

**Exploring Medicine Procurement through the lens of
the Basel Statements: A comparative study between
Australia and Nepal**

**A thesis submitted in fulfilment of the requirements
for the degree of Master of Philosophy (Pharmacy)**



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Declaration

This thesis, undertaken under the supervision of Dr. Betty Char and associate supervision of Dr. Rebekah Moles, is submitted as a part of the fulfilment requirements for the degree of Master of Philosophy (Pharmacy) in the Faculty of Pharmacy, at the University of Sydney.

The work presented in this thesis is, to the best of my belief and understanding, original, except as acknowledged in the text. I hereby would like to declare that this work has not been submitted in part or whole for the award of a degree at any other university.



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Abstract of Thesis

Background

The global scenario of hospital pharmacy practice shows that hospital pharmacy practice differs in developed and developing countries with the latter often being confined to more primitive product-centred models. In order to standardise hospital pharmacy practice around the world, international guidelines named the Basel Statements were developed by the International Pharmaceutical Federation (FIP) and cover six key elements of hospital pharmacy, one of which is medicines procurement. Despite disparity in global hospital pharmacy practice, equitable access to affordable and evidence-based high quality medicines is a common priority. Accessibility, affordability, safety, and quality of medicines are influenced by medicine procurement, therefore making medicine procurement one of the most important aspects of healthcare systems. It is believed that developed countries are more efficient in managing medicine distribution and have stronger regulatory frameworks that contribute to better access to medicines. Meanwhile there is a large proportion of people in low-income developing countries like Nepal that are deprived of access to essential medicines. Therefore, this study aimed to compare medicine procurement practices in hospitals of Australia (a high-income developed country) and Nepal (a low income developing country) based on the internationally recognized guidelines, the Basel Statements, with the objective of discovering facilitators and barriers to procurement practice and improving current medicine procurement practice in Nepal.

Chapter 1 of this thesis is a literature review conducted to explore medicine procurement issues utilising a framework of procurement statements of the Basel Statements. This literature review revealed that different aspects of procurement practice have been studied in different ways; however, it was found that there were some principles reflected in the Basel Statements in which there were a dearth of literature. Furthermore, much of the literature contained opinion pieces and individuals' perceptions of barriers to good procurement practices and there was a lack of scientific studies in the field. In regard to Nepal, there were very few studies and information available about medicine procurement practice in the country, indicating the need for a thorough study on medicine procurement practice and its issues, dissemination of public procurement reports, and other procurement related information.

Chapter 2 describes the methodology used for the two qualitative studies which comprise chapters 3 and 4. This chapter provides a short description of semi-structured interviews conducted and the framework analysis method and its suitability for this study, as well as the rationale for data division into the two manuscripts.

Chapter 3 contains the manuscript pertaining to a qualitative study about medicine procurement in hospital pharmacies of Nepal based on the Basel Statements. This chapter describes the medicine procurement procedures, compliance of hospitals to procurement guidelines of the Basel Statements, barriers to guideline implementation, and other procurement issues. This study revealed that the Basel Statements were implemented to some extent and barriers were reported to be privatisation of hospital pharmacies, influences on medicine selection procedures, sole authority of doctors on selecting medicines, and inefficient regulatory enforcement. Utilization of expensive procurement methods, lack of well-defined procurement procedures, influences on prescription based medicine selection, lack of systems for managing relationships between decision makers and pharmaceutical companies, lack of strategic preparedness plans, and availability of unregistered medicines especially during emergencies in hospital pharmacies near the Indian border were some of the major findings of this study. This study indicated that there is a need for improvement in some procurement issues; however, hospital pharmacies of Nepal are doing well in some aspects of procurement procedures.

Chapter 4 contains the manuscript pertaining to a comparative study of medicine procurement practices of Australia and Nepal conducted with the objective of discovering good procurement procedures and proposing evidence-based recommendations to improve current procurement practices of Nepal. The procurement theme of the Basel Statements is used as a reference standard to compare guideline compliance rates of public hospital pharmacies in the two countries. As expected, guideline implementation rates were higher in Australia compared to that of Nepal. Variation in procurement elements such as procurement methods, medicine selection processes, relationships between decision makers and pharmaceutical companies, contingency plans, the working culture, and perceptions of key stakeholders were evident between Australian and Nepalese procurement practices. However, some comparable factors were also reported; information resources, storage facilities, quality assurance principles, and expertise involvement in the procurement process were common to both settings. Whilst it is understood that procurement

procedures of Nepal need some improvements to be in line with international standards, attempts of hospital pharmacies of Nepal in implementing national procurement guidelines and practising good procurement procedures are gaining momentum and some elements of current practice are satisfactory. Utilization of international guidelines and successful strategies of Australian practice adapted to fit country's needs and capacities is recommended for Nepal.

Chapter 5 is a concluding chapter that summarizes and discusses major findings of this research and proposes recommendations for improving procurement practice in Nepal. Procurement issues, barriers to guideline implementation, and possibilities of improvements were summarised in this research. The comparative study provided insights into how developed countries like Australia are conducting effective procurement practices that meet international standards and how this country has been successful in providing equitable access to affordable and high-quality medicines to its population. Having said this, it was encouraging to see that there were good elements of procurement procedures also reported from Nepalese practice suggesting the progressive nature of procurement practices in Nepal. Good procurement procedures such as e.g. group contracting strategies, formulary systems, well-managed relationship between doctors/pharmacists and pharmaceutical companies are amongst many recommendations for Nepal to consider. Therefore, amendments of existing guidelines to incorporate missing elements and strengthening enforcement of national policies and guidelines would be recommended as a starting point for Nepal to work towards better practice. In addition to this, adoption and adaption of international guidelines to suit national requirements, resources and capacities are highly recommended for Nepal that would advance the current procurement practice to meet international standards.

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List of Abbreviations and Acronyms

ASHP	American Society of Health System Pharmacists
CIAA	Commission for the Investigation of Abuse of Authority
CME	Continuing Medical Education
DDA	Department of Drug Administration
EAHP	European Association of Hospital Pharmacists
EML	Essential Medicines List
FIP	International Pharmaceutical Federation
GDP	Gross Domestic Product
GMP	Good Manufacturing Practice
HDI	Human Development Index
HIV/AIDS	Human Immunodeficiency Virus Infection and Acquired Immune Deficiency Syndrome
HPV	Health Purchasing Victoria
INGOs	International Non-Governmental Organizations
Med-safe	Medication Safety
OECD	Organisation for Economic Co-operation and Development
P&T Committee	Pharmacy and Therapeutic Committee

PBS	Pharmaceutical Benefits Scheme
PP	Participant
SDGs	Sustainable Development Goals
SHPA	Society of Hospital Pharmacists of Australia
TB	Tuberculosis
TGA	Therapeutic Goods Administration
UK	United Kingdom
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
US FDA	United States Food and Drug Administration
US\$	United States Dollar
USA	United States of America
WHO	World Health Organization

Publications Arising from this Thesis

This thesis contains two chapters that are presented in the form of manuscripts submitted to journals for publication. Both chapters were under review during time of submission of thesis.

Chapter 3

Shrestha M., Moles R., Ranjit E., & Char B.

Medicine Procurement in hospital pharmacies of Nepal: A qualitative study based on the Basel Statements. PLoS ONE. 2016

Chapter 4

Shrestha M., Moles R., & Char B. How do we procure medicines? A comparative study between Australia and Nepal based on the Basel Statements. Health & Place. 2016

Conference Presentations

Poster Presentation

Mina Shrestha, Rebekah Moles, Eureka Ranjit, Betty Char. Medicine Procurement in hospital pharmacies of Nepal: A qualitative study based on the Basel Statements presented at **APSA-ASCEPT 2015 Joint Scientific Meeting Conference** held at Hotel Grand Chancellor Hobart, Tasmania, Australia. 29 November-2 December 2015.

Oral Presentation

Mina Shrestha, Rebekah Moles, Eureka Ranjit, Betty Char. Medicine Procurement in hospital pharmacies of Nepal: A qualitative study based on the Basel Statements at **Postgraduate Conference** held at the Faculty of Pharmacy, The University of Sydney. 18-20 November 2015.

Background to this Thesis

Background to this Thesis

Medicines are the primary vehicle for healthcare delivery and have huge impact on the health and well-being of people around the globe [1-3]. Medicines, in conjunction with other healthcare services, assist in treating diseases, promoting quality of life, and minimizing mortality rates [4]. Equitable access to affordable and quality medicines is therefore considered as a fundamental human right [5] and one of the targets of the Sustainable Development Goals [6]. Equitable access to medicines is also vital for achieving several other Sustainable Development Goals (SDGs) such as minimizing child death, improving maternal health and fighting against diseases like HIV/AIDS and tuberculosis [1-3, 6].

Costs of medicines utilize a large proportion of total health expenditure, especially in developing countries where expenditure could be as high as 60% of total health expenditure, making access to health care heavily reliant on availability and affordability of medicines [1, 7-9]. The World Health Organization (WHO) has emphasized the importance of availability, affordability, quality and safety of medicines for saving lives and improving health [4]. However, more than half of the population in low-income countries in Africa and Asia do not have regular access to essential medicines, either due to lack of regulatory authority or limited capacity to regulate medicines distribution [1, 8, 9]. Although the Essential Medicines List (EML) Programme of WHO has been hugely successful in improving accessibility of essential medicines in many low and middle-income countries, access to medicines is still a vast global problem, particularly for underprivileged populations [10]. Due to poor availability of medicines in the public sector, high prices in private sectors, and lack of universal healthcare in many low-income countries, medicines tend to be unaffordable for the majority of the population in these countries [8]. This causes lack

of access to medicines and healthcare, which can lead to loss of income and increase in healthcare cost creating a never ending poverty cycle for poor and underprivileged populations [11].

One such country with poor accessibility and affordability of essential medicines [12] in South-Asia is Nepal, which is categorized by the World Bank in the low-income group [13]. It is a landlocked country with a population of 28.17 million [14] with a Gross National Income (GNI) per capita (Atlas method) of US\$730 [14]. This is half of the average South Asian value of US\$1496, lower than average least-developed countries value of US\$844 and much lower than the global value of US\$10787 [15]. Nepal ranks 145th in Human Development Index (HDI) with 0.540 value (2014) [16] and has Gross Domestic Product (GDP) growth of 5.4% (2014) [14], forcing 25.2% of its population to live under the poverty line [13]. With 5.69% of Nepal's GDP spent on health [17], the health status of Nepal is poor, and life expectancy at birth is only 68 years [13]. The adult mortality rate is 176 per 1000 population [18] and the under-five mortality rate is 35.8 per 1000 live births [19].

Health services in Nepal are provided mainly by three types of healthcare facilities: governmental institutions, non-governmental and non-profit organizations, and private health institutions [20]. Availability of medicines is poor in public health institutions, whilst prices of medicines are 66.3% higher in private health institutions of Nepal [21]. The government health expenditure accounted for 39.04% of total expenditure (including 33.8% contribution from external development partners and donor organizations) and private health expenditure covered the remaining 60.96% of total health expenditure [17, 22]. The government and donor organizations provide funding for selected healthcare services and freely distributed essential medicines and patients then have to pay for all other healthcare facilities and medicines [22, 23]

which in total means that out-of-pocket expenditure comprises of 48.68% of total health expenditure [17].

WHO has recommended rational selection and use of essential medicines, affordable prices, sustainable financing, and reliable health supply systems to improve accessibility of essential medicines [4, 9].

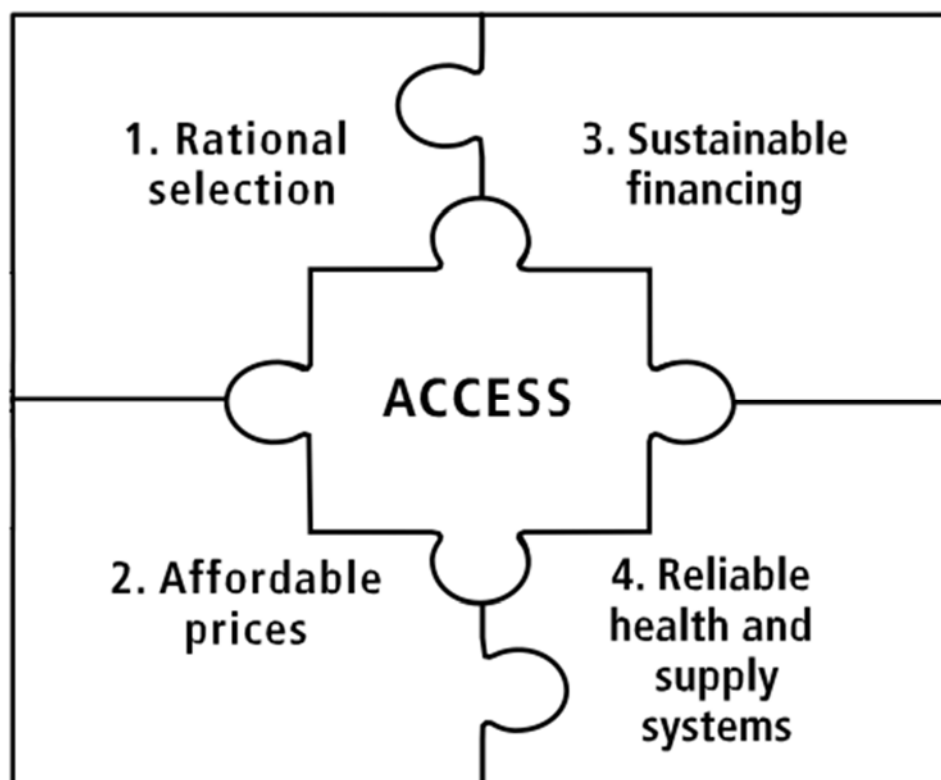


Figure 1: Access framework (adapted from WHO 2004) [4]

Similarly, Bigdeli *et al.* (2013) (Figure 2) have also proposed recommendations which emphasised improving affordability, perceived quality of medicines and attitudes of healthcare providers, health financing and resources, policy reforms, pharmaceutical innovations, transparency, and external funding system [10]. These factors included in recommendations from WHO and Bigdeli *et al.* constitute elements of the procurement process [24-26].

