma I as a Pharmacy technician, and 13 a Bachelor of Pharmacy. Meanwhile, a further 20 had pharmacy training at secondary school level, and one was a primary school graduate. These figures exclude those working in the Special Autonomous Region of Oecússe-Ambeno which have not been updated. In an interview with staff at the National Directorate of Pharmacy, it was noted that one person had

just completed his Master of Sciences in Pharmacy and transferred to the Directorate of Pharmacy (Department of Personnel Management of Ministry of Health Timor-Leste 2017).

There were clear indicators in the National Health Sector Strategic Plan 2011-2030 on human resource requirements according to the number of healthcare facilities. The construction of more health posts, which numbered 187 in 2011, had been achieved according to the target and, as of October 2017, there were 313 health posts. However, there is no indication that pharmacists will be deployed at the health post level. Likewise, in 2011, there were 67 Community Health Centres, which had increased to 69 in total. These two achievements were recorded in the construction roadmap of health facilities (Ministry of Health Timor-Leste 2011, pp. 127-133; Interviewee No. 9).

The National Health Sector Strategic Plan aimed for 16 pharmacy technicians by 2020 at the National Hospital Guido Valadares (Ministry of Health Timor-Leste 2011, p. 131). There is a surplus of pharmacists at this top referral hospital; however, there was no clear definition of qualification level of pharmacy technicians (Department of Personnel Management of Ministry of Health Timor-Leste 2017). The target to be achieved by 2017 for the number of pharmacy technicians for the referral hospitals (Dili, Baucau, and Maubisse) was 24. According to interviewee No. 09, 40 individuals who had completed their Diploma III pre-service training returned to the country in 2017; however, it was not clear whether or not they had been included in these figures.

7.1.2 Pharmaceutical quantification method

Documents for pharmaceutical quantification consisted of the quantification guidelines formula (Departamento Planificação e Gestão de Aquisição 2016), monthly reports and requests from the Municipal Health Services for medicines, and requests of approval for the annual pharmaceutical quantification requirements. The quantification guidelines consist of a half-page set of instructions using the Proxy Consumption Based Method formula to calculate the pharmaceutical needs of the country. This formula is applied in an Excel spreadsheet so that calculations can be made to determine the final pharmaceutical quantities required for a year. The formula consists of the following 11 variables:

AMC = Average monthly consumption, adjusted for stock-outs (adjusted average monthly consumption)
C_T = Total consumption during review period, in basic units
D_{OS} = Number of days an item was out of stock during the review period
LT = Lead Time
M_{OS} = Estimated number of months an item was out of stock during the review period
P = Procurement period
Q_O = Quantity to order in basic units, before adjustment for losses or program change
R_M = Reviewed period in months (number of months of data reviewed for forecasting)
S_I = Stock now in inventory, in basic units = stock on hand

S_O = Stock now on order, in basic units = stock on order/pipeline stock
S_S = Quantity needed for safety stock = buffer stock

The pharmaceutical quantification formula is divided into three steps: adjusted average monthly consumption, safety stock, and quantity to order. The average monthly consumption (AMC) adjusted for stock-out (adjusted average monthly consumption) has two options, the preferred method and an alternative method. The preferred method AMC is calculated through total consumption in a review period (C_T) divided by the number of months pharmaceutical data is reviewed for forecasting, denoted R_M subtracted by number of days an item is out of stock during the review period, denoted by D_{OS} divided by 30.5. The alternative AMC is calculated by having the total consumption review period divided by the product of number of months pharmaceutical data is reviewed for forecasting (R_M) subtracted by the estimated number of months an item was out of stock during the review period, denoted as $M_{OS.}$ The adjusted average monthly consumption equation is stated as follows:

The preferred method

$$AMC = \frac{C_T}{\left[R_M - \left(\frac{D_{OS}}{30.5}\right)\right]}$$

The alternative method

$$AMC = \frac{C_T}{\left(R_M - M_{OS}\right)}$$

The second step of the calculation is the safety stock (S_S) or buffer stock which consists of a preferred safety calculation method and an alternative approach. It is obtained by multiplying the figures from AMC with the procurement lead time (LT). Lead time is the period between issuing an order to a contractor to prepare goods (pharmaceutical items), and the time taken before the goods are received at the intended destination. The alternative safety stock can only be expressed by having the pharmaceutical needs for half of the period being reviewed. The period of review is normally one year. This means that safety stock is the pharmaceutical quantities required for a six-month period. The safety stock calculation is expressed as:

S_S = AMC X LT; or S_S = ½ Review period (quantity needed for ½ the review period).

Once the figure for safety stock is obtained, the final part of the calculation of the quantity to order (Q_O) can be made. This is calculated by multiplying the AMC with the product of the addition of lead time (LT) and procurement period (PP). Then, the product of safety stock is subtracted by stock inventory (S_I) or stock on hand (S_{OH}), to which stock on order is added. The formula for quantity to order is denoted as:

Q_O = AMC x (LT+PP) + S_S – (S_{OH} +S_O)

Application of the Formula into an Excel Spreadsheet

This formula was applied correctly in the Excel spreadsheet for pharmaceutical quantification for the review period of 2015; however, the data required to perform all the calculations was incomplete. The list of medicines was divided into 'vital', 'essential', and 'necessary' medicines. Only 33 of 83 'vital' medicines needed to be ordered. In the category of 'essential' medicines, a total of 78 of 152 'necessary' items needed to be ordered, and 46 items were not needed. Only 51 out of 69 of the 'necessary' pharmaceutical items were ordered (Departamento Planificação e Gestão de Aquisição 2015c).

Overall, there were 304 pharmaceutical items in the three categories in the period under review (2015). There were incorrect statements in the quantification spreadsheets for all categories (Departamento Planificação e Gestão de Aquisição 2015c) (see Table 7.1). There was no reported reason why certain pharmaceutical items were not ordered for the period. One possible reason an item was not ordered may have been based on average monthly consumption and stock on hand. For example, a closer look at one pharmaceutical item (Adenosine Injection Solution 3mg/ml), showed that the average consumption was 2, and yet the stock on hand was 78. This validates the assumption.

Table 7.1 Incorrect pharmaceutical items to order for period of 2015

Pharmaceutical category	**Total**	**Stated to be ordered**	**Not to be ordered**	**Total correct items to be ordered**
Vital	83	33	45	38
Essential	152	78	46	74
Necessary	69	51	21	48
Total	304	162	112	160

Also examined was a pharmaceutical item called Acetylsalicylic acid tablets 100mg. The average consumption data was obtained from total distribution data for one period (2014) from all health facilities for each pharmaceutical item from the previous period divided by 12 months. There was no data on total months of stock-out (D_{OS}) for this item and all remaining items. Lead time was three months, and the procurement period was six months. There was no data on stock inventory (stock on hand) or stock on order. Safety stock figures for each facility were only available for SAMES, the National Hospital Guido Valadares, and the Municipal Health Services of Manufahi. The safety stock figure for SAMES was correctly quantified, but the figures were estimations only. The formula for quantity to order was correct, but the final quantity to order was also only an estimation (Departamento Planificação e Gestão de Aquisição 2015c).

The quantification method used was the WHO's Proxy Consumption Method, which is based on consumption data. However, it was clear that the data used to quantify what was needed for 2015 was the distribution data. The data used to compute pharmaceutical needs were incomplete. These two factors may have resulted in incorrect quantities being procured by the Ministry of Health.

Approval of Pharmaceutical Quantification

Spreadsheets for the 2016 and 2017 periods were not available for review. However, a final list of the number of pharmaceuticals needed was attached to letters of request for approvals. Revised quantified pharmaceutical documents are sent to the Central Medical Authorities (SAMES) in the second or third quarter of any given fiscal year. The cause of delays comes either from the National Directorate of Pharmacy or SAMES. For example, revised quantified pharmaceuticals for all categories (vital, essential, and necessary) for 2016 were sent to SAMES on the 15th of August 2016. A similar delay also occurred for the revised quantified pharmaceuticals for all categories for 2017 to SAMES on the 25th of October 2016. Considering the defined procurement lead time, and the procurement period, the provision of pharmaceuticals for 2016 was quite late. The same also happened to the provision of pharmaceuticals for 2017. If the procurement of pharmaceuticals is not initiated in time, stock-out cannot be avoided, resulting in a recurrent cycle for future periods.

7.1.3 Difficulties in obtaining data

Obtaining pharmaceutical supply chain management data was a challenge. The main factor was the recording system and storage. At the central level, there was a serious lack of management of information. There were a mix of approaches to managing data. Information on pharmaceutical supply chain management was either in electronic files in computers, or a combination of electronic records and hard paper copies. Links between information in the electronic files could not be traced. For example, there was no record of pharmaceutical consumption from all health facilities in some CHCs (Community Health Centre of Aileu Villa 2017; Community Health Centre of Maubara 2017a). Various reasons for poor data management and reports were provided, ranging from no reports from lower-level facilities to lack of personnel and high workloads (ABD-290 2017; ABN-390 2017; AJ-100 2017; AM-130 2017).

7.1.4 Pharmaceutical consumption reports and requests

There are similarities in the monthly pharmaceutical reports and requests. Every three months, Municipal Health Services must report their pharmaceutical inventory or stock levels and, at the same time, request pharmaceuticals for stock replenishment. The data for inventory levels and requests is expected to come from monthly pharmaceutical reports and requests from the offices of the Municipal Health Services and all healthcare facilities. Pharmaceutical items managed at the municipal level, this being in the CHCs, the CHCs located at the sub-district level and, the health posts, are different according to defined roles, services, and medical equipment.

7.1.5 Lack of data on certain pharmaceutical items and overall stock-out

Aileu was one among 13 Municipal Health Services with minimum frequency of stock-out in the period between January to June 2017. There were 469 pharmaceutical items available in the health system, excluding consumable items (Direção Gestão de Armazenamento e Distribuiçao de Medicamentos 2017b). Of these, 193 items were included in the list in the pharmaceutical report and on the request forms for the Municipal Health Services level. Total items requested for the first three months of 2017 were 135, with only 78 items being delivered by SAMES. At the beginning of the second quarter, on 5th April 2017, Aileu requested another 86 items, of which 47 per cent (40 out of 86) were out of stock.

In the list of 193 total pharmaceutical items for the Municipal Health Service of Aileu, 98 items contained no data or any comment on why these lines were left blank (Serviço Saúde Municipiu Aileu 2017b). One assumption for this is that these 98 items were medicines not provided to Municipal Health Services, and therefore could not be ordered. It is very time-consuming for pharmacists coordinating pharmaceutical supply chain management to deal with this unnecessary task. Examples of these pharmaceuticals were Vitamin A (Retinol) 100 000 IU, Penicillin Procaine Benzyl PFI 1mu=1g Chloramphenicol HCL, and Lidocaine with Adrenalin 2% 1:800000 cartridge and 2% 1:100000. However, it seems strange that a Community Health Centre level 1 which is located at the capital of a Municipal is not allowed to access these medicines. The claim that there was only 47 per cent of pharmaceutical stock-out at the time is incorrect. The correct figures are that 72 per cent (138 out of 193 pharmaceutical items (excluding consumables) were stocked-out. This seems to be in line with the progress report on inventory levels from SAMES obtained four months later in August 2017. At the time, stock- out of vital pharmaceutical items was 33 per cent (31 out of 94); essential pharmaceutical items was 58 per cent (173 out of 299); and necessary pharmaceutical items was 71 per cent (53 out of 75). Total stock-out for all 468 pharmaceutical items at the Central Medical Store was 55% (Serviço Autonomo Medicamentos e Equipamentos de Saúde - SAMES 2017).

According to the distribution records from the Central Medical Store (SAMES), 76 per cent (65 out of the 86 requested) of items were delivered. In June that year, Aileu requested 10 pharmaceutical items of which 80 per cent were delivered by SAMES. However, when examining an issue docket[22] on the 25th of July 2017, SAMES delivered 150 items to the Municipal Health Services of Aileu. Of this delivery, 105 were pharmaceutical items and 45 were consumable items (Serviço Saúde Municipiu Aileu 2017c). There were no request documents from the Municipal Health Services of Aileu to compare to the delivery docket from SAMES.

If a report of inventory or stock level at SAMES is available for a particular period, a comparison can be made to identify the similarities of stocked-out items. However, there was no information available. SAMES relied on its electronic inventory report and did not have detailed information in

[22] *A receipt of distributed/ delivered pharmaceutical items*

hard copy for every month. Instead, SAMES only has the most recent information on stock balance for all categories.

The Aileu quarterly report and request form consists of five variables represented in five columns. These are: (a) the balance of pharmaceutical stock in the last month/period; (b) stock received last month/ period from SAMES; (c) the stock balance in the last month/period; (d) total stock used during the period which is made up of the combination of total stock in the past month/period and stock received from SAMES in the past month/period, then subtracted by stock balance in the past month/period (D= (A+B)-C); and (e) the quantities of pharmaceuticals requested, which is generally the same as D (Serviço Saúde Municipiu Aileu 2017b).

The reporting form raises a number of questions. The first question is the information about the stock used during the period. This does not contain any information about pharmaceutical consumption at all. This information is purely based on distribution data. The second question is what constitutes the stock balance? Stock balance data is made up of total stock on hand subtracted by total consumption at any given point in time. It would make sense if the quantities of pharmaceuticals requested for a given period were the same as the quantities used in the period. However, this would mean there would be no buffer or safety stock at all. To prevent stock-out, total consumption is not the only factor to be considered in any pharmaceutical request. Safety stock must also be factored in based on a defined level of safety stock. Unfortunately, there is no policy document relating to this matter.

7.1.5.1 Pharmaceutical R & R of Municipal Health Services of Ermera

In this case, the pharmaceutical consumption report and request (R & R) letter for the second quarter (April, May, and June) was dated 5th of April 2017. The form used to report pharmaceutical consumption and request was LMIS 005, a newly created form in 2015 (Departamento Planificação e Gestão de Aquisição 2015a, 2015b), distributed by the Department of Pharmaceutical Planning and Acquisition Management, with different variables from the previous form. The information is divided into two parts: last report period and request. Last report period contains data on: initial stock balance carried from the previous quarter; quantities received; consumption quantities; adjusted consumption quantities, D=(Hx90)/(90-K); losses/adjustment; duration of stock-out in days; last balance, G=(A+B) – (C±E); minimum quantities (which should state average monthly consumption), H=(D/3) x2; maximum quantities i=(D/3) x 5; and approaching expiry date. In the second part, the pharmaceutical request contains two variable sets of data: quantity requested K=H-G, and quantity approved (Municipal Heath Services of Ermera 2017). The information from one quarter to another is hyperlinked, and the stock balance from previous periods is always carried over to the next review period. This is a better management tool for pharmacists and other health professionals managing pharmaceutical supply chain management in their health facilities.

There were two issues identified in the second quarterly pharmaceutical report and request from the Municipal Health Services of Ermera. The first was the misreporting of the minimum quantities. The correct name of this variable should be ‘average monthly consumption’, rather than ‘minimum

consumption'. A test of the Excel spreadsheet using the LMIS-005 form indicated that the formulae in the form had been used correctly (Departamento Planificação e Gestão de Aquisição 2015a; Municipal Heath Services of Ermera 2017).

The second issue was related to the application of the safety stock and the lead time factors not being taken into account in quantifying pharmaceutical needs. The only factors that were taken into account in the quarterly pharmaceutical report and request from the Municipal Health Services of Ermera was the review period, minimum stock levels, and maximum stock level (all recorded in months) (Departamento Planificação e Gestão de Aquisição 2015a; Municipal Heath Services of Ermera 2017). Pharmaceutical stock-out might be prevented if the formula for all variables and all factors affecting stock levels are considered.

There were 230 pharmaceutical items (excluding consumables) listed in the report and request for the quarter. Forty-five per cent (104 out of 230) pharmaceutical items were stocked-out. There was no data at all for the line items, including how many days these items had been in stock-out. A total of 48 pharmaceutical items had been out of stock for more than two months (30-75 days). The only way to know what point in time during the last quarter these items were unavailable would be to have access to the first quarter of pharmaceutical report and requests in 2017 (Departamento Planificação e Gestão de Aquisição 2015a). A similar pattern of stock-out was noted in the same report for the Municipal Health Services of Aileu for the same period.

There were similarities in the items being completely stocked-out between the two Municipal Health Services (Aileu and Ermera) with only slight variations; for example, Vitamin A (Retinol), Penicillin Procaine Benzyl PFI 1mu=1g, Chloramphenicol HCL, Lidocaine with Adrenalin 2% 1:800000 cartridge and 2% 1:100000 (Municipal Heath Services of Ermera 2017; Serviço Saúde Municipiu Aileu 2017b). A cross-check with the Timor-Leste Essential Medicines List rejected the above assumption. These items were specified to be used at Municipal CHCs and at the health post level (Comittee for Selection of Medicines 2015, pp. 8-37).

7.1.5.2 Pharmaceutical R & R from Community Health Centres

The use of a template for pharmaceutical reports and requests, known as an R & R form at CHCs, varies between one facility and another. At this level, there are two forms used for pharmaceutical reports and requests. CHCs must report and make a request to replenish their pharmaceuticals every month. Health facilities at this level use the form known as "*Relatorio Konsumu Mensal Aimoruk"* or Monthly Pharmaceutical Consumption Report. The form was developed by the Pharmacy Department of the Ministry of Health. There is no request section in this form. The template consists of information of patients/pharmaceutical quantities used, name of pharmaceutical items, and the five following variables: (a) quantities received and stock balance from past month; (b) quantities issued; (c) stock balance at the warehouse and the chemist (obtained by subtracting b from a); (d)

stock indication (composed of subtracting c from b); and (e) percentage of stock balance (obtained by having the stock balance at the warehouse and the chemist subtracted from the quantities issued).

There is no indication of how many pharmaceutical items must be available at a sub-district Community Health Centre. For example, in February 2017, CHC Laulara only reported 29 pharmaceutical items dispensed to patients. However, it reported an inventory level for 46 pharmaceutical items dispensed to patients in the previous month (Community Health Centre of Laulara 2017a, 2017b, 2017). CHC Ermera used the same form as Laulara for its pharmaceutical reporting for January 2017. It contained 112 pharmaceutical items of which 41 per cent (46 items) were stocked-out (Community Health Centre of Ermera 2017a). However, in its pharmaceutical report and request for May 2017, it used a form developed by the Central Medical Store, SAMES. This form consisted of four variables: minimum-maximum stock for 2-3 months; consumption; stock balance; and quantity requested. There are additional pre-filled sections on the form such as code, name of pharmaceutical items, dose or strength, and unit price. There were 220 pharmaceutical items listed in this report, excluding six items for vaccines and pharmaceuticals for the tuberculosis program. Overall stock-out was 52 per cent (114 out of 220) of pharmaceutical items. Pharmaceutical items were spread over six pages without a sequence number to enable easy reference. Information on the stocked-out items were filled in correctly and completely. Based on this report and request form, on the 2nd of May 2017, CHC Ermera received 34 pharmaceutical items from the office of the Municipal Health Service of Ermera (Community Health Centre of Ermera 2017b). One can see the stock balance of the reported items, but it is not comprehensive. This makes it a challenge to establish the percentages of stock-out in any given month. The Municipal Health Services office is able to detect numbers of pharmaceutical items and stock level at this facility, and the entire inventory level can only be seen through a request form.

Most health facilities have not used the R & R form developed in 2015 by the Ministry of Health (Departamento Planificação e Gestão de Aquisição 2015b). The reason for this is that they had not received adequate training in using the form. Many pharmacists (interviewee Nos. 13, 23, 25, 29, 39) felt that the language and the formulae used in the form required more explanation (ABD-290 2017; ABN-390 2017; AM-130 2017; AW-230 2017; AY-250 2017).

7.1.5.3 Another reporting form used in a CHC in Liquiça

The Community Health Centre of Maubara (in Liquica) used another self-developed pharmaceutical reporting form. The title of the reporting form was “Farmacia SSM Liquicça. Formatu Relatori Konsumu Aimoruk Mensal” or Pharmacy of Municipal Health Services (MHS) of Liquiça, Monthly Pharmaceutical Consumption Report Form. The reporting form consisted of information on the number of pharmaceutical items, including quantities received from the MHS added to stock balance; consumption quantities; balance; expiry date; stock-outs; and over-stock. At the end of the reporting form, there was a section on the total number of patients seen in April 2017. However, there were no formulae used to calculate the pharmaceuticals in the form, and there was no access

to an Excel spreadsheet to see the calculations. There were 101 pharmaceutical items listed in the report. Of these, 48 per cent were out of stock. However, in a column headed stock-out and over-stock, each pharmaceutical line was filled with zero (Community Health Centre of Maubara 2017i). This information could be true for over-stocked items, because in the balance section, it was clear that there were 48 items unavailable in the inventory. The Community Health Centre of Maubara used this form consistently from January to July 2017 (Community Health Centre of Maubara 2016, 2017a, 2017b, 2017c, 2017d, 2017e, 2017f, 2017g, 2017h, 2017i).

7.1.5.4 CHCs in the Municipal Health Service of Dili

CHCs in the Municipal Health Service of Dili used a different approach to the reporting of pharmaceutical consumption and inventory. Dili is the capital of Timor-Leste and the CHCs are relatively close to the Central Medical Store compared to the remaining municipalities, except the Community Health Centre of Ataúro.

To address the issue of pharmaceutical stock-out and lack of confidence in the data, the Director of the Municipal Health Services instructed each Community Health Centre to prepare and send weekly pharmaceutical reports on top of their monthly reports (ABO-400 2017). The weekly pharmaceutical consumption report form has a number of variables that would provide the data required for the monthly reports and requests. The variables included are: pharmaceutical items, past stock, pharmaceuticals received, adjustments, total daily consumption for each week, total pharmaceutical consumption, total patients, total prescriptions, and final inventory balance. Pharmaceutical items are grouped into categories and provided with sequence numbers. This enables easy counting of pharmaceutical items managed at the centre and locating items that are stocked-out. There are no formulae displayed on the form.

An example of the report can be seen in the weekly and monthly reports from the Community Health Centre at Becora. In its weekly pharmaceutical consumption reports for 3rd to 23rd of January 2017, the following details were reported: there were 142 pharmaceutical items; initial stock-out at the beginning of the month was 56 per cent (84 out of a total of 147 items); the stock-out figure at the beginning of the month was constituted by 123 stocked-out items subtracted by 41 items replenished at the beginning of the month; a total of 4,419 prescriptions were recorded; and at the end of January, the stock-out was 65 per cent (95 out of 147 items) (Community Health Centre of Becora 2016 2017h). No single cell in the report was left bank. When there was no data, a zero was put in the cell. The average stock-out for January-July 2017 was 64 per cent (Community Health Centre of Becora 2017a, 2017b, 2017c, 2017d, 2017e, 2017f, 2017h).

In summary, there is no common pharmaceutical report and request form used across all visited CHCs in Aileu, Dili, Ermera, and Liquiça. The forms used for monthly pharmaceutical reports and requests in all CHCs varied substantially. Apart from using the MoH reporting form, other CHCs also received requests from SAMES. These health facilities also made adjustments to the reporting request forms through modification of the categories of the pharmaceuticals. This poses a challenge

for analysing the pharmaceutical inventory effectively and efficiently. There was little consistency in the implementation of the weekly pharmaceutical consumption reports. Each health facility is obliged to report its weekly pharmaceutical consumption, but only two out of eleven CHCs were able to provide weekly pharmaceutical consumption reports. If all 69 CHCs are using different reporting and request forms, it is difficult to compile and analyse them at the central services of the Ministry of Health to estimate supply and stock-out. Improvements in the use of the pharmaceutical reports and requests is primarily dependent on leadership at the Municipal Health Services and Ministry of Health levels.

7.1.5.5 Monthly pharmaceutical R & R from health posts

Three health posts, Guiço, Vatuboro 1, and Loidahar, were successfully visited and interviews conducted. The recording and reporting of pharmaceutical consumption at these health facilities varied. The number of pharmaceuticals managed at this level were between 60 and 87 items.

Vatuboro-1 was the most consistent in the use of reporting forms (Health Post of Loidahar 2017; Health Post Quico Vatuboro 1 2017a). The average pharmaceutical stock-out for Vatuboro-1 for the period between January and August 2017 was 63 per cent, with details of monthly stock-out as follows: in January 2017, the health post operated with only 10 pharmaceutical items and stock-out was 87 per cent (77 out of 87); in May 2017, the total pharmaceutical items reportedly managed and requested were 70 items. Of these, 53 per cent or 46 pharmaceutical items were stocked-out (Health Post Quico 2016a, 2016b; Health Post Quico Vatuboro 1 2017e); A month later, in June, stock-out was 48 per cent (42 out of 86 total items), and in August, stock-out out reached 57 per cent (Health Post Quico 2016b; Health Post Quico Vatuboro 1 2017a, 2017b, 2017c, 2017d).

The other two health posts (Quiço and Loidahar) managed different quantities of pharmaceuticals compared to Vatuboro 1. The number of pharmaceutical items managed was 64 (Health Post of Loidahar Liquica 2017c; Health Post Quico Maubara 2016). Quiço is the most efficient health post, with an excellent pharmaceutical record. All pharmaceuticals received and consumed were clearly captured in a self-made pharmaceutical registration book. The items managed were consistently recorded, maintained, and reported monthly. Daily consumption data was completed at the end of day, and at the end of each month, the balance was calculated in the last column of the pharmaceutical consumption record which is the stock-balance. This health post had managed 72 pharmaceutical items consistently over the previous two years (2016-7). The average pharmaceutical stock-out for January to September 2017 was 70 per cent (Health Post Quico, M, , 2017; Health Post Quico Maubara 2016). However, if the denominator was replaced with the total items managed by Vatuboro-1, the average stock-out would only be 50 per cent. This enabled the facility manager to know exactly what their pharmaceutical inventory numbers were, and what action to take to replenish them. However, regardless of how good the inventory management was, it appears that there is consistency in the stock-out of more than 50 per cent across all health posts and CHCs.

7.1.6 Stock cards for pharmaceuticals

A pharmaceutical stock card is a small cardboard record-keeping system for each pharmaceutical item. It contains vital information on the strength of the pharmaceutical, the form, the expiry date, and movement of the item in a given period. It records the date of replenishment, dispensing, and balance. At the health facilities, there are two type of stock cards: open stock cards (also known as operating stock cards) and closed stock cards. Open stock cards are placed in dispensing rooms, wards, and consulting rooms where pharmaceuticals are dispensed directly to patients, and are updated daily. The closed stock cards are for each pharmaceutical item in the facility pharmaceutical warehouses. It was observed during field visits to the health facilities that healthcare professionals used self-developed pharmaceutical registration books as operating stock cards. There are inconsistencies in the use of pharmaceutical stock cards to report on pharmaceutical inventories across all CHCs and in the health posts. At the Community Health Centres, the closed stock cards were not updated regularly. There was no unified method for inventory management at all levels of health facilities. This was evident from analysis of the pharmaceutical inventory management at the health posts. At the health post level, healthcare professionals managing pharmaceuticals mostly preferred to use a daily consumption tally sheet as their inventory method instead of the open stock cards. The following examples revealed that there was no uniform approach to the use of R & R (report and request) forms for reporting pharmaceutical consumption and requests.

At the health post level, most stock cards for pharmaceutical items are updated when a pharmaceutical item is dispensed or distributed. A sample of three pharmaceutical items were examined from Vatuboro 1: Carbamazepine 200mg tablet, Promethazine 25mg tablet (26-06-2017), and Griseovulvin tablet 250mg. There were 46 Carbamazepine tablets, single entry noted on the stock card on the 3rd of September 2017. In the search to establish the stock balance of Carbamazepine 200mg, it was found that the item was among the 87 pharmaceuticals dispensed for August 2017. The same approach was used for Promethazine (Health Post Quico, V, , 2017; Health Post Quico Vatuboro 1 2017d). There were 50 Griseovulvin tablets 250mg received on the 23rd of August 2017, and again, it was the only single entry for that year. There were no records on the quantities distributed, but the leftover balance was recorded. In the pharmaceutical consumption report dated 31 August 2017, Vatuboro 1 received 100 tablets, dispensed 67, leaving a balance of 33 tablets. There were 50 Griseovulvin tables unaccounted for over the same month (Health Post Quico, V, , 2017; Health Post Quico Vatuboro 1 2017a).

The health post at Loidahar did not use stock cards to record pharmaceutical inventory. They used a hand-made pharmaceutical registration book and a daily consultation registry book. The pharmaceutical registration contained information on daily pharmaceutical consumption only for items dispensed within any given month. However, in the report, the stock balance for 87 items was reported (Health Post of Loidahar, L, , 2017a, 2017b; Health Post of Loidahar Liquica 2017a, 2017b, 2017c). For example, for the period of May 2017, it was reported that only 25 pharmaceutical items were used; however, a full stock balance was reported (Health Post of Loidahar, L, , 2017b; Health Post of Loidahar Liquica 2017c). There was correct recording between the total of pharmaceutical

items consumed daily at the end of each month and the report sent to the Municipal Health Services. For example, for the period of May 2017, the total monthly Promethazine 25mg tablets total of 167 can be validated in the pharmaceutical report for that month. However, there were noted discrepancies in the consumption data between the total consumption data in the hand-made pharmaceutical registration book and the monthly report send to the Municipal Health Services. For example, for the period of May 2017, a total of 247 Amoxicillin caplet 500mg were registered as having been dispensed to patients, but the total consumption report was 580 caplets, leaving 333 Amoxicillin 500 caplets unaccounted for. The same discrepancy was found for iron tablets (Sulphate Ferrous). The health post dispensed 341 tablets during the period; however, zero consumption was reported (Health Post of Loidahar, L, , 2017b; Health Post of Loidahar Liquica 2017c).

The detailed analysis of inventory management made it clear that there were inconsistencies in the use of inventory management tools to record the pharmaceutical stock levels and use at health facilities. There were discrepancies in the stock cards or the hand-made pharmaceutical registration records and monthly pharmaceutical reports. Claims from senior management about the lack of data validity are indeed accurate.

7.1.7 Temperature control

There is no policy on temperature management of pharmaceutical storage at warehouses in the health facilities, with the exception of the Central Medical Store. In all the health facilities, there was no record of temperatures kept. The only information available for review was the temperature control for vaccine storage. Random collection of temperature control for vaccines indicated regular monitoring of vaccine temperatures in all health facilities. Examples of this can be found in the CHC of Becora, Maubara, Laulara, and Remexio (Community Health Centre of Becora 2017g; Community Health Centre of Laulara 2017c; Community Health Centre of Remexio 2017; Serviço Saúde Municipiu Aileu 2017a). Room temperature control at the warehouses of the health facilities was not a matter that required further analysis, unless there was an indication that some pharmaceuticals had lost their potential due to lack of temperature control.

7.2 Other Challenges

7.2.1 Infrastructure – road conditions

There roads connecting the CHCs and the districts were mostly damaged and required repairs. This goes some way to explaining the difficulty of transporting medicines to outlying clinics. Improvements in road conditions were visible in Aileu and Ermera. In the capital, nearly 90 per cent of the roads were in good condition. The main road to Ermera and Liquiça are of world-class standard. For the road between Balibar and Solerema, more than 40km was in very bad condition. A trip from Dili to Aileu, which in the past took one hour, took two hours. These road conditions go some way to understanding why the municipal ambulance service is limited, given that

maintenance costs are so high. An alternative road from Solerema, only a few metres from the connecting road from Seloi Kraik to Tokoluli, Gleno, Ermera, is being built. This road will connect Solerema with the upper stream of the Comoro River, Manleuana, Dili, the capital of Timor-Leste. The road is being built by a Chinese construction company and is twice as wide as the current road from Dili to Aileu. The dusty road from Aileu to Dili only took 45 minutes to descend. Once this road is completed, the trip between Dili, Aileu, and other southern coast municipalities will be faster. The road to Lequidoe is the worst among all the sub-district roads in the municipality of Aileu. The road to Lequidoe, which is approximately 30km east of the capital of Aileu, was also poor. It would be very difficult to drive this road during the rainy season.

7.2.2 Political interference

Information to note about the mSupply system is that the software has been installed in all CHCs across the entire country, and pharmaceutical inventory data and consumption data flowed very well. Stock levels at the Central Medical Store and the health facilities could be accessed immediately by senior managers at the Ministry of Health. However, according to a participant from the Central Medical Store, SAMES, the Ministry of Health issued an order on the 23rd of December 2017 to stop the use of the mSupply system and replace it with another software package known as AdenBox. The order to stop mSupply was difficult to comprehend, as the newly developed software, AdenBox, needs to start from scratch, and its effectiveness is yet to be evaluated. This change has affected inventory management of pharmaceuticals in the healthcare sector across the country. All inventory management has had to return to paper-based systems, and the information about pharmaceutical inventory has been compromised. Since the government was replaced by the 8th Constitutional Government, and the new Acting Minister of Health took office, she has received many complaints. The system appears not to be working. This represents an example of the difficulties experienced when politicians interfere in the internal running of a system without adequate knowledge of the consequences.

7.3 Summary of findings

The misleading figures on the number of pharmacists and the impact of having mixed healthcare professionals involved in pharmaceutical supply chain management have been significant. Each pharmaceutical coordinator at the Municipal Health Services level has tried their best to record and report the pharmaceutical inventory at their facilities. However, there is no uniform recording and reporting system for all health facilities to use. This is further jeopardised by the lack of translation of policies and guidelines into daily pharmaceutical management practices, and political interference in technical matters of pharmaceutical inventory management. There were no clearly defined pharmaceutical items for each health facility level, and this overwhelmed the health professionals with filling in too many unnecessary cells in the stock balance and regular reports. Consumption data was not reported regularly in the Municipal Health Services.

There are also no uniform records (stock cards) and reporting forms, resulting in the incoherence of the consumption data analysis due to difficulties in reconciling the data at the central level. The

impact of the messy inventory data and reporting meant that there was little confidence in the consumption data, which posed a challenge for quantification and forecasting at the Ministry of Health. The WHO Proxy Consumption Method for 2015-6 was used, but with incomplete distribution data from the previous year, which may have resulted in incorrect quantities, delays in quantification, subsequent delays in the pharmaceutical supply chain process, such as in the procurement processes, and delays in having the pharmaceuticals in the country as planned. It was found that there was a 30 to 75 days stock-out of 45 pharmaceutical items at the Municipal Health Services level. The Central Medical Store, SAMES, has only been able to deliver an average of 50 per cent of requested pharmaceuticals to the Municipal Health Services. A push-based system was frequently used by SAMES for the Municipal Health Services, indicating an over-prediction of certain pharmaceutical items.

7.4 Next Steps

The findings from the first stage of the data collection suggests that human resources are a systemic problem along with other issues, such as infrastructure deficits. As this chapter has outlined, there is considerable variability in the reporting of pharmaceutical consumption throughout the country, making it difficult to have reliable data on amounts needed to avoid stock-out. This can be partly explained by the fact that Timor-Leste shares a colonial legacy of weak state institutions and a lack of managerial and technical staff in positions to ensure that pharmaceutical supply chain management is secure and efficient. This is reflected in the level of pharmaceutical stock-out experienced at government healthcare facilities during 2016-7.

While the government experienced pharmaceutical stock-out, according to information from the interviewees, government partner agencies such as the Global Fund and the United Nations Fund for Population Agency (UNFPA), as well as clinics operated by non-government organisations did not experience stock-outs. This warranted further investigation to be conducted through a second visit to Timor-Leste to conduct further interviews and document reviews from three non-government organisations providing services or supply of pharmaceuticals in the country. The results of the investigation conducted on these non-government organisations is presented in Chapter 8.

CHAPTER 8. PHARMACEUTICAL PROVISION AND MANAGEMENT AT NON-GOVERNMENT ORGANISATIONS

This chapter describes the second phase of data collection for the study to gain an understanding of pharmaceutical stock-out in Timor-Leste and identify the factors that have an impact on pharmaceutical quantification in Timor-Leste. The chapter reports on the interviews and the document reviews conducted and analysed from the United Nations Fund for Population Agency (UNFPA) Timor-Leste, the Global Fund, and one local non-government organisation (NGO), Cliníca Café Timor (CCT). The data collection was guided by the objectives of the study and anecdotal information gathered during the first visit to Timor-Leste, when many individuals who were interviewed claimed that these agencies did not experience stock out. The following information was collected for each organisation: the focus of their health services; inventory management of pharmaceuticals; quantification, forecasting, and procurement of, and expenditure on, pharmaceuticals; and pharmaceutical stock-out.

8.1 United Nations Fund for Population Agency (UNFPA)

8.1.1 Focus of UNFPA support

An informal interview with a manager in the UNFPA indicated there were low levels of stock-out of commodities such as the Combined Oral Contraceptive (COC), condoms, injectables, and emergency pills funded by the organisation. Each year, there was an evaluation of the country's program, including the supply chain of reproductive health commodities. Reports of the evaluation of the reproductive health commodities for 2015 and 2016, and draft reports of the family planning assessment 2017, were shared with me. Assurance was given that access to information about pharmaceutical quantification and forecasting was allowed. The main person managing the quantification of reproductive health commodities was a local staff member and an international expatriate. An official letter from my supervisor was directed to the country representative of the UNFPA.

Since Timor-Leste gained independence in 2002, the United Nations Fund for Population Agency (UNFPA) has supported the government and NGOs in addressing demographic issues, with its main focus on reproductive rights and gender equality. The agency provides support to various sectors such as health, the national statistics office, and the state secretary for gender equality in the area of institutional framework development. It began its country assistance programs in the "development of institutional framework, establishing of social services and getting the demographic data" (The Government Democratic Republic of Timor-Leste and United Nations Population Fund (UNFPA) 2009, pp. 4-5). The three sectors that reflect the UNFPA's main activities are maternal and reproductive health, support for the population and housing census, and gender equality and elimination of gender-based violence (United Nations Population Fund (UNFPA) 2018). Since

independence, the UNFPA has supported reproductive health and family planning programs. It provides technical support, funds maternal health programs such as emergency obstetric care and the development of a curriculum for midwifery, and family planning education. However, there has been a shift in the funding of these programs. Since 2015, the reproductive program has been fully funded by the government, with the UNFPA only providing funding for family planning commodities (ABY-480 & ABZ-490 2018a).

8.1.2 Quantification and procurement of family planning commodities

Pharmaceutical quantification is part of pharmaceutical planning. This begins with gathering the data required for the programs and analysing relevant policies and past evaluations. All of these are required to enable quantification of pharmaceutical items to meet future needs. Quantification estimates are based on requests coming from the Ministry of Health. At the program level, requests come from the health facilities, as well as from Marie Stopes International Timor-Leste. An interview with senior officers indicated that the last quantified figures used are the monthly consumption rates (ABY-480 & ABZ-490 2018a). In the absence of the consumption data, the projection of the reproductive age of the total population is used for procurement. One of the officers who was jointly interviewed stated that:

> *... Lack of confidence [on data quality] leads to factoring-in of buffer stock, safety stock and lead time into the quantification formulae. Lead time is 18 months, sometimes 24 months (ABY-480 & ABZ-490 2018a).*

A cross-check with the Department of Mother and Child Health (MCH) indicated that there was only one data point for estimated figures for family planning commodities. There was no detailed consumption record from all Municipal Health Services because this data was not reported through the Health Management Information System at the Ministry of Health. A promise was made by the Officer for Supply Chain Management at the MCH department to provide the data at a later date. This gesture indicated that there was an issue with data management. This was not available in a format that was ready to be shared, and the data was not received.

Marie Stopes International (MSI) is an NGO that provides family planning services in Timor-Leste. It procures family planning commodities on its own, but is also fully supported by the UNFPA. There are two reasons for this. First, it has a memorandum of understanding and agreement with the UNFPA to have a full supply of family planning commodities wherever it operates. The second reason is the high taxation liability. In the past, MSI has had difficulties managing clearance of its family planning commodities at the seaport in Dili. Therefore, the best approach has been to have all family planning commodities procured through the UNFPA because they are tax exempt. For these reasons, NGOs providing family planning services and the government submit their data to the UNFPA to enable a single quantification and procurement approach for the entire country.

Table 8.1 UNFPA budget for family planning commodities 2016-2018

Fiscal Year	Budget ('000)
2016	90.1
2017	219.3
2018	161.3

To enable the procurement of commodities required for the following year, requests must be submitted by the 1st of March every year and is entered into a UNFPA online procurement tool and discussed with the Ministry of Health. There is only one procurement plan for the country. However, the Ministry of Health lacks confidence in the requested data it receives from the health facilities. Therefore, during the quantification process, buffer-stock or safety-stock and lead-time are considered. Ten per cent of the buffer stock, and a 12- or 24-month lead-time is factored into the proposed annual consumption requirement. The aim in doing this is to prevent stock-out of family planning commodities. The quantification is conducted off-line, and the results are then entered into the procurement tool. The UNFPA expects that Timor-Leste will receive family planning commodities at the Central Medical Store (SAMES) in August or September every year.

The funding for procurement is a pre-determined budget set by the UNFPA through its offices in Copenhagen. This might contradict the requests from the health facilities; however, it is believed that there is always a small percentage increase in funding each year based on forecast annual consumption data (United Nations Fund for Population Agency - UNFPA) 2018). Increases or decreases in budget allocations are handled centrally. The total annual budget for family planning commodities varies from one year to another. International bidding processes are applied in the provision of family planning commodities with pre-determined detailed unit costs in the UNFPA's procurement catalogue. Delays in the receipt of the goods at the Central Medical Store have been experienced; for example, clearance from customs can be delayed due to political turbulence. Political instability results in frequent changes of political appointees, such as directors. Table 8.1 indicates the current budgets 2016-2018.

8.1.3 Inventory management, expiration of condoms, and push-based distribution system

Family planning commodities were stored at the Central Medical Store, SAMES, and inventory management of family planning commodities is controlled by the Ministry of Health (MoH). It was not known whether midwives had been trained in inventory management or supply chain management, although they did handle orders. The Department of MCH updates the UNFPA every month. However, stock-out was only discovered in annual facility audits or assessments completed at the end of the financial year.

One clear stock level observed in 2016 was an over-stock of condoms at the Central Medical Store and in the health facilities. This was because health facilities do not order condoms because the people do not request them, hence the Central Medical Store is over-stocked. The lack of demand for condoms arises from the fact that there are very few requests for them, despite condoms being used for sexually transmitted infection programs in the hospitals and at some CHCs. Culturally, the population assumes that free condoms are associated with free sex and promiscuity so tend not to

request them. The challenges in pharmaceutical supply chain management for family planning programs remains problematic. However, an unpublished report on the national strategy in 2010 showed that demand for reproductive health commodities was increasing, despite a lack of technical capacity to maintain adequate stock levels at the Municipal Health Services. In addition, there had been a history of stock-out prior to the 2010 survey (Belton 2010).

8.1.4 Quantification training for government officials and the UNFPA

In-service training for pharmaceutical quantification and inventory management has been conducted for government officers at national and municipal level. At the national level, the training on quantification for government officials and UNFPA staff was conducted in 2016. It was planned that training in pharmaceutical quantification be provided to government staff every year. So far, there have been six government staff members trained in pharmaceutical quantification at an Indian university known as the IHMR. One of the trainees interviewed stated that during the training, it was recommended that the best model for pharmaceutical quantification was estimates of morbidity-mortality data. With this method, there would be no stock-outs or over-stocks. However, the method cannot be used for all drug items; for example, Paracetamol. The best method of quantifying this drug is a consumption rate model. This training was suspended due to political turbulence in the country (ABY-480 & ABZ-490 2018a). As well, there was no training material on pharmaceutical forecasting.

At the municipal level, staff members who were tasked with the management of family planning commodities had not been trained in pharmaceutical quantification, but had been trained in inventory management. Inventory management of reproductive health commodities is the responsibility of midwives. According to a UNFPA senior officer, the training of midwives was funded by the UNFPA and managed by the Department of Mother and Child Health, Ministry of Health (ABY-480 & ABZ-490 2018a). There has been no evaluation of how many midwives have been trained, or on the effectiveness of the training.

8.1.5 Data for quantification of family planning commodities - UNFPA

The expenditure data for family planning commodities was obtained from the UNFPA office in Timor-Leste. It only contained information on the total quantity for each family planning commodity and the unit price and total cost for all commodities (ABY-480 & ABZ-490 2018b; United Nations Fund for Population Agency - UNFPA) 2018; United Nations Fund for Population Agency-UNFPA 2018). I was advised to seek disaggregated consumption data for each municipality from the Department for Mother and Child Health, Ministry of Health. Therefore, the follow-up visits to the Ministry of Health ended with a visit to the Mother and Child Health department to obtain the quantification data for family planning commodities. However, Internet connectivity delayed access to the data, thereby forcing use of the use “snipping tool” function to

copy files which were then transferred into an Excel spreadsheet. The data gathered was for 2018, and one of the employees prepared quantification data for 2016 and 2017 to be recorded as well. The extracted data were similar to that at the UNFPA, with one page of procurement data for each year.

8.1.5.1 The quantification spreadsheet

A verification of the quantification method and the Excel spreadsheets was conducted on the supply chain with the Management Officer of the Department of Mother and Child Health, Ministry of Health, Timor-Leste. No consumption data for family planning items was recorded. There was also no forecasting of family planning pharmaceuticals. The officer stated that the quantification data alone was sufficient to address the needs for family planning commodities. Officials use the quantification spreadsheet to collect information on the five family planning commodities, the POP, Depo-Provera, CoC (Combined Oral Contraceptive) pill, subdermal hormonal implant, and IUDs, as well as the annual proxy consumption data, the average monthly consumption data, lead-time, procurement period, buffer/safety stock, stock in inventory, and quantity to order, and then upward adjusting this at 10 per cent to cover for losses (Department of Mother and Child Health - Ministry of Health Timor-Leste 2018).Table 8.2 below depicts a snapshot of the Excel spreadsheet used for the quantification of family planning commodities for 2018 (Department of Mother and Child Health - Ministry of Health Timor-Leste 2018).

Table 8.2 UNFPA Quantification Spreadsheet 2018

	A	B	C	D	E	F	G	H	I	J
1	**Name of Medicine**	**Annual Proxy consumption (12 months consumption)**	**Average Monthly Consumption**	**Lead Time**	**Procurement Period (PP)**	**Safety Stock (SS)/Buffer Stock)**	**Stock on Order**	**Stock in inventory (Stock on hand)**	**Quantity to order**	**Adjusted 10% for losses**
2	PoP*	24,862	2,072	12	12	24,862	0	136,476	61,890	68,079
3	Depo**	96,330	8,028	12	12	96,330	0	344,625	55,635	61,199
4	CoC***	49,972	4,164	12	12	49,972	0	169,448	19,532	21,485
5	Implant	7,635	636	12	12	7,635	0	5,935	-16,970	- 18,667
6	IUD****	4,543	379	12	12	4,543	0	6,950	- 6,679	- 7,347

*Progestin only pill
**Depo-Provera
***Combined Oral Contraceptive Pill
****Intra-Uterine Device

The total quantities of family planning commodities required is calculated by having the stock-on-hand subtracted from the annual proxy consumption. This figure is then subtracted from the lead-time and procurement period. Lead-time and the procurement period are calculated by the average monthly consumption. The total quantity to order is topped up by a 10 per cent adjustment for losses. The spreadsheet is then shared with the UNFPA and entered into its procurement planning tool. Total expenditure for this is automatically generated by the system. The parameters and variables for the equation for the quantification of family planning commodities are expressed in Table 8.3.

Table 8.3 Parameters and variables of family planning quantification

PARAMETER	*VARIABLE*
Annual Proxy Consumption	*a*
Monthly Average Consumption	*b*
Lead-time	*c*
Procurement Period	*d*
Safety/buffer stock	*e*
Stock on order	*f*
Stock on hand	*g*
Order quantity	*h*
10% adjustment for losses	*i*

The equation is divided into two parts. First, it quantifies the quantities of a specific item to be procured. The 10 per cent for losses is then added to the order.

(a) $$Order\ quantity = (g - a) - (b \cdot c) - (b \cdot d)$$

(b) $$Loss\ adjustment\ = \ (i \cdot 0.1) + h$$

For example, the quantities of the PoP (Progesterone Only Pill) ordered for 2018 for the country were estimated as follows:

$$Order\ quantity\ = \ (136476\ - 24862\ ) - (2072 \cdot 12) - (2072\ \cdot\ 12)$$

$$Loss\ adjustment\ = \ (61890 \cdot 0.1) + 61890$$

$$Final\ quantity\ to\ order\ = 68079$$

The data used in this example has come from the quantification of family planning commodities for 2018 provided by the Department of Mother and Child, Ministry of Health (Department of Mother and Child Health - Ministry of Health Timor-Leste 2018).

8.1.5.2 Unit price of family planning commodities

The unit cost of family planning commodities varies from one year to another, depending on the market price. The cited unit prices for family planning items for 2018 (United Nations Fund for Population Agency-UNFPA 2018) are presented in Table 8.4

Table 8.4 Unit price of family planning commodities in 2018

Item	*Unit of Measurement (UoM)*	*Quantity*	*Unit Price in USD*	*Total price*
Levonorgestrel 0.15mg	*Pack of 3*	*42,300*	*0.78*	*33,696*
Levonorgestrel .03mg	*Pack of 3*	*28,800*	*0.90*	*25,920*
IUD sealed in polymer	*Piece*	*9,000*	*0.32*	*2,853*
Implant-Levonorgestrel 75mg x2	*Set*	*3,900*	*8.50*	*33,150*
Medroxyprogesterone acetate 15	*Vial*	*59,400*	*0.76*	*45,025*

Regardless of the equation above, there has been a serious lack of disaggregated data of family planning commodities for the Municipal Health Services. This lack of data means there are challenges in quantifying and forecasting the demand for family planning commodities. The Department of Mother and Child Health has no records of municipal reports on the inventory management and consumption of the family planning commodities nor for reproductive health pharmaceuticals. Information on stock-out of family planning commodities and reproductive health pharmaceuticals is only obtained once a year from facility audits conducted in all healthcare facilities. The information on the distribution of family planning commodities was only available from the Central Medical Store, SAMES (Department of Mother and Child Health - Ministry of Health Timor-Leste 2018; Division of Warehousing and Distribution 2016a, 2016b). This is because information on consumption of family planning commodities and reproductive health pharmaceuticals is no longer accommodated in the routine indicators reported by municipality health services to the Department of Health Management Information System (HMIS) in the Ministry of Health. For example, when the data on quantification of family planning commodities for 2016 and 2017 was requested, the only documents available were for 2018, and this was difficult to retrieve because of the slow Internet connectivity and the fact that few people have the skills required to extract the data.

The data in the spreadsheet could only be used to run Andersen's behavioural model to generate total expenditure and per-capita quantification for primary healthcare at the national level, but not for total expenditure per health facility and total primary healthcare expenditure per visit. The department does not have disaggregated data for the Municipal Health Services, only for national level data. This presents a challenge for operating a forecasting method; for example, the Exponential Smoothing Forecast Method (simply known as smoothing).

8.1.6 Inventory management and stock-out

The information about inventory management of family planning items from the health facilities was not reliable. At the national level (SAMES), it was reported that there was no stock-out; nevertheless, facility audits indicated otherwise. In the last three years, surveys measuring assessment of reproductive health commodities and services, have uncovered stock-outs in health facilities. The aim of these surveys has been to assess the availability of essential commodities for reproductive health and family planning, and the key issues related to the services (Martins 2015 2016; Ministry of Health -Timor-Leste 2017). According to two senior officers (interviewed together) who oversaw the pharmaceutical quantification and procurement process:

> … the real cause was not known. *At national level (SAMES) reports there was no stock-out. An operation research was planned to uncover the issue* (ABY-480 & ABZ-490 2018a).

However, the facility audits indicated otherwise. An investigation was planned to uncover the issues and showed that stock-out was between 30 and 40 per cent at the Community Health Centre level

(Department of Mother and Child Health - Ministry of Health Timor-Leste 2018; Martins 2015 2016; Ministry of Health -Timor-Leste 2017).
When challenged with the question of stock management and supervision, one of the senior officers stated that:

> *Inventory management of family planning commodities is the responsibility of Ministry of Health hence the monitoring is conducted by the Government. Regular information is shared with UNFPA, however, when this was checked with the Department of Mother and Child Health information was not available. Senior officers at UNFPA stated that stock-out is only noted at the end of each year in the annual family planning commodity audits for health facilities (ABY-480 & ABZ-490 2018b).*

Audits have reported increased levels of stock-out over the 24 months of 2016 and 2017. The reasons for stock-out were similar. Most family planning commodities were managed by midwives, there were no updates to inventory, and there was no regular monitoring and reporting of the inventory data. The health facilities surveyed at all levels of service delivery were the health posts, CHCs, and hospitals. A report on the assessment of reproductive health commodities of 237 healthcare facilities in 2016 in Timor-Leste indicated that overall, 48 per cent of healthcare facilities experienced stock-out of one or more family planning items in the three months prior to the survey (Martins 2016). In terms of reproductive health medicines, the survey showed that, on average, the stock-out rate was 78 per cent for 16 essential items over the three months prior to the survey (Martins 2016, p. 43). Interestingly, only 35 per cent of the health facilities surveyed experienced stock-out. The reasons cited for stock-out were delays in healthcare facilities requesting items from the warehouse, delays in distribution from warehouses to healthcare facilities, a lack of trained staff, and a lack of client demand. Stock-out for oral and injectable contraceptives were 62 per cent and 65 per cent respectively. This was attributed to delays in re-stocking from warehouses. Similarly, stock-outs of IUDs (Intra-Uterine-Device) and Implanon were 53 per cent and 65 per cent respectively. The reported reason for stock-out was the lack of trained staff available to provide the services. These reasons were consistent with an assessment conducted in 2017 (Martins 2016, pp. 43-60; Ministry of Health -Timor-Leste 2017, p. 31).

In total, 85 per cent of service delivery points (231 health facilities) surveyed in 2017 experienced stock-out. The highest stock-out rate was observed in the eastern region municipalities, although some improvements were noted in the assessment of family planning commodities and reproductive health services in 2017, especially in the hospitals and at the CHCs. This indicates a slight improvement on previous years. For example, only 21 per cent of service delivery points had stock-out of oxytocin, and magnesium sulphates in 2017 (Ministry of Health -Timor-Leste 2017, pp. 30-4).

A variety of healthcare professionals are engaged in the inventory management of family planning commodities, with midwives undertaking up to 36 per cent, followed by pharmacists at 27 per cent, and doctors or nurses at 24 per cent at the 345 health facilities. Lack of trained staff was the main reason for stock-out. The survey found that 97 per cent of doctors, 92 per cent of nurses, and 53 per cent of midwives working at the health facilities were trained in family planning services (Martins 2016, pp. 64-8). Similar patterns were noted in the 2017 assessment. (Ministry of Health -Timor-Leste 2017, p. 42). There was no specific information or training provided to staff in inventory

management. Location of the site of the health facilities also had no correlation with the level of inventory for family planning commodities found in the two surveys (Martins 2016, p. 25; Ministry of Health -Timor-Leste 2017, p. 30).

It is clear from the two reports that the level of stock-out increased by 43 per cent over 2016 and 2017. The cause of stock-outs at various facilities were similar. No major improvements have been seen in the overall inventory management of family planning commodities and reproductive health medicines. Distance from a pharmaceutical warehouse in a municipality or the SAMES was not a contributing factor to stock-out.

8.2 Cliníca Café Timor (CCT)

8.2.1 CCT services

Cliníca Café Timor (CCT) is a local non-government organisation (NGO) operated by Cooperativa Café Timor. It provides health services to more than 28,000 coffee farmers in Ermera, AiIeu, Ainaro, Manufahi, and Liquiça. The focus of the health services is maternal and child health programs for coffee farmers and their communities (Clinica Café Timor 2018; Cooperativa Café Timor 2018). There has been only limited information in the media of pharmaceutical stock-out experienced by this local agency. This could be due the nature of its services and its catchment area. It has three mobile clinic teams that cover 27 locations in five municipalities. There is a clear definition of catchment area of services between CCT clinics and government clinics, and the services are unrestricted, meaning that whoever comes is served. The organisation was previously supported by USAID, but it now independently funds its clinics from coffee trading revenues.

Prior to visiting the organisation, a telephone consultation was organised with the Head of the Division for Member Services, Mrs. MPNBS, to confirm basic information and to guarantee access to information on its activities and pharmaceutical quantification and funding. According to the Director, "… CCT also experiences pharmaceutical stock-out" (ABT-450 2018); however, due to its limited area of services, the issue is not commonly known. In running its services, this local NGO receives pharmaceuticals from the government through the Central Medical Store, SAMES. This means that when SAMES has a stock-out, the CCT also has a stock-out. However, the organisation is allocated additional funds of around USD 200 to 300 thousand a year to procure pharmaceuticals, quantifying them based on real consumption data.

8.2.1.1 Pharmaceutical supplies and stock-outs at CCT

Stock-out at the government Central Medical Store has an impact on pharmaceutical availability at the CCT clinics. During the interview with one of the senior officers at the CCT, in response to the question of stock-outs and its impact on the organisation the officer stated that:

> *... In principle principally, when there is stock-out at national level, our organisation also experiences the impacts. We have an MOU about the supply of pharmaceuticals from the government. Hence when there is a stock-out at SAMES [Serviço Autonoma Medicamentos e Equipamento de Saúde] it impacts on you. Stock-out is mostly experienced at type-A clinics;...especially the mobile clinics providing daily services to remote areas that have between 100 to 300 patients a day (ABT-450 2018).*

Around 20 to 30 per cent of CCT's total annual budget (around a million US Dollar) for healthcare services is earmarked to address pharmaceutical stock-out for its clinics. This funding figure is subject to variation depending on requirements. The Head of the Member Service Division of CCT stated that:

> *... pharmaceuticals are distributed regularly, but they also respond to emergency orders. We also analyse internal stock at the warehouse, the needs of clinics and adjustments are made accordingly with a 20% top up (ABT-450 2018).*

However, in a cross-check with the pharmacy coordinator on the preliminary analysis of the distribution and consumption data, there did not appear to be any analysis of the consumption data. Stock-out was dealt with through regular monthly meetings and regular phone calls to the heads of the clinics, rather than through sound data on consumption.

8.2.2 Inventory management at CCT clinics

CCT has a central warehouse located in Comoro, Dili, Timor-Leste, and each clinic has its own smaller warehouse. Stock cards are only used at the central warehouse, but not at the clinics. Nurses are responsible for inventory management in the clinics. There is only one pharmacist, who is the coordinator for all the clinics. The coordinator is not a trained pharmacist. When asked about the principles of inventory management, the coordinator was confused. They stated that inventory management in the clinics used simple principles. The pharmacists would notify the Municipal Coordinator if there was stock-out, and there would be an immediate response.

Rigorous monitoring was also in place. There was a weekly check on Wednesday, Thursday, or Saturday, with reports and quarterly general meetings with staff. Total pharmaceutical items were the same as for the government health posts (that is 60 to 80 items including some family planning items). Staff members had not had specific training on supply chain management and inventory management, but there was always an induction and briefing for new staff prior to starting employment. Upon observation, there was no official induction manual for newly recruited staff. Quarterly monitoring was conducted at all facilities. There was a team leader in each facility and FIFO (First-In-First-Out) and FEFO (First-Expired-First-Out) principles were applied to avoid drug

expiration. Rigorous checking on stock at the central office and in the clinics was applied. Pulling all drugs that were close to expiration and a push-based distribution system to the clinics was applied most of the time.

8.2.3 Pharmaceutical quantification for CCT clinics

Even though the CCT received pharmaceutical support from the Ministry of Health, it was not directly involved in annual quantification with the government. When asked about the involvement of her organisation in the quantification processes, the Pharmacy Coordinator at this local NGO, stated that "… about that, the organisation does not become involved directly in annual quantification with the government" (ABS-440 2018). The pharmacist did not identify which quantification systems were used within the organisation. A simple calculation was generally conducted using the past weekly/monthly consumption data from all clinics, with a 10 per cent buffer applied. The 10 per cent buffer could not be evaluated in the Microsoft Word files related to requests for procurement of pharmaceuticals for 2016 and 2017 (ABS-440 2018). The pharmacist was not aware of which quantification and forecasting methods had been applied.

8.2.4 Preliminary drug consumption data reviews for Cliníca Café Timor (CCT)

Cleaning of data on pharmaceutical consumption of clinics and mobile clinics overseen by Cliníca Café Timor (CCT) was performed. There were many inconsistencies in the pharmaceutical data from one month to another, so it took a long time to connect monthly data from one month to another in summary form. The data was required in order to provide monthly and annual figures for each clinic. A summary of the consumption data for 2016 was completed. All the distribution and consumption data were in Microsoft Word and Microsoft Excel. This required much data management in order to gain a clear picture on pharmaceutical consumption and expenditures of the 118 items. As the pharmaceuticals came from two sources, there was another data aggregation required to see clearly how much the pharmaceutical expenditure was from CCT (Pharmacy Department of Cliníca Café Timor 2016). It was apparent that there were no pharmaceuticals requested or distributed to all CCT clinics from September to November 2016. For the same period in 2017, there were 161 pharmaceutical items listed in the report. However, there were only 6 to 11 items reported for distribution and consumption from January to December 2017. It was not clear if this was due to stock-out of most items from the government warehouse at SAMES.

There were 132 items listed to be managed and made available throughout all the CCT clinics. The list is similar to the government community healthcare centres. Overall, static and mobile clinics managed and provided the same quantities of pharmaceutical items (see summary in Table 8.5). There were variations of additional items added to the list in the Airacalau and Lauana Clinics. The distribution took place in all months of the period (Pharmacy Department of Cliníca Café Timor 2017).

Table 8.5 Variation in pharmaceutical registers in Excel spreadsheet at CCT clinics

Number of rows	Remark
155	Total rows
3	(-) Heading rows
20	(-) 20 Pharm Categories rows
50	(-) Items without data
72	(=) Filled with consumption data

In the Excel spreadsheet there were 132 filled rows. Of these 132 pharmaceutical items, only 72 items, or 55 per cent, were available (Pharmacy Department of Cliníca Café Timor 2017). The top pharmaceutical items in use were Paracetamol 500mg tablet and Amoxicillin 500mg tablet. This was in line with the average government pharmaceutical stock-out for 2017 from the Central Medical Store (Serviço Autonomo Medicamentos e Equipamentos de Saúde - SAMES 2017).

One of the weaknesses in data management was the security of the data. All the spreadsheets were 'un-locked'. This made the data susceptible to minor or major mistakes due to incorrect data entry or unintentional deletion of recorded data. Most of the daily, weekly, and monthly data were not linked to a dashboard to enable a summary to be generated of pharmaceutical data consumption and distribution within the organisation.

8.2.5 Pharmaceutical stock-outs in CCT and pharmaceutical expenditure

It was acknowledged by two interviewees (ABT-450 2018) at CCT that stock-out happens in the CCT health facilities (ABS-440 2018; ABT-450 2018). One of the interviewees stated that "… principally … when there are stock-outs at government Central Medical Store, SAMES … her organisation was also affected". Document analysis indicated that there was, on average, a 50 per cent stock-out in the CCT clinics in 2016 and 2017 (Cliníca Café Timor 2016a, 2017b). The main reason was that when SAMES has stock-outs, so too did the CCT clinics. Other contributing factors to stock-out were delays in distribution, lead-times, and delays in custom clearance at the port (ABS-440 2018; ABT-450 2018).

As the need for pharmaceuticals for the CCT clinics is met by the government, expenditure for pharmaceuticals is only committed to when there is a request for a pharmaceutical item that is out of stock and has to be re-stocked immediately to maintain service provision. The documentation of the requests from the clinics and the procurement of pharmaceuticals indicated that there were only two stock-outs in November and December 2016. Ten items were out of stock, with antibiotics and analgesics the most in demand. There were nine stock-outs of antibiotics, analgesics, and other pharmaceutical items. The stock-outs were experienced in January, February, March, May (twice), June, and September of 2017 (Cliníca Café Timor 2016b, 2017c).

CCT management considered these needs and acted upon the requests to replenish the pharmaceuticals at its clinics. Unlike the government and the larger multilateral agencies, the CCT did not require a lengthy procurement process when faced with a stock-out. The organisation procures pharmaceuticals directly from the local chemists in Dili and distributes them immediately to the clinics. The total expenditure for pharmaceuticals covering stock-outs in 2016 was USD 2,150.00, and for 2017 it was USD 8,668.50 (Cliníca Café Timor 2016b, 2017c).

8.2.6 Unit price of pharmaceutical items procured by CCT locally in Timor-Leste

There were 12 essential pharmaceutical items that were considered essential in all CCT clinics. The unit cost of these are presented in Table 8.6. These pharmaceutical items were procured locally in Timor-Leste at a private chemist when not available from SAMES. The unit prices of these pharmaceuticals remained the same over the period 2016 to 2017 (Cliníca Café Timor 2016a, 2016b, 2017a, 2017b, 2017c).