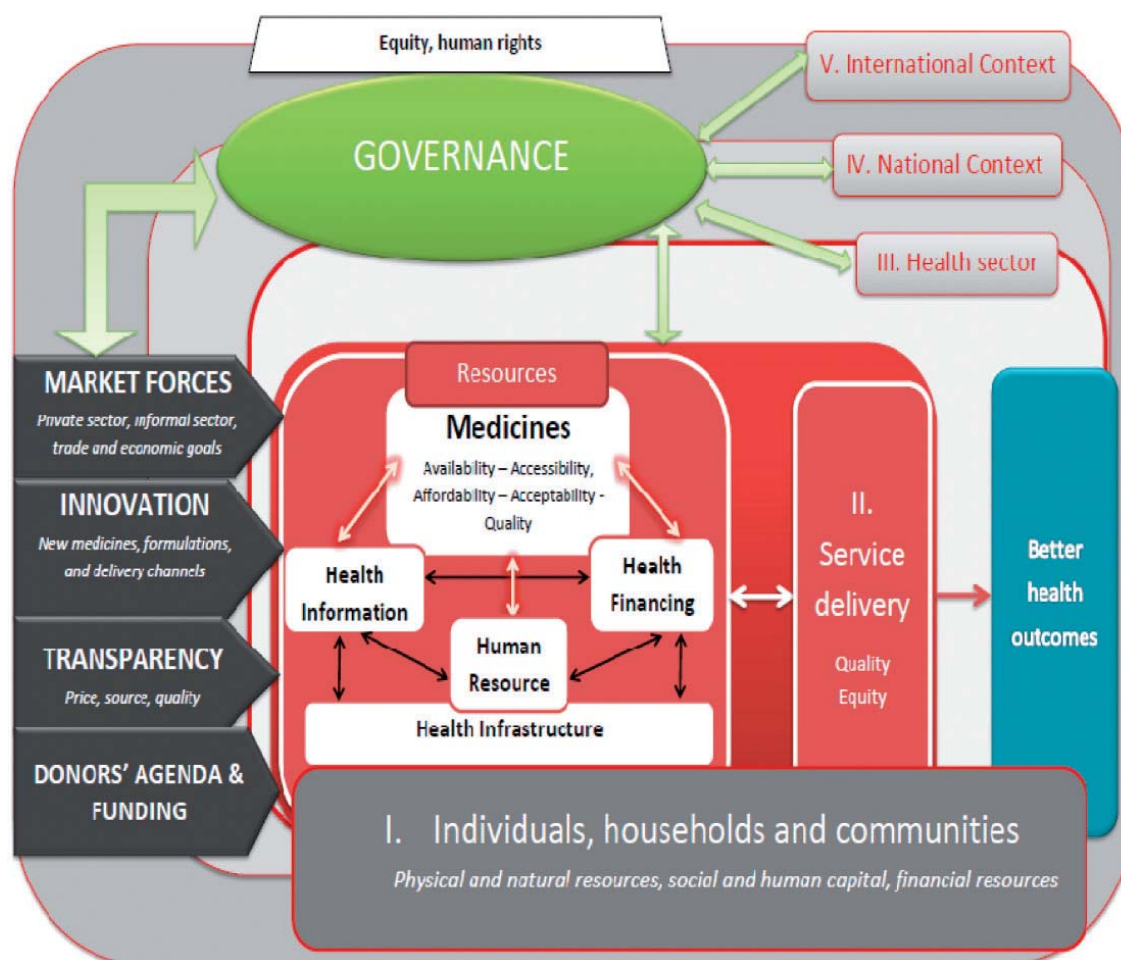


Figure 2: A conceptual framework of Access to Medicines (adapted from Bigdeli *et al.*, 2013) [10]

Much research has been conducted to identify barriers and recommend solutions to the lack of access to medicines for those in need, and a common element among them has been improvements in medicine procurement processes [8, 9, 11, 27, 28].

Procurement can be defined as the process of acquiring supplies through purchase from manufacturers or suppliers or distributors [1]. Medicine procurement has a huge influence on accessibility and affordability of evidence-based high quality medicines [1]. In addition to this, efficient medicine procurement systems have a significant influence on the overall functioning of healthcare systems [1]. The Organisation for

Economic Co-operation and Development (OECD) in 2005 has also emphasized the importance of efficient public sector procurement systems in achieving the Millennium Development Goals and sustainable development [27]. Thus, medicine procurement is considered an essential element of healthcare and the health economy, due to its huge impact on total health expenditure and quality, safety, availability and affordability of medicines [1, 7]. Effective procurement is critical for efficient medicine management and supply systems in any healthcare institution [1]. It is often a complex and specialized process involving a series of interdisciplinary processes under the supervision and involvement of persons with different expertise [1]. An effective procurement process should ensure availability of the right medicines in the right quantities, at the right time, for the right patients at reasonable prices, and at recognizable standards of quality [1]. Moreover, an effective procurement procedure should be able to assure the quality of medicines procured, manage timely delivery of medicines to avoid shortages and over stock, manage transparent and ethical relationship between suppliers and decision-makers, and select reliable suppliers [25]. The procurement process is illustrated in Figure 3.

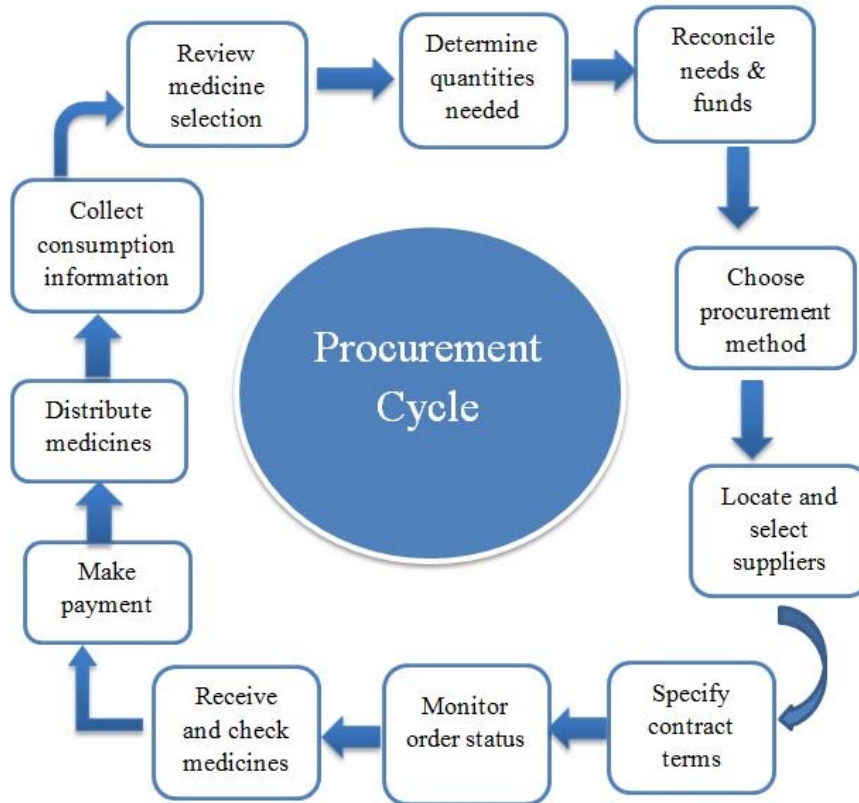


Figure 3: Procurement Cycle (adapted from MSH 2012) [25]

Procurement procedures may vary depending on the types of health institutions [25] and may utilize one or a combination of the following strategies:

1. **Centralized Procurement** governed by the central government [27].
2. **Parastatal Organization or Autonomous Supply Agency**, in which procurement is controlled centrally by an independent agency which is wholly or partly owned or regulated by the government [27].
3. **Decentralized Procurement** that works locally at the regional, district or municipal levels [27].

4. **Procurement Agents**, in which procurement procedures are carried out by independent procurement agents to assist government or as a requirement of funding organizations [27].
5. **Direct Delivery**, in which procurement is managed centrally but delivery is decentralized and occurs directly to individual health institution [4].
6. **Fully Private Supply** is a decentralized system that is managed by private organizations [4].

Procurement in Nepal differs, depending on whether the health institution is governmental, a non-profit organization or a private institution. Public procurement in Nepal is conducted in three different ways: central push/pull systems, district level drug programs, and community drug programs [29].

Procurement methods can be categorised into four basic types: open tender, restricted tender, competitive negotiations (including local and international procurement) and direct procurement [25]. Definitions of each type are listed below.

Open Tender is a type of competitive process which is open to all local and international suppliers with predefined terms and conditions [25].

Restricted Tender: In this type of tendering process, tender is restricted to suppliers that have been approved through a prequalification process conducted by procurement agency. This is also applicable to locally licensed manufacturers or importers which have been prequalified by national medicines regulatory authorities and analyses manufacturing and analytical procedures, compliance to national and international regulations, performance of suppliers, and financial viability [25].

Competitive Negotiations: In this method, a limited numbers of suppliers are contacted and asked for price quotations and are later subjected to a process of price negotiations. This can occur at local and international level. This method is usually utilized by private organizations, as public procurement might not allow bargaining with suppliers [25].

Direct Procurement: The simplest but most expensive method involves direct purchasing from a single supplier at either an allocated price or negotiated discount price. Purchase of medicines with a single source supplier is usually conducted through this procurement method [25].

Each category has both advantages and disadvantages (Table 1) [30].

Table 1: Procurement Methods

Procurement Method	Advantages	Disadvantages
Open tender	Higher number of bidders, more competitive price, and discovery of new potential suppliers	Higher workloads for evaluation and selection
Restricted tender	Relatively fewer bidders, prequalification of suppliers, easier for evaluation	Limited choices prequalification system should be designed
Competitive negotiations	Well-known suppliers therefore easy and less work	Relatively higher prices
Direct procurement	Easy and quick	Higher prices

Selection of procurement methods is generally influenced by funding mechanisms, procurement policies and regulations, quality assurance systems, price of medicines, expertise involvement, and capabilities of management [27]. Written guidelines should be made available to the committee and the procurement staff in helping to choose the best procurement method for a given product, to obtain the lowest possible purchase price for assured quality from reliable suppliers [1]. Public hospitals of Nepal are encouraged to procure medicines in accordance with the Public Procurement Guidelines. The Public Procurement Guidelines published by Ministry of Health and Population, Government of Nepal provides detailed stepwise description on formulating procurement unit and necessary sub-committees, selecting appropriate procurement methods depending on quantity and nature of goods/services, carrying out procurement process, and conducting evaluation process. The guideline advocates for competitive and open tendering process to purchase of low-cost quality products and gives high preference for goods manufactured locally in Nepal, even the price is higher up to 10%. Although, this is a general guideline applicable to all products/services purchased, special evaluation criteria have been formulated for medicines [31].

In relation to procurement specifically, the WHO has recognized the following issues as major problems associated with procurement of medicines [24]:

- Inadequate rules, regulations and structures
- Public sector staff with little experience in responding to market situations
- Absence of a comprehensive procurement policy
- Insufficient and irregular government funding

- Conflicting procurement regulations of donor agencies
- Fragmented provincial or district levels procurement system (decentralized system)
- Lack of unbiased market information
- Lack of trained procurement staff

The aim of this study was to explore the issue of medicine procurement in hospital pharmacies of Nepal, compare medicine procurement practices of hospital pharmacies between Nepal and Australia, and propose evidence-based recommendations to overcome existing barriers, to improve current procurement practice.

Although Nepal has the Public Procurement Act and Guidelines [31, 32], National Medicine Policy [33], and Hospital Pharmacy Directives [23], these policies and guidelines do not address medicine procurement in much detail. Moreover, the country does not have any specific medicine procurement-related policies and guidelines.

In order to compare medicine procurement practices between two different countries, an international standard which could suit practices of both countries was needed.

The FIP Basel Statements are international guidelines that standardise the global hospital pharmacy practice and medicine procurement is one of the themes included.

The Medicine Procurement theme of the Basel Statements provides guidance on procurement procedure in hospital pharmacy and advocates for transparency, professional and ethical procurement practice that leads to timely purchase of high-quality, affordable and safe medicines under the supervision of skilled and qualified

personnel. The Basel Statements were therefore selected as reference standards for exploring medicine procurement in hospital pharmacies of Nepal. Additionally, we aimed to analyse compliance of procurement practices with medicine procurement-related policies that have been included in national policies and guidelines of Nepal.

The work outlined in **Chapter One** pertains to a review of the literature regarding medicine procurement practices with reference to procurement guidelines of the Basel Statements.

Chapter Two outlines qualitative methods used to interview pharmacists from both Nepal and Australia.

Chapters Three and Four then outline the findings of the qualitative work, and have been inserted in manuscript format as they have been submitted for publication.

Finally, the thesis concludes with **Chapter Five** which draws this original work together and concludes with recommendations for Nepal.

References

1. Baghdadi-Sabeti G, Cohen-Kohler JC, Wondemagegnehu E. Measuring Transparency in the Public Pharmaceutical Sector. World Health Organization. 2009. Available from: <http://apps.who.int/medicinedocs/documents/s16732e/s16732e.pdf>. Accessed 2 February 2016.
2. Doloresco F, Vermeulen LC. Global Survey of Hospital Pharmacy Practice. *Am J Health Syst Pharm*. 2009. 66(5 Suppl 3):S13-9.
3. Hogerzeil HV. Essential Medicines and Human Rights: What Can They Learn from Each Other? *Bull World Health Organ*. 2006. 84(5):371-5.
4. World Health Organization. Equitable Access to Essential Medicines: A Framework for Collective Action. WHO Policy Perspectives on Medicines. 2004.1-6.
5. Office of the United Nations High Commissioner for Human Rights, World Health Organization. The Right to Health. United Nations. 2008. Available from: http://www.who.int/hhr/activities/Right_to_Health_factsheet31.pdf. Accessed 4 February 2016.
6. The United Nations. Sustainable Development Goals. UN Web Services Section, Department of Public Information, United Nations. 2015. Available from: <http://www.un.org/sustainabledevelopment/health/>. Accessed 4 February 2016.
7. Ombaka E. Current Status of Medicines Procurement. *Am J Health Syst Pharm*. 2009. 66(5 Suppl 3):S20-8. doi: <http://dx.doi.org/10.2146/ajhp080604>.
8. Cameron A, Ewen M, Auton M, Abegunde D. The World Medicines Situation 2011: Medicines Prices, Availability and Affordability. World Health

- Organization. 2011. Available from:
<http://apps.who.int/medicinedocs/documents/s18065en/s18065en.pdf>
Accessed 5 February 2016.
9. World Health Organization. Access to Medicines. World Health Organization. 2016. Available from: <http://www.who.int/trade/glossary/story002/en/>.
Accessed 3 January 2016.
10. Bigdeli M, Jacobs B, Tomson G, Laing R, Ghaffar A, Dujardin B, et al. Access to Medicines from a Health System Perspective. Health Policy Plan. 2013. 28(7):692-704. doi: 10.1093/heapol/czs108.
11. Peters DH, Garg A, Bloom G, Walker DG, Brieger WR, Hafizur Rahman M. Poverty and Access to Health Care in Developing Countries. Ann N Y Acad Sci. 2008. 1136(1):161-71. doi: 10.1196/annals.1425.011.
12. Babar ZU, Lessing C, Mace C, Bissell K. The Availability, Pricing and Affordability of Three Essential Asthma Medicines in 52 Low- and Middle-Income Countries. Pharmacoeconomics. 2013. 31(11):1063-82.
13. The World Bank. Nepal. The World Bank Group. 2015. Available from: <http://data.worldbank.org/country/nepal>. Accessed 6 February 2016.
14. The World Bank. World Development Indicators: Nepal. The World Bank Group. 2015. Available from: <http://databank.worldbank.org/data/reports.aspx?source=2&country=NPL&series=&period=>. Accessed 6 February 2016.
15. The World Bank. Economy and Growth. The World Bank Group. 2014. Available from: <http://data.worldbank.org/topic/economy-and-growth>.
Accessed 6 January 2016.

16. United Nations Development Programme. 2014 Human Development Report. United Nations Development Programme. 2015. Available from: <http://www.undp.org/content/undp/en/home/librarypage/hdr/2014-human-development-report/>. Accessed 8 February 2016.
17. World Health Organization. Health Expenditure Ratios, All Countries, Selected Years Estimates by Country. 2013. Available from: <http://apps.who.int/gho/data/node.main.75?lang=en>. Accessed 5 February 2016.
18. World Health Organization. Adult Mortality Data by Country. World Health Organization. 2015. Available from: <http://apps.who.int/gho/data/view.main.1360?lang=en>. Accessed 5 February 2016.
19. World Health Organization. Probability of Dying Per 1 000 Live Births Data by Country. World Health Organization. 2015. Available from: <http://apps.who.int/gho/data/node.main.ChildMort-2?lang=en>. Accessed 5 February 2016.
20. Dixit H. The Quest for Health: The Health Services of Nepal. Kathmandu: Educational Enterprise (P) Limited; 1999.
21. Mendis S, Fukino K, Cameron A, Laing R, Filipe Jr A, Khatib O, et al. The Availability and Affordability of Selected Essential Medicines for Chronic Diseases in Six Low- and Middle-Income Countries. Bull World Health Organ. 2007. 85(4):279-88. doi: 10.2471/BLT.06.033647.
22. Government of Nepal, Ministry of Health and Population. Current Status of Mohp's Annual Work Plan and Budget. Government of Nepal, Ministry of Health and Population. 2013. Available from:

- <http://www.mo hp.gov.np/images/pdf/publication/Budget-Analysis-2070-71.pdf>.
Accessed 6 February 2016.
23. Government of Nepal, Ministry of Health and Population. Hospital Pharmacy Directives. Government of Nepal, Ministry of Health and Population. 2013. Available from: http://www.slideshare.net/niraj_bartaula/hospital-pharmacy-service-directives-2070-55955345. Accessed 3 February 2016.
24. Rankin J, Quick JD, Muziki. S, Woldeyesus K, Fresle DA, Grayston G, et al. Operational Principles for Good Pharmaceutical Procurement. WHO's Department of Essential Drugs and Medicines Policy (EDM). 1999. Available from: <http://www.who.int/3by5/en/who-edm-par-99-5.pdf>. Accessed 6 February 2016.
25. Barraclough A, Clark M. Managing Procurement. 2012. In: Managing Access to Medicines and Health Technologies [Internet]. Arlington, VA: Management Science for Health. [18.1-.26]. Available from: <http://apps.who.int/medicinedocs/documents/s19577en/s19577en.pdf>. Accessed on 7 February 2016.
26. The Basel Statements on the Future of Hospital Pharmacy. Am J Health Syst Pharm. 2009. 66(5 Suppl 3):S61-6.
27. Dickens T. The World Medicines Situation 2011-Procurement of Medicines. World Health Organization. 2011. Available from: <http://apps.who.int/medicinedocs/documents/s18769en/s18769en.pdf>. Accessed 5 February 2016.
28. Cameron A, Ewen M, Ross-Degnan D, Ball D, Laing R. Medicine Prices, Availability, and Affordability in 36 Developing and Middle-Income Countries: A Secondary Analysis Lancet. 2009. 373(9664):632.

29. Harper I, Brhlikova P, Subedi MS, Bhattarai S, Basu S, Gupta AD, et al. Drug Procurement in Nepal. 2007. Available from: http://www.csas.ed.ac.uk/_data/assets/pdf_file/0009/38826/DrugProcurementNepal.pdf. Accessed 3 February 2016.
30. World Health Organization. Practical Guidelines on Pharmaceutical Procurement for Countries with Small Procurement Agencies. WHO Regional Office for the Western Pacific. 2002. Available from: <http://apps.who.int/medicinedocs/pdf/h2999e/h2999e.pdf>. Accessed 6 February 2016.
31. Government of Nepal, Ministry of Health and Population. Public Procurement Guidelines. Government of Nepal, Ministry of Health and Population. 2009. Available from: <http://mohp.gov.np/index.php/publication-1/guideline>. Accessed 3 February 2016.
32. Public Procurement Act 2007, Act Number 36 (2007). Government of Nepal.
33. Government of Nepal. National Medicines Policy 2007. 2007. Available from: <http://www.mohp.gov.np/images/pdf/policy/National%20Medicine%20Policy.pdf>. Accessed 5 February 2016.

Chapter 1

Literature Review

Chapter 1: Literature Review

Medicine Procurement in hospital pharmacies through the lens of the Basel Statements: Lessons for Nepal

1.1. Background

Pharmacy is an integral part of healthcare in health institutions. Pharmacists are responsible for managing medicines and related health processes to optimize outcomes and enhance safety and quality of health services provided to patients. Hospital pharmacy is a specialized area of pharmacy practice, described as the “practice of selecting, manufacturing, managing, and dispensing medicines and medical devices, and advising healthcare professionals and patients on the safe, effective and efficient use of medicines” [1]. Hospital pharmacy is responsible for ensuring the 7 “rights” of medicine use for patients: the right patient, right dose, right route, right time, right drug with the right information and documentation [1].

Hospital pharmacy practice has evolved from traditional product-centred practice models to contemporary patient-oriented models of services [2, 3]. In the early 1900s up until the 1950s, the pharmacy profession was solely focused on medicine production, compounding and dispensing. The first substantial change in practice came in the mid-1960s when the concept of patient-oriented clinical pharmacy services was introduced [3]. There was gradual progression, with academic curricula being revised to include clinical pharmacy and providing clinical training to pharmacy students. Pharmacists were being considered as drug experts, and there was adoption of multidisciplinary collaboration in patient services [2, 3]. It was the early 1990s when the concept of pharmaceutical care was introduced which emphasised the role of pharmacists in rationalising drug therapy [3].

Some major advancement also took place throughout the last decade with adoption of the concept of personalized medicine, evidence-based decision making processes, as well as advanced and specialized education programs [2].

Contemporary hospital pharmacy practice in many developed countries is now focused on activities such as patient care services, promotion of rational use of medications, individualized drug therapy, specialty pharmacy practice, drug-use evaluation, and cost-effective analysis [2, 3]. In addition to this, collaborative or supplementary prescribing models are flourishing globally and already in practice in countries like Canada, United Kingdom (UK) and United States of America (USA) [2]. This increasingly complex and diverse nature of hospital pharmacies' and pharmacists' roles in the health-care system requires established, effective standards of services and practice objectives [4].

Many countries have developed their own national guidelines for various aspects of healthcare services and professional practices. For instance, the United States of America has American Society of Health-System Pharmacists (ASHP) guidelines [5], Australia follows The Society of Hospital Pharmacists of Australia (SHPA) practice standards [6], and Europe has the European Association of Hospital Pharmacists (EAHP) guidelines [7]. Some developing countries have adapted the FIP-WHO Good Pharmacy Practice guidelines to formulate national guidelines to suit their country's health needs in pharmacy. For example, Nepal has adapted FIP-WHO guidelines to formulate the National Good Pharmacy Practice Guidelines [8]. The government of Nepal has also published Hospital Pharmacy Directives 2013 [9].

Doloresco and Vermeulen (2009) conducted a global survey exploring the status of hospital pharmacy practice around the world and discovered the existence of traditional product-oriented practice models in many countries [10]. Despite the fact

that present day hospital pharmacy practice have progressed exclusively in some countries, hospital pharmacy in many countries, especially developing and low and middle-income countries still follow traditional medicine distribution practices, and are still struggling to establish basic clinical practice [11, 12]. For instance, Australia, a developed country [13], is advancing clinical pharmacy practices and is practising patient-centred specialty pharmacy practices [14, 15] whereas Nepal, a developing country [16], still has not progressed from out-dated product-centred pharmacy practice models [17, 18]. Therefore, there is a need for adoption of global standards based on essential elements of hospital pharmacy practice, in order to improve and standardise the pharmacy profession globally, and achieve professional goals, societal expectations and patient care goals [11, 12].

With the objective of developing global consensus statements about the advancement of hospital pharmacy practice, the 'Global Conference on the Future of Hospital Pharmacy' was held by the Hospital Pharmacy Section of International Pharmaceutical Federation (FIP) in Basel, Switzerland in 2008 [10, 19, 20]. This global conference resulted in the development of the first set of international consensus statements named the Basel Statements [20], which were based on mutual agreement by representatives of hospital pharmacists from around the world. These Basel Statements consisted of 75 statements under six key elements of hospital pharmacy practice [20], and have been considered as valuable guidelines for standardizing hospital pharmacy practice around the globe [21, 22]. Medicine procurement is one of the six themes included [12] [20]:

1. Medicines procurement
2. Influences on prescribing
3. Preparation and delivery of medicines

4. Administration of medicines
5. Monitoring of medicines
6. Human resources and training

According to the Basel Statements 2008, the “Procurement” theme consists of nine statements (Table 2) [20].

Table 2: Procurement Guidelines of the Basel Statements 2008

Statement Number	Statements
17	The procurement process must be transparent, professional, and ethical to promote equity and access and to ensure accountability to relevant governing and legal entities.
18	Procurement should be guided by the principle of procuring for safety.
19	Procurement of pharmaceuticals is a complex process that requires pharmacist control and technically competent staff.
20	Operational principles for good procurement practice should be regularly reviewed and procurement models adapted to fit different settings and emerging needs in the most appropriate and cost effective way.
21	Procurement must be supported by strong quality assurance principles to ensure that poor quality medicines are not procured or allowed into the system. Proper storage to ensure maintenance of quality in the whole supply pipeline is mandatory
22	Procurement should not occur in isolation, but rather be informed by the formulary selection process.
23	Good procurement must be supported by a reliable information system that provides accurate, timely, and accessible information
24	A formal mechanism must be in place for pharmacists to request designated funds to procure medicines for their patients.
25	Each pharmacy should have contingency plans for medicines shortages and purchases in emergencies.

The Basel Statements 2008 were revised in September 2014 and published in 2015 [23]. The current version, the Basel Statements 2015, are comprised of 65 statements, instead of 75 statements in the first version, however the statements are still organised under the same six themes. The procurement guidelines of the revised Basel Statements 2015 have been tabulated as below (Table 3) [23].

Table 3: Procurement Guidelines of the Basel Statements 2015

Statement Number	Statements
20	Hospital pharmacists should be involved in the complex process of procurement of medicines and health products, promoting equity and access. They should ensure transparent procurement processes are in place in line with best practice and national legislation, are free from conflict of interest, and are based on the principles of safety, quality and efficacy.
21	Procurement practices must be supported by strong quality assurance principles, regularly reviewed and adapted to fit different settings and emerging needs in the most appropriate and cost effective way.
22	Procurement should not occur in isolation, but rather be guided by the formulary selection process. This includes the procurement of standard concentrations of high-risk medicines including electrolytes.
23	Procurement must be supported by a reliable information system that provides accurate, timely, and accessible information.

Whilst the revised version of Procurement Statements of the Basel Statements 2015 [23] consists of only four statements, the sentiment of procurement practices has remained unchanged. Some statements have remained in their entirety, whilst a few similar statements have been merged and few statements have been shifted into the overarching and governance statements section, however nothing in the original set of statements has been lost [20, 23].

Since the release of the Basel Statements 2008, studies have been conducted exploring the implementation of different themes of the Basel Statements and alignment of country's national guidelines with the Basel Statements [21, 24-30]. Although a couple of studies assessed compliance of hospital pharmacy practice [30] and national guidelines [29] with the Basel Statements, most research has focused on exploring clinical pharmacy services, formulary systems, and other medicine-use related matters pertaining to Influences on Prescribing theme (theme 2) of the Basel Statements [21, 24-28]. Research has been conducted in the Western Pacific region, China, Uganada and Canada only [21, 24-30]. However, to date no studies have been conducted to explore the implementation of the Basel Statements in South Asia.

As medicines are the primary vehicle for medical intervention in the modern era, providing access to medicines to patient from all backgrounds is an important issue for Nepal. Moreover, hospital pharmacy practice of Nepal is in its infancy, still in the medicine distribution model [17, 18]. Therefore, for conducting research in countries like Nepal, starting with the basic, yet very crucial theme of "Procurement" from the Basel Statements is both practical and relevant. A few reports about procurement of a few selected essential medicines purchased by government for free distribution in governmental organizations have been published [31-33], but they do not mention procurement procedures for all types of medicines and health institutions. Therefore, we aimed to explore procurement practice in hospital pharmacy in Nepal with reference to the Basel Statements.

Since the revised version was published late in 2015 after this research had commenced, nine statements from the first version, the Basel Statements 2008 (Table 2), have been referred to throughout this literature review and thesis. The

term Basel Statements used in this literature review and throughout the thesis refers to the first version, the Basel Statements 2008.