Table 8.6 Top 10 drugs procured by CCT Timor-Leste during 2016-2017

Item	*Package*	*Qty Tablets*	*Unit (USD) cost/package*	*Cost per tablet (USD)*
Amoxicillin 500mg	*box*	*200*	*4.50*	*0.02*
Antacid 500mg	*bottle*	*100*	*15.00*	*0.15*
Calcium Lactate	*Jar*	*100*	*10.00*	*0.10*
Cotrimoxazole 480mg	*box*	*100*	*3.50*	*0.04*
Ferrous Sulphate	*Jar*	*1000*	*15.00*	*0.02*
Glycerine Gluconate	*botte*	*1000*	*5.00*	*0.01*
Metronidazole 500mg	*box*	*100*	*4.00*	*0.04*
Multivitamin	*box*	*100*	*2.00*	*0.02*
Vitamin B Complex	*jar*	*1000*	*5.00*	*0.01*
Paracetamol 500mg	*box*	*100*	*1.50*	*0.02*
Promethazine 25 mg	*box*	*100*	*12.00*	*0.15*
Salbutamol	*box*	*100*	*3.50*	*0.04*

8.2.7 Request and distribution of pharmaceuticals and reporting in CCT

CCT has a short distribution pathway. Pharmaceuticals received from the central warehouse (SAMES) are directly distributed to the clinics. Tally sheets and daily and monthly records of pharmaceuticals are undertaken at each clinic. The total pharmaceuticals dispensed at the facility level is counted based on the number of patients served. Internal reporting forms are converted into government reporting forms that contain information about quantity received and used, and the stock balance (ABS-440 2018).

In summary, CCT runs its seven not-for-profit clinics by obtaining pharmaceuticals from the government. It quantifies its pharmaceuticals based on consumption data. Distribution is undertaken by its central warehouse directly to the clinics. Inventory management at its health facilities is overseen by either a nurse or a midwife who is trained in simple warehouse management skills, such as the application of FEFO and FIFO. Strict attention to the expiry date of the pharmaceuticals is applied. There has not been any specific training for healthcare professionals to manage

pharmaceutical inventory management and quantification. Stock-out appears to be the result of lack of supplies at SAMES.

8.3 Global Fund - Malaria Program

The Global Fund supports the government in funding and administering three programs (tuberculosis, malaria, and HIV-AIDS) in Timor-Leste. The agency is managed by a project management unit (PMU) composed of national and municipal staff. It is one of the largest multilateral development partners with investments of more than USD 60 million in Timor-Leste since the country gained independence in 2002. It has provided antiretroviral therapy for 250 HIV/AIDS patients, detected and treated 14,300 tuberculosis cases over the past 15 years, and distributed 987,000 treated bed-nets for the prevention of malaria (Global Fund Timor-Leste 2018). The Government of Timor-Leste and the Global Fund jointly fund the programs. The government funds the running costs of the program and the Global Fund finances the pharmaceuticals, laboratory needs, and the treated bed-nets. As a result of its work, there are now fewer malaria cases in the country. A global report by the WHO stated that there were zero malaria cases reported in Timor-Leste in 2018 (DTE Staff 2019; Horta 2019). Full support for the interviews and access to information on its pharmaceutical quantification models and data was guaranteed. The release of the data was subject to standard government procedure where a letter was made out to the General Director for Services Delivery for approval with copies made for the Global Fund Country Administrator and the Director of Communicable Disease. The focus of the data collection in this part of the study was on one of the Fund's programs, the malaria program. Data collection through interviews and document reviews revealed how the Global Fund quantifies, procures, and manages its inventories for the malaria program. The findings are presented in the following sub-sections.

Globally, the supply chain management issues of stock-outs and over-stocking of anti-retroviral and anti-malaria drugs was reported in 11 of the 15 selected Global Fund recipient countries in Asia and Africa for the auditing period 2017 (The GlobalFund 2017, pp. 4,8,15,7). This is presumed to be the result of a lack of skills in quantification and forecasting. However, there is only limited information to date on stock-out of pharmaceuticals and consumables for the Global Fund's programs in Timor-Leste. The Global Fund has an operation policy manual, and although there is no section in this manual on inventory management, there are clear guidelines on procurement and quality assurance policies for pharmaceuticals, diagnostics, and other health products (The GlobalFund 2017, pp. 4,8,15,7).

The country's progress reports for 2010, 2011, 2012, and 2016 indicated that municipalities rarely experienced pharmaceutical stock-out (Global Fund Timor-Leste 2012, 2016). For example, during period 25-29 (2015 and 2016) of the program, no Municipal Health Services reported pharmaceutical stock-out on the first line of the Directly Observed Treatments Short-course (DOTS) (Global Fund Timor-Leste 2016, pp. 30, 44). According to the program's technical adviser, the

malaria program has not experienced stock-out in the 24 months of 2016 and 2017. This was due to several factors, including the quantification of malaria drugs. The quantification of drugs is based on the number of cases and drugs used for each case, with a 10 per cent buffer-stock and damaged component factored into the required number of drugs. Where stock-out did occur in the Municipal Health Services, it was addressed by the transfer of pharmaceuticals from one municipality or facility to another (ABU-460 2018). According to the Country Administrator of Global Fund Timor-Leste, the Global Fund quantifies, procures, and distributes all necessary pharmaceutical items to health facilities in the country.

8.3.1 Procurement of malaria pharmaceuticals for the malaria program

Malaria drugs are procured in bulk, and distribution is based on district requested quantifications. The Global Fund only procures drugs specifically for malaria reagents, chemical use, and bed-nets. The procurement process is initiated by a request from the malaria program with detailed quantification. Where detailed information is missing, the request is returned for revision. Pharmaceutical requests must be submitted six months in advance. Tendering is not required because it is managed by the Global Fund in Geneva. There is a lengthy procurement approval process. Once this is completed, the information is entered into the Global Fund procurement system to be processed in Geneva. When the procurement document is placed and processed by a vendor, detailed consignment information is provided to the relevant parties (ABV-470 2018; Malaria Program - Global Fund Timor-Leste 2011).

Table 8.7 Global Fund for antimalaria drug in Timor-Leste 2016-2(

Year	Unit Price (USD)	Qty (Tablets)	Total cost (USD)
A2018	10.80	266	2,872.80
2017	5.10	265	1,351.50
2016	9.60	291	2,793.60

When the pharmaceuticals arrive in the country, all clearances are undertaken by the government through SAMES, the Central Medical Store. The Global Fund procurement officers coordinate the clearance and R & I (Report and Inspection). Six per cent of the funding for the Global Fund is allocated for pharmaceutical procurement, which is transferred to SAMES for custom clearance and distribution services (ABV-470 2018; Malaria Program - Global Fund Timor-Leste 2011). However, there were issues related to the quality of the pharmaceuticals procured by SAMES. In addition to the quality, there were also delays in having the pharmaceuticals in the country. A senior advisor to the Global Fund stated that:

> *Initially drugs were procured through SAMES. There were delays and concerns on the quality of drugs. Malaria cases increased so it was decided that the procurement would be done through the Global Fund system. Procurement of drugs was split into two; and there was no stock-out. The Government procures the Antibiotics required to treat severe and complicated malaria cases and Global Fund funds the malaria drugs, chemical for outdoors spraying and reagents for laboratory and diagnostic tests (ABU-460 2018).*

This was supported by the statement of a procurement officer for the Global Fund, who indicated that:

As the Government (SAMES) does not procure WHO pre-qualified drugs for malaria; Global Fund is currently procuring the ACT, Arthemether Combination Therapy through its system (ABV-470 2018).

Annual funding provided for these anti-malaria drugs is presented in Table 8.7

8.3.2 Inventory management in the malaria program and supervision

Information on pharmaceutical supply chain management from Global Fund is focused only on malaria program, and that covers inventory management for the malaria program, trainings, supervision, monitoring and evaluation, standard operation procedures, quantification, quality improvement and other associated data.

8.3.3 Inventory management of malaria drugs

Inventory management was integrated into the government system with minor variations at the district level. At the central level, pharmaceuticals for malaria and other items were stored at the Central Medical Store, SAMES. Pharmaceuticals were managed well, but not the treated bed-nets as this was not seen as a priority given that they are not pharmaceuticals. At the district level, pharmaceuticals were stored at the warehouses and managed by a pharmacist. Malaria officers kept records of the pharmaceuticals and the separate items such as bed-nets and IRS (Indoors Residual Spraying). Pharmaceutical inventory was managed by program officers at all levels of the service (health posts, CHCs, and the hospitals). The following forms were made available for recording, reporting, and controlling the pharmaceutical stock levels for the malaria program: a daily stock management book, monthly stock management forms, monthly reports to the Global Fund, monthly conferences, and reports of institutions with stock-out (Malaria Program - Global Fund Timor-Leste 2017b, 2017c, 2018b; Malaria Program - Global Fund Timor-Leste, , 2018; Malaria Program - Global Fund Timor-Leste 2018c, 2018d, 2018e).

8.3.3.1 Training in inventory management

The malaria program allocated funds for Training of the Trainer (TOT), a program for national officers at its quarterly meetings. These officers, in turn, train District Malaria Officers (DMOs) and Sub-District Malaria Officers at bi-monthly meetings. Extra training in inventory management is also carried out over three days annually for all officers. Additionally, the program also conducts regular supervision by vector controlled and regional malaria officers (Malaria Program - Global Fund Timor-Leste 2018c).

8.3.3.2 Supervision

The Global Fund provides excellent supervision for all its programs. It has guidelines and supervision checklists for auditing at the national and municipal levels (Malaria Program - Global

Fund Timor-Leste 2018e). Additionally, it also monitors its malaria drugs, treated bed-nets, and reagents. A seven-day stock-out report is regularly conducted at all levels (Malaria Program - Global Fund Timor-Leste 2018c). It is a form designed to capture information on the incidence of stock-out of each anti-malaria drug for more than one week in a health facility, and enables quick action to transfer the required pharmaceuticals from a nearby health facility within a Municipal Health Service or from another municipality.

The Global Fund's rigorous supervision was laid out in an interview with a senior adviser, who stated that,

> *... we bring all officers to the ... to the National for three days training program. Then, if we have problems when we go for supervision ... Ah ... supervision ... not only that. Our Regional Malaria Officers will go for supervision. They find some ... you know ... some problems, and everything they need we give them. In that year, we do another training. So, the whole people will get together, divided that into two program and we do a training. We discussed with them what the problem was. We want to have the problems ... not only the training actually ... Our people are ... for each region are responsible for one vector control and one regional malaria officer. They go for supervision; they check their inventories, everything else ... their availability at all levels. CHC, health posts and the community health volunteers (ABU-460 2018).*

The supervision checklist for national officers contains detailed information about stock and availability. The six page checklist enables officers to track information on all the reporting forms, including anti-malaria drugs, the availability of stock-books for malaria drugs, the availability of anti-malarial drugs at the municipal level, the quantity of malaria drugs distributed to CHCs and hospitals, destruction of malaria drugs, stock-books for bed-nets, quantity of bed-nets distributed to pregnant mothers, stock-laboratory reagents and equipment, municipal and sub-district maps, identification of problems, and recommendations (Malaria Program - Global Fund Timor-Leste 2018c). These forms also have questions about pharmaceutical availability, maintenance of stock-registers, and relevant responses.

The supervision checklist for municipalities is a two-page tool composed of seven sections that cover the availability of stock, recording and reporting forms, and activities. These sections include resources, availability of register guidelines, vector controls, checklists for malaria registers and malaria case investigations, treatment for malaria, information about past months' activities in the communities, and health promotion activities (Malaria Program - Global Fund Timor-Leste 2018c). In addition, the Global Fund also has regular reports on 'stock-out of anti-malaria drugs for more than seven-days for a total of 348 active health facilities, which includes 274 health posts, 68 CHCs, 5 referral hospitals, and 1 national hospital. The information is recorded in a simple spreadsheet containing the names of the health facilities in all municipalities and hospitals, the status of the health facility (active or not), and stock-out of anti-malaria tablets. This is reported every three months (ABU-460 2018; Malaria Program - Global Fund Timor-Leste 2018c).

8.3.4 Standard operating procedures in malaria drug management

Written standard operating procedures (SPOs) is an important document for all who are involved in any pharmaceutical supply chain management activity. It is a manual for daily practice that sets out the cycles of pharmaceutical supply chain management. The Global Fund is unique in that it has clear operating procedures for storing and distribution of malarial drugs and other related health products for its program in Timor-Leste (Malaria Program - Global Fund Timor-Leste 2011).

The Standard Operating Procedures (SOP) document contains basic information on the management of anti-malarial drugs and related health products. This information includes a clear distribution hierarchy for all levels of the health services, drug management cycles, procedures for receiving supplies, warehousing procedures, procedures for issuing or physical distribution of anti-malarial drugs and health products, inventory management applicable to the national malaria control program, and monitoring and evaluation (Malaria Program - Global Fund Timor-Leste 2011, pp. 3-38). The SOP becomes the reference guide for pharmaceutical quantification, procurement, warehousing, recording and reporting of inventory, distribution, monitoring, and supervision of inventory. The SOPs are translated into anti-malaria quantification and its principles, procurement, inspection and receipt of goods, registration of drug consumption, and all reporting forms (Malaria Program - Global Fund Timor-Leste 2011, 2016a, 2016c, 2017a, 2017b, 2017c, 2018a, 2018b; Malaria Program - Global Fund Timor-Leste, , 2018; Malaria Program - Global Fund Timor-Leste 2018c, 2018d, 2018e).

8.3.5 Quality improvement approaches in malaria program

Quality improvement of the malaria program has been accomplished through well-structured initiatives, training, and monitoring of performance. An evaluation of the program conducted in 2013 found failure in treatment. Consequently, changes were introduced in 2016 to use Artemether-Lumefantrine and Primaquine for baseline treatment. In addition, an external review is conducted every three years. The BIOSS (Biological Signalling Studies) approach is used to monitor the effectiveness of outdoor insecticide spraying and treated bed-nets. The DOTs (Directly Observed Treatment) approach is being implemented for all malaria cases. Monitoring the quality of laboratory equipment in private clinics and faith-based organisations is also routinely conducted. In addition, the program provides faith-based organisations with 30 RDT (Rapid Diagnostics Test) kits and carries out DOTs. Patients are not charged for the diagnostic tests or the malaria treatment (ABU-460 2018).

8.3.6 Pharmaceutical quantification for the malaria program

Quantification for the malaria program was based on the WHO Morbidity Model and consumption data. Quantification was based on the following information and was done in an Excel spreadsheet. First, physical counting was performed at all levels. Factors that were taken into account in the quantification were the consumption data and number of malaria cases, predictions of how many drugs were needed for a year, and then buffer stock and damage were also taken into account. The

Global Fund Timor-Leste applies a three-month buffer stock and a 10 per cent damage amount into the quantification equation. In addition, lead-time was also considered. The lead-time is six months if the pharmaceuticals are procured via the Global Fund, and 12 months if they are procured through the government system (ABU-460 2018; Malaria Program - Global Fund Timor-Leste 2016a, 2016b, 2018a).

8.3.6.1 Treatment of malaria cases

The treatment of malaria cases was administered according to the strain of parasites discovered through microscopic examination. The option of the drug required for the treatment of uncomplicated malaria cases is based on a national malaria treatment policy. The strains are plasmodium falciparum, plasmodium-Vivax, plasmodium-Ovalle, or mixed cases. Chloroquine tablets are always used as the first line of treatment for plasmodium-Vivax and plasmodium-Ovalle, while Primaquine is used to treat the liver stage parasite plasmodium-Vivax.

8.3.6.2 Chloroquine and Primaquine tablets

The quantification of Chloroquine and Primaquine tablets is based on the following guidelines. Each CHC and health post, with or without cases, is allocated 100 tablets of Chloroquine, which is equal to ten adult doses for plasmodium-Vivax cases. The Primaquine estimation also follows this assumption. Each CHC and health post is allocated 500 tables of Primaquine, or ten adult doses – 6 tablets (7.5mg) or 3 tablets (15mg) multiplied by 8 weeks for plasmodium-Vivax, which makes a total of 36 tablets (7.5mg) or 18 tablets (15mg) (Malaria Program - Global Fund Timor-Leste 2017a). Each health promoter in the community is supplied with 200 Primaquine tablets annually. The quantification of these anti-malarial drugs is conducted by the Global Fund. However, there is a split of funding for the provision of these drugs. Chloroquine and Primaquine tablets are funded and procured by the government, while the Global Fund funds artemisinin-based combined therapy (ACT), which is discussed in the next sub-section.

8.3.6.3 ACT - Artemisinin-based Combined Therapy (ACT)

On conducting the quantification of anti-malarial drugs (Artemisinin-based Combine Therapy) for each health facility, the following assumptions apply. Each CHC with plasmodium falciparum-Vivax (PF) cases is allocated 40 ACT blisters, which is equal to 10 adult doses[23]. Each health post with PF cases is allocated 8 ACT blisters, which is equal to 2 adult doses. The estimation of total quantities of tablets/blisters for all health facilities in a year is based on the assumption for ACT (Arthemether/Lumefantrine) quantities. A 30 per cent buffer stock is added to the total annual estimation. The total quantity required is then subtracted by the stock balance cited at the time of the quantification exercise. The expiry date of the drug is also considered prior to determining the

[23] One ACT adult dose consists of four tablets taken over three days. The first initial dose is four tablets, and another four tablets taken again eight hours later. Then four tablets need to be taken in the morning and evening for the following two days. This makes a total of 24 tablets in a course of treatment of a Plasmodium Falciparum case patient. Source: http://apps.who.int/iris/bitstream/handle/10665/162441/9789241549127_eng.pdf;jsessionid=78E2633793CC391E6A7833BB7995FEFA?sequence=1

lead-time. The Timor-Leste annual quantification estimation of ACT for 2017 is captured in Table 8.8 (Malaria Program - Global Fund Timor-Leste 2017a).

Table 8.8 Estimated required ACT (Arthemether/Lumefantrine) in Timor-Leste for 2017

	A	B	C	D	E	F	G
1	Total quantity ACT tablets required	30% buffer of A2	Estimated monthly tablet requirements = (A2+B2) / 12	Total required tablets = A2+ B2	Stock on hand (tab) in May 2016 (all will expire in April 2017)	No. of tablets to be ordered =D2-E2	No of blisters (6 tablets/blister) to be ordered =F2/6
2	36,826	11,048	921	47,874	33,600	47,874	7,979

The factors stated in columns A to G are the parameters, while the variables for the equation for the quantification of anti-malarial drugs are expressed in Table 8.9.

Table 8.9 Parameter and variable for Malaria quantification

PARAMETER	*VARIABLE*
Annual total quantities required	*a*
Estimated monthly tablets requirement	*b*
Lead-time	*c*
30% /buffer stock	*d*
Stock on hand	*e*
6 tablets/blister	*f*

The equation for the estimation of the required ACT (Artemether/Lumefantrine) tablets for Timor-Leste in 2017 is summarised as follows:

a) $Annual\ quantities\ of\ ACT\ required\ ,\ a = 36{,}826$

b) $Buffer\ stock\ \ d = a \cdot d$

c) $Total\ ACT\ tablets\ to\ be\ ordered\ = (a + b) - e$

d) $Total\ blisters\ to\ be\ ordered\ = \frac{a}{f}$

When the values are substituted into the equation, the total required tablets and blisters for one anti-malaria drug (ACT) to be procured can then be calculated.

a) $a = 36{,}826$

b) $d = \frac{36826}{100} 130 = 11{,}048$

c) $(36{,}826 + 11{,}048) - 0 = 47{,}874$

d) $\frac{47{,}874}{6} = 7{,}979$

An analysis of the equation applied to quantify the anti-malarial drugs indicates the exclusion of certain factors. The number of malaria cases was not directly included in the quantification; instead, assumptions were made to establish an estimated quantity only. It is noted from the equation that the value of stock-balance factors is set as zero due to the fact that when the quantification was conducted in May 2016, the ACT drugs on the balance were due to expire in April the following year, and the number was less than the estimated required tablets for the following year. In addition, the procurement period or lead-time was not factored into the equation. When cross-checked with the pharmaceutical expenditure for 2017, the total quantity of ACT blisters procured for 2017 was 266 with a unit cost of USD 5.10 per blister. The total cost was USD 1,356.50. The reduction of the quantified need was 97 per cent. If this was the case, the total quantity of ACT tablets procured was only 1,596.

However, as the country is heading for certification as a malaria-free country, it is entering the elimination phase. The quantification of pharmaceuticals is also changing. The estimated anti-malaria pharmaceuticals for Timor-Leste during the elimination phase has been determined. Every CHC and health post will be allocated 10 adult doses, regardless of the number of cases per annum, and each health post will be provided with 2 adult doses of ACT and Primaquine per year. Provision of ACT for each hospital is set at 20 adult doses per year, while two adult doses are allocated for community volunteers. The total requirement for all levels of health facilities will be topped up by 10 per cent to cover damage, then subtracted by the stock balance (ABU-460 2018; Malaria Program - Global Fund Timor-Leste 2018a).

8.3.7 Workforce for malaria program

There are approximately 120 staff working for the malaria program. Around 20 are permanent civil servants, while the other staff are contracted and funded by the Global Fund. The program is overseen by a Program Manager who is a permanent public servant. There are four funded Regional Malaria Officer positions, but only one currently paid by the government, while the other three are funded by the Global Fund. At the municipal level, there are 13 DMOs all of whom are permanent staff. At the sub-district level, there are 67 Sub-District Malaria Officers, all of whom are funded by the Global Fund. There is a concern that around 100 skilled workers who are contracted through the Global Fund, and are not public servants, will lose their positions, and their skills base will be lost. It is predicted that losing these skilled staff members will have an impact on how malaria is monitored in the country after it is declared malaria-free. Timor-Leste may experience a malaria epidemic again because parasites are transmitted through cross-border contamination with neighbouring countries such as Indonesia, or through overseas workers who carry the species into the country (ABU-460 2018; Malaria Program - Global Fund Timor-Leste 2018a).

8.3.8 Success factors in the malaria program

There are several factors that have influenced the success of the work of the malaria team. The first is a good situational analysis and solid cost strategy. The second most important factor is the availability of funding. Other success factors are the continuous training of officers and the

increase in the sense of importance of the program, which has contributed to its overall success. Staff members are provided with a simple instruction methodology. This is strengthened by regular monitoring and evaluation. Evaluation of the overall achievement of the program is done through individual performance evaluations based on the terms of reference (TOR), the achievement of targets, and annual and quarterly meetings to evaluate achievements (ABU-460 2018).

8.3.9 Exit strategies for the malaria program

The exit strategies for the malaria program are composed of several approaches. First, the provision of malaria drugs is important to prevent large outbreaks because immunity has gone down during the elimination phase. The second approach is to maintain the skilled staff in the government civil services system. An exit strategy for human resources for the malaria program has been submitted to the Human Resource Directorate at the Ministry of Health Timor-Leste. The third strategy is to improve inter-sectorial collaboration and working with neighbouring countries for malaria prevention in the future. The Rotary Club is working to broker an inter-sectorial agreement between neighbouring governments. Mandatory reporting on arrival in Oecusse Economic Zone for foreigners, and mass blood surveys are currently conducted (ABU-460 2018).

8.4 Other data

The government pharmaceutical distribution and expenditure data were obtained from the Central Medical Store (Division of Warehousing and Distribution 2016a, 2016b; Procurement Division of SAMES Timor-Leste 2016, 2017). These data were made available through mSupply, (the pharmaceutical supply chain management software). Information about the consumption data was obtained from the National Directorate of Pharmacy, Ministry of Health (Direcção Nacional da Farmacia e Medicamentos 2016 2017b; Dirrecção Nacional Farmacia e Medicamentos 2017).

Intensive follow-up of data disaggregation for pharmaceutical quantification was undertaken after the second phase of data collection. Information from an intensive follow-up with the Head of Department for Pharmaceutical Planning and Acquisition and the Head of Department for Pharmaceutical Market Authorization on the 9th of November 2018 concluded that the municipal consumption data for 2016 was not available. Municipal pharmaceutical consumption data for 2017 was partially available initially and had only been completed with the records from SAMES after an intensive follow-up. The only municipality with a complete annual consumption report submission was Dili, the capital of the nation. The Municipal Health Services with the highest number of monthly report submissions (9 in a year) were Ainaro and Oecusse. The third highest number of monthly report submissions were Baucau, Lautem, and Manatuto, each with 8 submitted reports. There were three municipal health services (Aileu, Ermera and Manufahi) without an annual consumption report submission in 2017. The highest number of reports received was in September (9 out of 13 municipalities), followed by February and March (8 reports each). The month with the lowest number of report submissions was December, with only 1 out of 13 municipal health services submitting a report (Departamento Planificação e Gestão de Aquisição 2018). The data availability matrix was shared by the Head of the Department for Pharmaceutical Planning and Acquisition (see

details in Table 8.10) There are two lessons to be learnt from this situation. First, the Division of Pharmacy had not used the pharmaceutical data available from mSupply, which was fully operational for the period of 2017. The second lesson learnt is that there was no detailed record of monthly consumption data at the Division of Pharmacy of the Ministry of Health. This was due to human resource limitations, especially data entry officers, who were specifically tasked to oversee the data recording and management at the Division.

Table 8.10 Consumption Report by Municipal Health Services Timor-Leste 2017

Municipal Health Services (MHS)	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total submission per MHS
Aileu	0	0	0	0	0	0	0	0	0	0	0	0	0
Ainaro	0	1	1	1	1	1	1	1	1	1	0	0	9
Baucau	0	0	0	1	1	1	1	1	1	1	1	0	8
Bobonaro	0	1	0	0	0	1	0	0	1	0	1	0	4
Covalima	1	1	1	1	1	1	0	0	0	0	0	0	6
Dili	1	1	1	1	1	1	1	1	1	1	1	1	12
Ermera	0	0	0	0	0	0	0	0	0	0	0	0	0
Lautem	1	1	1	1	1	1	1	0	1	0	0	0	8
Liquica	0	0	0	0	0	0	0	0	1	1	1	0	3
Manatuto	1	1	1	1	1	1	1	0	1	0	0	0	8
Manufahi	0	0	0	0	0	0	0	0	0	0	0	0	0
Oecusse	0	1	1	1	1	0	1	1	1	1	1	0	9
Viqueque	0	1	1	1	0	0	0	0	1	1	1	0	6
Total out of 13	4	8	7	8	7	7	6	4	9	6	6	1	

Source: hard copy reports from municipalities, from the archive of National Directorate of Pharmacy, Ministry of Health Timor-Leste

8.4.1 Replacement of mSupply with other logistics management information system

The mSupply software was installed in all CHCs across the country, and pharmaceutical inventory and consumption data were flowing very well. Stock levels at the Central Medical Store and in health facilities could be accessed immediately by senior managers at the Ministry of Health. However, as already noted, according to participants from the Central Medical Store, SAMES, the Ministry of Health issued an order on the 23 of December 2017 to stop using the mSupply system and to replace it with the AdenBox software. The replacement of mSupply by this newly developed software meant that the process of inventory and consumption management had to start from scratch, and its effectiveness is yet to be evaluated. This change affected every step of the inventory management of pharmaceuticals in the healthcare sector across the country. All inventory management has now returned to paper-based processes, and information about pharmaceutical inventory has been compromised.

Pharmaceutical data not being able to be extracted from mSupply was a major challenge. It was expected that health facilities would be able to use the mSupply software to request and submit their pharmaceuticals. According to updated information from SAMES (AD-040 2017) on the 11th of December 2017, by the time the order from the Minister of Health came to stop using mSupply for pharmaceutical inventory management, all staff in the health facilities had already had one month of training after being supplied with an iPad for inventory management. The mSupply-iPads were subsequently withdrawn from all healthcare facilities. When learning about the transfer of the monthly pharmaceutical consumption reports, the Director of Warehouse and Distribution of Pharmaceuticals at SAMES questioned the validity of the data, particularly in relation to whether

or not the data had been disaggregated into an Excel spreadsheet or whether they were in their original form. The originality of the reports was maintained and could be verified. All the reports had the name, signature, and stamp of the pharmacist or the Director of Municipal Health Services on them.

8.5 Conclusion

Of the three government development partners, two organisations had issues with inventory management and experienced stock-outs. The first factor related to the stock-outs was that the local NGO, CCT, received its medical supplies from the Central Medical Store, SAMES. A stock-out at SAMES has an immediate effect on the NGO. The second factor was that the UNFPA only managed funding, quantification, and procurement of reproductive health commodities while the inventory was managed by the Ministry of Health. Reproductive health commodities were stored at SAMES, and inventory at the Municipal Health Services was held by midwives. There was no information about regular inventory reports, and hence, no consumption data was reported. The remaining development partner, the Global Fund, administered the entire malaria program and maintained full control of its Logistic Management Information System (LMIS), funding, human resources, training, monitoring, and evaluation. It has not experienced stock-out due to rigorous training, inventory management, recording and reporting, quantification, and forecasting. There is a need to address the issues of lack of data and the capabilities of its human resources in the short and medium-term. This requires development of a quantification and forecasting model that predicts the need for pharmaceuticals. Andersen's model of healthcare utilisation is one of the best models to be applied to pharmaceutical quantification and forecasting and could be used, while more standardised improvements are being introduced into the health sector. This is explored in Chapter Nine.

CHAPTER 9. PHARMACEUTICAL QUANTIFICATION AND FORECASTING

The baseline for understanding pharmaceutical stock-out in Timor-Leste has been established through the identification of issues that have an impact on pharmaceutical stock-out, particularly the logistic information system and pharmaceutical quantification. The Ministry of Health uses a proxy consumption method for pharmaceutical quantification as reported in Phase One. No other quantification and forecasting methods had been considered since the country's independence in 2002. The political, socio-economic, and cultural determinants influencing pharmaceutical planning have been neglected. Further investigation of the socio-economic factors, together with quantified variables to better predict pharmaceutical needs, are required.

The objectives of Phase Two were to revisit the data already collected on the external environment and the healthcare system to establish the factors that could be quantified (e.g., outpatient data), and to identify the factors assumed within Andersen's model which are difficult to quantify (e.g. cultural/social factors). These two datasets formed the basis for a return visit to Timor to deepen the data collection that could be quantified, and secondly, to develop a set of processes (non-quantifiable factors) that could be used to support Andersen's model (1995) for more accurate pharmaceutical quantification and forecasting.

The data required for the quantification approach were generated from determinant factors identified using Andersen's model. Independent variables were classified into predisposing, enabling, and needs factors. Predisposing factors are demographic characteristics that trigger the provision of health services and the drive to use healthcare services. Examples of predisposing variables are total population, and the proportion of male and female population. Variables for enabling factors are the percentage of the rural population that live under the poverty line, the percentage of districts/sub-districts considered to be urban, the percentage of the population aged 15-65 who are employed, district accessibility, and literacy rates for males and females. Policy factor variables are the percentage of healthcare staff trained in the Standard Treatment Guidelines (STG) and pharmaceutical supply chain management, and the availability of technical staff in the districts. Healthcare resource variables are the percentage of district/sub-district populations that live within five kilometres of a health facility and the level of the health facility according to its service provision, and the percentage of planned staff positions that have been filled. Variables of the need factors are outpatient visits and immunisation coverage.

Cross-sectional data for the outcome variables for pharmaceutical expenditures was collected from 13 municipal healthcare services in Timor-Leste through the Central Medical Store and the National Directorate of Pharmacy. Predictor variables data were gathered from the National Directorate of Statistics, the Ministry of Finance, the State Secretary for Training and Employment, and the Ministry of Health.

Optimal statistical modelling for prediction was performed. This was initiated with a stepwise regression analysis to identify significant predictors, followed by a nested stepwise regression

analysis to test the change in coefficient values and the percentage of variability of the explanatory variables to the predicted variables. Statistical tests on both linear-linear and log-linear models were determined by the best fit of the model. Eight prediction models were produced. The explanatory power of the models ranged from 55 to 94 per cent. A final prediction model with 89 per cent explanatory power is proposed for future pharmaceutical provision and budget setting.

In order to perform the same analysis on the government development partner agencies, information on inventory management, quantification, and procurement of pharmaceuticals in various settings in Timor-Leste was gathered; however, due to a lack of data, quantification for the UNFPA and the CCT could not be conducted. The Global Fund used the best approach to pharmaceutical provision, and therefore, had a more robust quantification approach method which considered demographics and healthcare system predictors. This method can be maintained until a reliable system that provides more reliable health management system data is available for pharmaceutical planning. Andersen's model for healthcare utilisation is one of the more reliable forms of quantification that could be applied to unstable systems in Timor-Leste.