1.2. Objective

The objective of this literature review was to explore literature about procurement in hospital pharmacy based on the Basel Statements that could pose as beneficial information for improving procurement systems in Nepal.

1.3. Method

A narrative literature review was conducted initially to gather relevant information and ideas. The literature search was conducted using online databases including “Medline via OvidSP”, “PubMed”, “International Pharmaceutical Abstracts via OvidSP” and “Cinahl via Ebsco” using the keywords “procurement”, “purchasing”, “medicines”, “drugs”, “pharmaceuticals”, “hospital/hospitals”, “Basel statements”, “hospital pharmacy practice”, “pharmacy practice”, “transparency”, “corruption”, “quality”, “hospital formulary”, “medicines formulary”, “formulary system”, “medicines selection”, “drug selection”, “cost-effective”, “cost control”, “medicines safety”, “drug safety”, “pharmacists”, “supervision”, “role of pharmacists”, “pharmacy and therapeutics committee”, “medicines shortage”, “hospital funding”, “hospital expenditure”, “information” and “information system” under the time frame of 2000-current.

Bibliographies of articles were also hand searched to find additional relevant articles.

The website of the World Health Organization (WHO) was searched for gathering relevant health statistics and guidelines on pharmacy practice and procurement.

Websites of the International Pharmaceutical Federation (FIP), American Society of

Health-System Pharmacists (ASHP) and European Association of Hospital Pharmacists (EAHP) were searched for identification of different guidelines on various aspects of hospital pharmacy practice and procurement. Websites of the Department of Drug Administration and Ministry of Health of Nepal were browsed for statistical, financial and regulatory information and guidelines.

References from both developing and developed countries were reviewed and discussed within the framework of each of the 9 Basel Statements 2008 on Procurement.

1.4. Results

Pertinent papers that were related to each of the procurement statements of the Basel Statements 2008 are referred to under each section.

1.4.1 “The procurement process must be transparent, professional, and ethical to promote equity and access and to ensure accountability to relevant governing and legal entities.”

Pharmaceutical procurement is very susceptible to unethical practices and a study has shown that transparency, professionalism and equity are some of the major concerning issues of key stakeholders for procurement in healthcare settings [34]. Although a global problem, multiple predisposing factors, such as having a weak regulatory authority, lack of regulation enforcement, low staff remuneration, poor procedures, and inadequate payment practices, place developing countries at higher risk of corruption [34]. Lack of transparency can have negative health and economic consequences [35] and can have greater impact on poor people because they can

neither afford these consequences nor opt for any other alternatives, making them deprived of access to medicines [36].

Medicines selection processes can be influenced by marketing strategies of pharmaceutical industries that sometimes manipulate scientific evidence in favor of newer, more expensive, on-patent drugs [37]. Such influential practices are common in developing countries such as India [38] and China [28], and have also been observed in Nepalese hospitals [39]. However, pharmaceutical companies can try to influence physicians practicing in developed countries like United States of America (USA) to add medicines onto the formulary [40]. To manage such influential practices, countries like USA and Australia have developed specific codes of conduct for this purpose [41-45]. Moreover, pharmaceutical companies of these countries are attempting to avoid unethical practices by following their own internal code of conduct [43, 46] that require them to disclose details of promotional activities. The Department of Drug Administration of Nepal has formulated “Guidelines on Ethical Promotion of Medicine” [47] but these are reportedly yet to be fully enforced. Nepal Medical Council has developed the Code of Medical Ethics [48] for promoting ethical practice but has failed to cover ethical issues between healthcare professionals and pharmaceutical companies. Nepalese pharmaceutical companies and regulatory authorities could develop similar codes to further promote ethical medicine use and relationships between pharmaceutical companies and decision-makers. Nepal can also benefit from international codes and ethical guidelines [49, 50] while amending their existing codes and guidelines. WHO further suggested that there should be provision for declaration of a conflict of interest by members of P&T Committees and tender committees to minimize opportunities for corruption, favouritism or political influence [35].

Garuba *et al.* conducted a study to explore perspective of policy makers on transparency in Nigerian public pharmaceutical procurement and reported that Nigeria, a developing country like Nepal, has adopted competitive procurement procedures, unbiased tender processes and well defined tender committees. However, lack of conflict of interest guidelines and public availability of audit results were reported to increase vulnerability to corruption in the public procurement of Nigeria [51]. Nepal, similar to other developing countries, is also extremely vulnerable to corruption [52].

WHO has published an assessment instrument for measuring transparency that provides a description about the rationale for assessment, assessment criteria and scoring [35]. A few proven effective methods proposed include: choosing transparent procurement methods that are open and fair, having written procurement guidelines, dividing key procurement functions different individuals or committees to avoid favouritism and bias, having public dissemination of information (especially of tender process and results), having an appeals system, and making sure regular auditing and monitoring occur [35, 53]. Ombaka (2009) has outlined that establishing good incentive structures may foster ethical behavior [34]. Transparency and corruption-free procurement practices are essential to gain trust and to maintain mutual relationships between implementers and governance organizations [34].

1.4.2 “Procurement should be guided by the principle of procuring for safety.”

Access to safe medicines is considered a fundamental right of patients [54]. Patient safety is therefore a major priority of any health institution, and medicines should be procured based on their proven safety and efficacy [35] [34]. A survey by WHO in

2005 showed that the majority (63%) of counterfeit medicines came from East Asian countries with India (a neighboring country to Nepal) being the leader of counterfeit medicines production (35%) [55]. Developing and low-income countries like Nepal, which rely on other countries (India, in case of Nepal) for many life-saving and essential medicines, and active pharmaceuticals required for medicine production, are more susceptible to the introduction of counterfeit and substandard medicines because of weak regulatory policies, which can pose serious threats to patient's health [56]. Developed countries like Australia and United States of America (USA) have been prioritizing safety in their practices, policies and regulatory procedures [54, 57-59]. WHO have published guidelines for developing strategies to prevent entry of counterfeit and substandard medicines [60] which can be useful for developing countries like Nepal. It has been stated in a literature review by Ombaka in 2009, that there should be written procurement procedures with description of criteria for selection of medicines that can promote safe practices, strategies for decreasing medication errors associated with labelling and packaging, and criteria for risk assessment [34]. National Medicine Policy 2007 of Nepal advocates for quality of medicines, but safety issues have not yet been given adequate attention [61]. Risk assessment tools should be developed and used for suppliers with unknown or poor histories and for procurement of new generic products, problematic products, parallel import products, products requiring specialized labelling such as injectable and products in high-risk therapeutic categories like anticoagulants [34].

1.4.3. *“Procurement of pharmaceuticals is a complex process that requires pharmacist control and technically competent staff.”*

Pharmaceutical procurement is a multi-disciplinary process requiring medical, pharmaceutical, managerial, financial and sometimes even political expertise [62].

Personnel involved in the procurement process should be competent to ensure the availability of acceptable quality medicines at the lowest possible price in a timely and appropriate manner [34]. The staff involved in the process should possess good communication skills and knowledge of medicines inventory and consumption [62]. WHO recommended the presence of at least one pharmacist in a senior position overseeing the process, as well as pharmacists with expertise in different aspects of the pharmaceutical procurement throughout the supply chain [53]. A practical ASHP guideline on P&T Committees and the Formulary Systems [63] and a WHO guideline on P&T Committees and the Formulary Systems [63] and a WHO guidelines titled “Drug and Therapeutics Committees-A Practical Guide” (2003) [64] have highlighted the role of pharmacists in medicines selection while procuring medicines. Nepal’s National Good Pharmacy Practice guidelines also state the involvement and supervision of pharmacists in the procurement process [8]. The involvement of clinical pharmacologists, pharmacoconomics and pharmacoepidemiology experts can also be beneficial in cost-effective analysis and medicines selection [65].

1.4.4. “Operational principles for good procurement practice should be regularly reviewed and procurement models adapted to fit different settings and emerging needs in the most appropriate and cost effective way.”

In order to make the procurement process easier, simpler and effective, several operating principles and guidelines have been published by different international organizations. One of the best known is the WHO’s “Operational Principles of Good Pharmaceutical Procurement” [53] which can be adapted by individual governments organizations to develop their own national and internal procurement procedures to achieve optimal outcomes from the procurement process. The operational principles

should also provide guidance for selecting the most cost-effective medicines of appropriate quality to treat common diseases prevalent within the health institution. These principles tackle and minimize possible procurement-related problems, help develop improvement plans, pre- and post-qualification procedures, continuous monitoring of system and suppliers, and management of procurement and delivery [34, 53].

The Government of Nepal has developed the Public Procurement Act 2007 [66] and Public Procurement Regulations 2007 [67] to regulate public procurement in Nepal. In order to assist public procurement procedures, Nepal has also published the Public Procurement Guidelines [68] that could be utilized by all health organizations. Similarly public procurement in Australia must be conducted in Australian public hospitals by utilizing their own hospital policies in accordance to the Commonwealth Procurement Rules [69] and their state and national policies.

Clinical and pharmaceutical advancements and innovations around the world are causing incremental increases in medicine and total health expenditure [70]. According to Milovanovic et.al., 2004, there is therefore an urgent need to control health expenditure through the development and implementation of national medicines policies, with a focus on procurement [65]. Decisions should be based initially on considerations of clinical effectiveness and then on cost-effectiveness [71]. Cost containment is even more important in developing countries like Nepal, which have limited resources and a lack of medicines financing facilities, and where the general public is required to pay completely by themselves [32, 62].

Purchasing medicines based on a formulary list is one of the methods to control medicines expenditure [72]. Two approaches have been proposed to control medicines expenditure [73]:

1. Supply-side management- focuses on negotiations and includes price control, profit control, pooled procurement, rebates, reference pricing, expenditure ceilings
2. Demand-side management- focuses on the management of medicines use by prescribers and patients and includes educational campaigns, prescribing guidelines, patient co-payments, switching prescription medicines to over-the-counter medicines, promoting the use of generics, budget decentralization, and regulating medicines promotion.

European countries have also developed similar price control policies and have been successful at controlling costs of medicines [74]. Australia has the Pharmaceutical Benefits Scheme which provides medicines to the public at government-subsidized prices [75]. According to Barraclough and Clark (2012), pooling volumes of medicines from each unit, institution, region or country to create a single large volume, has been reported to attract more suppliers and provide more competitive prices [62]. Several organizations like United Nations Children's Fund (UNICEF), United Nations Development Programme (UNDP), and Stop TB Global Drug Facility, and countries like New Zealand and India have utilized pooled procurement to control medicine expenditure and increase availability of medicines [62, 73, 76]. Nepal also utilizes a pooled procurement system, but only for purchasing some essential medicines that are freely distributed for public health institutions [33]. Additionally, group contracting or contractual agreements have been suggested as

useful add-ons in pooled procurement. These group contracting agreements follow centralized tendering systems (i.e. tender conducted and the best price negotiated centrally by the central governing body of group/organization/country on behalf of all associated member organizations), but allow decentralized purchasing by individual organizations in a group or parent organization or country [77, 78]. Various international organizations like United Nations Children's Fund, United Nations Population Fund and Global Fund, and countries like the United States in their Department of Veterans' Affairs and Department of Defense have also benefitted from these strategies [78]. Similar strategies have also been recommended for low and middle-income countries like Nepal [79]. Nepal could also utilize ASHP guidelines on cost management which provides guidance on budget planning, maximizing resource use, and managing procurement and inventories [70]. Good price negotiation is achievable with the support of local and global price information and market surveillance [34]. Furthermore, transparency in the tender process can attract suppliers which can increase competition, giving the lowest possible price. Reliable payment mechanism and prompt payment methods can also minimize prices [62].

1.4.5. "Procurement must be supported by strong quality assurance principles to ensure that poor quality medicines are not procured or allowed into the system. Proper storage to ensure maintenance of quality in the whole supply pipeline is mandatory."

The quality of medicines is one of the key components of pharmaceutical procurement because of increasing availability of counterfeit, substandard and contaminated medicines on the market that have the potential to pose serious health threats [62]. Problems with counterfeit medicines are more common in developing

countries because of their weak regulatory policies and enforcement capacities as compared to developed countries with strong enforcement of regulatory policies and more transparent supply chains [56]. For instance, developed countries like Australia have well-developed regulatory frameworks such as the Therapeutic Goods Australia (TGA), for ensuring quality of medicines, and preventing entry of counterfeit medicines [80]. In comparison, 25-50% of medicines in developing countries are reportedly counterfeit [81]. Counterfeit and substandard medicines can have serious health and economic consequences, that may complicate the work of healthcare providers and policy makers in correcting and preventing such problems [56]. The loss of economy, quality of life and work productivity can create a never-ending vicious cycle of poverty in the developing world [81]. Nepal shares an open border with India, where availability and production of counterfeit and substandard medicine are high [55]. Since Nepal heavily relies on India for medicines, especially life-saving medicines, and raw materials for local pharmaceutical manufacturing, Nepal is very susceptible to introduction of counterfeit and substandard medicines. It is therefore necessary for health organizations to develop and implement their own internal quality-assurance systems based on national or international guidelines and evaluate the quality of products and suppliers before, during and after purchasing. A model of quality assurance system developed by the WHO [82] and a guide published by the Management Sciences for Health [62] could be utilized to develop and implement internal quality-assurance systems. Although both prequalification and post-qualification have been used for analysis of suppliers of medicines, prequalification is generally preferred and considered to be more effective [62]. An effective procurement procedure should assure that procured medicines are of the

specified quality and should monitor and maintain the quality throughout the distribution chain [62].

Four components for making a quality assurance system effective are: selection of reliable suppliers, use of existing international mechanisms, established programmes for product defect reporting and use of targeted quality control testing [53]. Quality of products can be examined by various physical and qualitative tests which can be undertaken in a hospital's own laboratory or in coordination with other independent or national quality control laboratories [34]. Moreover, inexpensive and easy to use quality control test kits are also available [83].

In an attempt to combat counterfeiting globally, the WHO has also established guidelines for the development of measures to combat counterfeit drugs [60], which could be a useful resource for Nepal. Purchasing medicines from prequalified suppliers is another recommended way of avoiding counterfeit and substandard medicines. The WHO has a prequalification of medicines programme to review quality of medicines [84] and Nepal can utilize this list of WHO prequalified suppliers to minimize the risk of purchasing poor quality medicines, especially when purchasing from countries with high rate of counterfeit medicine production like India.