9.1 Conceptual Framework

9.1.1 Andersen's behavioural model of healthcare utilisation

Since its introduction in 1990, Andersen's model has been used as a conceptual framework by researchers to predict and understand the utilisation of healthcare resources in clinical and management settings (Andersen 1995a). A detailed description of the model was presented in Chapter 4. The model consists of four primary components: the environment, population characteristics, health behaviour, and outcomes. Each of these components has several factors that influence an individual to use a healthcare service. Interactions between these factors determine health outcomes, utilisation, and subsequent quantification and costs.

The environmental factors include the healthcare system and the external environment. The external environment includes the health status of the physical environment (e.g. the number of latrines), as well as the political, cultural, social, and economic situation. Input factors that influence a healthcare system are its health policies, resources, and the organisation of the system, such as whether or not it is a universal healthcare service or one requiring patient payment. All these factors determine whether or not a population uses a service (Andersen 1995b). All these factors determine whether or not a population uses a service (Andersen 1995b).

Population characteristics involve specific demographic and epidemiological factors that have an impact on an individual's health, along with enabling factors and the need for healthcare. These predisposing characteristics include age, gender, geographic location, education, and socio-economic status. Enabling resources include the healthcare system, relevant policies,

infrastructure, road networks and transport, and health facilities. They also include input factors such as health beliefs and practices that influence how a person uses the healthcare service. Specific factors in the health system in relation to the provision of pharmaceutical include sound pharmaceutical supply chain management policies. The need predictors of a population are expressed through their perceived health status. This is linked to population characteristics, particularly literacy and health literacy, or policies that might induce demand for services (Andersen 1995b). One example of such a health policy would be mandatory child immunisation. This is linked to population characteristics, particularly literacy and health literacy, or policies that might induce demand for services (Andersen 1995b). One example of such a health policy would be mandatory child immunisation.

Health behaviours are a reflection of an individual's personal health beliefs and practices. These may be linked to their cultural beliefs (such as beliefs about child immunisation), or their socio-economic status. An example of how these beliefs might affect people can be seen in relation to beliefs about appropriate food, which may be dependent on the socio-economic status or cultural understandings of an individual or community.

Health outcomes are determined by how individuals perceive their health, but also by the level of health coverage of the population for such services as immunisation, antenatal care, or other preventative services (OECD 2008, p. 401). They are also dependent on consumer satisfaction with these services. Both health outcomes and health behaviours are heavily influenced by the predisposing, enabling, and needs factors which form part of the population characteristics. In fact, all four components interact (the environment, population characteristics, health behaviour, and outcomes). Factors from each of the sub-components are inputs that are essential for understanding healthcare service utilisation.

There has been very limited application of Andersen's model (1995b) in pharmaceutical supply chain management studies in developing countries. There has been very limited application of Andersen's model (1995b) in pharmaceutical supply chain management studies in developing countries. One example showing its application is a study on the predictors of pharmaceutical expenditure at district public health facilities in Uganda (Mujasi & Puig-Junoy, 2015). Mujasi and Puig-Junoy set out to identify the potential predictors of primary healthcare pharmaceutical expenditure at the District Health Service level. They developed an explanatory model that enabled predictions of the required budget and the allocation of pharmaceuticals for each district. This was achieved through a cross-sectional, retrospective, observational study using data from 87 randomly selected DHS from a total of 112. Drawing on the predictors considered in the four components of Andersen's conceptual model (the environment, population characteristics, health behaviour, and health outcomes), they demonstrated that it was possible to cost and quantify the pharmaceuticals required for a region with only limited data.

9.1.2 Measuring Components of the Andersen Behavioural Model

The relationship between the determinants of health behaviour and the utilisation of (the requirement for) pharmaceuticals and pharmaceutical management can be explained by looking at the factors within the four components that can be measured. For example, one way of taking into account forecasting of pharmaceutical needs for a population would be to measure factors such as the total population, gender, age, geographic location, literacy rates, poverty levels, employment, accessibility to a health facility, and transport availability.

Regarding the healthcare system, policies that establish health facilities that are accessible to the population based on a defined distance that can be reached on foot or by motor vehicle are determinants that can also be measured. In addition to the healthcare system, the number and skill level of human resources assigned to each healthcare facility is another measure that can be used to calculate pharmaceutical expenditures. These factors then become operationalised as independent variables. To predict pharmaceutical expenditure, dependent variables are required. For example, total pharmaceutical expenditure, pharmaceutical expenditure per capita, pharmaceutical expenditure per visit, and pharmaceutical expenditure per healthcare facility. The model is depicted in Figure 9-1 (Andersen 1995a).

Figure 9-1 Andersen's Behavioural Model of Healthcare Utilisation

9.2 Access to UN Agencies and International Aid Agencies

There are many government partner organisations working in the health sector. However, the organisations studied here are those that provide policy development support, technical support, and funding for their programs. A special focus was given to their pharmaceutical provision for vertical programs or in collaboration with the government. The Global Fund and Cliníca Café Timor (CCT) were selected for the second phase of the study. The Global Fund is a multilateral organisation that finances, procures, and implements its tuberculosis, malaria, and HIV-AIDS programs for the government of Timor-Leste. CCT plans and implements coffee production and

funds healthcare services from its own profits. Since the two organisations run programs that involve pharmaceutical quantification, procurement, and distribution, they met the comparison criteria. The aims were to see whether their quantification models were reliable and to improve understanding of why they have not experienced regular stock-outs. See Table 9-1.

Table 9-1. Non-Governmental Organisations and their roles in Timor-Leste

UN Agencies/NGO	Roles
World Health Organization (WHO)	• Health Policy Development Support • Expanded Program for Immunisation
Global Fund	• Malaria • Tuberculosis • HIV-AIDS
UNFPA (United Nations Fund for Population Agency)	• Reproductive Health Programs
Marie Stopes International	• Family Planning Program
CCT (Cliníca Café Timor)	• Coffee Production • Health Services

Successful contact was made with the main managers of the Global Fund and CCT. A preliminary review of the organisations was conducted to establish a basic understanding of their existence and operations in the country. Detailed information about the two organisations are provided below.

9.2.1 The Global Fund

The national malaria progress reports produced by Global Fund for 2010, 2011, 2012, and 2016 indicated that municipalities rarely experience pharmaceutical stock-out (Global Fund Timor-Leste 2012, 2016). For example, during period 25 to 29 of the program, 100 per cent of Municipal Health Services reported no pharmaceutical stock-out on the first line of DOTS (Directly Observed Treatments Short-course) (Global Fund Timor-Leste 2016, pp. 30, 44).

Following interviews and document reviews in the field, it was revealed that global success preventing stock-out was due to the following reasons. First, the Fund has tangible management tools e.g. standard operations procedures, inventory management, and quantification in place to operate the program effectively. Training in program management, inventory management, pharmaceutical quantification, supervision and monitoring, and evaluation has proven effective in the management of the malaria program. This effectiveness has been coupled with rigorous supervision, monitoring and evaluation, and refresher training for all malaria program officers. Procurement for the anti-malaria program was centralised at its headquarters in Geneva. The Fund has detailed information of all inventory, as well as the number of malaria cases across all 374 health facilities in the country. It applies morbidity-based quantification models for anti-malaria pharmaceuticals. The quantification of anti-malaria drugs is based on the reported

malaria cases for each strain, with 30% added as buffer stock. The funding allocated for anti-malaria pharmaceuticals were relatively small compared to the UNFPA. However, with these approaches, there was no stock-out for anti-malaria drugs in 2016 and 2017. Regardless of the method of quantification, the Global Fund has the best approach in pharmaceutical supply chain management and meeting demand. The approaches used by the Global Fund could be adopted by any organisation, including the government.

9.2.2 Cliníca Café Timor (CCT)

The focus of the healthcare services are on maternal and child health programs for 28,000 people made up of coffee farmers and their communities (Cliníca Café Timor 2018; Cooperativa Café Timor 2018). CCT applies a simple inventory management and streamlined procurement system. Clinical Café does not apply a quantification approach or any forecasting model in its pharmaceutical planning; instead, procurement is based on a reactive response to the stock-out and the needs of its clinics. CCTs eight clinics were run with pharmaceutical support from the government, which means that when there was a stock-out at SAMES, the CCT clinics were also affected. Nevertheless, records of pharmaceutical consumption data were kept, and CCT's strict monitoring and supervision of pharmaceutical consumption and stock has proved to be an effective measure to be able to have immediate information about overall pharmaceutical levels in all of its clinics. Although it has a simple system in place, it has been successful in addressing pharmaceutical stock-out at its clinics.

9.2.3 UNFPA (United Nations Fund for Population Agency)

An unpublished report on the UNFPA strategy for Timor-Leste in 2010 showed that demand for reproductive health commodities were increasing. However, there was a lack of technical capacity to maintain adequate levels of stock at the Municipal Health Services. In addition, there was a history of stock-outs prior to the 2010 survey (Belton 2010).

9.3 Cross-Sectional Quantitative Data Collection

Cross-sectional quantitative data collection is the second part of the thesis, containing information about how the data collection was conducted. The collection of the quantitative data was based on phase two objectives

a) Identify the current methods used to quantify pharmaceuticals by the government and three of its development partners;
b) Examine the social, cultural, political, and managerial/educational factors that contribute to the failure of the current quantification approach that has led to on-going stock out of pharmaceuticals;
c) Apply Andersen's explanatory model for pharmaceutical expenditure for two drug groupings (Antibiotics and Antipyretics) used by the three non-government agencies (the Global Fund, the UNFPA, and CCT) in order to see how they correlate with the

present model used by the government in terms of quantification and forecasting needs;

d) Establish if it produces the same or similar estimates;
e) Repeat the third objective (re: Andersen's model) using the government model; and
f) Draw conclusions about the strength of Andersen's model for pharmaceutical quantification/forecasting by comparing the estimates arrived at in the third and fourth objectives above, and the usefulness of the model for the Timor-Leste context.

Cross-sectional quantitative distribution and consumption data and pharmaceutical expenditures data were collected from the Ministry of Health, the UNFPA, the Global Fund, and Cliníca Café Timor. These data became the outcome variables for the study. There were 25 predictor variables collected from the General Directorate of Statistics Office of Timor-Leste, the Ministry of Health, the State Secretary for Employment and Training, and the Office of Water and Sanitation Services at the Ministry of Public Works.

9.3.1 Outcomes and predictors data for government

The government pharmaceutical distribution and expenditure data were obtained from the Central Medical Store (Division of Warehousing and Distribution 2016a, 2016b; Procurement Division of SAMES Timor-Leste 2016, 2017). This data has been made available through mSupply, the pharmaceutical supply chain management software. Information about the consumption data was obtained from the National Directorate of Pharmacy, Ministry of Health (Direcção Nacional da Farmacia e Medicamentos 2016 2017b; Dirrecção Nacional Farmacia e Medicamentos 2017).

9.3.2 Preliminary drug consumption review for CCT

The initial data analysis on Cliníca Café Timor (CCT) revealed great inconsistencies in the pharmaceuticals managed from one month to another; therefore, it took a long time to link the monthly data in summary form. The data aggregation for 118 pharmaceutical items consumed in 2016 required monthly and annual figures for each of its eight clinics. All the distribution and consumption data were in Microsoft Word and Microsoft Excel. As the pharmaceuticals came from two sources, there was another data aggregation required to clearly see how much the pharmaceutical expenditure was from CCT alone, as well as that combined with government expenditure. It took more than 10 hours to assemble the total annual consumption data for all 8 clinics (Pharmacy Department of Cliníca Café Timor 2016).

It was apparent that there were no pharmaceuticals requested or distributed to any CCT clinics from September-November 2016. The analysis then moved onto the same consumption data for 2017. There were 161 pharmaceutical items listed in the report. However, there were only 6 to 11 items reported to be distributed and consumed during the period from January to December 2017. It was later clarified in the interviews that stock-out involved only those items supplied by SAMES.

There were 132 pharmaceutical items listed to be managed and made available throughout CCT, which was similar to the government Community Health Centres. Overall, both the static and mobile clinics provided the same quantities of pharmaceutical items. There were variations of between 1 and 3 additional items added to the list for two clinics, the Airacalau Clinic and the Lauana Clinic. The distribution took place through all the months in the period of 2017 (Pharmacy Department of Cliníca Café Timor 2017).

Table 9-2. An Excel table of CCT drug

Number of rows	Remark
155	Total rows
3	(-) Heading rows
20	(-) 20 Pharm Categories rows
50	(-) Items without data
72	(=) Filled with consumption data

In the Excel spreadsheet shown to the right, there were 155 filled rows. Un-counted rows comprised 3 rows at the top of the page for headings, and 20 rows for each of the 20 categories. This led to 132 pharmaceutical items being listed under all categories. Out of these 132 items, only 55 per cent (72) were available (Pharmacy Department of Cliníca Café Timor 2017). The top pharmaceutical items in use were Paracetamol 500mg tablets and Amoxicillin 500mg tablets. This was in line with average government pharmaceutical stock-out for 2017 available from the Central Medical Store (Serviço Autonomo Medicamentos e Equipamentos de Saúde - SAMES 2017).

9.3.3 Quantification of family planning commodities - UNFPA

The expenditure data for family planning commodities was obtained from the UNFPA office in Timor-Leste. It has only the total quantities for each family planning commodity, unit price, and total cost for all commodities (ABY-480 & ABZ-490 2018b; United Nations Fund for Population Agency - UNFPA) 2018; United Nations Fund for Population Agency-UNFPA 2018). At the time of the data collection, the UNFPA was the sole funding organisation for the family planning program in Timor-Leste. It provided technical support and funding to the program. Its task in pharmaceutical supply chain management was to coordinate the quantification, procurement, and clearance of goods upon arrival in the country. Procurement of family planning commodities was centralised at the UNFPA's headquarters in Copenhagen, while the government managed the inventory, distribution, and reporting of consumption. Obtaining reliable data on segmentation of responsibilities in warehousing and distribution and inventory management at the central and municipal levels proved to be a challenge. Data for family planning commodities was available, but consumption data was lacking. The data for the quantification of consumption was supposed to come from the government. Due to the lack of consumption data, UNFPA has applied a proxy consumption model in pharmaceutical quantification and procurement. Stock level information has become an issue for the family planning programs. There was no inventory information for the 2016 and 2017 period. Annual facility audits have been the only method of identifying stock availability of family planning commodities in all health facilities in the country.

9.3.4 Pharmaceutical consumption for the malaria program - Global Fund

There was detail-disaggregated data for pharmaceutical consumption for all municipalities, while expenditure for the malaria program was obtained from the Global Fund (ABV-470 2018; Malaria Program - Global Fund Timor-Leste 2016a, 2016b, 2016c, 2017a). The expenditure data is provided as one data point because procurement is only done in a lump-sum, and not for each individual municipal health service.

9.3.5 The employment absorption rate variable

Employment absorption data was extracted from the last survey of disaggregated data from the Labour Survey in 2013 (SEFOPE, Ministerio das Finansas & Direcção Geral de Estatistica Timor-Leste 2013). The latest data for Labour Forces for 2016 was under review by the Ministry of Finance and could not be released.

9.3.6 Enabling factors, health policy, and needs predictors

Data on enabling factors, health policy, and needs predictors were obtained from the Department of Health Management Information System of the Ministry of Health and the General Directorate of Statistical Office, Timor-Leste. This covered predictors of antenatal care, vaccination coverage, human resources, and health facilities (Departamentu Estatistica e Informação de Saúde 2017; Department of Partnership and Cooperation 2018; Department of Personnel Management 2017).

9.3.7 Challenges in collecting government data

Obtaining outcome variables for pharmaceutical consumption data was also a challenge. There were many inconsistencies of data availability. Initially, there were only three Municipal Health Services that had submitted their annual pharmaceutical consumption data to the Ministry of Health. One had sent complete information for all 12 monthly reports, while the other two submitted only partially completed reports.

One reason for lack of data availability was due to lack of electronic data compilation of pharmaceutical at the National Directorate of Pharmacy. All hard copies of the reports from the municipalities were available but required time to locate them in the report archives storage room and could not be sent via email. The transfer of raw data on pharmaceutical consumption from the Municipal Health Services to the National Division of Pharmacy, Ministry of Health Timor-Leste took four months (October 2018 to January 2019). The data comes from monthly and quarterly pharmaceutical consumption reports. The reports were photographed using a mobile phone and were then transferred to me through WhatsApp. At the end of January 2019, consumption data from seven of the thirteen Municipal Health Services were successfully transferred. Further investigation of the data revealed more issues. Only Municipal Health Services had full consumption data for the 12 months of that period of 2017. The second highest

data availability was Lautem at 83 per cent. This was followed by Bobonaro and Covalima at 75 percent. The lowest data availability figures were from Ainaro, Baucau, and Manatuto at 25 per cent. Following intensive follow-ups via WhatsApp[24], it became apparent that the data on pharmaceutical consumption for 2016 was incomplete (Pharmaceutical Unit - Municipal Health Services of Baucau 2016; Pharmaceutical Unit - Municipal Health Services of Covalima 2016; Pharmaceutical Unit - Municipal Health Services of Dili 2016). Overall, there were systematic errors found in the data when completing the data entry. The calculations of the initial pharmaceutical stock at the beginning of the month and the balance at the end of the month of May 2016 were wrong. In addition, there were inconsistencies in the statement of the names of pharmaceuticals and their strength; for example, with Aspirin, Atenolol, Chlorpromazine, and other drugs throughout the documents to name only a few (Pharmaceutical Unit - Municipal Health Services of Covalima 2016).

Due to lack of consumption data for 2016, consumption data for 2017 was focused on because this had been well recorded in mSupply. Upon initial contact with the Department of Pharmaceutical Planning and Acquisition at the Ministry of Health, it was stated that all the consumption data from all Municipal Health Services were available. However, the data could not be obtained until I returned to Adelaide on the 26 of September 2018. The main reason was that mSupply, the pharmaceutical inventory management software that had previously been used, had been cancelled and replaced by another software package in December 2017, so all the consumption data could not be retrieved. This was overcome through an approach to the Warehouse Management Director at SAMES, who oversaw the mSupply data, agreed to extract all the data for the 2017 period. The transfer the of data via WhatsApp was completed at the end of April 2019.

9.3.8 Data processing, challenges, and limitations

Data processing poses a great challenge. Detail information on obstacles faced during design, data collection, data processing, results and limitation are presented in the following sections and subsections.

9.3.9 Management of outcome variables

It was initially planned to run Andersen's model for the quantification of five antibiotics and analgesic pharmaceuticals; however, considering the limits on the number of pharmaceutical items listed in the consumption data from the government and non-government organisations, it was decided to only run the model for two pharmaceutical items: amoxicillin 500 mg caplets and paracetamol 500 mg tablets. These two pharmaceutical items were the first and second items listed in the top-ten most highly-consumed pharmaceuticals during the January to December 2017 period.

[24] WhatsApp is a mobile phone text messaging application that enables users to send messages, pictures, videos, or voice messages free of charge over the Internet.

Expenditure data for all pharmaceutical items for 2017 was gathered from the Procurement Division of SAMES (Procurement Division of SAMES Timor-Leste 2016). There were three main suppliers of amoxicillin 500mg caplets and paracetamol 500mg caplets to the health sector in 2017. The price of these pharmaceuticals per tablet varied between one supplier and another. The compilation of the unit price was established, so an average unit cost could be obtained. The average unit cost was then multiplied by the total annual consumption for both pharmaceutical items and the outcome variable, which is the expenditure data for the seven municipal health services, was established for SSPS (Social Statistics Package for Social Sciences) analysis. Details of the unit cost per tablet for the two pharmaceuticals are presented in Table 9-3.

Table 9-3. Cost variation of Amoxicillin and Paracetamol caplets from providers to Timor-Leste Government during 2016

Pharmaceutical	Foho Osan Mean Farmacia	Bethesda Husada Farmacia	Eastern Surgical Company	Average unit cost
Paracetamol, double scored 500mg caps	0.04	0.04	0.03	0.037
Amoxicillin scored 500mg caps	0.02	0.01	0.01	0.013

9.3.10 Study design - cross-sectional observational study

The design of the study for the Phase Two was mixed methods. The data collection methods were based on the two main objectives of the study. Data collection for Objective 1 was completed through interviews with senior managers managing pharmaceutical quantification and forecasting at the government's development partners (the Global Fund, the UNFPA, and CCT). Cross-sectional data on pharmaceutical quantification and forecasting data also came from the government and its development partners. The data collection method for Objective 2 was a quantitative approach based on secondary data and econometric analysis. Detailed descriptions of the three objectives, the data sources, data collection, and data analysis are presented in the next sub-sections.

Objective One - The first objective of the study is to identify quantification and the forecasting model of the UN agencies and international multilateral organisations or NGOs (the UNFPA, the Global Fund, and Cliníca Café Timor).

The following interview questions were asked to explore the pharmaceutical supply chain process.

9.3.10.1 Interview questions

The investigation of quantification and forecasting in the government development partners was built on understanding the process. The following primary interview questions were asked of the respondents:

a) What is the current quantification and forecasting process in place?

b) What are the steps involved in the process?
c) What quantification and forecasting model is being used?
d) What data is used for pharmaceutical quantification and forecasting?
e) How is the quantification and forecasting process managed?

The method for reviewing the quantification and forecasting models of the developing partners was to document the review of the data, the predictors for quantification, outcomes, and stock levels during 2017. The outcome of the data collection for Objective 1 was an improved understanding of the pharmaceutical quantification and forecasting models. In the development partners' programs, there was a serious lack of disaggregated data, and hence, analysis could not be conducted. The prediction for pharmaceuticals for the malaria program was not performed using econometric analysis due to the nature of the program, which was better informed by using morbidity data for predictions.

Differences in the pharmaceutical quantification/forecasting model and predictors were then compared with the government quantification/forecasting model. Analysis of the quantification of pharmaceuticals from government consumption data for 2016 and all government development partner agencies indicated that statistical analysis for prediction models could not be conducted due to a severe lack of data. An alternative quantification/forecasting approach using Andersen's behavioural model for healthcare utilisation was presented. Cross-sectional data on pharmaceutical consumption and expenditure data for 2017 were obtained from mSupply records and the centralised National Statistics Office.

Objective Two - to establish an explanatory model for pharmaceutical expenditure that reflects both estimated pharmaceutical needs and pharmaceutical expenditure of the municipalities.

The first approach was to identify and examine both the external environment and the healthcare system characteristics (i.e., policies, strategic plans, staffing levels, and epidemiological data), and relevant population characteristics (i.e., predisposing factors, enabling factors, and the need for healthcare) (Andersen 1995a) for the factors that could be quantified. These factors have been used in previous research using Andersen's approach (Andersen 1995a; Mujasi, PN & Puig-Junoy, J 2015). The nature of the collection of the quantifiable factors was approached as a cross-sectional retrospective observational study using secondary administrative data. The outcome/dependent variable data were the annual pharmaceutical distribution/expenditure data for 2017 for the 13 Municipal Health Services from the Ministry of Health and the Central Medical Store Timor-Leste.

The predictor, or independent, variables were the factors that influenced pharmaceutical needs and expenditures identified from the external and demographic characteristics components in Andersen's behavioural model for healthcare utilisation. Details of the predictor variables can be seen Table 9-4. These identified predictor variables consisted of three dichotomic variables (availability of regional referral hospital, access to municipality, and urbanisation status) and 22 continuous variables.

9.3.11 Sampling

The current study drew on the population of 13 municipalities. Data on pharmaceutical needs/expenditures of the sampled CHCs were obtained from the central services of the Ministry of Health Timor-Leste and the Central Medical Store. As noted in Chapter Five an attempt was made to calculate the sample size using the sample calculator of the Australian Bureau of Statistics. The following basic measurements were entered into the calculator. Standard error 0.016, population size of 13, 0.75 proportion of the population, and 95 per cent level of confidence, returning a sample size of 12. Hence, the analysis was conducted cross-sectionally, and it was decided that it would be conducted on the entire population rather than only on selected municipalities.

9.3.12 Predictor variables

Predictor variables, or the independent variables, are factors that influence the pharmaceutical needs and pharmaceutical expenditures identified from the External and Demographic Characteristic components in Andersen behavioural model for health care utilization. Details of the predictor variables can be seen in Table 9-4. The variables data from the predisposing and enabling factors were collected from the National Directorate of Statistics, Ministry of Finance. This data was available from the latest population census, demographic health survey, and household expenditure survey. Employment data were also gathered from the State Secretary for Training and Employment. Variables for policy and healthcare resources, training, and need factors will be collected from the Ministry of Health.

Table 9-4. Description of independent variables and availability in Timor-Leste (adapted from Mujasi 2014)

Type of Variable	Variable	Description	Measurement	Data Sources
Predisposing factors	1.MUNTOP	Total population of Municipal	Total population municipal population 2015	National Directorate of Statistics Timor-Leste (NDSTL)
	2. PercFem	Municipal Female Population	Percentage of municipal female population, 2015	National Directorate of Statistics Timor-Leste
Enabling factors	3. RuralPov	Rural Poverty	Percentage of rural population below poverty line, 2015	National Directorate of Statistics Timor-Leste
	4. URBANIZATION	Urbanisation level	Percentage of Municipality considered to be urban	National Directorate of Statistics Timor-Leste (NDSTL)
	5. LABOURABSRATE	Labour Absorption Rate	Percentage of population working age (15-65) who are employed	National Directorate of Statistics Timor-Leste (NDSTL); State Secretary for Employment and Vocational Training
	6. LITERATETotal	Total Literacy Rate	Percentage of the population age 15 and above who can, with understanding, read and write short, simple statement on their everyday life.	National Directorate of Statistics Timor-Leste (NDSTL): Census 2015 and Household Survey 2015
	7. LITERATEFemale	Female Literacy Rate	Percentage of the female population age 15 and above who can, with understanding, read and write short, simple statement on their everyday life	
	8. LITERATEMale	Male Literacy Rate	Percentage of the male population age 15 and above who can, with understanding, read and write short, simple statement on their everyday life	
	9. MUNAccess	Municipal Accessibility	Whether or not MoH considers the municipality is difficult to reach. =1 if Yes, and =0 if No	National Directorate of Statistics Timor-Leste (NDSTL) and MoH
Need for healthcare	10. BCGCover	Immunisation Coverage for Tuberculosis	Percentage of children under one fully immunised against Tuberculosis	Department of Health Management Information System (HMIS) MoH Timor-Leste

Type of Variable	Variable	Description	Measurement	Data Sources
				2017
	11. OPV3	Immunization coverage for Poliomyelitis	Percentage of children under five fully immunised against Poliomyelitis	Department of Health Management Information System (HMIS) MoH Timor-Leste 2017
	12. ANC4	Coverage of Ante natal care	Percentage of pregnant women who had four ante natal care visits	Department of Health Management Information System (HMIS) MoH Timor-Leste 2017
	13. DELIVERYHllthProf	Deliveries Assisted by Health professionals	Percentage of deliveries at home or health facilities assisted by health professionals	Department of Health Management Information System (HMIS) MoH Timor-Leste 2017
	14. OPDCapita	Outpatient visits	Outpatient visits per capita	Department of Health Management Information System (HMIS) MoH Timor-Leste 2017.
	15. ACCESSWater	Access to drinking water	Percentage of population with access to safe drinking water	National Directorate of Statistics Timor-Leste (NDSTL): Census 2015 and MoH and Timor-Leste Demographic and Health Survey 2016 (General Directorate of Statistics (DGS) Ministry of Health and ICF 2018)
	16. LATCoverage		Percentage of population with latrine	National Directorate of Statistics Timor-Leste (NDSTL): Census 2015; and TL Household Survey 2015 and Environmental Health Department of MoH
Healthcare resources	17. HFGovTot	Government Health Facilities	Total Number of Government health facilities in the Municipality (excluding hospitals)	Office of Quality Control and HMIS MoH Timor-Leste
	18. HospTot	Government Hospital Services	Total number of general hospitals, both government and private, in the municipality	Office of Quality Control and HMIS MoH Timor-Leste
	19. HFNGO	Non-Government Health facilities	Total Number of Non-Government Organisations (NGO) health facilities in the Municipality	Office of Quality Control and HMIS MoH Timor-Leste
	20. RRHAvail	Referral Hospital Services	Availability of Regional Referral Hospital in the Municipality; Yes =1, No=0	Office of Quality Control and HMIS MoH Timor-Leste
	21. MunCHC1	Health facility I	Number of government facilities that are CHC Municipal level	Office of Quality Control and HMIS MoH Timor-Leste
	22. MunCHC2	Health facility II	Number of government facilities that are CHC Sub-district level	Office of Quality Control and HMIS MoH Timor-Leste
	23. MunHp	Health facility III	Number Health Post in municipality	Office of Quality Control and HMIS MoH Timor-Leste
	24. STAFFSTRENGTH	Staff Strength	Number of staff posts filled	National Directorate of Human Resources and HMIS MoH Timor-Leste
	25. StaffStrengthPhy	Staff Strength =Physicians	Number of Medical Officer positions filled	National Directorate of Human Resources and HMIS MoH Timor-Leste

9.3.13 The dependent/outcome variables

The selection of the outcome variables was guided by Andersen's behavioural model of healthcare utilisation (Andersen 1995a) and the Ugandan study on the predictors of pharmaceutical expenditure for primary healthcare (Mujasi, PN & Puig-Junoy, J 2015). The value of pharmaceutical expenditure was gathered by multiplying the total quantity of each pharmaceutical item by the average unit price. The pharmaceutical expenditure items were generated by having the total annual pharmaceutical items supplied to health facilities converted into US dollars based on unit cost of each pharmaceutical item. The pharmaceutical expenditure data was the source of information for the outcome variables.

There were four outcome variables related to pharmaceutical expenditures. These were total pharmaceutical needs/expenditures, average pharmaceutical needs/expenditures per capita, average pharmaceutical needs/expenditures per visit to health facility, and average pharmaceutical needs/expenditures per health facility. The total value of pharmaceutical expenditure per capita was captured from the average value of pharmaceutical expenditure in US Dollars supplied by SAMES to the Municipal Health Services during one financial year, based on projected population for 2017 for each municipality. The final dependent variable, the pharmaceutical expenditure per visit per health facility, was collected by having the average value in US dollars for pharmaceuticals supplied by SAMES to each municipality in one financial year for all reported outpatient department (OPD) visits to PHC facilities in a municipality. Primary healthcare pharmaceutical expenditure per PHC facility was obtained by having the average value in US Dollars of pharmaceuticals supplied by SAMES and the National Directorate of Finance Management to health facilities to each municipality in one financial year per reported number of total PHC facilities in the period (Mujasi, PN & Puig-Junoy, J 2015).

9.3.14 Hypotheses

There are five hypotheses that aim to test the differences in pharmaceutical expenditure based on the following observed variables.

- There is no difference in the pharmaceutical needs/expenditures between groups of municipalities;
- There is no difference in total primary healthcare pharmaceutical needs/expenditures among municipalities;
- There is no difference in pharmaceutical needs/expenditures per capita between municipalities;
- There is no difference in primary healthcare pharmaceutical needs/expenditures per health facility between municipalities; and
- There is no difference in primary healthcare pharmaceutical needs/expenditures per OPD (Outpatient Department) visits between municipalities.

9.4 Data Analysis

SPSS-25 was used to undertake the analysis of the data. The study has 4 outcome variables and 25 variables. The outcome variables are total pharmaceutical expenditure for primary healthcare (PHCPETotal), pharmaceutical expenditure for primary healthcare per capita (PHCPECapita), pharmaceutical expenditure for primary healthcare per visit to outpatient department (PHCPEVisit), and pharmaceutical expenditure for primary healthcare per health facility (PHCPEFacility). There are 22 continuous variables and three explanatory dichotomic variables. The dichotomic variables are accessibility to a municipality (MunAccess), urbanisation status (UrbanStat), and availability of a regional referral hospital (RRHAvail). Each of these explanatory variables has two grouping variables: *Yes = 2 or No = 1.*

The whole statistical test on the cross-sectional data on the pharmaceutical quantification and forecasting was initiated with univariate analysis to determine the data distribution and identification of outliers as assessed by descriptive statistics. Bivariate analysis was conducted to determine the association predictor variables to the outcome variables in order to determine the mean differences between municipal health services. The equality was tested to determine means through Pearson correlation coefficients for continuous independent variables and the outcome variables. This was then followed by the testing of independent sample t-tests for dichotomic variables. However due to the sample size the Shapiro-Wilk's tests were conducted.