Storage is an important aspect of total drug control, and proper control has to be made in and throughout the institution [85]. Proper storage of medicines is essential to maintain integrity of packaging which preserves quality of medicines and to avoid contamination, deterioration, pest infestation, theft and losses. Medicines should be stored in environmentally controlled storage areas that have adequate temperature, sufficient lighting, humidity control, clean and cold storage facilities, and proper ventilation, to ensure integrity of medicines [85, 86]. Storage areas should be

secured and designed to restrict access only to designated and authorized persons [87]. Medicines should be arranged in a systematic way to avoid errors, especially for lookalike and sound-alike medicines and medicines with identical packaging [87]. Storage of hazardous, flammable and poisonous medicines should be given special considerations. Hospitals should establish a proper method for identifying and managing expired, deteriorated, recalled or obsolete medicines and supplies [85].

1.4.6. “Procurement should not occur in isolation, but rather be informed by the formulary selection process.”

Poor selection of medicines is considered one of the important factors for problems associated with medicines use [64]. Furthermore, complexity of the prescribing process can also lead to irrational prescribing practices. Data from the WHO shows that more than half of all medicines prescribed, dispensed or sold are inappropriate. One of the effective and recommended solutions is to develop formulary system to restrict medication choices, promote rational use of medicines and ensure effective medicines management [24]. Moreover, formulary processes involve different stakeholders in decision making, which avoids influences by special interests and contributes to professionalism, accountability and avoidance of conflicts of interest [35].

The formulary system is a continuous process of selecting evidence-based cost-effective medicines in health care organizations with the aim of achieving the best therapeutic outcomes with minimal adverse effects. This system works on establishing policies on use of medicine and related products, treatment protocols, and selecting cost-effective and appropriate medicine and treatment that are best suited for targeted population. A formulary consists of a list of medicines and

associated products, medicine use policies, important drug information, decision-support tools, and organizational guidelines. This formulary system could be utilized by hospitals, acute and chronic care facilities, home care settings, and health service payers like Medicaid, Medicare and insurance companies. [88]. Countries like the USA, Europe and Australia adopt the formulary process for selecting medicines [24]. Hospital Pharmacy Directives 2013 [9] of Nepal also recommend formulary selection process.

Pharmacy and Therapeutics (P&T) Committees are the responsible bodies for the development of formulary list through evidence-based selection of medicines and standard treatment guidelines [64]. Hospital Pharmacy Directives of Nepal define the role of the P&T Committees in selection of medicines for procurement in consultation with each committee of the procurement system [9]. P&T Committees' work and members should be free of influential strategies like inappropriate drug advertisements, promotional activities, personal financial interests or any kind of beneficiaries [64]. The WHO and ASHP have published guidelines for establishing P&T Committee and formulary system [64, 88]. The WHO has published model formularies [89] which can be a useful resource for hospital pharmacists of Nepal. Similarly, the government of Nepal has published Nepalese National Formulary [90] which can be used by hospitals to develop their own formulary based on standard treatment guidelines or protocols best suited for use in the hospital and local populations [64].

Alternatively, the national list of essential medicines could be utilized for medicine selection and guide public medicine procurement process. The national list of essential medicines is the list of essential medicines developed by the country on the basis of national health and drug policies, patterns and prevalence of diseases,

pharmaco-economic evaluation, and quality and levels of service provided. This list could also be utilized for medicine donations, local pharmaceutical manufacturing, and medicine reimbursement scheme [91]. Hospital pharmacies of Nepal could follow the National List of Essential Medicines [92] developed by the government of Nepal.

The criteria for drug selection should include: cost-effectiveness, affordability, disease prevalence, safety, efficacy and quality. Appropriate selection can finally result in cost containment, improved access to essential medicines and improved quality of care.

1.4.7. “Good procurement must be supported by a reliable information system that provides accurate, timely, and accessible information.”

Information is the lifeblood of an effective procurement system. Accurate and timely information exchange within the institution as well as between suppliers and the institution can reduce inaccuracies in cost and procurement [34]. A management information system should be available for the procurement office and its clients to monitor and track the status and different aspects of medicine procurement process and problems encountered during the process. The information system must be available for monitoring the performance of health system, financial management, quality assurance system and overall pharmacy management [35, 62].

The information of the hospital system can be documented manually or electronically, but electronic systems are preferred as they minimize chances of human error [34]. Reliable information systems that provide updated information on reference prices can provide basis for price negotiation to achieve favorable prices

[34]. Dissemination of information is also important for maintaining transparency in the procurement process [35] and managing medicines shortage at hospitals [93].

Countries like USA and Australia circulate information about medicines safety and shortages through their websites of US FDA [94, 95] and TGA [96, 97] respectively. Nepal can also develop similar online information systems for providing information about medicines and medicine shortages that would help in managing medicine procurement in hospitals.

1.4.8. “A formal mechanism must be in place for pharmacists to request designated funds to procure medicines for their patients.”

Financing is the driving force of the procurement process and the appropriate financing mechanism should be chosen to ensure availability and resourceful use of funds [34]. Different financing mechanisms are available that include: public financing, health insurance, user fees, donor financing, and development loans [34]. Prompt and reliable payment can attract suppliers and provide competitive prices and good service from suppliers. Procurement may be funded differently depending on type of health institutions [62].

Public procurement in Australia is funded by the Australian government, whereas in Nepal it is funded partially by the government and donor organizations (only for a few freely distributed essential medicines) and the remainder is based on the sales of medicines or the budget of healthcare organizations [9, 98]. In addition to this, medicines approved for use in Nepal and listed in the national EMLs could be donated by donor agencies in accordance to the Guidelines for Drug Donation and with import approval from the Department of Drug Administration of Nepal. Normally, medicine can be donated to either legally registered health institutions or Ministry of

Health and Population of Nepal. However, during emergencies, medicines donations can occur only through Ministry of Health and Population of Nepal [68].

1.4.9. “Each pharmacy should have contingency plans for medicines shortages and purchases in emergencies.”

Medicines shortages can have serious implications on healthcare delivery, economy of the hospital and patient’s health [93]. There are many contributing factors that can cause medicines shortages, but the major causes that can arise from within healthcare institutions are: poor inventory management, lack of information flow and communication, and change in clinical practice.

Due to the unpredictable and unavoidable nature of medicines shortages, strategic planning should be developed for its management. Existence of contingency plans is of utmost importance in Nepal because of its difficult geography, and susceptibility to natural disasters, health epidemics and political instability that are likely to trigger medicine shortages [99-102].

ASHP has recommended a three-phased approach for managing medicines shortages: 1. identification and assessment of the shortage and its impact, 2. preparation for alternatives and managing shortages, and 3. contingency planning to deal with medicines shortages [93]. Healthcare institutions should establish guidelines for dealing with unavailability of critical or essential medicines, as well as rationalizing the distribution of available medicines ethically. Hospitals should develop strong policies for purchasing medicines of unassured quality and safety from compounding sources and non-traditional sources so that actions can be taken against any possible problems [93, 103].

While implementing contingency plans, ASHP has recommended that hospital pharmacists or concerned departments should also evaluate economic aspects, because alternative medicines and sources can increase the cost of treatment [104]. Moreover, a reliable information management system similar to those utilized by countries like USA [94] and Australia [97] that can facilitate communication and circulation of information about the status of medicines shortage among all concerned and affected departments, clinicians and patients is very essential [104]. This information sharing process could be made more effective by making it mandatory, as in the USA [105]. Regular reporting on key procurement performance indicators and auditing, are also equally important for planning and managing procurement [53].

1.5. Discussion

Medicines procurement is an important element of health care facilities that requires expertise from different disciplines. However, not all aspects of medicines procurement are well reported in the literature. Some aspects like transparency, corruption, counterfeit products, cost containment, medicines quality and medicines selection have been studied extensively, whereas other aspects such as quality assurance systems, storage, funding mechanisms and information systems were found to be poorly studied and limited to policies and guidelines. It was also found that some elements like safety and information systems were studied from the perspective of medicines distribution and administration rather than procurement.

Corruption and unethical practices were considered to have large influences on the procurement process, especially in developing countries, due to weak regulatory policies and enforcement capacities, as compared to developed countries with

strong regulatory enforcements in place. Division of different procurement functions was found to minimize the corruption, bias and favouritism in the procurement process.

There is evidence that an open and transparent procurement method is more effective for procuring the right medicines, with recognizable standards of quality at the most competitive prices. Medicines selection processes have been found to be influenced by marketing strategies of big pharmaceutical companies in both developed countries and developing countries.

Another key issue identified was counterfeiting, especially in Asian countries where the majority (63%) of counterfeit products are manufactured. Due to physical proximity and porous borders between the two countries, medicine procurement in Nepal is highly susceptible to entry of counterfeit medicines produced in India, so special emphasis should be placed on ensuring the authenticity of drugs. As such, prequalification and post-qualification of medicines and suppliers are very important in developing countries where financial resources are limited, and health and economic losses from counterfeit and substandard medicines are unaffordable.

The literature supported the role of pharmacists in the procurement process, especially in the selection of medicines. Furthermore, cost containment was considered to be an urgent need. Procuring medicines at lowest possible prices is important for Nepal where budgets are limited and accessibility of medicines depends on proper utilization of available funds. Pooled procurement, group contracting strategies, price negotiation, transparency, reliable/ prompt payment mechanisms, use of generic medicines and strong market information were found to be effective in achieving lowest possible prices.

The procurement system should be supported by a reliable information system and strong funding mechanisms. Although some funding mechanisms were found to be in place, no evidence for use of such information systems in Nepal was found in the literature. Therefore, one way Nepal can strengthen its procurement system is by establishing a strong information system.

The management of medicines shortage should be addressed with emphasis on the safety and costs of healthcare delivery. However, evidence of such contingency plans was not found in Nepal from the literature and guidelines. Nepal could consider developing some strategic plans for managing medicines shortages by following the three-phased approach of ASHP.

In summary, this review provided insight into guidelines, influential factors, inefficiencies and solutions to different aspects of medicines procurement in hospitals, which can be used for strengthening the procurement system in developing countries like Nepal where improving availability of medicines is a current health need. This review revealed that some aspects of hospital pharmacy in Nepal have not been studied at all; for example, information facilities and contingency plans. This suggests that there is a need to conduct more thorough and broad studies looking at all aspects of medicines procurement at hospital pharmacies in Nepal. The governmental regulatory body should also have a system in place to publish public reports annually or every few years on the performance of hospital pharmacies.

1.6. References

1. European Association of Hospital Pharmacists. What Is Hospital Pharmacy? European Association of hospital pharmacists. 2012. Available from: <http://www.eahp.eu/practice-and-policy/hospital-pharmacy>. Accessed 2 February 2016.
2. Pearson GJ. Evolution in the Practice of Pharmacy--Not a Revolution. CMAJ. 2007. 176(9):1295-6. doi: 10.1503/cmaj.070041.
3. Abramowitz PW. The Evolution and Metamorphosis of the Pharmacy Practice Model. Am J Health Syst Pharm. 2009. 66(16):1437.
4. International Pharmaceutical Federation. Joint FIP/WHO Guidelines on Good Pharmacy Practice: Standards for Quality of Pharmacy Services. International Pharmaceutical Federation and World Health Organization. 2011. Available from: https://www.fip.org/www/uploads/database_file.php?id=331&table_id=. Accessed 6 February 2016.
5. American Society of Health-System Pharmacists. Policy Positions and Guidelines. American Society of Health-System Pharmacists. 2014. Available from: <http://www.ashp.org/menu/PracticePolicy/PolicyPositionsGuidelinesBestPractices.aspx>. Accessed 11 February 2016.
6. The Society of Hospital Pharmacists of Australia. SHPA Practice Standards. The Society of Hospital Pharmacists of Australia. 2014. Available from: <http://www.shpa.org.au/Practice-Standards>. Accessed 11 February 2016.
7. European Association of Hospital Pharmacists. EAHP Policy and Advocacy. European Association of Hospital Pharmacists. 2014. Available from:

- <http://www.eahp.eu/practice-and-policy/advocacy>. Accessed 11 February 2016.
8. Nepal Pharmacy Council. National Good Pharmacy Practice Guidelines. Nepal Pharmacy Council. 2005. Available from: http://nepalpolicy.net.com/images/documents/publichealth/regulations/DoDA_2005_National%20Good%20Pharmacy%20Practice%20GuidelinesDraft.pdf. Accessed 6 February 2016.
 9. Government of Nepal, Ministry of Health and Population. Hospital Pharmacy Directives. Government of Nepal, Ministry of Health and Population. 2013. Available from: http://www.slideshare.net/niraj_bartaula/hospital-pharmacy-service-directives-2070-55955345. Accessed 3 February 2016.
 10. Doloresco F, Vermeulen LC. Global Survey of Hospital Pharmacy Practice. *Am J Health Syst Pharm*. 2009. 66(5 Suppl 3):S13-9.
 11. Vermeulen LC, Vulto AG, Zellmer WA. Editorial: The Promise of Basel. *Am J Health Syst Pharm*. 2009. 66(Suppl 3):S7.
 12. American Society of Health System Pharmacists, International Pharmaceutical Federation. Global Conference Proceedings Executive Summary. *Am J Health Syst Pharm*. 2009. 66(Suppl 3):S1-6. doi: 10.2146/ajhp080664.
 13. World Health Organization. Australia: WHO Statistical Profile. World Health Organization. 2013. Available from: <http://www.who.int/gho/countries/aus.pdf?ua=1>. Accessed 12 February 2016.
 14. The Society of Hospital Pharmacists of Australia. Fact Sheet: The Society of Hospital Pharmacists of Australia. The Society of Hospital Pharmacists of

- Australia. 2013. Available from: <http://www.shpa.org.au/About>. Accessed 11 February 2016.
15. Advanced Pharmacy Practice Framework Steering Committee. An Advanced Pharmacy Practice Framework for Australia. 2012. Available from: www.advancedpharmacypractice.com.au. Accessed 13 January 2016.
 16. The World Bank. Nepal. The World Bank Group. 2015. Available from: <http://data.worldbank.org/country/nepal>. Accessed 6 February 2016.
 17. LeBlanc JM, Dasta JF. Scope of International Hospital Pharmacy Practice. *Ann Pharmacother*. 2005. 39(1):183-91.
 18. Thapa RK, Bajracharya KS, editors. Hospital Pharmacy Practice in Nepal, Present Situation and Future Vision. NPSA-NPSS Workshop – Paradigm Shift in Pharmacy Profession; 2010.
 19. Gray A, Tredree R. Implementing the Basel Statements on the Future of Hospital Pharmacy. *IPJ*. 2010. 26(2):32-4.
 20. The Basel Statements on the Future of Hospital Pharmacy. *Am J Health Syst Pharm*. 2009. 66(5 Suppl 3):S61-6.
 21. Penm J, Chaar B, Moles R. Validating a Hospital Medicines Formulary Survey in the Western Pacific Region-a Global Hospital Pharmacy Initiative Based on the Basel Statements. *Res Social Adm Pharm*. 2012. 8(4):298-308. doi: 10.1016/j.sapharm.2011.07.003.
 22. Gray A, Vermeulen L. The Basel Statements Moving the Hospital Pharmacy Agenda Forward. *IPJ*. 2008. 23(2):10-3.
 23. International Pharmaceutical Federation Hospital Pharmacy Section. Revised FIP Basel Statements on the Future of Hospital Pharmacy 2015. International Pharmaceutical Federation Hospital Pharmacy Section. 2015. Available from:

<http://apps.who.int/medicinedocs/documents/s22090en/s22090en.pdf>.

Accessed 15 December 2015.

24. Penm J, Chaar B, Dechun J, Moles R. Formulary Systems and Pharmacy and Therapeutics Committees in the Western Pacific Region: Exploring Two Basel Statements. *Am J Health Syst Pharm*. 2013. 70(11):967-79. doi: 10.2146/ajhp120396.
25. Penm J, Chaar B, Moles R. Hospital Pharmacy Services in the Pacific Island Countries. *J Eval Clin Pract*. 2015. 21(1):51-6. doi: 10.1111/jep.12227.
26. Penm J, Chaar B, Moles R. Clinical Pharmacy Services That Influence Prescribing in the Western Pacific Region Based on the FIP Basel Statements. *Int J Clin Pharm*. 2015. 37(3):485-96. doi: 10.1007/s11096-015-0084-5.
27. Penm J, Chaar B, Rose G, Moles R. Pharmacists' Influences on Prescribing: Validating a Clinical Pharmacy Services Survey in the Western Pacific Region. *Res Social Adm Pharm*. 2015. 11(1):63-73. doi: 10.1016/j.sapharm.2014.04.001.
28. Penm J, Moles R, Wang H, Li Y, Chaar B. Factors Affecting the Implementation of Clinical Pharmacy Services in China. *Qual Health Res*. 2014. 24(3):345-56. doi: 10.1177/1049732314523680.
29. Wright A, Vaillancourt R, Bussi eres J-F, Lebel D, Wong E, Mancini D, et al. Best of Both Worlds: A Comparison of Canadian and International Best Practices for Hospital Pharmacy Services. *Can J Hosp Pharm*. 2015. 68(1):48-53.
30. Poh J, Vaillancourt R, Lamarre D, Oyella J. Use of the 2008 Basel Consensus Statements to Assess, Realign, and Monitor Pharmacy Practice at a Tertiary

- Care Hospital in Northern Uganda: Illustrative Case Study. *Can J Hosp Pharm.* 2013. 66(5):318-27.
31. Health Sector Programme, Ministry of Health and Population, Deutsche Gesellschaft für Technische Zusammenarbeit. Essential Drug Procurement and Supply Management System in Nepal: Current Challenges and How to Address Them. GTZ/GFA Consulting Group GmbH and Health Sector Programme, Department of Health Services. 2009. Available from: http://www.ministerial-leadership.org/sites/default/files/resources_and_tools/Essential_Drug_Procurement_Policy_Brief.pdf. Accessed 6 February 2016.
32. Government of Nepal, Ministry of Health and Population. Nepal Pharmaceutical Country Profile. Government of Nepal, Ministry of Health and Population and World Health Organization. 2011. Available from: http://www.who.int/medicines/areas/coordination/nepal_pharmaceutical_profile.pdf. Accessed 7 February 2016.
33. Harper I, Berhlikova P, Subedi MS, Bhattarai S, Basu S, Gupta AD, et al. Drug Procurement in Nepal. The Centre for International Health Policy. 2007. Available from: http://www.csas.ed.ac.uk/data/assets/pdf_file/0009/38826/DrugProcurementNepal.pdf. Accessed 3 February 2016.
34. Ombaka E. Current Status of Medicines Procurement. *Am J Health Syst Pharm.* 2009. 66(5 Suppl 3):S20-8. doi: <http://dx.doi.org/10.2146/ajhp080604>.
35. Baghdadi-Sabeti G, Cohen-Kohler JC, Wondemagegnehu E. Measuring Transparency in the Public Pharmaceutical Sector. World Health Organization. 2009. Available from:

- <http://apps.who.int/medicinedocs/documents/s16732e/s16732e.pdf>. Accessed 2 February 2016.
36. Mostert S, Sitaresmi MN, Njuguna F, van Beers EJ, Kaspers GJ. Effect of Corruption on Medical Care in Low-Income Countries. *Pediatr Blood Cancer*. 2012. 58(3):325-6.
 37. Wazana A. Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift? *JAMA*. 2000. 283(3):373-80. doi: 10.1001/jama.283.3.373.
 38. Roy N, Madhiwalla N, Pai SA. Drug Promotional Practices in Mumbai: A Qualitative Study. *Indian J Med Ethics*. 2007. 4(2):57.
 39. Thapa BB. Ethical Promotion of Medicine: Benefit to Consumers. *Drug Bulletin of Nepal*. 2007. 19(1):3-4.
 40. Nguyen NY, Bero L. Medicaid Drug Selection Committees and Inadequate Management of Conflicts of Interest. *JAMA Internal Medicine*. 2013. 173(5):338-43.
 41. Hatton RC, Hutchison LC, Matzke GR, Noviasky JA, Rospond RM, Kelloway JS, et al. Pharmacists and Industry: Guidelines for Ethical Interactions. *Pharmacotherapy*. 2008. 28(3):410-20. doi: 10.1592/phco.28.3.410.
 42. Medicines Australia. Code of Conduct Guidelines. Medicines Australia. 2015. Available from: <https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/01/20150513-PUB-E18-Guidelines-FINAL-V1a.pdf>. Accessed 1 February 2016.
 43. Pharmaceutical Research and Manufacturers of America. Code on Interactions with Healthcare Professionals. Washington. Pharmaceutical Research and Manufacturers of America. 2008. Available from:

- http://www.phrma.org/sites/default/files/pdf/phrma_marketing_code_2008.pdf.
Accessed 5 February 2016.
44. Medical Board of Australia. Good Medical Practice: A Code of Conduct for Doctors in Australia. Medical Board of Australia. 2014. Available from: <http://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code-of-conduct.aspx>. Accessed 4 February 2016.
45. American Medical Association. AMA's Code of Medical Ethics. American Medical Association. 2015. Available from: <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics.page>. Accessed 4 February 2016.
46. Medicines Australia. Code of Conduct. Medicines Australia. 2015. Available from: <https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/01/20150617-PUB-Code-Edition-18-FINAL.pdf>. Accessed 2 February 2016.
47. Department of Drug Administration. Guidelines on Ethical Promotion of Medicine, 2007. Department of Drug Administration. 2007. Available from: <http://www.dda.gov.np/guidlines/Ethical%20Promotion%20Guidelines%202007.pdf>. Accessed 17 April 2015.
48. Nepal Medical Council. Nmc-Code of Ethics. Nepal Medical Council. 2016. Available from: <http://www.nmc.org.np/information/nmc-code-of-ethics.html>. Accessed 16 February 2016.
49. International Federation of Pharmaceutical Manufacturers and Associations. IFPMA Code of Pharmaceutical Marketing Practices. International Federation of Pharmaceutical Manufacturers and Associations. 2006. Available from:

- http://www.ifpma.org/fileadmin/content/Ethics/IFPMA_Marketing_Code/The_Code/IFPMA_Code_2006_Revision_EN.pdf. Accessed 3 February 2016.
50. World Health Organization. Ethical Criteria for Medicinal Drug Promotion. World Health Organization. 1988. Available from: <http://apps.who.int/medicinedocs/documents/whozip08e/whozip08e.pdf>. Accessed 14 January 2016.
51. Garuba HA, Kohler JC, Huisman AM. Transparency in Nigeria's Public Pharmaceutical Sector: Perceptions from Policy Makers. *Global Health*. 2009. 5:14.
52. Transparency International. Corruption by Country/Territory: Nepal. Transparency International. 2014. Available from: <http://www.transparency.org/country/#NPL>. Accessed 9 February 2016.
53. Rankin J, Quick JD, Muziki. S, Woldeyesus K, Fresle DA, Grayston G, et al. Operational Principles for Good Pharmaceutical Procurement. WHO's Department of Essential Drugs and Medicines Policy (EDM). 1999. Available from: <http://www.who.int/3by5/en/who-edm-par-99-5.pdf>. Accessed 6 February 2016.
54. SHPA Standards of Practice for Medication Safety. *JPPR*. 2012. 42(4):300-4. doi: 10.1002/j.2055-2335.2012.tb00193.x.
55. Wertheimer AI, Santella TM. Counterfeit Drugs: Defining the Problem and Finding Solutions. *Expert Opin Drug Saf*. 2005. 4(4):619-22. doi: 10.1517/14740338.4.4.619.
56. Seiter A. Health and Economic Consequences of Counterfeit Drugs. *Clin Pharmacol Ther*. 2009. 85(6):576-8. doi: 10.1038/clpt.2009.47.

57. Australian Government, Department of Health and Ageing. National Medicines Policy. Commonwealth of Australia. 2000. Available from: <http://www.health.gov.au/internet/main/publishing.nsf/Content/national-medicines-policy>. Accessed 6 December 2015.
58. Australian Government, Department of Health, Therapeutic Goods Administration. Advisory Committee on the Safety of Medicines (Acsom). Therapeutic Goods Administration. 2015. Available from: <https://www.tga.gov.au/committee/advisory-committee-safety-medicines-acsom#role>. Accessed 12 January 2016.
59. Shane R. The Food and Drug Administration Amendments Act of 2007: Drug Safety and Health-System Pharmacy Implications: Introduction. Am J Health Syst Pharm. 2009. 66(24 Suppl 7):S2. doi: 10.2146/ajhp090459.
60. World Health Organization. Guidelines for the Development of Measures to Combat Counterfeit Drugs. 1999. Available from: http://whqlibdoc.who.int/hq/1999/WHO_EDM_QSM_99.1.pdf. Accessed 5 February 2016.
61. Government of Nepal. National Medicines Policy 2007. 2007. Available from: <http://www.moHP.gov.np/images/pdf/policy/National%20Medicine%20Policy.pdf>. Accessed 5 February 2016.
62. Barraclough A, Clark M. Managing Procurement. 2012. In: Managing Access to Medicines and Health Technologies [Internet]. Arlington, VA: Management Science for Health. [18.1-.26]. Available from: <http://apps.who.int/medicinedocs/documents/s19577en/s19577en.pdf>. Accessed on 7 February 2016.

63. ASHP Statement on the Pharmacy and Therapeutics Committee and the Formulary System. *Am J Health-Syst Pharm*. 2008. 65(24):2384.
64. Holloway K, Green T. *Drug and Therapeutic Committees-a Practical Guide*. World Health Organization and Management Sciences for Health. 2003. Available from: <http://apps.who.int/medicinedocs/pdf/s4882e/s4882e.pdf>. Accessed 2 February 2016.
65. Milovanovic DR, Pavlovic R, Folic M, Jankovic SM. Public Drug Procurement: The Lessons from a Drug Tender in a Teaching Hospital of a Transition Country. *Eur J Clin Pharmacol*. 2004. 60(3):149-53.
66. Public Procurement Act 2007, Act Number 36 (2007). Government of Nepal.
67. The Public Procurement Regulations 2007, Section 74 (2007). Government of Nepal.
68. Government of Nepal, Ministry of Health and Population. *Public Procurement Guidelines*. Government of Nepal, Ministry of Health and Population. 2009. Available from: <http://mohp.gov.np/index.php/publication-1/guideline>. Accessed 3 February 2016.
69. Commonwealth Procurement Rules, S105B(1) (2014). Australian Government, Department of Finances.
70. Rubino M, Hoffman JM, Koesterer LJ, Swendrzynski RG, ASHP Expert Panel on Medication Cost Management. *ASHP Guidelines on Medication Cost Management Strategies for Hospitals and Health Systems*. *Am J Health Syst Pharm*. 2008. 65(14):1368-84. doi: 10.2146/ajhp080021.
71. Hughes D, Reynolds DJ. *Pharmacoeconomics: Principles and Relevance to the Activities of Drug and Therapeutics Committees*. *Clinical Medicine*. 2009. 9(5):490-2.