Finally, optimal statistical modelling for prediction was performed. It was initiated with a stepwise regression analysis to determine the significant predictors, followed by linear-linear and log-linear stepwise regression testing of coefficient values and percentage of variability of the explanatory variables to the predicted variables to select the models that best fit. Table 9-5 shows the variables used in multiple regression to determine the variation of pharmaceutical expenditure between the Municipal Health Services.

9.4.1 Descriptive statistics

The descriptive statistics data were divided into three sections: outcome variables, continuous explanatory variables, and categorical explanatory variables.
The total primary healthcare (PHC) pharmaceutical expenditure was positively skewed, and more than three times the standard deviation. A similar spread was noted in the PHC pharmaceutical expenditure per facility which was also more than twice the standard deviation. Further statistical tests were conducted to normalise the spread of these outcome variables. The spread of expenditure for the other two outcome variables was approximating normality.

There were 22 continuous explanatory variables identified in the study. Most of the variables were positively skewed at more than three times the standard deviation from the mean. The total population variable reflected the overall abnormal distribution. The skewness could have been influenced by three municipalities which have very high total populations. One municipality (Dili, the capital of the country) has the highest population concentration at 227,279 people (23.5 per cent of the total national population). Rural poverty was a constant variable because it had only one rate for all municipalities. Further statistical tests were conducted to overcome the normal distribution of the data to enable an analysis of the association between the explanatory variables and the predicted variables

Table 9-5. Factors entered in multiple regression procedure to determine variations in pharmaceutical expenditure (n=13)

Continuous variables	Minimum (000)	Maximum (000)	Mean (000)	Standard Deviation	Correlation Coefficient with			
					PHPETotal	PHPECapita	PHCPEVisit	PHCPEFacility
Outcome variables								
PHCPETotal	$7,538.88	$68,561.40	$22,230.9138	$14,816.01473				
PHCPECapita	$0.09	$0.55	$0.2643	$0.11466				
PHCPEVisit	$0.19	$1.49	$0.6530	$0.36521				

Continuous variables	Minimum (000)	Maximum (000)	Mean (000)	Standard Deviation	Correlation Coefficient with			
					PHPETotal	PHPECapita	PHCPEVisit	PHCPEFacility
_PHCPEFacility	$1,353.18	$8,570.17	$3,947.0273	$2,120.07485				
Explanatory Variables								
Predisposing Factors								
MunTOP	46619	227279	87203.31	49148.548	.910**	.781**	0.277	.648*
PercFem	48	51	49.41	.755	0.116	0.265	0.149	-0.024
Enabling Factors								
RuralPov	47	47	47.10	.000	A	a	a	a
LabourAbsRate	1	2	1.38	.506	-.732**	-.727**	-0.338	-.634*
Urbanisation	36	60	51.21	6.273	0.487	0.14	-0.293	0.446
LiterateTotal	37	74	50.85	8.946	.736**	0.47	0.154	.610*
LiterateFemale	23	56	32.67	8.209	.790**	0.528	0.196	.643*
LiterateMale	28	58	37.00	7.615	.763**	0.517	0.228	.619*
Need for Health Care								
OPDCapita	1	5	2.47	1.001	-0.332	0.005	.745**	-0.271
BCGCover	64	106	77.89	10.845	.883**	.679*	0.423	.693**
OPV3Cover	62	96	78.01	10.128	0.442	0.418	.608*	0.289
ANC4Cover	38	80	51.81	11.193	0.143	0.195	.651*	0.23
DeliverP	47	84	60.68	14.523	.595*	0.309	0.162	0.535
Policy Factor								
ACCESSWater	32	86	65.93	14.368	-.772**	-0.39	0.151	-0.439
LatrineCoverage	36	93	52.86	15.354	.723**	.619*	0.216	0.428
Healthcare Resources								
HFGovTot	5	27	12.92	6.551	-0.403	-0.518	-0.444	-0.523
HospTotal	0	1	.46	.519	0.425	-0.033	-0.489	0.238
HFNGO	0	12	3.00	3.488	.761**	.696**	0.415	0.396
RRHAvail	0	1	.46	.519	0.425	-0.033	-0.489	0.238
MunCHC1	1	2	1.08	.277	-0.042	0.117	0.155	-0.202
MunCHC2	2	12	5.00	2.646	0.241	-0.016	-0.212	-0.318
MunHP	12	136	28.31	32.821	-0.004	-0.455	-0.349	-0.01
MunAccess	40	331	135.54	76.053	A	a	a	a
StaffStrength	13	111	48.23	25.746	.901**	.718**	0.254	.805**
StaffStrengthPhy	5	27	12.92	6.551	.867**	.769**	0.286	.773**

Explanation of the significant level (at 0.05 or 0.01) of correction from result of t-test 2-tailed.
*Correlation is significant at the 0.05 level (2-tailed)
** Correlation is significant at the 0.01 level (2-tailed)
a. Cannot be computed because at least one of the variables is constant

9.4.2 Test of normal data distribution - descriptive statistics

The normality test for scale variable of 4 outcome variables and 24 predictor variables showed that most variables are highly positively skewed except the labour absorption rate and the percentage of female population, these being highly negatively skewed. Details of this are presented in Table 9-6. The rural poverty variable is constant, hence there is no calculation for skewness. Normality was assessed using the descriptive statistical test with attention to skewness and kurtosis (Laerd Statistics 2015).

Table 9-6. Descriptive statistical test of normality (skewness and kurtosis)

Normality test		Statistic	Std. Error
PHC Pharmaceutical Expenditure (Total)	Skewness	2.866	.616
	Kurtosis	9.425	1.191
	Skewness	.908	.616

Normality test		Statistic	Std. Error
PHC Pharmaceutical Expenditure Per Capita	Kurtosis	2.171	1.191
	Skewness	.833	.616
PHC Pharmaceutical Expenditure Per Visit	Kurtosis	.816	1.191
	Skewness	.956	.616
PHC Pharmaceutical Expenditure Per Facility	Kurtosis	.195	1.191
	Skewness	2.195	.616
Municipal Total Population	Kurtosis	5.430	1.191
	Skewness	-.136	.616
Percent of Female Population	Kurtosis	-.027	1.191
	Skewness	-1.235	.616
Labour Absorption Rate	Kurtosis	2.212	1.191
	Skewness	1.134	.616
Total Literacy Rate	Kurtosis	3.208	1.191
	Skewness	1.914	.616
Female Literacy Rate	Kurtosis	5.470	1.191
	Skewness	1.733	.616
Male Literacy Rate	Kurtosis	4.673	1.191
	Skewness	1.416	.616
Coverage of BCG	Kurtosis	3.150	1.191
	Skewness	.173	.616
Coverage of Polio3	Kurtosis	-.657	1.191
	Skewness	1.341	.616
Antenatal Care 4	Kurtosis	2.488	1.191
	Skewness	.546	.616
Delivery Assisted by Health Professionals	Kurtosis	-1.622	1.191
	Skewness	1.230	.616
OPD Visit Per Capita	Kurtosis	1.117	1.191
	Skewness	-.879	.616
Access to Water	Kurtosis	1.391	1.191
	Skewness	1.549	.616
Coverage of Latrine	Kurtosis	3.318	1.191
	Skewness	1.069	.616
Total Government Health Facilities	Kurtosis	.334	1.191
	Skewness	.175	.616
Total Hospitals	Kurtosis	-2.364	1.191
	Skewness	2.033	.616
NGO Health Facilities	Kurtosis	3.563	1.191
	Skewness	3.606	.616
Municipal CHC Level 1	Kurtosis	13.000	1.191
	Skewness	1.595	.616
Municipal CHC Level 2	Kurtosis	3.332	1.191
	Skewness	3.429	.616
Number of Health Posts	Kurtosis	12.085	1.191
	Skewness	1.038	.616
Staff Strength	Kurtosis	2.194	1.191
	Skewness	.713	.616
Number of Physicians	Kurtosis	1.259	1.191

	N	Std. Deviation	Skewness		Kurtosis	
			Statistic	Std. Error	Statistic	Std. Error
LnPHCPETotal	13	.49776	.884	.616	3.607	1.191
LnPHCPECapita	13	.01112	.865	.616	2.063	1.191
SqRtPHCPEVisit	13	.05563	.790	.616	.708	1.191
LogPHCPEFacility	13	.23081	.068	.616	-.589	1.191
MunTop_Log	13	.19363	1.204	.616	1.386	1.191
PerFem_Log	13	.13804	-.882	.616	1.980	1.191
LabAbsRt_Log	13	.40198	-2.004	.616	5.885	1.191
LitTotal_Log	13	.05803	-1.620	.616	3.330	1.191
LitFem_Log	13	.09729	1.014	.616	2.652	1.191
LitMale_Log	13	.08151	1.014	.616	2.386	1.191

BCGCover_Log	13	.05704	.971	.616	1.861	1.191
OPV3Cover_Log	13	.05660	-.070	.616	-.629	1.191
ANC4_Log	13	.08738	.755	.616	.968	1.191
DeliveryP_Log	13	.10078	.447	.616	-1.782	1.191
OPDCap_Log	13	.16133	.590	.616	-.375	1.191
AccessWat_Log	13	.11124	-1.701	.616	4.083	1.191
LatrineCover_Log	13	.11452	.758	.616	.993	1.191
HFGovTot_Log	13	.21057	.221	.616	-.400	1.191
HFNGO_Log	11	.31602	1.370	.661	1.405	1.279
MunCHC1_Log	13	.08349	3.606	.616	13.000	1.191
MunCHC2_Log	13	.20968	.346	.616	.029	1.191
MunHp_Log	13	.27131	2.292	.616	6.731	1.191
StaffSrngth_Log	13	.23386	-.100	.616	.789	1.191
Physicians_Log	13	.24023	-.434	.616	.789	1.191
Valid N (listwise)	11					

As the data were not normally distributed, transformation was conducted on the data to compare it with the original data. The transformation of the variables used two approaches, applying the square root for variables with zero square, and log10 for variables which are highly positively skewed.

Table 9-7. Descriptive statistics of the log-transformed continuous dependent and independent variables

To satisfy the application of log10, the variable must satisfy the assumptions that there is no zero or negative values, and it must be positively skewed. Hence, variables with zero were square rooted. Reflection on log10 was conducted by placing the maximum values of the particular variable, adding one, and subtracting the variable itself, and then running the logarithm. A descriptive statistics test for the log-transformed of all continuous dependent and independent variables is presented in Table 9-7 for comparison with the descriptive statistics before the transformation.

9.4.3 The Shapiro-Wilk test

Having run the descriptive statistics and the test of correlation, an independent sample t-test was conducted for dichotomic variables to assess the null hypothesis of no differences in the mean of pharmaceutical expenditures between Municipal Health Services for all dichotomic

variables, urban status, access to municipality, and availability of a regional referral hospital. Independent sample t-testing could not be conducted because there was a violation of the assumptions. The sample size was relatively small, even though it covered all Municipal Health Services in the country. In addition, all the dichotomic variables had only two categories (Yes and No). With a very small sample size of fewer than 50 observations (<50), hence the Shapiro-Wilk test for normality was recommended (Laerd Statistics 2015). The Shapiro-Wilk test was conducted on all three dichotomic variables against the four outcome variables with the original data, and to the data that had been transformed using the logarithm.

Results as observed through the Shapiro-Wilk tests for data distribution for the dichotomic variables against the outcome variables with linearity are displayed in Table 9-8. The null hypothesis of no difference in total primary healthcare expenditure for primary healthcare was rejected for all Municipal Health Services that could be accessed *(p = 0.000);* all municipalities that were considered urban *(p = 0.022);* and that had a regional referral hospital (*p=0.005);* but was not rejected for municipalities that were not considered urban and did not have a regional referral hospital. The null hypothesis for pharmaceutical expenditure per capita, per visit, and per facility for primary healthcare (*p >0.05)* were not rejected for the municipalities that were accessible, rural and urban, and that had and did not have a regional referral hospital.

In order to have a better comparison to the test using original data, the Shapiro-Wilk's test was repeated on the outcome variables that had been transformed using the logarithm. The results of the test showed significance with (*p>0.05)* for all variables. The null hypothesis of no difference in pharmaceutical expenditure between Municipal Health Services based on total pharmaceutical expenditure, per capita pharmaceutical expenditure, per capita visit to OPD, and pharmaceutical expenditure per health facility was not rejected. Details are presented in Table 9-9.

The report from the Shapiro-Wilk test of data distribution for the dichotomic variables for the original (linear-linear) outcome variables and the log-linear outcome variables are summarised in Tables 9-8 and 9-9.

Table 9-8. Summary of Shapiro-Wilk test of normality for linear-linear outcomes

DICHOTOMIC VARIABLES		OUTCOME VARIABLES			
		PHCPETotal	PHCPECapita	PHCPEVisit	PHCPEFacility
Municipal Accessibility (MunAccess)					
No	*n*				
	Mean				
	Std. Deviation				
	Skewness				
	Sig. (Shapiro-Wilk)				
Yes	*n*	13	13	13	13
	Mean	$22,230.91	$0.26	$0.65	$3,947.03
	Std. Deviation	$22,230.91	$0.11	$0.37	$2,120.07
	Skewness	2.866	0.908	0.833	0.956
	Sig. (Shapiro-Wilk)	0.000	0.208	0.484	0.178
	Mean difference	-22230.9138	-0.2643	-0.653	-3947.0273
Urbanisation Status (Urbanisation)					

	n	8	8	8	8
	Mean	$16,754.64	$0.25	$0.73	$3,229.48
No	*Std. deviation*	$5,020.35	$0.07	$0.40	$1,712.42
	Skewness	-0.367	-0.655	0.753	1.045
	Sig. (Shapiro Wilk)	0.88	0.086	0.837	0.133
	n	5	5	5	5
	Mean	$30,992.96	$0.28	$0.52	$5,095.10
Yes	*Std. deviation*	$21,412.38	$0.17	$0.30	$2,382.25
	Skewness	2.018	0.823	0.701	0.811
	Sig. (Shapiro-Wilk)	0.022	0.833	0.779	0.56
	Mean difference	-$14,238.33	-$0.03	$0.21	-$1,865.63
Availability of Regional Referral (Hospital (RRHAvail)					
	n	7	7	7	7
	Mean	$16,635.11	$0.27	$0.81	$3,497.52
No	*Std. deviation*	$5,410.29	$0.06	$0.36	$1,658.48
	Skewness	-0.267	-1.121	1.165	1.062
	Sig. (Shapiro-Wilk)	0.938	0.108	0.368	0.081
	n	6	6	6	6
	Mean	$28,759.35	$0.26	$0.47	$4,471.45
	Std. deviation	$19,917.98	$0.16	$0.30	$2,621.79
Yes	*Skewness*	2.221	1.138	0.939	0.661
	Sig. (Shapiro-Wilk)	0.005	0.556	0.353	0.785
	Mean difference	-$12,124.24	0.0074	0.3444	-973.9284

9.4.4 Optimal statistical modelling for prediction

Having completed the Shapiro-Wilk's test, a multiple nested stepwise regression analysis was conducted on the cross-sectional data on primary healthcare pharmaceutical expenditure for 13 Municipal Health Services in Timor-Leste for fiscal year 2017 as the predicted variable. The value of pharmaceutical expenditure was obtained through conversion of total pharmaceutical consumption for the period using the pharmaceutical procurement values. The regressor data were collected from various government offices: the National Statistical Office, the Ministry of Finance, the Ministry of Health, the State Secretary for Training and Employment, and the Ministry of Public Works.

Table 9-9. Summary of Shapiro-Wilk test of normality for log-linear outcomes

DICHOTOMIC VARIABLES		**OUTCOME VARIABLES**			
		PHCPETotal	PHCPECapita	PHCPEVisit	PHCPEFacility
Municipal Accessibility (MunAccess)					
	N				
	Mean				
No	*Std. Deviation*				
	Skewness				
	Sig. (Shapiro-Wilk)				
	N	13	13	13	13
	Mean	9.877	2.3286	-0.5861	3.5401
Yes	*Std. Deviation*	0.49776	0.01112	0.61846	0.23081
	Skewness	0.884	0.865	-0.487	0.068
	Sig. (Shapiro-Wilk)	0.096	0.23	0.605	0.959
	Mean difference	-9.877	-2.3286	0.5861	-3.5401

Urbanisation Status (Urbanisation)					
	N	8	8	8	8
	Mean	9.6785	2.3275	-0.4564	3.4591
No	*Std. deviation*	0.35187	0.00722	0.6201	0.22072
	Skewness	-1.412	-0.66	-0.83	0.298
	Sig. (Shapiro Wilk)	0.209	0.085	0.759	0.716
	n	5	5	5	5
	Mean	9.4902	2.3305	-0.7936	3.6697
Yes	*Std. deviation*	0.56724	0.01653	0.62219	0.20109
	Skewness	1.421	0.791	-0.321	0.258
	Sig. (Shapiro-Wilk)	0.27	0.851	0.938	0.839
	Mean difference	$0.19	-$0.00	$0.34	-$0.21
Availability of Regional Referral (Hospital (RRHAvail)					
	n	7	7	7	7
	Mean	9.6647	2.329	-0.2848	3.5059
No	*Std. deviation*	0.37771	0.00624	0.41698	0.19072
	Skewness	-1.248	-1.127	0.388	0.695
	Sig. (Shapiro-Wilk)	0.362	0.106	0.84	0.335
	n	6	6	6	6
	Mean	10.1246	2.3282	-0.9375	3.58
Yes	*Std. deviation*	0.53547	0.41698	0.65882	0.28401
	Skewness	1.664	1.111	0.131	-0.499
	Sig. (Shapiro-Wilk)	0.136	0.582	0.539	0.915
	Mean difference	-$0.46	0.0008	0.6527	-0.0741

Nested stepwise regression analysis was conducted to determine if the addition of another variable or group of variables in a block would lead to improvement in the prediction of the total pharmaceutical expenditure for primary healthcare. The 22 continuous independent variables (see Table 9-4) were entered into the four blocks against each outcome variable for analysis to produce the best fit models for pharmaceutical quantification and forecasting.

The four outcome variables, total pharmaceutical expenditure for primary healthcare (PHCPETotal), per capita pharmaceutical expenditure for primary healthcare (PHCPECapita), pharmaceutical expenditure for primary healthcare per visit (PHCPEVisit), and pharmaceutical expenditure for primary healthcare per facility (PHCPEFacility), all are known as the predicted models.

Table 9-10. Explanatory variables

Group	Name in SPSS	Label - description
A. Predisposing factors	1. TotPop	Municipal total population
	2. PercFem	Percentage of female population
B. Enabling factors	1. UrbanStat	Urban status
	2. RuraPov	Rural Poverty Index
	3. LabAbsRate	Labour Absorption rate
	4. LitTotal	Total Literacy Rate
	5. LitFemale	Female Literacy Rate
	6. LitMale	Male Literacy Rate
	7. MunAccess	Accessibility to a Municipality
C. Need for healthcare factor		
	1. OPDCap	Outpatient Department visit per capita
	2. DeliverP	Delivery by health professionals
	3. OPV3	Coverage of Polio-3
	4. BCGCover	Coverage of BCG
	5. ANC4	Coverage of Antenatal care 4th visits

D.	Policy factor	1.	AccessWat	Access to Clean and Safe Water
		2.	LatCover	Coverage of latrine
E.	Health Care resources factors			
	E.1. Facilities	1.	HFGovTotal	Total Government Health Facilities
		2.	HospTotal	Total number of hospitals
		3.	HFNGO	Health facilities operated by NGOs (Non-governmental Organisations)
		4.	RRHAvail	Availability of Regional Referral Hospital
		5.	MunCHC1	Number of Community Health Centre (CHC) – level1
		6.	MunCHC2	Number of Community Health Centre (CHC) – level2
		7.	MunHP	Number of Health Posts
	E.2. Human Resources	1.	StafStrngth	Staff Strength
		2.	Physicians	Staff Strength - Physicians (Physicians

The procedures for the nested stepwise regression test were initiated by entering the predicted variable within the dependent variable (DV) box, and explanatory variables consecutively within the block of independent variables (IV). Every IV, or block of IVs, was entered into the block by hitting next until the desired number of blocks of IV was completed according to the plan. The method of linear regression is set at "Enter". The desired results of the regression were detailed in four out of six linear regression parameters: statistics, options, plots, and options. Within the regression statistics, the test was set to provide calculation on two parameters: the regression coefficient and residuals. In the statistics box, the test was set to calculate the estimates, the confidence intervals were set at 95 per cent, an alpha value of 0.05, model fit, R-Square change, descriptive statistics, part and partial correlation, and collinearity diagnostics. In the residuals sub-section, the test was set to provide the calculation of Durbin-Watson and Casewise diagnostics with three outliers outside of the standard deviations. In the regression plots section, the test was set to display standardised residual plots by selecting histograms, normal probability plots, and 'produce all' partial plots. In the linear regression: the test was set to calculated unstandardised predicted values, studentised and studentised deleted residuals, and Cook and Leverage's distance values. Within the options for the linear regression, the default setting of stepping method of the "use of probability of F" with entry values of 0.05 and removal values of 0.10, inclusion of constant in equation, and exclusion of cases listwise in the mission values, were selected (Laerd Statistics 2015; Pallant 2007).

The results of the nested stepwise regression analysis were based on the summary of the regression model of fit, an ANOVA test, and the coefficient values. The results of the assessment of the assumptions for each predictor group, normality data for each outcome variable, the variable inflation factor (VIF), residual statistic values, and observation of the residuals over a range of values through attention to the heteroscedasticity[25] and homoscedasticity are also presented (Frost 2019; Waterman 2017).

9.4.5 Results of the nested stepwise regression tests

As the test of nested stepwise regression analysis was conducted by having the explanatory variable in blocks according to four categories (predisposing, enabling, healthcare needs, and healthcare resources) against each of the outcome variables of pharmaceutical expenditure for primary healthcare (PHC), the presentation of the results followed this pattern in order, starting

[25] Heteroscedasticity is "a systematic change in the spread of the residuals over the range of measured values", Frost, J. 2019, Heteroscedasticity in regression analysis, (Online), Available: https://statisticsbyjim.com/regression/heteroscedasticity-regression/

with total pharmaceutical expenditure for primary healthcare (PHCPETotal), then pharmaceutical expenditure for PHC per capita (PHCPECapita), followed by pharmaceutical expenditure per capita visit (PHCPEVisit), and finishing with pharmaceutical expenditure for PHC per healthcare facility (PHCPEFacility).

In order to have the best fit models, linear-linear and log linear nested stepwise regression analysis were conducted. For each outcome variable, the presentation of the results was initiated with a linear-linear model followed by a log-linear model until all four outcome variables had been completed. The results are eight comparable principal prediction models consisting of four linear-linear models and four log-linear models. The report of the results is based on the best fit model of the sub-models produced for each outcome variable. Detailed statistical analysis results are displayed in Table 9-12 through to Table 9-43. Please note that the variable of the rural poverty rate has been excluded from all models because it has a constant value for all Municipal Health Services.

Results of the nested stepwise regression analysis revealed that there are two prediction models with high explanatory powers (Models 1, 2, and 5). The details are presented in Table 9-11.

Table 9-11. Summary of prediction models explaining pharmaceutical expenditure in Timor-Leste

	Model 1 PHCPETotal	Model 2 lnPHCPETotal	Model 3 PHCPECapita	Model 4 lnPHCPECapita	Model 5 PHCPEVisit	Model 6 lnPHCPEVisit	Model 7 PHCPEVisit	Model 8 lnPHCPEVisit
Constant	251390.70	7.495	.052	2.308	-1.220	-2.126	3067.275	3.126
Predisposing Factors								
MunTop	.304	0.000E+0*	0.000E+0*	0.000E+0*			.033	
PercFem	-5175.15							
Enabling Factors								
LabourAbsRate								.002
Need for Health Care								
OPDCapita		-.189			.260	.478		
Delivery by professionals					.018			
BCGCover		.035						
Policy Factor								
Healthcare Resources								
HospTotal			-.160	-.016				
HFNGO			-.028	-.003				
PercMunCHC2							-401.106	
MunHP					-.005	-.007		
StaffStrength								.002
StaffStrengthPhy						.002		
N	13	13	13	13	13	13	13	13
F	(1,10) =5.304	(1,9) =17.050	(1,9) =5.652	(1,9) = 5.776	(1,9) = 15.399	(1,9) =11.807	(1,10) = 6.867	(1,10) = 5.347
R^2	.887	.939	.848	.847	.900	.836	.656	.552
Adjusted R^2	.865	.918	.797	.796	.867	.781	.587	.463
Sig.	.044	.003	.041	040	.003	.007	.026	.043

**Though the p-value for the full model is significant, but the individual p-value for the municipal total population was not statistically significant (p>.05) and it is excluded from the prediction model.*

9.4.5.1 Model 1: Linear model of total pharmaceutical expenditure for PHC

Sub-models have been produced for total primary healthcare expenditure, with only two significant variables, total municipal population and percentage of female population. Table 9-12 shows the predictors entered into the equation.

Table 9-12. Model 1, linear-linear model summary[c] for PHCPETotal

	Change Statistics

Model	R	R Square	Adjusted R Square	Standard Error Estimate	R Square Change	F Change	df1	df2	Sig. F Change	Durbin-Watson
1	.910[a]	.828	.812	$6,421.80202	.828	52.875	1	11	.000	
2	.942[b]	.887	.865	$5,444.47816	.060	5.304	1	10	.044	2.186

a. Predictors: (Constant), Municipal total population
b. Predictors: (Constant) Municipal total population, percent of female population

The models presented in Table 9-12 indicated that 89 per cent (.887) of the variance in total pharmaceutical expenditure for primary healthcare can be explained by the total municipal population and percentage of female population. The addition of the percentage of female population to predict total pharmaceutical expenditure for primary healthcare sub-model 2) lead to a subtle decrease in statistical significance, R^2 =.887 F (1, 10) = 5.304, p .044. The full model of total municipal population and percentage of female population to predict total pharmaceutical expenditure for primary healthcare was statistically significant, at R^2 = .887 F (1, 10) = 5.304, p .044, adjusted R^2=.865. The addition of the other 20 predictors were not significant and were excluded from the model.

Table 9-13. Model 1, linear-linear ANOVA[a] of Predisposing factors for PHCPETotal

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	2180536557.15	1	2180536557.15	52.88	.000b
	Residual	453634953.25	11	41239541.21		
	Total	2634171510.40	12			
2	Regression	2337748086.09	2	1168874043.05	39.43	.000c
	Residual	296423424.30	10	29642342.43		
	Total	2634171510.40	12			

a. Dependent Variable: PHC Pharmaceutical Exp_Total
b. Predictors: (Constant), Municipal total population
c. Predictors: (Constant), Municipal total population, Percent of female population

Model 2 has an R^2 of 0.887, indicating that 88.7 per cent of changes in the predictor variables, in this case, total population and percentage of female population, explains the change or variation in the total pharmaceutical expenditure for primary healthcare. The beta values showed that total municipal population remained significant at *p 0.00* and percentage of female population with a p-value of 0.044. The value of B-value (0.304) for the total population indicated that a unit change in the total municipal population will increase the total pharmaceutical expenditure for primary healthcare by 30.4 per cent, while the B-value coefficient of the percentage of the female population has a negative coefficient value indicating that a unit increase in the predictor will on average decrease the value of the total pharmaceutical expenditure for primary healthcare by USD 5,175 (see Table 9-14).

Table 9-14. Model 1, linear-linear Coefficients[a] of predisposing factors for PHCPETotal

		Unstandardized Coefficients		Standardized Coefficients			95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
Model		B	Std. Error	Beta	t	Sig.	Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF*
1	(Constant)	-1686.45	3740.46		-.451	.661	-9919.14	6546.24					
	Municipal total population	.274	.038	.910	7.27	.000	.19	.36	.910	.910	.910	1.000	1.000
2	(Constant)	251390.70	109937.98		2.28	.045	6433.61	496347.78					
	Municipal total population	.304	.035	1.009	8.81	.000	.22	.38	.910	.941	.935	.858	1.165
	Percent of female population	-5175.15	2247.18	-.264	-2.30	.044	-10182.17	-168.13	.116	-.589	-.244	.858	1.165

a. Dependent Variable: PHC Pharmaceutical Exp_Total
*VIF: Variable Inflation Factor

Assessment of the assumptions was conducted next. There was a linear relationship evaluated by partial regression plots and a plot of studentised residuals against the predicted values. There was independence of residuals evaluated by a Durbin-Watson statistical value of 2.186. The assumption of normality was met through visual evaluation of P-P plot. Assessment of the residual statistics showed that there were no studentised deleted residuals greater than ± 3 standard deviations. The value of VIF in the model was 1.165, less than 10.00. Homoscedasticity was observed as assessed by the partial regression plots.

Table 9-15. Linear residuals statistics[a] for model 1- PHCPETotal

	Minimum	Maximum	Mean	Std. Deviation	N
Predicted Value	$10,861.9951	$64,677.0898	$22,230.9138	$13,957.51914	13
Std. Predicted Value	-.815	3.041	.000	1.000	13
Standard Error of Predicted Value	1550.782	5040.173	2451.931	947.429	13
Adjusted Predicted Value	$10,249.5811	$41,399.3242	$20,704.7642	$8,966.25678	13
Residual	-$8,051.59229	$8,241.32520	$0.00000	$4,970.10584	13
Std. Residual	-1.479	1.514	.000	.913	13
Stud. Residual	-1.678	1.887	.069	1.131	13
Deleted Residual	-$10,370.12207	$27,162.07617	$1,526.14968	$9,811.18572	13
Stud. Deleted Residual	-1.879	2.230	.081	1.233	13
Mahal. Distance	.051	9.361	1.846	2.499	13
Cook's Distance	.001	7.110	.630	1.951	13
Centered Leverage Value	.004	.780	.154	.208	13

a. Dependent Variable: PHC Pharmaceutical expenditure (Total)

9.4.5.2 Model 2: Log-linear model of total pharmaceutical expenditure for PHC

When it comes to the analysis of total pharmaceutical expenditure for primary healthcare where the outcome variable has been log transformed, the test returned three models compared to Model 1 with different variables. The models presented in Table 9-16 revealed that 94 per cent (.939) of the variance in the log transformed total pharmaceutical expenditure for primary healthcare was explained by total municipal population, coverage of BCG vaccination, and OPD visit per capita (see Table 9-16).

Table 9-16. Linear summary[d] model for LnPHCPETotal – Model 2

					Change Statistics				
Model	R	R^2	Adjusted R^2	Std. Error of the estimate	R^2 Change	F Change	df1	df2	Sig.F Change	Durbin-Watson
1	.841a	.708	.681	.28100	.708	26.654	1	11	.000	
2	.907b	.823	.787	.22946	.115	6.497	1	10	.029	
3	.969c	.939	.918	.14217	.116	17.050	1	9	.003	1.731

a. Predictors: (Constant), Municipal total population
b. Predictors: (Constant), Municipal total population, Coverage of BCG
c. Predictors: (Constant), Municipal total population, Coverage of BCG, OPD Visit per capita
d. Dependent Variable: LnPHCPETotal

Addition of the coverage of BCG vaccination, and OPD visit per capita to predict total pharmaceutical expenditure for primary healthcare sub-model 3 resulted in statistical significance of R^2 =.939 F(1, 9) = 17.050, *p 0.003.* The full model of total municipal population, coverage of BCG vaccination, and OPD visit per capita to predict total pharmaceutical expenditure for primary healthcare was statistically significant, R^2 = .939 F(1, 9) = 17.050, p

.003, adjusted R^2=.918. The addition of the other 19 predictors were not significant and were excluded from the model.

Table 9-17. Log-linear ANOVA [a] of LnPHCPETotal – Model 2

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	2.105	1	2.105	26.654	.000b
	Residual	.869	11	.079		
	Total	2.973	12			
2	Regression	2.447	2	1.223	23.235	.000c
	Residual	.527	10	.053		
	Total	2.973	12			
3	Regression	2.791	3	.930	46.034	.000d
	Residual	.182	9	.020		
	Total	2.973	12			

a. Dependent Variable: LnPHCPETotal
b. Predictors: (Constant), Municipal total population
c. Predictors: (Constant), Municipal total population, Coverage of BCG
d. Predictors: (Constant), Municipal total population, Coverage of BCG, OPD Visit per capita

Sub-model 3 of Model 2 has an R^2 of 0.939, indicating that 94 per cent of the change in the predictor variables, in this case the total population, coverage of BCG vaccination, and OPD visits per capita, explains the variation in total pharmaceutical expenditure for primary healthcare. The log-linear coefficient values of the LnPHCPETotal (see Table 9-18) showed that the p-value of the total municipal population was insignificant at *p 0.*361, and the addition of the two other variables, BCG coverage and OPD visit per capital, brought significant p-value to the overall model with a *p-value of 0.003.* The value of B-value (0.035) for BCG[26] coverage indicated that a unit change in the percentage of the coverage of the BCG vaccination will increase the total pharmaceutical expenditure for primary healthcare by 3.5 per cent. While the B-value coefficient of OPD per capita visit (-0.189) has a negative coefficient indicating that a unit increase in the predictor will decrease the value of the total pharmaceutical expenditure for primary healthcare by 19 per cent. The log-linear model for total pharmaceutical expenditure is the best of the two models for the PHCPETtotal because it covers one predisposing factor and two healthcare needs factors.

Table 9-18. Log-linear coefficients[a] of LnPHCPETotal – Model 2

		Unstandardised Coefficients		Standardised Coefficients			95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
Model		B	Std. Error	Beta	t	Sig.	Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
1	(Constant)	9.134	.164		55.806	.000	8.774	9.494					
	Municipal total population	0.000E+0	.000	.841	5.163	.000	.000	.000	.841	.841	.841	1.000	1.000
2	(Constant)	7.557	.633		11.939	.000	6.147	8.967					
	Municipal total population	0.000E+0	.000	.412	1.919	.084	.000	.000	.841	.519	.255	.384	2.603
	Coverage of BCG	.025	.010	.547	2.549	.029	.003	.047	.870	.628	.339	.384	2.603
3	(Constant)	7.495	.392		19.100	.000	6.608	8.383					
	Municipal total population	0.000E+0	.000	.143	.963	.361	.000	.000	.841	.306	.079	.310	3.228
	Coverage of BCG	.035	.007	.761	5.332	.000	.020	.050	.870	.872	.440	.334	2.998
	OPD Visit per capita	-.189	.046	-.379	-4.129	.003	-.292	-.085	-.412	-.809	-.340	.806	1.240

a. Dependent Variable: LnPHCPETotal

[26] BCG: Bacillus Calmette Guerin is a vaccine provided to children under one year of age to prevent tuberculosis

Assessment of the assumptions was conducted (see Table 9-19). There was a positive linear relationship for BCG evaluated by partial regression plots and a plot of studentised residuals against the predicted values and negative linear relationship noted for OPD visit per capita. There was independence of residuals evaluated by a Durbin-Watson statistical value of 2.799. The assumption of normality was met through visual evaluation of P-P plot. Assessment of the residual statistics showed that there were no studentised deleted residuals greater than ± 3 standard deviations. The value of VIF in the model was less than 10.00; 1.240 for OPD visit per capita, and 2.998 for BCG. A homoscedasticity was observed as assessed by the partial regression plots.

Table 9-19. Log-Linear Residual Statistics [a] of LnPHCPETotal – Model 2

	Minimum	Maximum	Mean	Std. Deviation	N
Predicted Value	9.2043	11.1993	9.8770	.48229	13
Std. Predicted Value	-1.395	2.742	.000	1.000	13
Standard Error of Predicted Value	.043	.126	.076	.023	13
Adjusted Predicted Value	9.3242	11.4332	9.8982	.54171	13
Residual	-.27647	.14370	.00000	.12312	13
Std. Residual	-1.945	1.011	.000	.866	13
Stud. Residual	-2.329	1.140	-.048	1.063	13
Deleted Residual	-.39638	.18267	-.02128	.19670	13
Stud. Deleted Residual	-3.482	1.162	-.143	1.295	13
Mahal. Distance	.190	8.504	2.769	2.377	13
Cook's Distance	.000	.862	.186	.278	13
Cantered Leverage Value	.016	.709	.231	.198	13

a. Dependent Variable: LnPHCPETotal

9.4.5.3 Model 3: Linear model of pharmaceutical expenditure for PHC per capita visit

Examination of the assumptions for the linear model for pharmaceutical expenditure per capita visit displayed a linearity observed through normal P-P plot for regression standard residual. Total municipal population returned a positive linearity, while total hospital and health facility run by NGOs showed a negative linearity. A normal distribution of the data was assessed by a histogram of residual standard regression. There was a homoscedastic as assessed through partial regression plots for all predictors. There was no collinearity found as assessed by the tolerance value of the collinearity statistics. The value of variable inflation factors (VIF) was less than 10 (2.799) as noted in Model 3 in Table 9-20. Cook's Distance maximum value was observed at 1.370 (slightly higher than 1.00). No-autocorrelation was assessed by Durbin-Watson value 2.799. Standard residual values were within the range of -1.870 and 1.582. Details of these observations are presented in Table 9-23.

Table 9-20. Linear Model Summary[d] model of PHCPECapita – Model 3

Mode				Std. Error	Change Statistics					
l	R	R Square	Adjusted R Square	of the Estimate	R Square Change	F Change	df1	df2	Sig. F Change	Durbin-Watson
1	.781a	.610	.574	$0.07482	.610	17.183	1	11	.002	
2	.867b	.752	.702	$0.06258	.142	5.724	1	10	.038	
3	.921c	.848	.797	$0.05170	.096	5.652	1	9	.041	2.799

a. Predictors: (Constant), Municipal total population

b. Predictors: (Constant), Municipal total population, Total Hospitals

c. Predictors: (Constant), Municipal total population, Total Hospitals, NGO health facilities

d. Dependent Variable: PHC Pharmaceutical Expenditure per capita

A nested stepwise regression was run to determine whether adding one independent variable or a block of predictor variables to the prediction of total pharmaceutical expenditure for primary healthcare would return a statistically significant result. Values of R^2, ANOVA, and coefficients revealed the results displayed in Tables 9-21, 9-22, and 9-23.

Table 9-21. Linear ANOVA[a] for PHCPECapita – Model 3

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	.096	1	.096	17.183	.002b
	Residual	.062	11	.006		
	Total	.158	12			
2	Regression	.119	2	.059	15.144	.001c
	Residual	.039	10	.004		
	Total	.158	12			
3	Regression	.134	3	.045	16.676	.001d
	Residual	.024	9	.003		
	Total	.158	12			

a. Dependent Variable: PHC Pharmaceutical Expenditure per capita
b. Predictors: (Constant), Municipal total population
c. Predictors: (Constant), Municipal total population, Total Hospitals
d. Predictors: (Constant), Municipal total population, Total Hospitals, NGO health facilities

Sub-model 3 of linear Model 3 (PHCPEcapita) in Table 9-20 indicated that 85 per cent (.848) of the variance in total pharmaceutical expenditure for primary healthcare can be explained by total municipal population and percentage of female population. The addition of the percentage of total hospitals and health facilities operated by the NGOs to predict total pharmaceutical expenditure for primary healthcare in Model 3 lead to a subtle decrease in statistical significance $R^2 = .848\ F(1, 9) = 5.652,\ p\ .041$. The full model of total municipal population, total hospitals, and healthcare facilities operated by NGOs to predict total pharmaceutical expenditure for primary healthcare was statistically significant, $R^2 = .848\ F(1, 9) = 5.304,\ p\ .041$, adjusted $R^2 = .797$. The addition of the other 19 predictors was not significant and so they were excluded from the model.

Table 9-22. Linear Coefficients for PHCPECapita – Model 3

Model		Unstandardized Coefficients		Standardized Coefficients			95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
		B	Std. Error	Beta	t	Sig.	Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
1	(Constant)	.105	.044		2.419	.034	.010	.201					
	Municipal total population	0.000E+0	.000	.781	4.145	.002	.000	.000	.781	.781	.781	1.000	1.000
2	(Constant)	.114	.037		3.110	.011	.032	.196					
	Municipal total population	0.000E+0	.000	.945	5.499	.000	.000	.000	.781	.867	.866	.840	1.190
	Total Hospitals	-.091	.038	-.411	-2.393	.038	-.176	-.006	-.033	-.603	-.377	.840	1.190
3	(Constant)	.052	.040		1.299	.226	-.038	.142					
	Municipal total population	0.000E+0	.000	1.827	4.601	.001	.000	.000	.781	.838	.599	.108	9.301
	Total Hospitals	-.160	.043	-.724	-3.740	.005	-.257	-.063	-.033	-.780	-.487	.452	2.210
	NGO health facilities	-.028	.012	-.866	-2.377	.041	-.056	-.001	.696	-.621	-.309	.128	7.830

a. Dependent Variable: PHC Pharmaceutical Expenditure per capita

The predictors of total hospitals and health facilities operated by NGOs had negative coefficients -0.160 and -0.028, indicating that one unit increase in these health facilities will lead to a decrease in pharmaceutical expenditure for primary healthcare per capita. For example, an increase in the number of hospitals in a municipal health service area will lead to a decrease in pharmaceutical expenditure of 3 per cent (-0.028), whereas total municipal population displayed a positive coefficient, indicating that one unit increase in the total population lead to an increase in pharmaceutical expenditure for primary healthcare per capita.

Table 9-23. Linear Residuals Statistics[a] for PHCPECapita – Model 3

	Minimum	Maximum	Mean	Std. Deviation	N
Predicted Value	$0.1133	$0.5189	$0.2643	$0.10555	13
Std. Predicted Value	-1.430	2.412	.000	1.000	13
Standard Error of Predicted Value	.020	.045	.028	.008	13
Adjusted Predicted Value	$0.1280	$0.4420	$0.2648	$0.10028	13
Residual	-$0.09668	$0.07397	$0.00000	$0.04477	13
Std. Residual	-1.870	1.431	.000	.866	13
Stud. Residual	-2.542	1.582	-.014	1.093	13
Deleted Residual	-$0.17866	$0.10925	-$0.00057	$0.07515	13
Stud. Deleted Residual	-4.515	1.755	-.147	1.543	13
Mahal. Distance	.794	8.158	2.769	2.184	13
Cook's Distance	.002	1.370	.212	.414	13
Centered Leverage Value	.066	.680	.231	.182	13

a. Dependent Variable: PHC Pharmaceutical Expenditure per capita

9.4.5.4 Model 4: Log-linear Model of Pharmaceutical Expenditure for PHC Per Capita

While the percentage of change variation of p-values in Model 3 (PHCPECapita) was well explained by a predisposing factor, the remaining two significant variables were from the healthcare resources and the total hospitals and healthcare facilities managed by the NGOs. The percentage and magnitude of changes of pharmaceutical expenditure in Model 4 – log-linear model (LnPHCPECapita) can be explained by exactly the same predictors (Table 9-24).

Table 9-24. Log-linear summary[d] model for LnPHCPECapita – Model 4

					Change Statistics					
Model	R	R^2	Adjusted R^2	Std. Error of the estimate	R^2 Change	F Change	df1	df2	Sig.F Change	Durbin-Watson
1	.777a	.604	.568	.00731	.604	16.805	1	11	.002	
2	.865b	.749	.699	.00611	.144	5.752	1	10	.037	
3	.920c	.847	.796	.00502	.098	5.776	1	9	.040	2.803

a. Predictors: (Constant), Municipal total population
b. Predictors: (Constant), Municipal total population, Total Hospitals
c. Predictors: (Constant), Municipal total population, Total Hospitals, NGO health facilities
d. Dependent Variable: LnPHCPECapita

Table 9-24 indicates that 75 per cent (.749) of the variance in total pharmaceutical expenditure for primary healthcare can be explained by total municipal population and percentage of female population. The addition of the predictors of total hospitals and health facilities operated by NGOs to predict total pharmaceutical expenditure for primary healthcare Model 3 lead to increased variability of 10 per cent from 75 to 85 per cent, but a subtle decrease in statistical

significance R^2 =.847 *F(1, 9)* = 5.776, *p .040*. The full model of total municipal population and total hospitals and health facilities operated by NGOs to predict total pharmaceutical expenditure for primary healthcare was statistically significant, R^2 = .847 *F (1, 9) = 5.776, p .040*, adjusted R^2=.796. The addition of the other 19 predictors was not significant and so they were excluded from the model.

Table 9-25. Log-linear ANOVA [a] of for LnPHCPECapita – Model 4

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	.001	1	.001	16.805	.002b
	Residual	.001	11	.000		
	Total	.001	12			
2	Regression	.001	2	.001	14.909	.001c
	Residual	.000	10	.000		
	Total	.001	12			
3	Regression	.001	3	.000	16.612	.001d
	Residual	.000	9	.000		
	Total	.001	12			

a. Dependent Variable: LnPHCPECapita
b. Predictors: (Constant), Municipal total population
c. Predictors: (Constant), Municipal total population, Total Hospitals
d. Predictors: (Constant), Municipal total population, Total Hospitals, NGO health facilities

Unstandardised coefficients B-value of total hospital and health facilities run by NGOs displayed negative coefficients resulting in a one unit increase in the total of these health facilities in a municipality which leads to a decrease in pharmaceutical expenditure per capita in a municipal health service by 1.6% and 0.3%, respectively.

Table 9-26. Log linear coefficients a of Ln for LnPHCPECapita – Model 4

		Unstandardized Coefficients		Standardised Coefficients			95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
Model		B	Std. Error	Beta	t	Sig.	Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
1	(Constant)	2.313	.004		543.433	.000	2.304	2.323					
	Municipal total population	0.000E+0	.000	.777	4.099	.002	.000	.000	.777	.777	.777	1.000	1.000
2	(Constant)	2.314	.004		647.483	.000	2.306	2.322					
	Municipal total population	0.000E+0	.000	.943	5.455	.000	.000	.000	.777	.865	.865	.840	1.190
	Total Hospitals	-.009	.004	-.415	-2.398	.037	-.017	-.001	-.037	-.604	-.380	.840	1.190
3	(Constant)	2.308	.004		594.513	.000	2.299	2.317					
	Municipal total population	0.000E+0	.000	1.836	4.617	.001	.000	.000	.777	.839	.602	.108	9.301
	Total Hospitals	-.016	.004	-.731	-3.772	.004	-.025	-.006	-.037	-.783	-.492	.452	2.210
	NGO health facilities	-.003	.001	-.877	-2.403	.040	-.005	.000	.693	-.625	-.313	.128	7.830

a. Dependent Variable: LnPHCPETotal

Evaluation of the assumptions for a linear model for pharmaceutical expenditure per capita visit displayed a linearity observed through normal P-P plot for regression standard residual. Total municipal population returned a positive linearity, while total hospital and health facility run by NGOs showed negative linearity. A normal distribution of the data as assessed by a histogram of residual standard regression showed a normal distribution. There was a homoscedastic as assessed through partial regression plots for all predictors. There was no collinearity found as assessed by the tolerance value of the collinearity statistics. The value of VIF (Variable Inflation Factors) was less than 10 (7.830), as noted in sub-model 3 (see Table 9-26). Cook's Distance, maximum value was observed at 1.356 (slightly higher than 1.00). There was no-autocorrelation as assessed by Durbin-Watson value 1.585. Standard residual values are within the range of -1.870 and 1.582. Details of the observation are presented in Table 9-27.

Table 9-27. Log-Linear Residual Statistics[a] of for LnPHCPECapita – Model 4

	Minimum	Maximum	Mean	Std. Deviation	N
Predicted Value	2.3139	2.3532	2.3286	.01024	13
Std. Predicted Value	-1.440	2.402	.000	1.000	13
Standard Error of Predicted Value	.002	.004	.003	.001	13
Adjusted Predicted Value	2.3153	2.3458	2.3287	.00975	13
Residual	-.00935	.00727	.00000	.00435	13
Std. Residual	-1.861	1.447	.000	.866	13
Stud. Residual	-2.529	1.600	-.015	1.089	13
Deleted Residual	-.01727	.01024	-.00007	.00725	13
Stud. Deleted Residual	-4.434	1.783	-.143	1.524	13
Mahal. Distance	.794	8.158	2.769	2.184	13
Cook's Distance	.002	1.356	.206	.404	13
Cantered Leverage Value	.066	.680	.231	.182	13

a. Dependent Variable: LnPHCPECapita

Considering the explanatory power and p-value values between linear Model 3-PHCPECapita and Model 4: LnPHCPECapita, the latter is the best out of the two, although there are slight differences in their values.

9.4.5.5 Model 5: Linear model of pharmaceutical expenditure for PHC per visit

The nested stepwise regression test on Model 5: linear model for PHCPE per OPD visit (see Table 9-28) produced three sub-models. Overall, Model 5 (linear-linear model) consisted of two healthcare needs variables and one healthcare resource.

Table 9-28. Linear summary[d] model for PHCPEVisit – Model 5

					Change Statistics					
Model	R	R^2	Adjusted R^2	Std. Error of the estimate	R^2 Change	F Change	df1	df2	Sig.F Change	Durbin-Watson
1	.745a	.555	.515	$0.25433	.555	13.744	1	11	.003	
2	.854b	.730	.676	$0.20787	.175	6.466	1	10	.029	
3	.949c	.900	.867	$0.13308	.170	15.399	1	9	.003	1.585

a. Predictors: (Constant), OPD Visit per capita
b. Predictors: (Constant), OPD Visit per capita, Coverage of BCG
c. Predictors: (Constant), OPD Visit per capita, Coverage of BCG, Number of Health Posts
d. Dependent Variable: PHC Pharmaceutical Expenditure per Visit

Table 9-29. Linear ANOVA[a] of for PHCPEVisit – Model 5

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	.889	1	.889	13.744	.003b
	Residual	.712	11	.065		
	Total	1.601	12			
2	Regression	1.168	2	.584	13.520	.001c
	Residual	.432	10	.043		
	Total	1.601	12			
3	Regression	1.441	3	.480	27.125	.000d
	Residual	.159	9	.018		
	Total	1.601	12			

a. Dependent Variable: PHC Pharmaceutical Expenditure per Visit
b. Predictors: (Constant), OPD Visit per capita
c. Predictors: (Constant), OPD Visit per capita, Coverage of BCG
d. Predictors: (Constant), OPD Visit per capita, Coverage of BCG, Number of Health Posts

Table 9-28 indicates that 90 per cent (0.900) of the variance in the pharmaceutical expenditure for primary healthcare per visit can be explained by OPD visit per capita, BCG coverage, and number of health posts, to predict pharmaceutical expenditure led to statistical significance of R^2 *=0.900 F(1, 9) =15.399, p 0.003*.

The full model of OPD visit per capita, BCG coverage, and number of health posts to predict total pharmaceutical expenditure per visit was statistically significant, R^2*= 0.900, F(1, 9)= 15.399, p-value of 0.003*, adjusted R^2*=0.867.* The addition of the other 19 predictors was not significant and so were excluded from the model.

Table 9-30. Linear coefficients[a] for PHCPEVisit – Model 5

Model		Unstandardised Coefficients		Standardised Coefficients			95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
		B	Std. Error	Beta	t	Sig.	Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
1	(Constant)	-.018	.194		-.095	.926	-.446	.409					
	OPD Visit per capita	.272	.073	.745	3.707	.003	.110	.433	.745	.745	.745	1.000	1.000
2	(Constant)	-1.112	.458		-2.426	.036	-2.133	-.090					
	OPD Visit per capita	.271	.060	.742	4.518	.001	.137	.404	.745	.819	.742	1.000	1.000
	Coverage of BCG	.014	.006	.418	2.543	.029	.002	.026	.423	.627	.418	1.000	1.000
3	(Constant)	-1.220	.295		-4.140	.003	-1.887	-.554					
	OPD Visit per capita	.260	.038	.713	6.765	.000	.173	.347	.745	.914	.712	.995	1.005
	Coverage of BCG	.018	.004	.520	4.801	.001	.009	.026	.423	.848	.505	.942	1.062
	Number of Health Posts	-.005	.001	-.426	-3.924	.003	-.007	-.002	-.349	-.794	-.413	.938	1.066

a. Dependent Variable: PHC Pharmaceutical Expenditure per Visit

The p-value value of sub-model 3 of Model 5: PHCPEVisit is statistically significant (p 0.003), with both OPD visit per capita and coverage of BCG returning positive coefficient values at 0.260 and 0.018 respectively (see Table 9-30). An increase in one unit of these two predictors indicated an increase in the percentage of pharmaceutical expenditure. For example, an increase in the OPD visit per capita will lead to an increase of the pharmaceutical budget by 25 per cent. Predictors of number of health posts displayed a negative coefficient, -0.005, meaning that an increase in one unit of health posts in a municipality would lead to a decrease in pharmaceutical expenditure by 0.5 per cent.

Table 9-31. Linear Residual Statistics[a] for PHCPEVisit – Model 5

	Minimum	Maximum	Mean	Std. Deviation	N
Predicted Value	$0.2174	$1.3371	$0.6530	$0.34655	13
Std. Predicted Value	-1.257	1.974	.000	1.000	13

Standard Error of Predicted Value	.041	.131	.068	.030	13
Adjusted Predicted Value	$0.2471	$1.3762	$0.7581	$0.38614	13
Residual	-$0.19321	$0.20001	$0.00000	$0.11525	13
Std. Residual	-1.452	1.503	.000	.866	13
Stud. Residual	-1.645	1.656	-.125	1.127	13
Deleted Residual	-$1.18783	$0.32561	-$0.10516	$0.37837	13
Stud. Deleted Residual	-1.855	1.873	-.134	1.230	13
Mahal. Distance	.196	10.784	2.769	3.427	13
Cook's Distance	.002	19.432	1.725	5.341	13
Cantered Leverage Value	.016	.899	.231	.286	13

a. Dependent Variable: PHC Pharmaceutical Expenditure per Visit

Observations of the assumptions for linear Model-5: pharmaceutical expenditure per capita visit, displayed a linearity observed through normal P-P plot for regression standard residual. Number of health posts returned a negative linearity, while OPD visit per capita and BCG coverage showed positive linearity. A normal distribution of the data was assessed by a histogram of residual standard regression. There was a homoscedastic as assessed through partial regression plots for all predictors. There was no collinearity found as assessed by the tolerance value of the collinearity statistics. The value of VIF (Variable Inflation Factors) was low (1.006). No autocorrelation was assessed by Durbin-Watson value 1.585. Standard residual values were within the normal range of -1.452 and 1.503. Details of these observations are presented in Tables 9-30 and 9-31.

9.4.5.6 Model 6: Log-linear model of pharmaceutical expenditure for PHC per capita visit

The statistical analysis of the logarithmic transformation of the outcome variable pharmaceutical expenditure per capita visit to OPD has all the predictors from the category of health resources, OPD visit per capita, number of health posts, and number of physicians (see Table 9-32), with three sub-models compared to model 5 – PHCPEVisit, which has one healthcare need predictor, BCG coverage (see Table 9-30).

Table 9-32. Log-linear summary[d] model for LnPHCPEVisit – Model 6

						Change Statistics				
Model	R	R^2	Adjusted R^2	Std. Error of the estimate	R^2 Change	F Change	df1	df2	Sig.F Change	Durbin-Watson
1	.653[a]	.426	.374	.48948	.426	8.157	1	11	.016	
2	.788[b]	.621	.545	.41725	.195	5.138	1	10	.047	
3	.914[c]	.836	.781	.28926	.215	11.807	1	9	.007	1.954

a. Predictors: (Constant), OPD Visit per capita
b. Predictors: (Constant), OPD Visit per capita, Number of Health Posts
c. Predictors: (Constant), OPD Visit per capita, Number of Health Posts, Number of Physicians
d. Dependent Variable: LnPHCPEVisit

Table 9-32 indicated that 84 per cent (0.836) of the variance in the pharmaceutical expenditure for primary healthcare per capita visit can be explained by OPD visit per capita, number of health posts, and number of physicians to predict pharmaceutical expenditure, leading to statistical significance of $R^2 = 0.836\ F(1, 9) = 11.807,\ p\ 0.007$.

The full model of OPD visit per capita, OPD visit per capita, number of health posts, and number of physicians to predict total pharmaceutical expenditure per visit was statistically significant, $R^2 = 0.836$ $F(1, 9) = 11.807$, p 0.007, adjusted $R^2 = 0.781$. The addition of the other 19 predictors was not significant and so they were excluded from the model.

Table 9-33. Log-linear ANOVA[a] of for LnPHCPEVisit – Model 6

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	1.954	1	1.954	8.157	.016b
	Residual	2.636	11	.240		
	Total	4.590	12			
2	Regression	2.849	2	1.424	8.182	.008c
	Residual	1.741	10	.174		
	Total	4.590	12			
3	Regression	3.837	3	1.279	15.285	.001d
	Residual	.753	9	.084		
	Total	4.590	12			

a. Dependent Variable: LnPHCPEVisit
b. Predictors: (Constant), OPD Visit per capita
c. Predictors: (Constant), OPD Visit per capita, Number of Health Posts
d. Predictors: (Constant), OPD Visit per capita, Number of Health Posts, Number of Physicians

The p-value of the full Model 6: LnPHCPEVisit is statistically significant (p 0.007) with both OPD visit per capita and number of physicians returning positive coefficient values at 0.478 and 0.011, respectively, which means that an increase in one unit of these two predictors indicated an increase in the percentage of pharmaceutical expenditure. For example, an increase in OPD visits per capita will lead to an increase in the pharmaceutical budget by 48 per cent. Predictors of number of health posts displayed a negative coefficient value of -0.007, meaning that an increase in one unit of health posts in a municipality leads to a decrease in pharmaceutical expenditure by 0.7 per cent (see details in Table 9-34).

Table 9-34. Log-linear coefficients[a] of Ln for LnPHCPEVisit – Model 6

		Unstandardised Coefficients		Standardised Coefficients			95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
Model		B	Std. Error	Beta	t	Sig.	Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
1	(Constant)	-1.582	.374		-4.228	.001	-2.405	-.758					
	OPD Visit per capita	.403	.141	.653	2.856	.016	.092	.714	.653	.653	.653	1.000	1.000
2	(Constant)	-1.301	.342		-3.803	.003	-2.063	-.539					
	OPD Visit per capita	.385	.121	.623	3.193	.010	.116	.654	.653	.711	.622	.996	1.004
	Number of Health Posts	-.008	.004	-.442	-2.267	.047	-.017	.000	-.484	-.583	-.441	.996	1.004
3	(Constant)	-2.126	.338		-6.299	.000	-2.890	-1.363					
	OPD Visit per capita	.478	.088	.773	5.437	.000	.279	.676	.653	.876	.734	.902	1.109
	Number of Health Posts	-.007	.003	-.387	-2.837	.019	-.013	-.001	-.484	-.687	-.383	.982	1.019
	Number of Physicians	.012	.003	.490	3.436	.007	.004	.020	.295	.753	.464	.898	1.113

a. Dependent Variable: LnPHCPEVisit

Observation of the assumptions for linear Model-6: LnPHCPEVisit displayed a linearity observed through normal P-P plot for regression standard residual. Number of health posts returned a negative linearity, while OPD visit per capita and number of physicians showed positive linearities. There was a normal distribution of the data as assessed by a histogram of

residual standard regression. There was a homoscedastic as assessed through partial regression plots for all predictors. There was no collinearity as assessed by the tolerance value of the collinearity statistics. The VIF (Variable Inflation Factors) for the overall model was low (1.113). No autocorrelation was assessed by Durbin-Watson value 1.954 (see Table 9-32). Standard residual values were within the normal range of -1.501 and 1.611. Details of these observations are presented in Tables 9-32 and 9-35.

Table 9-35. Log-Linear Residual Statistics[a] of for LnPHCPEVisit – Model 6

	Minimum	Maximum	Mean	Std. Deviation	N
Predicted Value	-1.6148	.5884	-.5861	.56546	13
Std. Predicted Value	-1.819	2.077	.000	1.000	13
Standard Error of Predicted Value	.088	.286	.150	.060	13
Adjusted Predicted Value	-1.0223	.8667	-.3874	.57976	13
Residual	-.43416	.46597	.00000	.25051	13
Std. Residual	-1.501	1.611	.000	.866	13
Stud. Residual	-1.828	1.751	-.126	1.046	13
Deleted Residual	-2.19264	.55059	-.19870	.68838	13
Stud. Deleted Residual	-2.173	2.033	-.137	1.149	13
Mahal. Distance	.181	10.780	2.769	3.113	13
Cook's Distance	.000	14.008	1.168	3.861	13
Cantered Leverage Value	.015	.898	.231	.259	13

a. Dependent Variable: LnPHCPEVisit

A comparison of p-values, R-Square values lead to model 6 -LnPHCPEVisit as the preferred prediction model for pharmaceutical expenditure for primary healthcare per capita visit. This engaged one predictor from the healthcare needs category and two from the healthcare resources category (Tables 9-32 and 9-34).

9.4.5.7 Model 7: Linear model of pharmaceutical expenditure for PHC per facility

A nested stepwise linear-linear regression test on Model 7: PHCPEFacility yielded two sub-models consisting of two predictors, one from the predisposing factors and another explanatory variable from the health resources factors. The addition of the latest variables led to a significant model for predicting pharmaceutical expenditures per facility. See Table 9-36 for details.

Table 9-36. Linear summary[c] model for PHCPEFacility – Model 7

						Change Statistics				
Model	R	R^2	Adjusted R^2	Std. Error of the estimate	R^2 Change	F Change	df1	df2	Sig.F Change	Durbin-Watson
1	.648a	.420	.367	$1,687.08552	.420	7.950	1	11	.017	
2	.810b	.656	.587	$1,362.43992	.236	6.867	1	10	.026	2.326

a. Predictors: (Constant), Municipal total population
b. Predictors: (Constant), Municipal total population, Municipal CHC level 2
c. Dependent Variable: PHC Pharmaceutical Expenditure per facility

Table 9-37. Linear ANOVA[a] of for PHCPEFacility – Model 7

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	22627775.120	1	22627775.120	7.950	.017[b]
	Residual	31308833.253	11	2846257.568		
	Total	53936608.373	12			
2	Regression	35374182.910	2	17687091.455	9.528	.005[c]
	Residual	18562425.464	10	1856242.546		
	Total	53936608.373	12			

3	Regression	22627775.120	1	22627775.120	7.950	.017[b]
	Residual	31308833.253	11	2846257.568		
	Total	53936608.373	12			

a. Dependent Variable: PHC Pharmaceutical Expenditure per facility
b. Predictors: (Constant), Municipal total population
c. Predictors: (Constant), Municipal total population, Municipal CHC level 2

Table 9-36 indicates that 66 per cent (0.656) of the variance in pharmaceutical expenditure for primary healthcare per facility can be explained by municipal total population and Community Health Centre (CHC) level 2 to predict pharmaceutical expenditure, leading to statistical significance of R^2 *=0.656 F(1, 10) =6.867, p 0.026.*
Full model municipal total population and Community Health Centre (CHC) level 2 to predict total pharmaceutical expenditure per health facility was statistically significant, R^2 *=0.656 F(1, 10) =6.867, p 0.026,* adjusted R^2*=0.587.* The addition of the other 20 predictors was not significant, and so they were excluded from the model.

Table 9-38. Linear coefficients[a] for PHCPEFacility – Model 7

Model		Unstandardised Coefficients		Standardised Coefficients			95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
		B	Std. Error	Beta	t	Sig.	Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
1	(Constant)	1510.605	982.664		1.537	.152	-652.223	3673.433					
	Municipal total population	.028	.010	.648	2.820	.017	.006	.050	.648	.648	.648	1.000	1.000
2	(Constant)	3067.275	991.284		3.094	.011	858.557	5275.993					
	Municipal total population	.033	.008	.767	4.015	.002	.015	.051	.648	.786	.745	.943	1.060
	Municipal CHC level 2	-401.106	153.067	-.501	-2.620	.026	-742.160	-60.051	-.318	-.638	-.486	.943	1.060

a. Dependent Variable: PHC Pharmaceutical Expenditure per facility

The p-value of the full Model 7: PHCPEFacility was statistically significant *(p 0.26)* with municipal total populations returning a positive coefficient value of 0.033 and municipal CHC level 2 with a negative coefficient value of -401.106. These two have different implications for the prediction of pharmaceutical expenditure per health facility. For example, an increase in one unit of total municipal population will lead to an increase in pharmaceutical expenditure per facility by 3 per cent, while an increase in one unit of CHC level 2 led to an average decrease in pharmaceutical expenditure by USD 402.11 (see details in Table 9-38).