72. Collao JF, Smith F, Barber N. Selection of Medicines in Chilean Public Hospitals: An Exploratory Study. *BMC Health Serv Res.* 2013. 13:10.
73. Tordoff JM, Norris PT, Reith DM. Managing Prices for Hospital Pharmaceuticals: A Successful Strategy for New Zealand? *Value Health.* 2005. 8(3):201-8.
74. Vieira FS, Zucchi P. Resource Allocation for Pharmaceutical Procurement in the Brazilian Unified Health System. *Revista de Saude Publica.* 2011. 45(5):906-13.
75. Australian Government, Department of Health. The Pharmaceutical Benefits Scheme. Commonwealth of Australia. 2015. Available from: <http://www.pbs.gov.au/info/about-the-pbs>. Accessed 6 February 2016.
76. Kotwani A, Ewen M, Dey D, Iyer S, Lakshmi P, Patel A, et al. Prices & Availability of Common Medicines at Six Sites in India Using a Standard Methodology. *Indian J Med Res.* 2007. 125(5):645.
77. Hussain Z, Tukai M, A. J, Adu A, Khan I. Workshop on Framework Agreement and Two-Year Procurement Cycle at Proshika Hrdc, Koitta, Manikgonj, March 6–8, 2012. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health, 2012.
78. Arney L, Yadav P, Miller R, Wilkerson T. Strategic Contracting Practices to Improve Procurement of Health Commodities. *Glob Health Sci Pract.* 2014. 2(3):295-306. doi: <http://dx.doi.org/10.9745/GHSP-D-14-00068>.
79. Nguyen TA, Knight R, Roughead EE, Brooks G, Mant A. Policy Options for Pharmaceutical Pricing and Purchasing: Issues for Low- and Middle-Income

- Countries. Health Policy Plan. 2015. 30(2):267-80. doi:
10.1093/heapol/czt105.
80. Ratanawijitrasin S, Wondemagegnehu E. Effective Drug Regulation: A Multicountry Study. World Health Organization. 2002. Available from: <http://apps.who.int/medicinedocs/pdf/s2300e/s2300e.pdf>. Accessed 6 February 2016.
81. Wertheimer AI, Norris J. Safeguarding against Substandard/Counterfeit Drugs: Mitigating a Macroeconomic Pandemic. Res Social Adm Pharm. 2009. 5(1):4-16.
82. World Health Organization. A Model Quality Assurance System for Procurement Agencies. World Health Organization. 2007. Available from: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf>. Accessed 5 February 2016.
83. Hall C. Technology for Combating Counterfeit Medicine. Pathog Glob Health. 2012. 106(2):73-6. doi: 10.1179/204777312X13419245939485.
84. WHO Prequalification of Medicines Programme. WHO Drug Information. 2012. 26(2):99.
85. American Society of Health-System Pharmacists. ASHP Technical Assistance Bulletin on Hospital Drug Distribution and Control. American Society of Health-System Pharmacists. 2014. Available from: http://www.ashp.org/s_ashp/docs/files/BP07/Distrib_TAB_Hosp.pdf. Accessed 11 February 2016.
86. World Health Organization Regional Office For Africa. Managing of Drugs at Health Center Level. [Training Manual]. World Health Organization Regional Office For Africa. 2004. Available from:

- <http://apps.who.int/medicinedocs/pdf/s7919e/s7919e.pdf>. Accessed 6 February 2016.
87. Ardern-Jones J, Hughes DK, Rowe PH, Mottram DR, Green CF. Attitudes and Opinions of Nursing and Medical Staff Regarding the Supply and Storage of Medicinal Products before and after the Installation of a Drawer-Based Automated Stock-Control System. *Int J Pharm Pract*. 2009. 17(2):95-9.
88. Linda S. Tyler, Cole SW, May JRe, Millares M, Valentino MaA, Jr. LCV, et al. ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System. *Am J Health Syst Pharm*. 2008. 65:1272-83.
89. World Health Organization. WHO Model Formulary. World Health Organization. 2014. Available from:
<http://apps.who.int/medicinedocs/documents/s16879e/s16879e.pdf>. Accessed 6 February 2016.
90. Kafle KK, Thapa BB. Nepalese National Formulary 2nd Edition. Government of Nepal, Ministry of Health and Population, and Department of Drug Administration 2010. Available from:
https://www.researchgate.net/publication/262562432_Nepalese_National_Formulary_2010. Accessed 16 February 2016.
91. World Health Organization. Essential Medicines and Health Products. World Health Organization. 2016. Available from:
http://www.who.int/medicines/services/essmedicines_def/en/. Accessed 20 June 2016.
92. Government of Nepal, Ministry of Health and Population, Department of Drug Administration. National List of Essential Medicines. Department of Drug

- Administration, Nepal. 2011. Available from:
<http://www.dda.gov.np/druglist/nlem2011.pdf>. Accessed 11 February 2016.
93. Fox ER, Birt A, James KB, Kokko H, Salverson S, Soflin DL, et al. ASHP Guidelines on Managing Drug Product Shortages in Hospitals and Health Systems. *Am J Health Syst Pharm*. 2009. 66(15):1399-406. doi: 10.2146/ajhp090026.
94. U.S. Food and Drug Administration. Drug Shortages. U.S. Food and Drug Administration. Available from:
<http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm>. Accessed 14 January 2016.
95. U.S. Food and Drug Administration. Medwatch: The Fda Safety Information and Adverse Event Reporting Program. U.S. Food and Drug Administration. Available from: <http://www.fda.gov/Safety/MedWatch/default.htm>. Accessed 14 January 2016.
96. Australian Government, Department of Health, Therapeutic Goods Administration. Safety Information. Therapeutic Goods Administration. 2015. Available from: <https://www.tga.gov.au/safety-information>. Accessed 14 January 2016.
97. Australian Government, Department of Health, Therapeutic Goods Administration. Medicine Shortages Information Initiative. Therapeutic Goods Administration. 2014. Available from: <https://www.tga.gov.au/medicine-shortages-information-initiative>. Accessed 14 January 2016.
98. Government of Nepal, Ministry of Health and Population. Current Status of Mohp's Annual Work Plan and Budget. Government of Nepal, Ministry of Health and Population. 2013. Available from:

- <http://www.mohe.gov.np/images/pdf/publication/Budget-Analysis-2070-71.pdf>. Accessed 6 February 2016.
99. Sanyal D. Jajarkot Pandemic and Some Home Truths. *The Rising Nepal*. 25 April 2015. Available from: <http://therisingnepal.org.np/news/3111>. Accessed 16 February 2016.
100. National News Agency. Medicine Shortage Hits Locals in Mugu. *My Republica*. 19 February 2014. Available from: http://www.myrepublica.com/portal/index.php?action=news_details&news_id=69810. Accessed 16 February 2016.
101. World Health Organization. WHO Issues Rapid Health Assessment on Impact of Nepal Earthquake. 1 May 2015. Available from: <http://www.who.int/mediacentre/news/releases/2015/health-assessment-nepal/en/>. Accessed 6 February 2016.
102. Post Report-Parsa. Shortage of Medicines Hits Health Services. *The Kathmandu Post*. 9 November 2015. Available from: <http://kathmandupost.ekantipur.com/news/2015-11-09/shortage-of-medicines-hits-health-services.html>. Accessed 16 February 2016.
103. Manolakis M. Ethical Integrity in Managing Drug Shortages. *Am J Health Syst Pharm*. 2012. 69(1):17. doi: 10.2146/ajhp110640.
104. Mark SM, Mark LK, ASHP Council on Administrative Affairs *Am J Health-Syst Pharm*. ASHP Guidelines on Managing Drug Product Shortages. *Am J Health Syst Pharm*. 2001. 58(15):1445-50.
105. The White House Office of Press Secretary. Fact Sheet: Obama Administration Takes Action to Reduce Prescription Drug Shortages in the U.S. The White House President Barack Obama. 2011. Available from:

<https://www.whitehouse.gov/the-press-office/2011/10/31/fact-sheet-obama-administration-takes-action-reduce-prescription-drug-sh>. Accessed 5 February 2016.

Chapter 2

Aim, Method and Rationale of the Study

Chapter 2: Aim, Method and Rationale of the Study

As stated in Chapter One, public healthcare expenditure is less than 5% of the total healthcare expenditure and availability of medicines in the public sector is poor in the majority of developing countries in Asia [1]. About 60-75% of South-East Asian countries therefore have to rely on expensive private health institutions for their health needs [2]. Availability of medicines in public hospitals is lower than that in private hospitals whereas price is 66.3% higher in private hospitals of Nepal [3]. Due to poor availability and higher prices of medicines along with lack of universal healthcare in many low-income countries, medicines tend to be unaffordable for the majority of the population in these countries [4]. The government of Nepal has been distributing a selected few essential medicines to the general public through public health institutions as part of a free basic health program. However, public procurement and availability of essential medicines in public institutions has been reported to be poor [5]. Increasing the availability of affordable and quality medicines in public health institutions is beneficial in ensuring equitable access of medicines to the general public of all backgrounds.

For these reasons, this study was divided into two parts-1. Medicine Procurement in both private and public hospitals of Nepal, 2. Comparison of medicine procurement procedures in public hospitals of Nepal and Australia with the aim of identifying ways to strengthen public procurement of Nepal. In doing so, dissemination of the results of this research could provide strategies that will have meaningful impact on medicine access by a wide range of the country's population.

This chapter describes the overall aims and methods of a large study, divided into two parts that are reported as manuscripts ready for publication in Chapters three and four of this thesis.

2.1. Aim

This study aimed to explore the implementation of international hospital pharmacy guidelines (FIP Basel Statements 2008) in the context of procurement in hospital pharmacies of Nepal and to compare with the current procurement practice in hospital pharmacies of Australia.

2.2. Objectives

The major objective of this study was to provide insight into current procurement practices in Nepalese and Australian hospital pharmacies, highlight facilitators and barriers for guideline implementation in current practices, and report good procurement procedures. Another objective was to provide evidence-based recommendations to improve current practices of Nepal to facilitate equitable access to quality and evidence-based safe medicines to the general public of Nepal.

2.3. Rationale of the Study

This study was divided into two parts: 1) study of medicine procurement in hospital pharmacies of Nepal (Chapter Three), and 2) comparative study of medicine procurement in hospital pharmacies of Australia and Nepal (Chapter Four).

The first part of the study aimed to explore medicine procurement practices in both private and public hospitals of Nepal in order to discover facilitators and barriers to guideline implementation. Chapter Three therefore describes medicine procurement procedures in hospital pharmacies of Nepal, assesses compliance of the

procurement guidelines of the Basel Statements, highlights barriers to compliance, and finally provides recommendations based on international guidelines and experiences from other countries.

Chapter Four pertains to the second part of the study comparing medicine procurement practices in public hospitals of Nepal to Australia, as it was hypothesized that Australia, being a more developed country would have stronger regulatory and policy frameworks and be better at adopting procurement policy guidelines. Therefore, the reason for comparing procurement practices in these two diverse countries was to determine if procurement procedures that were thought to be better in Australia could be utilized to improve the current procurement practices in Nepal. In this part of the study, comparisons were drawn again in the context of the international procurement guidelines of the Basel Statements, which were developed to promote best procurement practices around the world.

2.4. Ethics

This study was approved by the Human Research Ethics Committee at the University of Sydney [Project No. 2014/619]. All documents, including Participant Consent Form and Interview Protocol were approved by the ethics committee.

2.5. Method

2.5.1. Sampling

Hospital pharmacists or procurement officers at hospital pharmacies of both private and public hospitals of Nepal were contacted. In Australia, hospitals pharmacist or procurement officers of public hospitals were approached for participation. A passive snowballing sample collection technique was used [6]. Involvement in procurement

procedures, speaking fluent English or Nepali were the only inclusion criterion for participation. Hospital pharmacists or procurement officers working at major hospitals of all five regions of Nepal, and public hospitals in six states and two territories of Australia, were targeted for inclusion in this study. Hospital pharmacies were selected regardless of whether the hospital pharmacy was regulated/ owned by the hospital itself or if it was under a private lease agreement to provide medicines to the hospital. Sample characteristics are presented in Table 4.

Table 4: Sample Characteristics

Sample	Sample Characteristics/Quantity
Participants	Hospital Pharmacists or Procurement Officers
Inclusion Criteria for Participants	Involvement in the procurement process
Sampling Technique	Passive Snow Balling
Key Contact Points	<p>1. Nepal</p> <ul style="list-style-type: none"> a. The Hospital Pharmacists' Association of Nepal, b. A private company of pharmaceutical products, and c. Prominent figures in the profession such as the Vice President of the Hospital Section of International Pharmaceutical Federation (FIP) for the South East Asian Region <p>2. Australia</p> <ul style="list-style-type: none"> a. The Society of Hospital Pharmacists of Australia b. Academics of author's institution
Area Targeted	Nepal: 5 regions of Nepal
	Australia: 6 states and 2 territories of Australia
Area Covered	Nepal: 4 major regions of Nepal
	Australia: 4 states and 2 territories of Australia
Hospitals	Nepal:

	a. Public hospitals including Logistic Management Division, Department of Health Services, Ministry of Health and Population, Nepal b. Private hospitals including International Non-Governmental Organization (INGO) funded hospitals	
	Australia	
	a. Public hospitals	
Number of Sample	Australia: 9	
	Public hospitals	9
	Nepal: 53	
	Public Hospitals	12
	Private Hospitals	37
	INGO-funded hospitals	3
	Logistic Management Division, Department of Health Services, Ministry of Health and Population, Nepal	1
Total Sample for first study (Chapter 3)	53	
Total Sample for second study (Chapter 4)	22	

In Nepal, the Hospital Pharmacists' Association of Nepal, executives of a private pharmaceutical company, and the Vice President for the Hospital Pharmacy Section of International Pharmaceutical Federation (FIP) in the South East Asian Region assisted in the recruitment process. In Australia, the Society of Hospital Pharmacists of Australia and academics at the University of Sydney helped invite prospective participants.

2.5.2. Data Collection and Analysis

Data were collected using a standard semi-structured interview protocol (Appendix 1; Page 173). The procurement statements from the Basel Statements (Table 2) [7] were used as a benchmark, for developing interview questions. Additionally, two other assessment tools “Measuring Transparency in the Public Pharmaceutical Sector” [8] and “Operational Principles for Good Pharmaceutical Procurement” [9] published by World Health Organization (WHO) were also used in conjunction to formulate more specific questions. Interviews in Australia and Nepal were conducted using the same interview protocol. English was the language used for conducting interviews in Australia, whereas participants could choose either English or Nepali language for their interviews. All participants consented for interviews in written form. All interviews were audio-recorded and then transcribed verbatim. A bilingual native Nepali speaker translated Nepali transcripts into English. Data collection continued until “saturation”, that is when no new concepts emerged [10].

Table 2: Procurement Guidelines of the Basel Statements 2008

Statement Number	Statements
17	The procurement process must be transparent, professional, and ethical to promote equity and access and to ensure accountability to relevant governing and legal entities.
18	Procurement should be guided by the principle of procuring for safety.
19	Procurement of pharmaceuticals is a complex process that requires pharmacist control and technically competent staff.
20	Operational principles for good procurement practice should be regularly reviewed and procurement models adapted to fit different settings and emerging needs in the most appropriate and cost effective way.

21	Procurement must be supported by strong quality assurance principles to ensure that poor quality medicines are not procured or allowed into the system. Proper storage to ensure maintenance of quality in the whole supply pipeline is mandatory.
22	Procurement should not occur in isolation, but rather be informed by the formulary selection process.
23	Good procurement must be supported by a reliable information system that provides accurate, timely, and accessible information.
24	A formal mechanism must be in place for pharmacists to request designated funds to procure medicines for their patients.
25	Each pharmacy should have contingency plans for medicines shortages and purchases in emergencies.