Table 9-39. Linear Residual Statistics [a] of for PHCPEFacility – Model 7

	Minimum	Maximum	Mean	Std. Deviation	N
Predicted Value	$342.9779	$7,779.4751	$3,947.0273	$1,716.92999	13
Std. Predicted Value	-2.099	2.232	.000	1.000	13
Standard Error of Predicted Value	415.783	1196.441	601.214	269.223	13
Adjusted Predicted Value	-$3,061.3701	$5,817.9546	$3,503.8257	$2,167.74711	13
Residual	-$2,300.74097	$1,816.05151	$0.00000	$1,243.73180	13
Std. Residual	-1.689	1.333	.000	.913	13
Stud. Residual	-1.812	1.550	.105	1.091	13
Deleted Residual	-$2,648.444	$4,414.548	$443.202	$2,051.351	13
Stud. Deleted Residual	-2.097	1.687	.108	1.169	13
Mahal. Distance	.195	8.331	1.846	2.867	13
Cook's Distance	.000	2.699	.363	.797	13
Cantered Leverage Value	.016	.694	.154	.239	13

a. Dependent Variable: PHC Pharmaceutical Expenditure per facility

Observation of the assumptions for linear Model 7: PHCPEFacility displayed a linearity observed through normal P-P plot for regression standard residual. Municipal total population returned a positive linearity, and municipal CHC level showed a negative linearity. There was a normal distribution of the data as assessed by a histogram of residual standard regression. There was a homoscedastic as assessed through partial regression plots for all predictors. There was no collinearity as assessed by the tolerance value of the collinearity statistics. The VIF (Variable Inflation Factors) for the overall model was low (1.060). There was no autocorrelation as assessed by Durbin-Watson value 2.326 (see Table 9-38). Standard residual values were within normal ranges, -1.689 and 1.333. Details of the observation are presented in Tables 9-38 and 9-39.

9.4.5.8 Model 8: Log-linear model of pharmaceutical expenditure for PHC per facility

The log-linear regression test for pharmaceutical expenditure for primary healthcare per facility (LnPHCPEFacility) displayed full prediction model explained by one enabling predictor (labour absorption rate) and a predictor from the healthcare resource category (staff strength). The addition of the last predictor to the labour absorption rate returned a statistically significant value for the overall model. Variation of the pharmaceutical expenditure per health facility was explained by different predictors compared to linear Model 8-PHCPEFacility (see Table 9-38).

Table 9-40. Log-linear summary[c] model for LnPHCPEFacility – Model 8

						Change Statistics				
Model	R	R^2	Adjusted R^2	Std. Error of the estimate	R^2 Change	F Change	df1	df2	Sig.F Change	Durbin-Watson
1	.559[a]	.313	.250	.19984	.313	5.007	1	11	.047	
2	.743[b]	.552	.463	.16918	.239	5.347	1	10	.043	1.879

a. Predictors: (Constant), labour Absorption Rate
b. Predictors: (Constant), labour Absorption Rate, Staff Strength
c. Dependent Variable: LogPHCPEFacility

Table 9-40 indicates that 55 per cent (0.552) of the variance in pharmaceutical expenditure for primary healthcare per facility can be explained by the labour absorption rate and staff strength to predict pharmaceutical expenditure, which led to statistical significance, *R^2 =0.552 F(1, 10) =5.347, p 0.043.*

The full model labour absorption rate and staff strength to predict total pharmaceutical expenditure per healthcare facility was statistically significant, *R^2 =0.552 F(1, 10) =6.347, p 0.043,* adjusted *R^2=0.463.* The other 20 predictors were found to be insignificant and so were excluded from the model.

Table 9-41. Log-linear ANOVA[a] of for LnPHCPEFacility – Model 8

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	.200	1	.200	5.007	.047[b]
	Residual	.439	11	.040		
	Total	.639	12			
2	Regression	.353	2	.177	6.167	.018[c]
	Residual	.286	10	.029		

	Total	.639	12			
3	Regression	.200	1	.200	5.007	.047[b]
	Residual	.439	11	.040		
	Total	.639	12			

a. Dependent Variable: LogPHCPEFacility
b. Predictors: (Constant), labour Absorption Rate
c. Predictors: (Constant), labour Absorption Rate, Staff Strength

The p-value of the coefficients table of the full Model 8: LnPHCPEFacility is statistically significant (p 0.043) with both municipal total population returning a positive coefficient value of 0.002 and municipal CHC level 2 with a negative coefficient value of 0.002, implying that a one unit increase in these predictors would lead to an increase in total pharmaceutical expenditure per capita. For example, an increase in one unit of both predictors will lead to an increase in pharmaceutical expenditure per facility by 0.2 per cent (see details in Table 9-42).

Table 9-42. Log-linear coefficients[a] of Ln for LnPHCPEFacility – Model 8

Model		Unstandardised Coefficients		Standardised Coefficients			95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
		B	Std. Error	Beta	t	Sig.	Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
1	(Constant)	4.594	.474		9.688	.000	3.550	5.638					
	labour Absorption Rate	-.021	.009	-.559	-2.238	.047	-.041	.000	-.559	-.559	-.559	1.000	1.000
2	(Constant)	3.126	.751		4.161	.002	1.452	4.800					
	labour Absorption Rate	.002	.012	.049	.146	.886	-.026	.030	-.559	.046	.031	.392	2.548
	Staff Strength	.002	.001	.781	2.312	.043	.000	.005	.742	.590	.489	.392	2.548

a. Dependent Variable: LogPHCPEFacility

Observation of the assumptions for linear Model-8: LnPHCPEfacility (see Table 9-40) displayed a linearity observed through normal P-P plot for regression standard residual. Municipal total population returned a positive linearity, and municipal CHC level showed a negative linearity, a similar linearity trend observed in the linear model of Model 7: PHCPEFacility (see Table 9-36). A normal distribution of the data was assessed by a histogram of residual standard regression. There was a homoscedastic as assessed through partial regression plots for all predictors. No collinearity was found as assessed by the tolerance value of the collinearity statistics. The VIF (Variable Inflation Factors) for the overall model was low at 2.548 (Table 9-42). There was no autocorrelation, as assessed by Durbin-Watson value 1.874 (see Table 9-40). Standard residual values are within normal ranges, -1.502 and 1.333. Details of these observations are presented in Table 9-43.

Table 9-43. Log-Linear Residual Statistics [a] of for LnPHCPEFacility – Model 8

	Minimum	Maximum	Mean	Std. Deviation	N
Predicted Value	3.3175	3.9754	3.5401	.17152	13
Std. Predicted Value	-1.298	2.538	.000	1.000	13
Standard Error of Predicted Value	.048	.139	.077	.026	13
Adjusted Predicted Value	3.3232	4.0617	3.5419	.19558	13
Residual	-.25415	.31714	.00000	.15444	13
Std. Residual	-1.502	1.874	.000	.913	13
Stud. Residual	-1.633	2.147	-.001	1.018	13
Deleted Residual	-.30027	.41588	-.00180	.19386	13
Stud. Deleted Residual	-1.809	2.773	.049	1.164	13
Mahal. Distance	.038	7.120	1.846	1.948	13
Cook's Distance	.003	.478	.085	.131	13
Cantered Leverage Value	.003	.593	.154	.162	13

a. Dependent Variable: LogPHCPEFacility

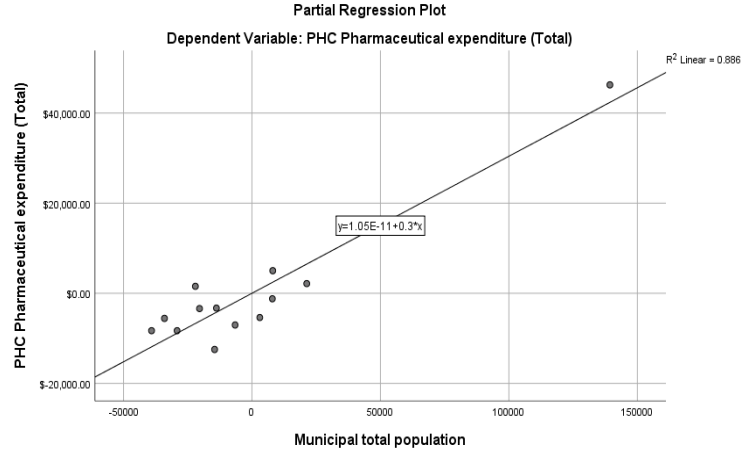
Considering the magnitude of the variation in the pharmaceutical expenditure per healthcare facility from the full model of Model 7: PHCPEFacility and Model 8: LnPHCPEFacility, it is preferable to go with Model 7 (see Table 9-36), which has slightly higher variability (66 per cent), as explained by the total municipal population and CHC level 2, and better precision in prediction, as assessed through its p-value of 0.026.

9.5 Discussion

The results of the nested stepwise regression on the cross-sectional data for pharmaceutical consumption for Timor-Leste for the 2017 period revealed eight prediction models. Overall, there were 264 pharmaceutical items on the essential drug list. Fifty to 75 per cent of stock-outs happened during the 2016 and 2017 period. The data was approached by ranking the most affected drug items, which was then further reduced into a list of the top 10 pharmaceutical items consumed during the period under observation. The top pharmaceutical items, Paracetamol 500 mg caplets and Amoxicillin 500 mg caplets, have been the focus of the analysis of pharmaceutical expenditure in the study during this phase of the study.

Having determined the pharmaceutical items, a return trip was made to Timor-Leste to collect the consumption data and predictors identified using Andersen's behavioural model for healthcare utilisation. The consumption data were then transformed into total pharmaceutical expenditure using the collected pharmaceutical procurement costs and expenditure for these items.

Figure 9-2. Pharmaceutical prediction based on total municipal population



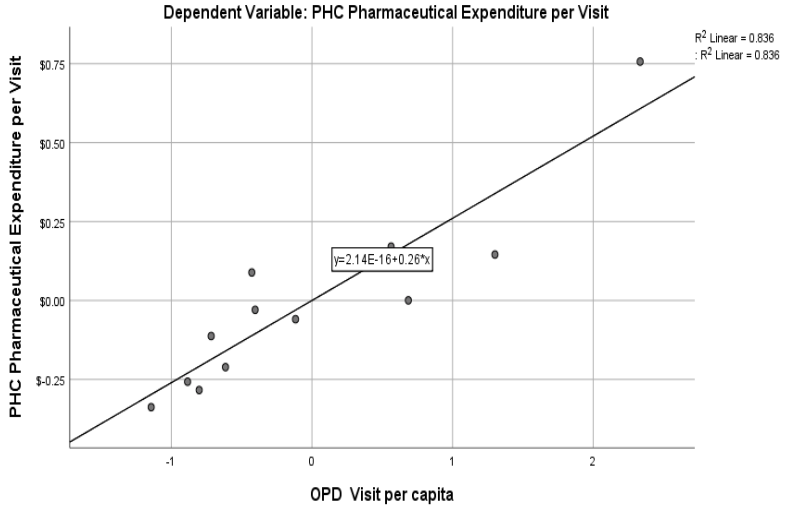
Instead of analysing total pharmaceuticals only as a single observed predictor, the model from the Ugandan study (Mujasi & Puig-Junoy 2015) was used to classify pharmaceutical expenditure into four observed/ outcome variables, hence the prediction models regressed against the predictor variables.

On average, the R-square explained 81 per cent of the variation or percentage change of the explanatory variables in predicting pharmaceutical expenditure for primary healthcare levels for all four outcome variables. This ranged from 55 per cent for Model 8 to 94 per cent for Model 2 (see details in Table 9-11).

The p-values of the models were significant and ranged from 0.003 to 0.044. All eight models exhibited statistical significance at $p<0.005$. Only 12 out of 22 continuous variables explained the variation in predicting pharmaceutical expenditures across all models. Total municipal

population was the most common predictor found in all the models. This was positively associated with Models 1, 2, 3, 4, and 7. The second most common predictor found in the models was OPC per capita which was prevalent in Models 2, 5, and 6. The third predictor was total hospital (HospTotal) and health facilities operated by NGOs (HFNGOs), which explained the variabilities in Models 3 and 4. The remaining variables, such as percentage of female population, labour absorption rate, staffing strength, and number of physicians, appeared only once each in the models.

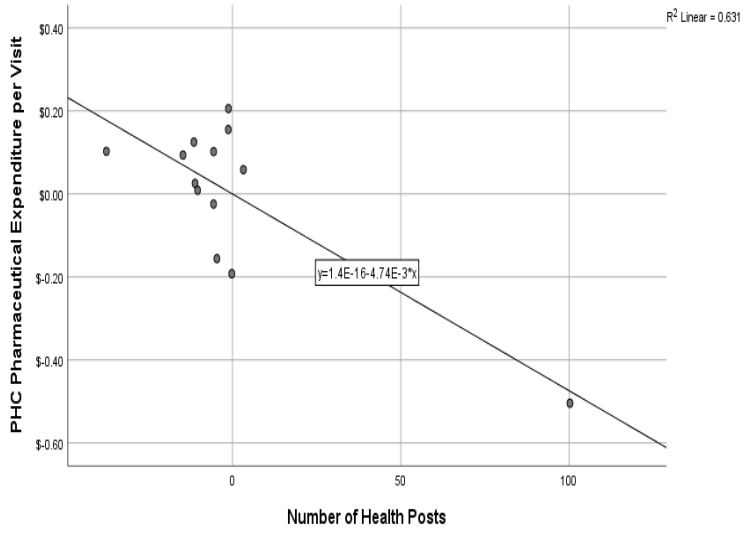
Figure 9-3. Predicted pharmaceutical based on OPD per capita



Variables in the log-linear model for total pharmaceutical expenditure (LnPHCPETotal) – Model 2, explained 94 per cent of the variation in the observed pharmaceutical expenditure for primary health in the country. It consisted of one predictor from the predisposing factors, and two from the healthcare needs factors. However, this was not the best fit model. The overall p-value for the model was 0.003; however, the p-value for this total municipal population was 0.361. Hence, it cannot be proposed as the best fit model for prediction of pharmaceutical expenditure in the healthcare sector due only to its higher R^2.

Variables in the linear-linear model (Model 5) for pharmaceutical expenditure for primary healthcare per capita visits explained 90 per cent of the variation in observed pharmaceutical expenditure. This was considered the best fit model because it can be explained by predictors from two categories, two from the healthcare needs factors and one from the healthcare resources factors. The combination of these predictors are the factors that represent healthcare needs and basis for service provision for healthcare. However, this model does not have a predictor from the predisposing category. The best predisposing predictors could be adapted from Model 1, which consists of two predisposing predictors with an overall model

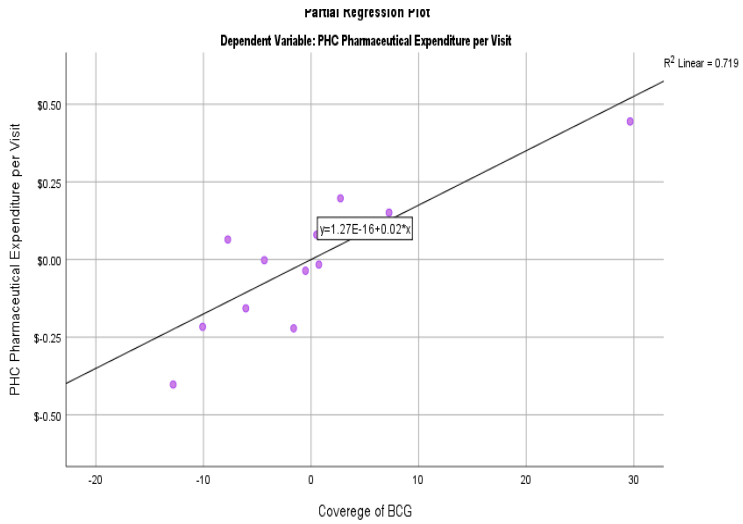
Figure 9-4. Predicted pharmaceuticals by number of health posts



p-value of 0.044. The p-value of total municipal population alone is significant, with *p-value 0.000,* coefficient value of *0.304.* The full Model 1 that consists of total population and percentage of female population was statistically significant, R^2=.887, F (1,10) =5.304, Significance 0.044, Adjusted R^2=865.

Since there is no single best fit model to predict pharmaceutical expenditure, it is proposed to combine Models 1 and 5 as a single approach to pharmaceutical planning. In this study, this has been called Model PHCPEVIsit+. The combination with Model 1 is due to its R^2 values where it is the third model with the highest explanatory power of 89%. Details of the proposed final prediction model for pharmaceutical expenditure predictors are detailed in Table 9-44.

Figure 9-5. Predicted pharmaceutical based on BCG overage of BCG



The positive coefficient value of total municipal population indicated that a unit increase would increase the value of the pharmaceutical expenditure for a Municipal Health Service by 30 percent. As it is seen in **Figure 9-2**, an increase of total population by 50,000 would increase the total pharmaceutical expenditure by on average of USD 20,000. Hence, a total 2017 annual expenditure for Amoxicillin 500mg tablet which wash USD 23,623. A 30 percent increase leads to a total annual expenditure of USD 30,709 and this figure is divided by the unit cost (USD 0.013/tablet see Table 9-3) for the commodity, total 2,362, 280 tablets needed for that year alone. A municipality with the highest total population would be expected to have the highest pharmaceutical expenditure. The same way of interpreting the coefficient values applied to all models in this thesis.

Table 9-44. Proposed prediction models for pharmaceutical expenditure for PHCPEVisit+[27] in Timor-Leste

Model	Variable	Coefficient	Std. Error	Student t	Sig.
1	Constant [a]	251390.70	1099937.98	2.28	0.045
	MunTop [a]	0.304	0.035	8.81	0.000*
5	Constant [b]	-1.220	0.295	-4.140	0.003*
	OPDCapita [b]	0.260	0.038	6.765	0.000*
	BCG Coverage [b]	0.018	0.004	4.801	0.001*
	Number of Heal Posts [b]	-0.005	-0.426	-3.924	0.003*

a. Dependent variable: PHCPCTotal, R^2=.887, Adjusted R2=865, F=5.304, Significance 0.044
b. Dependent Variable PHCPEVisit, R^2=.900, Adjusted R2=867, F=15.399, Significance 0.003
**p<0.01*

The need for healthcare services is reflected in the healthcare factors captured in visits to health facilities, increased coverage of vaccination, and birth deliveries that are assisted by trained healthcare professionals. All of these are primary healthcare services. In Model 5, as expected, both OPD per capita visit and coverage of BCG vaccinations have positive coefficient values. This shows that a unit increase in the value of these two predictors will increase the pharmaceutical expenditure per visit in a Municipal Health Service. OPD per capita has a

[27] PHC: Primary healthcare

positive coefficient, therefore, an increase in the total OPD attendance is expected to increase healthcare utilisation and pharmaceutical expenditure for a Municipal Health Service.

The last predictor, the number of health posts in a municipality in Model 5, displayed a negative coefficient value. It showed that a one unit increase in the number of health posts will decrease pharmaceutical expenditure. This is expected due to the established roles and functions of the health posts. Health posts are the front-line health facilities in a healthcare system that aim to provide preventative rather than curative services. The coefficient value does explain this concept of primary healthcare in the role and functions of the health posts.

Concerns of stock-outs can be addressed by inclusion of stock-out adjustment factors into the quantification formulae of the proposed model. Three important factors to be considered for stock-out adjustment are a percentage (15-20%) of based on the average of monthly stock-outs immediate past twelve months prior to the new quantification period of a new fiscal year. The percentage of stock-out can also be moderated by an arbitrary decision by a panel of pharmaceutical expert. The second factor is 5-10 precents of buffer stock that can cover the need for three months before the arrival of new stock in any given financial year. The third stock-out moderation factors are a procurement lead-time of three to six months.

9.6 Conclusion

Model PHCPEVisit+ is comprised of one predisposing variable (MunTop), two predictors (OPD capita and BCG coverage), and one healthcare resource predictor (MunHP). This model has the highest explanatory power. These models are essential grounding for the Ministry of Health in Timor-Leste for the provision of pharmaceutical expenditure and budget negotiations with the National Parliament and the Ministry of Finance.

Although this model is the best fit to be used as a starting point, attention must be given to the other predictors, especially to the enabling factors and other relevant predictors in the healthcare resources for the coming year. The display of the explanatory powers in the eight models in this study could have been influenced by the number of pharmaceutical items included in the study. This study may serve as a pilot study that can be used as a catalyst for further analysis using more pharmaceutical items when more reliable data is available so that more balanced predictive models can be established. Future studies based on more reliable data are recommended which will be able to equip any pharmaceutical planning team with more suitable models that can be applied to various healthcare settings.

CHAPTER 10. DISCUSSION OF PHARMACEUTICAL SUPPLY CHAIN MANAGEMENT IN TIMOR-LESTE

10.1 Introduction

This thesis has explored factors that have an impact on pharmaceutical supply chain management in Timor-Leste. The supply chain dependency model was used to explore management issues by providing an overview of the current supply issues that have an impact on the health sector. This was complemented by using Andersen's (1995) behavioural model of healthcare utilisation which provided an alternative way of investigating the factors that drive the demand for healthcare services, and of exploring how socio-economic factors can impact on the provision of pharmaceuticals as one essential component of health service management. The results and conclusions presented in this thesis provide a mechanism for improving pharmaceutical supply chain management in a post-conflict country with a colonial legacy.

In addition, Andersen's model of healthcare utilisation provided an alternative approach to predicting pharmaceutical needs by using a range of socio-economic factors that have been proven to be effective in many healthcare settings where conventional quantification and forecasting models have not addressed the issue of stock-out satisfactorily, due to a lack of human resource capacity and low confidence in the quality of the data. The prediction models in this study address the problematic quantification issues in the health sector.
This chapter provides a summary of the study, the research methodology and the findings, as well as a discussion of the theoretical dependency model, healthcare utilisation, and healthcare needs, and the gaps in these frameworks. It closes with a conclusion and recommendations.

10.2 Background of the study

Access to healthcare and pharmaceuticals are human rights. Access is achieved through the provision of comprehensive health services to a population, including adequate supply of drugs. Stock-out of pharmaceuticals affects the effectiveness of a healthcare system, demoralises health professionals, and jeopardises health outcomes for patients. For a supply chain management system to be effective, it requires capable human resources, processes, and integration of technology (Slota 2002). These characteristics are not fully available in the Timor-Leste health system. Pharmaceutical stock-out is common in the country, and has been so since it gained independence in 2002 (Diarío 2016; Ministerio da Saúde Timor-Leste 2013; Norris et al. 2007; The Dili Weekly 2019; Ximenes 2014). This study has examined the underlying causes of stock-out in Timor-Leste and has applied Andersen's behavioural model as adapted by Mujasi & Puig-Junoy (2015) to a Ugandan study, with modifications made to provide an alternative and reliable short-term approach to reducing stock-out.

10.3 Research Methodology and Findings

10.3.1 Research methods

With Timor-Leste as the case study in focus, the main research question of this study was 'what factors contribute to the continuous pharmaceutical stock-out in health facilities, and what alternative approaches could be applied to remedy the situation?' This was further elaborated through the objectives of the study, which were divided among the two phases of the study. The first phase sought to describe and identify the gaps in the existing supply chain processes, specifically to:

- Examine how inventory management and demand information are managed;
- Explore how quantification and forecasting of medicines are managed;
- Establish what the predictors or determining factors influencing pharmaceutical forecasting are; and
- Explore whether the current forecasting model meets pharmaceutical needs given the frequent stock-out.

The objectives of the second phase of the study were to:

a) Identify the current methods used to quantify pharmaceuticals by the government and three of its development partners;
b) Examine the social, cultural, political, and managerial/educational factors that contribute to the failure of the current quantification approach that has led to on-going stock out of pharmaceuticals;
c) Apply Andersen's explanatory model for pharmaceutical expenditure for two drug groupings (Antibiotics and Antipyretics) used by the three non-government agencies (the Global Fund, the UNFPA, and CCT) in order to see how they correlate with the present model used by the government in terms of quantification and forecasting needs;
d) Establish if it produces the same or similar estimates;
e) Repeat the third objective (re: Andersen's model) using the government model; and
f) Draw conclusions about the strength of Andersen's model for pharmaceutical quantification/forecasting by comparing the estimates arrived at in the third and fourth objectives above, and the usefulness of the model for the Timor-Leste context.

To approach the mixed methods research questions, a sequential mixed methods study was undertaken where the analysis of qualitative data in phase one led to quantitative data collection and analysis in phase two with the goal of improving understanding of the phenomenon and to test a solution. This process has been outlined in Chapter Four.

The study started with an exploration of the management of the pharmaceutical supply chain using qualitative interviews. The aim was to identify the factors that contributed to pharmaceutical stock-out. The methods used for the data collection were semi-structured interviews with senior officers within government and non-government organisations in addition to document reviews. This qualitative approach allowed for a comprehensive understanding of the factors contributing to the continuous pharmaceutical stock-outs across

the country. Identification of additional issues not covered by the supply chain dependency model (Privett & Gonsalvez 2014), were informed through use of Andersen's behavioural model of healthcare utilisation (Andersen 1995a).

Given that the issue of pharmaceutical forecasting could not be addressed through a qualitative approach, a second phase was conducted using a quantitative approach. This focused on the collection of the predictors of pharmaceutical expenditure and need. The outcome and predictor variables were identified using Andersen's model. Data for the outcome variables came from pharmaceutical consumption data that has been transformed into pharmaceutical expenditure in US dollar values. Predictor variables came from socio-economic data and health service data organised into four categories: predisposing factors, enabling factors, healthcare needs, and healthcare resources. Univariate and bivariate analysis were used to determine data distribution and correlations. The Shapiro-Wilk's test of means for the dichotomic variables was performed. An optimal statistical modelling for predictions was conducted. Then, a nested stepwise regression analysis was performed to see the explanatory power of the predictors for the outcome variables. Linear-linear and log-linear regressions were conducted, and eight prediction models were produced. One best model was proposed for pharmaceutical forecasting and quantification. This model is called PHPEVisit+, and consists of two needs predictors, one health resource predictor, and one enabling predictor.

10.3.2 Findings: Phase One

The findings of the research are organised according to the phases of the study. The first phase presents the findings from the interviews with government officials according to their level of authority and managerial responsibilities. The outcome of the document review is also summarised. This is followed by the findings from the investigation of the non-government organisations. The final section of the findings deals with the outcomes from the statistical tests that aimed to discover the best prediction models.

The findings from phase one confirmed that Timor-Leste experiences 10 problematic pharmaceutical issues, as outlined by Privett and Gonsalvez (Privett & Gonsalvez 2014), that are found in other developing and post-conflict countries (Mujasi & Puig-Junoy 2015; Tetteh & Mwangi 2004 ; Wagenaar et al. 2014; Wales et al. 2014). Chapter 3 outlines this framework for data collection, and the findings are presented in Chapters 6 and 7. These factors can be attributed to a lack managerial capacity at every level of the supply chain. The lack of human resources expertise, in terms of the number of staff with experience, has a domino effect that has a negative impact on the management of the pharmaceutical supply chain. Apart from the top 10 problems outlined by Privett and Gonsalvez (2014), a number of other contributing factors were identified using Andersen's (1995) model, which are summarised below.

How Managers at MoH and Municipal Health Services see the Issues of Pharmaceutical Stock-out

As detailed in Chapter Five, according to the twelve senior bureaucrats from the Central Services of the Ministry of Health (two Executive Directors, six National Directors and four Heads of Departments, the major predictors contributing to continued pharmaceutical stock-out were: a lack of definition of what stock-out means; a non-existent national supply chain strategy; incorrect quantification and forecasting models; a lack of data quality and inventory management; a lack of supervision of staff, as well as failure to monitor and evaluate the performance of pharmaceutical chain management due to lack of staff at the central services level; a tight fiscal climate that has had a negative impact on timely procurement services; a lack of pharmacists with experience and skills in supply chain processes; a lack of in-service training in supply chain management; a failure to introduce policies, regulations, and guidelines to assist health staff in the management of pharmaceuticals; a high level of dependence on international experts; and political interference in supply chain processes and in auditing which consequently leads to a lack of data to justify rational budget allocations for pharmaceutical procurement. Coupled with this is the lengthy procurement process which further exacerbates the problem.

Pharmaceutical coordinators and managers at health facilities and in the municipalities identified the following factors as contributing to poor pharmaceutical management: inadequate budget allocation, a lengthy procurement process, poor inventory management at the health facilty level due to a lack of human resource capacity, poor training opportunities; and the fact that quantification is done centrally and does not take account of the data that is sent to them from health facilities with quantifications based on distribution rather than consumption.

Impact of Pharmaceutical Stock-out on Clinicians and Patients

Chapter 6 also reported on the views of the clinicians. As noted in the past few years, over 1,000 doctors have returned from Cuba to Timor-Leste to take up positions across the country. This should have automatically led to an increase in the supply of pharmaceuticals simply because there were more health professionals to prescribe them. This does not appear to have occurred. As a consequence, the impact of stock-out on the work of clinicians and on patients is significant. Clinicians reported that stock-out lead to: the rationing of pharmaceuticals as normal practice; emergency procedures sometimes being performed without pre-medicated intervention, such as stitching of injuries without local anaesthesia; increased out-of-pocket expenses for patients; clinicians had little knowledge on the essential medicine lists due to insufficient dissemination and in-service training; and according to clinicians, a system of unfair distribution of pharmaceuticals due to stock-out at the central medical store. Frequent pharmaceutical stock-outs affected the clinical practice of physicians, nurses, and midwives at health facilities in the Municipal Health Services of Aileu, Dili, Ermera, and Liquiça. Clinicians assumed that pharmaceutical distribution was subject to favouritism. They attempted to remedy the situation by using second choice items, such as generics, obtaining pharmaceuticals from

other government public health facilities, negotiating with private organisations to barter for pharmaceuticals, frequently submitting requests for pharmaceuticals to Municipal Health Services, reducing the dose in treatment regimens, and advising patients to use traditional herbal medicines from their villages. The last option was taken when all the above options were exhausted, as was asking patients to buy the prescribed pharmaceuticals from kiosks, the market, or from private chemists.

Most of the clinicians had not seen the Standard Treatment Guidelines or the National Essential Medicines List. There are two implications arising from this lack of awareness of the STG and the EML. This means that these healthcare professionals were not aware of the country's standard pharmaceutical stock, nor were they aware of the baseline for treatment interventions. Instead, all their treatment interventions were based on knowledge acquired during their pre-service training, which for many of the doctors was completed in Cuba. The second implication is that these healthcare professionals did not know exactly the number of pharmaceuticals available at the facilities in which they worked. A lack of knowledge of the EML or the STG means that healthcare professionals are not aware of the drugs that are most readily available, which drugs are more likely to be available centrally, or which drugs might need to be procured.

Document reviews

Chapter 7 is an analysis of key documents relevant to the pharmaceutical supply chain. The review was undertaken on more than 250 legal, policy, and quantification reports, pharmaceutical requests, and documents on the use of the logistic management information system. This review confirmed the lack of competent human resource management systems, a lack of administrators, inadequate application of pharmaceutical quantification methods, and serious inconsistencies in reports on pharmaceutical requests. All of these factors contributed to the disruption of the pharmaceutical supply chain and, as a result, led to continuous stock-out of pharmaceuticals.

Examination of the documentation revealed misleading assumptions about the number of professional pharmacists within the country and their lack of training in supply chain management. In many instances, health professionals who were not pharmacists were left to do this work. Each pharmaceutical coordinator at the municipal health service level tried their best to record and report the pharmaceutical inventory at their facility. However, there were no uniform records or reporting systems in place at the healthcare facilities. This situation was further exacerbated by a failure to translate policies and guidelines into daily pharmaceutical management practices. A further issue was the political interference in technical matters of pharmaceutical inventory management. This was indicated by the frequent replacement of logistic management information system software by the Ministry of Health. There was no clearly defined list of pharmaceutical items to be supplied at each level of a healthcare facility. When filling in requests, health professionals were overwhelmed with too many unnecessary cells in the stock-balance and regular reports. Further to this, consumption data was not reported regularly in the Municipal Health Services.

There was a lack of uniformity in recording (stock cards) and reporting forms resulting in uneven consumption data analysis due to difficulty in reconciling the data at the central level. The impact of this messy inventory data system and poor reporting meant that, at the central level, there was little confidence in the consumption data. This posed a challenge in quantification and forecasting for the Ministry of Health, who did not believe in the value of the figures, and hence, would reduce the budget. In 2015-16, the WHO's Proxy Consumption Method included incomplete and incorrect distribution data from the previous year, which resulted in incorrect quantities of pharmaceuticals being ordered. Further issues included delays in quantification. As a result, subsequent delays were experienced in initiating the procurement processes for pharmaceuticals to be shipped into the country as planned. Overall, the documentation revealed that stock-outs occurred between 30 and 75 days for over 45 pharmaceutical items at the municipal health service level. The Central Medical Store, SAMES, was only able to deliver on average 50 per cent of requested pharmaceuticals to Municipal Health Services. The push-based system was frequently applied by SAMES to the Municipal Health Services, resulting in an over-supply of certain pharmaceutical items; for example, cough syrups. The push-based system is a distribution system where pharmaceuticals are distributed by the Central Medical Store to health facilities who do not request the items.

Human Resources (HR) and Projected HR Needs: The Evidence

The majority of the issues outlined above can be explained through the failure of the central government to trust the human resource capacity within the health system. This can be explained as a result of Timor-Leste's colonial history. Chapter 2 provides a broad overview of the colonial history of Timor-Leste. As outlined, during the 450 years of Portuguese, and 24 year of Indonesian, colonisation, the East Timorese people were trained only to use low-level technical skills. Managerial jobs were held by the colonial officials. Little was done by the United Nations Transitional Administration (UNTAET) to remedy this or to set up a strategic plan to train a health administrator class in the newly independent Timor-Leste. Consequently, an important gap in the provision of health service delivery for the population exists. This results in a disorganised system that cannot deliver health services to the population as expected. It is assumed that this lack of capacity at the central bureaucratic level is mirrored at the municipal health service level, leading to widespread systemic distrust.

While there has been progress in line with the global movements of the 1970s that acknowledged indigenous rights, including an increase in the number of primary schools and registered students, at the time of independence from the Portuguese in 1974, the illiteracy rate was 78 per cent. The literacy rate improved during the Indonesian occupation, but there remained a lack of technical and administrative educated personnel, and few Timorese were appointed to positions as health service managers in the health sector. In the first 15 years after independence, the strategic plan for human resources focused more on training health professionals with clinical expertise, such as doctors, than those with management experience and expertise. The impact of this has been an over-reliance on international experts in the development of technical, policy, and regulatory systems, including the capacity to manage the pharmaceutical supply chain. For example, the development of the technical tasks involved in

pharmaceutical supply chain management was prepared by expatriates, with too few Timorese educated and trained to manage the system adequately.

Summary of the Issues of the Quantification Model Used by the Government

The following are issues that have impact on the accuracy of forecasting and quantification of pharmaceuticals. The quantification method used is the WHO's proxy consumption method, which is based on consumption data. However, this study has found that distribution data was used rather than consumption data, and only a limited number of staff knew about the national quantification guidelines. Distribution data does not provide an accurate account of the pharmaceuticals needed. There is a lack of reliable data from Municipal Health Services due to inconsistencies in the application of the reporting and requests from Municipal Health Services, as well as inconsistencies in the use of stock-cards from all healthcare facilities.

It is evident from the interviews and document analysis that stock-out happened across all healthcare facilities. The average stock-out at the facility and national levels at the Central Medical Store for the period of January-July 2017 was 50 per cent.

Pharmaceutical Stock-outs in Non-Government Organisations

While the government has experienced pharmaceutical stock-out, according to many of those interviewed during Phase One of this study, government partner agencies such as the Global Fund, the United Nations Fund for Population Agency (UNFPA), and the clinics operated by non-government organisations did not experience stock-out. This warranted a second visit to Timor-Leste to conduct further interviews and document reviews from three non-government organisations providing services or supplies of pharmaceuticals in the country. It was possible that the methods used by these agencies could be used by the government. Given this, it was decided that further investigation was warranted. The results of this investigation are presented in Chapter 8.

Of the three government development partners, two organisations had issues with inventory management and experienced stock-out. This was the result of these agencies having to use the Central Medical Store, SAMES, for their pharmaceutical supplies. If stock-out occurred at SAMES, it had an immediate effect on the NGO (Cliníca Café Timor - CCT). The second factor was that the UNFPA only managed funding, quantification, and procurement of reproductive health commodities, but the inventory was managed by the Ministry of Health. Reproductive health commodities were stored at SAMES, while inventory management at Municipal Health Services was carried out by midwives. There was no information about regular inventory reports, hence no consumption data was available. The remaining development partner, the Global Fund, administered the malaria program and had full control of its logistic management information system, funding, human resources, training, monitoring, and evaluation. It did not experience stock-out due to its rigorous training, efficient inventory management, accurate and thorough recording, reporting, quantification, and forecasting, and its complete independence from government services and resources. As a

result of this investigation, none of these three NGOs provided a solution to stock-out in Timor-Leste. While the Global Fund has a reliable system, its brief is too narrow.

In a post-conflict country where government institutions are weak and there is a lack of logistic management information system data, a valid data source is required to conduct pharmaceutical quantification and forecasting. No such data source exists. Timor-Leste has applied consumption-based pharmaceutical quantification parameters based on the World Health Organisation (WHO) recommendations; however, as noted, the data used appeared to be distribution rather than consumption data. There is an annual outcry about the lack of pharmaceuticals and continuous stock-out indicating that the models used are ineffective. A range of alternative models exist, but are not necessarily suitable for Timor-Leste. For example, models such as clinical risk groups or adjusted clinical groups, and Charlson's comorbidity index, are not viable due to a lack of well-trained human resources and logistics management information systems. A high level of data validity is required to run a pharmaceutical quantification based on this and similar models. One of the normative practices in conducting prediction models for pharmaceutical needs for other developing countries is to take the total population and age-specific groups to arrive at a final figure for pharmaceutical needs.

For example, the provision of basic vaccines for children is based on the total population of children under five years of age. The provision of reproductive health commodities, such as condoms, hormonal contraceptive pills, implants, or intra-uterine devices are based on the estimation of reproductive ages in the population. The stock-out of reproductive health commodities in Timor-Leste is evidence of the ineffectiveness of the model.

An alternative model, used in developing and post-conflict situations, is one that has proven to be effective in a Ugandan study reported by (Mujasi & Puig-Junoy 2015). The model is an adaptation of Andersen's behavioural model for healthcare utilisation (1995). The model provides an avenue for pharmaceutical predictions using any of four components in the model. In the study in Uganda, as well as in this study, the predictors used have been drawn from components of population characteristics which are: predisposing factors, enabling factors, healthcare needs, and healthcare resources. These are comprehensive predictors that are required to operate an effective healthcare service and includes total population, percentage of female population, labour absorption rates, literacy rates, urbanisation status, coverage of vaccinations, antenatal care, and health resources such as health facilities and human resources. Mujasi and Puig-Junoy (2015) used centralised data for pharmaceutical quantification and forecasting, which is essential for pharmaceutical expenditure planning.

Data for the predictors used in this research are the demographic characteristics identified in Andersen's behavioural model for healthcare utilisation, and are organised into four categories of predictors for each municipality. The first category is the predisposing factors, the total population, and the percentage of female population. The second category is the enabling predictors, which are labour absorption rates and literacy rates. The third category is the healthcare need predictors which are expressed through the coverage of health services such as coverage of vaccination rates, per capita visits to outpatient department clinics, antenatal care,

and deliveries assisted by healthcare professionals. The last category is for the healthcare resources which range from health facilities to human resources. The similarities between the significant predictors emanating from the Ugandan study and the findings from this study, which further confirmed the effectiveness of the application of Andersen's behavioural model for pharmaceutical quantification.

In order to apply Andersen's model (1995), as modified by Mujasi and Puig-Junoy (2015), it is necessary to have access to reliable data. While there is a general distrust of quantification data on pharmaceutical requirements from the health posts, as well as data produced at SAMES, the country does have centralised demographic and epidemiological data produced by the National Statistical Office, Ministry of Finance for the national census. This census and survey data have been managed by ICF Macro International, a trusted organisation that has carried out population censuses and surveys in many countries (ICF International 2019). The analysis of the data is inclusive of stakeholders. This data was used to model the pharmaceutical predictions presented in Chapter 9.

10.3.3 Findings: Phase Two

In Chapter 9, the model outlined in the Ugandan study was used to classify the pharmaceutical expenditure into four observed/outcome variables regressed against the predictor variables (Mujasi & Puig-Junoy 2015). This is presented in detail in Chapter 9, where eight optimal models of statistical prediction are outlined. On average, the R-square explained 81 per cent of variation or percentage of change of the explanatory variables predicting pharmaceutical expenditure for primary healthcare level for all four outcome variables, which ranges from 55 per cent in Model 8 to 94 per cent in Model 2.

Only 4 out of the 22 continuous predictors were the best fit models for pharmaceutical prediction. The positive coefficient value of the total municipal population indicated that a unit increase (one thousand of the total population) will increase the value of pharmaceutical expenditure for a Municipal Health Service. The municipality with the highest total population would be expected to have the highest rate of pharmaceutical expenditure.
The need for healthcare services is reflected in the health care factors captured in visits to health facilities, increased coverage of vaccination, and maternal deliveries that are assisted by trained healthcare professionals. All of these are primary healthcare services. As expected, both outpatient department visits per capita and coverage of BCG vaccinations have positive coefficient values. This shows that a unit increase in the value of these two predictors will increase pharmaceutical expenditure per visit in a Municipal Health Service. OPD per capita has a positive coefficient; an increase in total OPD attendance is expected to increase healthcare utilisation and pharmaceutical expenditure for a Municipal Health Service.
The last predictor, number of health posts in a municipality, displayed a negative coefficient value. It showed that one unit increase in the number of health posts will decrease pharmaceutical expenditure. This is expected due to the established roles and functions of the health posts. Health posts are front line healthcare facilities in a health system which aim to provide preventative rather than curative services, which means that fewer drugs are needed at

this level. The coefficient value does explain this concept of primary healthcare on the role and functions of the health posts.

The emergence of healthcare needs predictors across the eight models is expected. The more healthcare needs predictors found in a predicting model, the better a prediction model is. This is because the overall aim of the existence of a health system is to provide healthcare services according to the needs of the population. This is in line with findings on the variability of predictors in pharmaceutical costing using cross-sectional data. The healthcare needs predictors are expressed in healthcare utilisation indicated by service coverage or pharmaceutical claims. In some studies, healthcare needs explain most variabilities in pharmaceutical prediction modelling (Aguado et al. 2008; Mujasi & Puig-Junoy 2015; Powers et al. 2005). However, a balanced prediction model is preferable where it has predictors taken from predisposing factors, enabling factors, healthcare resources, and healthcare facilities. The preferred model is difficult to obtain in a real situation. Hence, for practicality, a combination of predictors across all models is recommended.

10.4 Proposed Solutions

10.4.1 Short-term solutions

The most suitable short-term approach to improve the performance of pharmaceutical supply chain management and to reduce stock-out is through the application of Andersen's behavioural model in order to predict the pharmaceuticals required. The proposed model in this study can be applied in determining the pharmaceuticals required and expenditure. It provides a basis for setting an annual pharmaceutical budget and predicting expenditure and could be presented to the Timor-Leste Ministry of Finance and the National Parliament. This approach would be a temporary measure while other forecasting models would be developed based on improvements in inventory management and logistics management information systems in the health sector.

Lengthy colonial legacies in Timor-Leste have produced weak state institutions and a lack of a managerial class across some sectors. What is required is a solution that draws upon the experiences of other states who have experienced similar situations. This is captured in the concept of hybrid political orders and institutional development theory (Lepsius 2017; March & Olsen 1998). The concept of hybrid political orders refers to situations where a less developed state borrows practices from countries with a similar history or situation. The practice needs to be scientific in its approach to finding solutions to the problems and, at the same time, considering the cultural, political, and social situation of the country. The solution offered in Chapter 9 to the pharmaceutical supply chain management issues can be seen as a hybridised model based on Andersen's (1995) work, as applied in Uganda (Mujasi & Puig-Junoy 2015). The country does not need to invent new approaches in pharmaceutical supply chain management. It can adapt proven effective and efficient supply chain management processes from other countries to improve its pharmaceutical supply chain management,

quantification, and forecasting. The approach itself is a learning process in state institutional development. By applying this approach, Timor-Leste can harness current support from its development partners and donors to work on developing competent human resources and state institutions to deliver healthcare services to its citizens. More mainstream approaches can be implemented when the necessary human resources and technologies are in place. The solutions to pharmaceutical supply chain management are both practical and political in the short-, medium-, and long-term.

10.4.2 Medium-term approaches

There are a number of medium-term approaches that could be taken. The first step is to work towards improvements in inventory management by building on current good practices in warehouse management.

Training of champions in the public service to oversee continuous data analysis of the consumption and forecasting trends is required. Once this is in place, the adaption of a single period inventory model (Arshinder, Kanda & Deshmukh 2008; Lee, YC et al. 2006) and safety stock inventory model (Mahendrawathi, Nurul Laili & Kusumawardani 2011; Wee 2011), which are detailed in sub-section 3.1.1.2 of Chapter 3, are recommended to avoid the risks of stock-out. Coordination and inventory models in pharmaceutical supply chain management can be modified as improvements in logistics information systems are developed and confidence in data quality increases. The periodical methods of inventory management where a determined periodical counting of stock is performed and compared with the desired stock-level to enable replenishment action is recommended. Detailed explanation of this inventory model is presented in sub-section 3.1.1.2 of Chapter 3. This is suitable for Timor-Leste's situation since the perpetual method of inventory cannot be applied due to unreliable Internet connectivity in the country (Ali 2011). The result of periodical inventory information could be captured in the defined recording and reporting period to enable good flow of information from all levels of service. This can be achieved through improving training for healthcare professionals handling pharmaceutical supplies at all levels. Recording and reporting forms must be made available and need to be user-friendly. A training curriculum, syllabus, and training blueprints should be developed, tested, implemented, and evaluated periodically. Training of trainers for overall supply chain management, inventory management, quantification, and forecasting should be initiated. Planned regular supportive supervision to solve bottleneck issues in pharmaceutical supply chain management is also highly recommended.

10.4.3 Long-term approaches

As the primary problem of pharmaceutical supply chain management is the lack of a managerial class in the healthcare sector, the focus for long-term approaches should be directed towards overcoming this. There are three long-term approaches required to improve pharmaceutical supply chain management in Timor-Leste. The first is the necessity for strategic improvements in the knowledge and skills of healthcare professionals, especially pharmacists and others involved in pharmaceutical supply chain management. Strategic improvement must

be translated into action by defining not only the number of staff required, but also the quality and level of pre-service and in-service training needed to establish the required system. Training must be followed by the development of positions for health supply chain management officers in the public service system with tangible job descriptions. The capacity to oversee pharmaceutical supply chain management must be included in civil servant and health administrator job descriptions. A reward system for the champions in health supply chain management needs to be established in tandem with reward systems for other categories of healthcare professionals. Simple rewards systems could be implemented in recognition of exemplary work in the pharmaceutical supply chain system through award certificates presented in ceremonies on national days, priority in continuing education programs, or promotion to senior management positions. Trained pharmaceutical supply chain staff may perform well if supported with guidelines and infrastructure that enables them to perform their tasks.

A set of processes for pharmaceutical quantification and forecasting needs to be agreed upon and institutionalised. This may be initiated by redefining the recording and reporting forms which capture the inventory level, distribution, and consumption of pharmaceuticals and requests. Promotion of an integrated health information system into the pharmaceutical supply chain management practices is crucial. Institutionalisation of supply chain management software connected to the Internet would be ideal. This would enable a smooth transition from paper-based inventory management to the virtual information of inventory management. All these long-term changes must be rooted in the establishment of policies and regulations on pharmaceutical supply chain management which are inclusively developed, introduced, and evaluated periodically. The policy must be translated into guidelines and forms which are easy to implement. One final long-term approach to promote pharmaceutical supply chain management is through the establishment of tertiary level operations management courses at the national university. The aim is not only to train operations management professionals, but also to improve the knowledge and skills in supply chain management through continuous research and development.

10.5 Strengths and Limitations

The mixed methods exploratory sequential study allowed for an in-depth analysis of the phenomenon of pharmaceutical stock-out at all levels of health services. The qualitative approaches employed in Phase One enabled the collection of rich information about the system which otherwise would not have been captured by using a quantitative approach. However, the qualitative approach only uncovered some of the factors in the overall story of pharmaceutical supply chain management. Logistical and geographical barriers prevented more interviews from being carried out with clinicians and practitioners in all municipalities. Nevertheless, the findings have drawn on interviews with a range of levels of professionals in the Timor-Leste pharmaceutical supply chain. The study gives a voice to the experiences of those who work within the system in order to better understand the challenges of the current situation.

This research has deliberately combined empirical qualitative analysis with the application of rigorous quantitative modelling in order to provide an authoritative set of proposed solutions. The specific interviews undertaken, the theoretical lenses applied, and the motivations of the researcher to provide practical solutions to the issue of stock out in Timor-Leste, have led to a rigorous study that provides robust strategies for how to address a complex logistical and socio-political issue. The model tested provides a prediction technique for quantification and forecasting of pharmaceuticals. It is offered as a solution to halt the continuous pharmaceutical stock-outs and meeting the need for pharmaceuticals in the country.

The thesis has provided an alternative approach to human resources in chapter two, inventory management in chapter three and proposed approaches sections however this is not adequate. Details of guidelines on quantification, inventory management and job aids to assist staff performing pharmaceutical supply chain management are essential when it comes to implementing forecasting approaches in the health system.

10.6 Future Research Directions

The prediction models proposed in the study are the not the only way to conduct quantification and forecasting for pharmaceuticals. As the recording and reporting system improves in the logistics management information system and the health management information system, and data reliability increases further, studies on potential prediction models for primary healthcare and hospitals could be promoted.

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APPENDICES

Health and Exercise Sciences
School of Medicine
Faculty of Medicine, Nursing and Health Sciences,
Flinders University of South Australia
Sturt Campus, Room S280
Phone: +61 8 8201 5773 (Extension: 12880)
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Dear [name]

My name is Lourenço Camnahas, A PhD student from faculty of Medicine, Nursing and Health Sciences at Flinders University.

I would like to invite you to participate in the study and am interested in talking to you on the factors influencing quantification of pharmaceuticals and how the quantification is done; and how this affects the availability of pharmaceuticals in health facilities in the country. Questions asked will be related to how information is used to quantify pharmaceuticals, how inventory is managed, reporting and request of pharmaceuticals are managed and any other issues you think are relevant. It would be appreciated if you would participate in this study.

The interview would take approximately 45-60 minutes. If you are willing, I would appreciate it if you could please confirm by indicating a suitable time for the meeting. I will share with you an information sheet, and other related information about the research. If you have any concern, you can contact me via my mobile phone number or email whichever is more convenient. The informed consent form will be signed before our interview session.

Be assured that any information provided will be treated in the strictest confidence and none of the participants will be individually identifiable in the resulting thesis, report or other publications. You are, of course, entirely free to discontinue your participation at any time or to decline to answer particular questions. Any information that you provide will not be directly attributed to you. You will not be personally named in the thesis.
Since I intend to make a tape recording of the interview, I will seek your consent, on the attached form, to record the interview, to use the recording or a transcription in preparing the report or other publications, on condition that your name or identity is not revealed, and to only make the recording available to other researchers on the same conditions. It may be necessary to make the recording available to secretarial assistants (or a transcription service) for transcription, in which case you may be assured that such persons will be asked to sign a confidentiality agreement which outlines the requirement that your name or identity not be revealed and that the confidentiality of the material is respected and maintained.

Any enquiries you may have concerning this research project should be directed to me at the address given above or by telephone on +61 8 8201 5773 (Extension: 12880) or +61 421 649 861, or email camn0001@flinders.edu.au

Thank you for your attention and support.

Yours sincerely
Lourenco Camnahas
PhD Candidate,
School of Medicine, Faculty of Medicine, Nursing and Health Sciences,
Flinders University of South Australia

This research project has been approved by the Flinders University Social and Behavioural Research Ethics Committee (Project number 6389). For more information regarding ethical approval of the project the Executive Officer of the Committee can be contacted by telephone on 8201 3116, by fax on 8201 2035 or by email human.researchethics@flinders.edu.au

Research title:
Understanding stock out of pharmaceuticals in Timor-Leste: a case study in identifying factors impacting on pharmaceutical quantification

Researcher
Lourenço Camnahas

Supervisors
Prof Eileen Willis
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Associate Professor Greg Fisher
Adjunct Professor Pascale Dettwiller

Purpose of the study
This study asks the broad question "What impact do funding models have on rationed or missed nursing care in rural aged care settings?"
We are interested in exploring the barriers that nurses and carer workers in rural aged care settings may face when providing care to residents, and the reasons why this may occur.

What you will be asked to do?
Participation is entirely voluntary. We will ask you to participate in a telephone, skype, or face-to-face interview that will take approximately 45-60 minutes at a time of your choosing. The interview will be audio recorded with your permission.
The questions will focus on:

- What factors enable or inhibit you to deliver care activities for residents
- How you rationalise care activities if you are unable to perform all care activities for residents in some circumstances
- What impact do you usually see from these rationalised care (missed care)?
- What impact do differences in funding pools have on rationing nursing resources (nurse managers only)

What are the potential benefits to participants?
Over the next 12 months the new mechanisms for calculating nurse-patient ratios will be determined. This will coincide with introduction of EPAS. While residential aged care beds are funded separately from acute public hospitals, the ANMF will seek to ensure parity where possible based on evidence. The data collected from this study will be used by the ANMF as the basis for enterprise bargaining negotiations.

Are there any risks or discomforts for participants?
We anticipate there to be few risks from your involvement in this study, however it is possible that participants may experience difficult emotions while discussing some topics in their interview such as identifying care that might have been missed. You will be free to leave the interview at any time or decline to answer particular questions. If the questions raise any industrial questions or matters that you would like to discuss further, you are welcome to contact the ANMF on 1800 809 642 or enquiry@anmfsa.org.au. You will also be able to access the free, confidential counselling services of Davidson Trahaire Corpsych (1300 360 364, www.davcorp.com.au) offered as part of the SA Health Employee Assistance Program.

As with all research, there is a small risk that participants will be inadvertently identified from the published output of the study or that their views will be misrepresented. However, the researcher will make every effort to remove all identifiable data from published outputs and to comprehend participants' meaning. Participants have the right to read the reports before they are published, or have them explained to them.

How will confidentiality be maintained?

No identifying information will be collected and the data will not be viewed by anyone outside of the immediate university research team listed above. If it becomes necessary for the recordings to be made available to an organisation for transcription you may be assured that such persons will be asked to sign a confidentiality agreement which outlines the requirement that your name or identity not be revealed and that the confidentiality of the material is respected and maintained.

How are you protected?

This project has been approved by the Flinders University Social and Behavioural Ethics Committee. Any concerns that you may have about the conduct of this project can be addressed to the Executive Officer of this committee:
Flinders University Social and Behavioural Ethics Committee: telephone 8201 3116 or email human.researchethics@flinders.edu.au

Funding and Dissemination

All participants will be provided with a copy of their transcript as well as a copy of the final report via email. A copy of the report will also be sent to the ANMF.
The research is funded by a Flinders University Faculty of Health Science seeding grant.

How can I find out more information?

Further information about this project can be obtained from Prof. Eileen Willis: telephone on

Removed due to privacy reasons

inspiring achievement

Semi-structured interview questions

Aims and major questions for the study

- The current model of qualification of pharmaceuticals in Timor-Leste
- The impact of political, social and organisational cultural factors on pharmaceutical quantification?
- And asks if the application of Anderson's model would improve quantification and forecasting.

This will involve examining

- How inventory management and demand information is managed by the Directorate of Pharmacy and Central Medical Store, SAMES?
- How the quantification of medicines is administered by the Directorate of Pharmacy, the Ministry of Health and District Health services level?
- And, does the current quantification model meet the pharmaceutical needs given the frequent stock-outs?

The following questions will serve as a guide to the interviews. Questions may be asked in a different order, or some omitted or added, depending on the participants' responses. The Questions that will be discussed in interviews are listed under the generic questions.

Questions to address the objective 1 for Chief Executive Officers and National Directors: How the quantification of medicines is managed by the Directorate of Pharmacy, the Ministry of Health and District Health services level?

a. What do you think major issues in pharmaceutical management in Timor-Leste? (Q1,2,4)
b. Does the Ministry of Health have a mechanism is place for quantification of pharmaceuticals? [Q3,5, 6,7, 8,14, 15, 16, 17]
c. Does the Ministry of Health have guidelines and standard operation procedure for pharmaceutical management? [Q8,9, 10,]
d. In other emerging countries, pharmaceutical inventory management is one of the key component in overall pharmaceutical management. How do you see this in Timor-Leste? [Q11, 12]
e. How the information does from inventory management fits in pharmaceutical logistics management system (or simply record and reporting system)? [Q11,12,13]
f. Does management influence final decision on pharmaceutical procurement?
g. Are there organizational cultural issues in overall pharmaceutical management?
h. Does Ministry of Health have support in pharmaceutical management?
i. How does support for pharmaceutical management implemented for national and district level?
j. How do external stakeholders support in pharmaceutical management?

Follow-up questions

1. What prevents Ministry of Health in having a pharmaceutical quantification that meets the need of the population?
2. What factors contribute to the successful quantification of pharmaceuticals at National and district level?
3. How does the process involve in quantifying pharmaceuticals for Ministry of Health?
4. What are the data requirement for pharmaceuticals quantification at Ministry of Health? Are there differences of Central dataset office of Ministry of Health and District level for pharmaceutical quantification?
5. Is there any software that is used to quantify pharmaceuticals for the country?
6. Who is responsible for pharmaceutical quantification at District Health Services and National level?
7. What is the current model used to quantify pharmaceutical needs for clinical and specific programs?
8. What is the process involve in the quantification of pharmaceuticals at Ministry of Health?
9. What guidelines, policies and other standard operating procedures (SOP) are used in the pharmaceutical quantification process?
10. Who has the knowledge and skills in using the guidelines and SOPs in pharmaceuticals quantification?
11. What is the status of inventory management at SAMES and warehouses at District Health Services?

12. How has the inventory management been done? Has there supportive supervision and training for improvement been made from National to District Health Services? How often the pharmaceuticals stock at all levels been updated? How does it work?
13. How has the request of and reporting of pharmaceuticals been managed at District Health Services, SAMES and Central Services of Ministry of Health?
14. How has the distribution of pharmaceuticals been conducted?
15. Does the current team manage pharmaceutical supply chain management adequately?
16. Why does the stock-out of essential pharmaceuticals continue to take place?
17. What the top ten essential pharmaceuticals that are always on stock-out?
18. Does funding from State Budget an issue in quantifying pharmaceuticals?

Questions to address the objective 2 for Chief Executive Officers and National Directors: How are politics, social and organisational culture factors influence on the pharmaceutical quantification?

1. Has there been any political interference in the quantification and procurement of pharmaceuticals in the past?
2. How the political factors influence the procurement of pharmaceuticals that response to the need of population?
3. What organisational factors have supported or challenged the quantification process in the country?
4. What specific organisational factors that mostly affect the pharmaceutical quantification?
5. Who makes the decision on final quantification figures to be procurement? Has it been made based on sound rational reasoning?
6. Why do pharmaceuticals stock-out continue to happen across health facilities in the country?
7. Are there sufficient trained staffs to carry out the supply chain of pharmaceutical in the country? How many trained pharmacists are there? How many trained heath logisticians/health professionals to manage the warehouse management in the pharmaceutical supply chain?
8. Does the coordination among entities in pharmaceutical supply chain management, especially in inventory management and quantification optimum?
9. Are there potential social issues that influence quantification and procurement of pharmaceuticals?
10. What are social and cultural issues that contribute to quantification and procurement of pharmaceuticals?
11. How politics influence the quantification and procurement of pharmaceuticals?
12. What managerial issues impacting on quantification of pharmaceutical and procurement;
13. How the level of education and training of health professionals contribute to the pharmaceutical supply chain management at all management levels.
14. What is the current method to quantify pharmaceuticals, information required to perform the quantification?
15. How is reporting and request of pharmaceuticals work?
16. How is annual expenditure allocation for pharmaceuticals decided?
17. Who perform quantification at district and national level, and v) tools used to perform quantification?
18. Are there policies and procedures for inventory management and quantification procedures? Have these been introduced? How many staffs have been trained in pharmaceutical supply chain and inventory management?
19. Has there been regular monitoring and evaluation of the performance of pharmaceutical inventory management or warehouse management? If there has been monitoring and evaluation of the performance of the pharmaceutical supply chain management, how often it is done in a year and does the Central Service Office provide regular feedbacks?
20. What type of supports are provided to District Health Services and health facilities in pharmaceutical supply chain management?

Questions related to objective 2 for Medical Doctors and Clinical Nurses: How are politics, social and organisational culture factors influence on the pharmaceutical quantification.

1. Has there been any political interference in the quantification and procurement of pharmaceuticals in the past?
2. What organisational factors supported or challenged the quantification process in the country?

3. What specific organisational factors that mostly affect the pharmaceutical quantification?
4. Why do pharmaceuticals stock-out continue to happen across health facilities in the country?
5. Does the coordination among entities in pharmaceutical supply chain management, especially in inventory management and quantification optimum?
6. What managerial issues impacting on quantification of pharmaceutical and procurement;
7. How the level of education and training of health professionals contribute to the pharmaceutical supply chain management at all management levels at your health facility?
8. What is the current method to quantify pharmaceuticals, information required to perform the quantification at your facility?
9. How is reporting and request of pharmaceuticals work?
10. Who performs quantification at your health facility? What tools are used to perform quantification?
11. Are there policies and procedures for inventory management and quantification procedures? Have these been introduced? How many staffs have been training in pharmaceutical supply chain and inventory management?
12. Has there been regular monitoring and evaluation of the performance of pharmaceutical inventory management or warehouse management? If there has been monitoring and evaluation of the performance of the pharmaceutical supply chain management, how often it is done in a year and does the Central Service Office provide regular feedbacks?
13. What type of supports are provided to District Health Services and health facilities in pharmaceutical supply chain management?
14. How does the pharmaceutical stock-out impacting on your prescription and treatment to patients?
15. What can be done to improve the pharmaceutical quantification?
16. Are you aware of the existing policies and procedures related to pharmaceutical management? For example, Standard Treatment Guidelines, National Essential Medicine List?
17. Have you ever involved in pharmaceutical quantification at your health facility?

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CONSENT FORM FOR PARTICIPATION IN RESEARCH
by interview

Chief Executive Officer, National Director, Director, Administrator, Senior Managers, Senior Officer

I ….....
being over the age of 18 years hereby consent to participate as requested in the letter of introduction and information sheet for the research project on understanding stock out of pharmaceuticals in Timor-Leste: a case study in identifying factors impacting on pharmaceutical quantification in Timor-Leste.

I have read the information provided.

1. Details of procedures and any risks have been explained to my satisfaction.
2. I agree to audio recording of my information and participation.
4. I am aware that I should retain a copy of the Information Sheet and Consent Form for future reference.
5. I understand that:
   - I may not directly benefit from taking part in this research.
   - I am free to withdraw from the project at any time and am free to decline to answer particular questions.
   - While the information gained in this study will be published as explained, I will not be identified, and individual information will remain confidential.
   - I may ask that the recording/observation be stopped at any time, and that I may withdraw at any time from the session or the research without disadvantage.
6. I agree/do not agree* to the tape/transcript* being made available to other researchers who are not members of this research team, but who are judged by the research team to be doing related research, on condition that my identity is not revealed.
7. I have had the opportunity to discuss taking part in this research with a family member or friend.

Participant's signature……Date……...

I certify that I have explained the study to the volunteer and consider that she/he understands what is involved and freely consents to participation.

Researcher's name: Lourenço Camnahas

Researcher's signature……...Date…….

NB: Two signed copies should be obtained. The copy retained by the researcher may then be used for authorisation of Items 8 and 9, as appropriate.

8. I, the participant whose signature appears below, have read a transcript of my participation and agree to its use by the researcher as explained.

Participant's signature……Date……...

9. I, the participant whose signature appears below, have read the researcher's report and agree to the publication of my information as reported.

Participant's signature……Date……

Appendix 5. Data collection form for predictor of pharmaceuticals in Timor-Leste

Municipality	TotPop*	PerceFem	RuralPov	Urban	AlbAbsRt	LitTotal	LitFem	LitMale	MunAcces	BCGCover	OPV3	ANC4	DeliverP	OPDCap	AccesWat	LatCover	HFGovTot	HospTot*	HFNGO*	RRHAvail	MunCHC1	MunCHC2	MunHp	StafStrg	Phys
Aileu																									
Ainaro																									
Baucau																									
Bobonaro																									
Covalima																									
Dili																									
Ermera																									
Lautem																									
Liquica																									
Manatuto																									
Manufahi																									
Oecusse																									
Viqueque																									
Timor-Leste																									