Data analysis was conducted iteratively, using a framework analysis approach [11] based on the procurement themes of the Basel Statements [7], with the assistance of NVivo software Version 10 [12]. Data from private and public hospitals of Nepal was used to explore medicine procurement practices in Nepal. The comparative study was conducted using data from public hospitals of Nepal and Australia to study differences and similarities between procurement practices of Nepal and Australia. The same dataset from public hospitals of Nepal, which was used for exploring medicine practice of Nepal, was re-utilized and new additional data set from Australian study was used for the comparative study. The research team was continuously involved throughout the analysis process to achieve consensus. The methodology can be summarised as below in Figure 4:

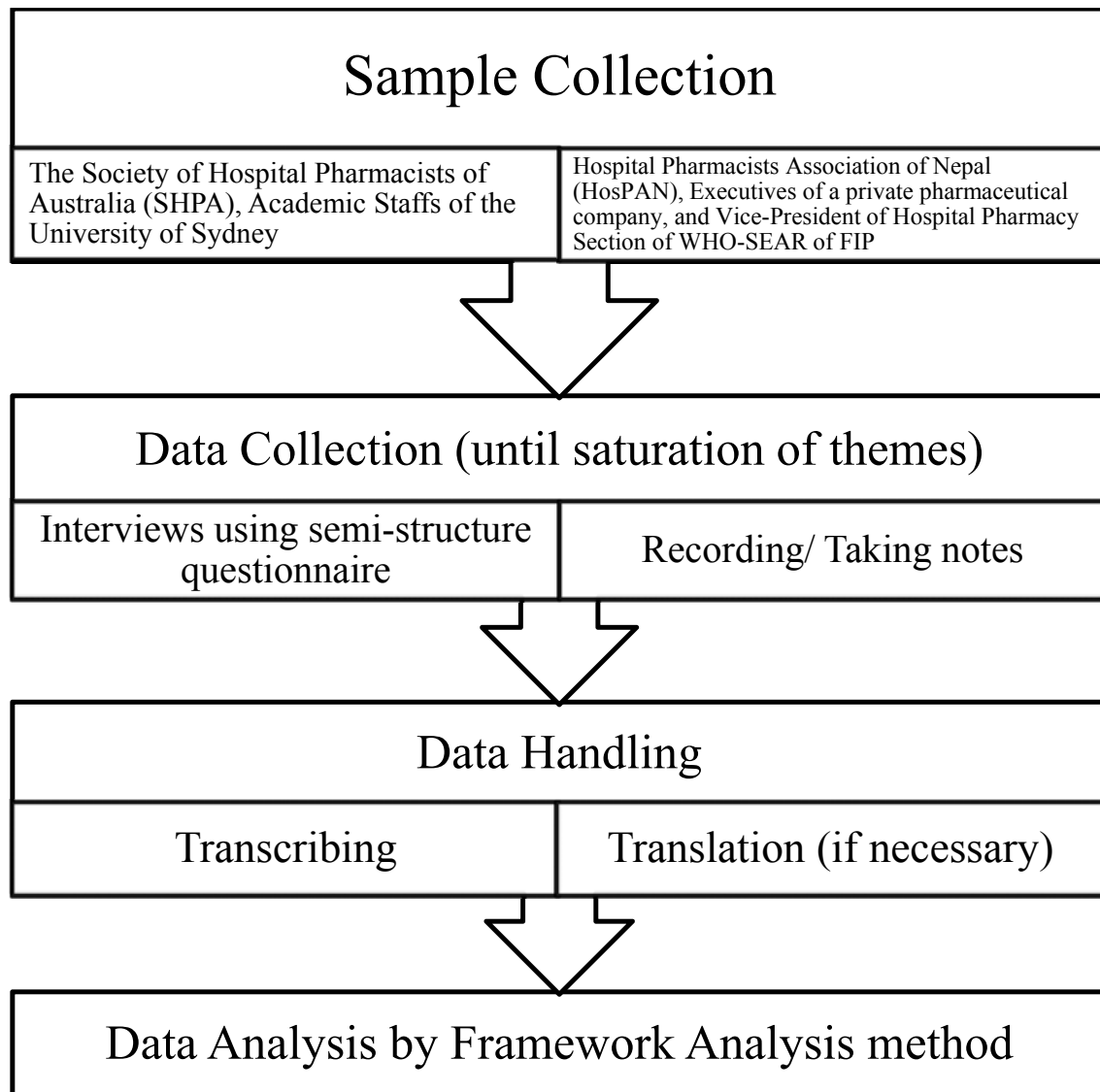


Figure 4: Methodology of Qualitative Study

2.5.2.1. Framework Analysis

Framework analysis is an analytical approach developed by Ritchie and Spencer in the 1980s. This method organises data and develops a matrix based on key themes, concepts and categories, making the process systematic and transparent facilitating retrieval and tracking of data [11, 13]. This approach can provide cross-case and

within-case analyses [13]. Framework analysis method consists of five stages which are as follows [13]:

1. Familiarisation
2. Constructing an initial thematic framework
3. Indexing and sorting
4. Reviewing data extracts
5. Data summary and display [13]

The framework analysis approach is primarily used for analysing data with interwoven and interspersed concepts, and also for data with predetermined concepts such as those of semi-structured interviews [13]. It is suitable for data covering similar topics or key issues that can generate themes capable of providing full description on the phenomenon under investigation [13, 14]. Framework analysis can be used for generating pre-selected themes from previous literature, existing theories or the specifics of the research questions during data collection (termed deductive method). It could also be from the data after data collection (termed inductive) depending on the research type [14, 15]. A combined approach can be utilized when the research study already has some particular issues to explore and aims to discover some unexpected aspects from the interviewees [13]. Since we used semi-structured interviews to conduct the study regarding a pre-existing concept (the Basel Statements), a pre-defined issue (procurement practices and their compliance to the Basel Statements) and also had an aim to discover excellent procurement procedures and identify facilitators and barriers, the framework analysis approach was considered suitable.

Whilst the same dataset from Nepal was used for the studies reported in Chapters Three and Four, additional Australian data were added to Chapter Four in order to make a comparison, therefore the two chapters have synergistic, yet different objectives.

2.5.3. References

1. World Health Organization. Health Financing Strategy for the Asia Pacific Region (2010-2015). World Health Organization. 2009. Available from: http://www.wpro.who.int/publications/docs/Healthfinancingstrategy_6188.pdf. Accessed 12 February 2016.
2. World Health Organization. Health Financing. World Health Organization. 2016. Available from: <http://www.who.int/trade/glossary/story047/en/>. Accessed 4 January 2016.
3. Mendis S, Fukino K, Cameron A, Laing R, Filipe Jr A, Khatib O, et al. The Availability and Affordability of Selected Essential Medicines for Chronic Diseases in Six Low- and Middle-Income Countries. Bull World Health Organ. 2007. 85(4):279-88. doi: 10.2471/BLT.06.033647.
4. Cameron A, Ewen M, Auton M, Abegunde D. The World Medicines Situation 2011: Medicines Prices, Availability and Affordability. World Health Organization. 2011. Available from: <http://apps.who.int/medicinedocs/documents/s18065en/s18065en.pdf>. Accessed 5 February 2016.
5. Health Sector Programme, Ministry of Health and Population, Deutsche Gesellschaft für Technische Zusammenarbeit. Essential Drug Procurement and Supply Management System in Nepal: Current Challenges and How to Address Them. GTZ/GFA Consulting Group GmbH and Health Sector Programme, Department of Health Services. 2009. Available from: http://www.ministerial-leadership.org/sites/default/files/resources_and_tools/Essential_Drug_Procurement_Policy_Brief.pdf. Accessed 6 February 2016.

6. Noy C. Sampling Knowledge: The Hermeneutics of Snowball Sampling in Qualitative Research. *Int J Soc Res Methodol*. 2008. 11(4):327-44. doi: 10.1080/13645570701401305.
7. The Basel Statements on the Future of Hospital Pharmacy. *Am J Health Syst Pharm*. 2009. 66(5 Suppl 3):S61-6.
8. Baghdadi-Sabeti G, Cohen-Kohler JC, Wondemagegnehu E. Measuring Transparency in the Public Pharmaceutical Sector. World Health Organization. 2009. Available from: <http://apps.who.int/medicinedocs/documents/s16732e/s16732e.pdf>. Accessed 2 February 2016.
9. Rankin J, Quick JD, Muziki. S, Woldeyesus K, Fresle DA, Grayston G, et al. Operational Principles for Good Pharmaceutical Procurement. WHO's Department of Essential Drugs and Medicines Policy (EDM). 1999. Available from: <http://www.who.int/3by5/en/who-edm-par-99-5.pdf>. Accessed 6 February 2016.
10. Mason M. Sample Size and Saturation in Phd Studies Using Qualitative Interviews. *Forum Qual Soc Res*. 2010. 11(3).
11. Ritchie J, Spencer L, O'Connor W. Carrying out Qualitative Analysis In: Ritchie J, Lewis J, editors. *Qualitative Research Practice: A Guide for Social Science Students and Researchers*. London: Sage Publications; 2003.
12. QSR International. *Nvivo 10 for Windows Getting Started*. QSR International. 2014. Available from: <http://download.qsrinternational.com/Document/NVivo10/NVivo10-Getting-Started-Guide.pdf>. Accessed 5 February 2016.

13. Spencer L, Ritchie J, Connor WO, Morrell G, Ormston R. Analysis in Practice. In: Ritchie J, Lewis J, Nicholls CM, Ormston R, editors. Qualitative Research Practice: A Guide for Social Science Students and Researchers. Second edition ed. Los Angeles, California: SAGE; 2014.
14. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the Framework Method for the Analysis of Qualitative Data in Multi-Disciplinary Health Research. BMC Med Res Methodol. 2013. 13(1):117. doi: 10.1186/1471-2288-13-117.
15. Ward DJ, Furber C, Tierney S, Swallow V. Using Framework Analysis in Nursing Research: A Worked Example. J Adv Nurs. 2013. 69(11):2423-31. doi: 10.1111/jan.12127.

Chapter 3

Medicine Procurement in hospital pharmacies of Nepal: A qualitative study based on the Basel Statements

Chapter 3: Medicine Procurement in hospital pharmacies of Nepal: A qualitative study based on the Basel Statements

This chapter is presented in the form of a manuscript that has been submitted to a peer reviewed journal “**PLoS ONE**” and is currently under review.

3.1. Abstract

3.1.1. Objective

Accessibility and affordability of evidence-based medicines are issues of global concern. For low-income countries like Nepal, it is crucial to have easy and reliable access to affordable, good-quality, evidence-based medicines, especially in the aftermath of natural or manmade disasters. Availability of affordable and evidence-based high quality medicines depends on the medicine procurement procedure, which makes it an important aspect of healthcare delivery. In this study, we aimed to investigate medicine procurement practices in hospital pharmacies of public and private hospitals of Nepal within the framework of International Pharmaceutical Federation [FIP] hospital pharmacy guidelines “the Basel Statements”.

3.1.2. Method

We conducted semi-structured interviews with hospital pharmacists or procurement officers in hospital pharmacies of four major regions in Nepal to explore procurement practices. Data were collected until saturation of themes, analysed using the framework approach, and organised around the statements within the procurement theme of the Basel Statements.

3.1.3. Results

Interviews conducted with 53 participants revealed that the procurement guidelines of the Basel Statements were adopted to a certain extent in hospital pharmacies of Nepal. It was found that the majority of hospital pharmacies in Nepal reported using

an expensive direct-procurement model for purchasing medicines. Most had no formulary and procured medicines solely based on doctors' prescriptions, which were heavily influenced by pharmaceutical companies' marketing strategies. Whilst most procured only registered medicines, a minority reported purchasing unregistered medicines through unauthorised supply-chains. And although the majority of hospital pharmacies had some contingency plans for managing medicine shortages, a few had none.

3.1.4. Conclusions

Procurement guidelines of the Basel Statements were thus found to be partially adopted; however, there is room for improvement in current procurement practices in hospital pharmacies of Nepal. Adoption and regulation of national and international policies is recommended for enhancing medicine accessibility, as well as improving preparedness for health emergencies during natural disasters and health epidemics.

3.2. Introduction

A hospital pharmacy is an integral part of healthcare in health institutions and is responsible for all medicine-related and management health processes to optimize outcomes and enhance the safety and quality of health services provided to patients [1]. There is large variation in the nature of services provided at hospital pharmacies around the globe, ranging from basic supply to advanced clinical services. However, with growing focus on patient-centred care, more complex services have become necessary in hospital pharmacies in many countries. In order to enhance hospital pharmacy practice globally, standardised guidelines based on essential elements of hospital pharmacy practice need to be followed [2, 3].

With the objective of developing global consensus statements for advancement of hospital pharmacy practice, the Hospital Pharmacy Section of International Pharmaceutical Federation (FIP) developed the first set of international consensus statements, named the Basel Statements, in 2008 [4]. The Basel Statements are 75 statements grouped under six key elements of hospital pharmacy practice, and are considered valuable guidelines for standardizing hospital pharmacy practice around the globe. Medicine Procurement is one of the six themes covered by the Basel Statements [4].

The procurement theme of the Basel Statements (Table 2) highlights different aspects of procurement, such as a) implementation of an appropriate and cost-effective procurement model with reliable information facilities and necessary funds to facilitate transparent and ethical purchasing, b) medicine selection based on formulary by adopting strong quality assurance principles, and c) establishment of contingency plans for effective management of medicine shortages [4].

Table 2: Procurement guidelines of the Basel Statements 2008

Statement Number	Statements
17	The procurement process must be transparent, professional, and ethical to promote equity and access and to ensure accountability to relevant governing and legal entities.
18	Procurement should be guided by the principle of procuring for safety.
19	Procurement of pharmaceuticals is a complex process that requires pharmacist control and technically competent staff.
20	Operational principles for good procurement practice should be regularly reviewed and procurement models adapted to fit different settings and emerging needs in the most appropriate and cost effective way.
21	Procurement must be supported by strong quality assurance principles to ensure that poor quality medicines are not procured or allowed into the system. Proper storage to ensure maintenance of quality in the whole supply pipeline is mandatory.
22	Procurement should not occur in isolation, but rather be informed by the formulary selection process.
23	Good procurement must be supported by a reliable information system that provides accurate, timely, and accessible information.
24	A formal mechanism must be in place for pharmacists to request designated funds to procure medicines for their patients.
25	Each pharmacy should have contingency plans for medicines shortages and purchases in emergencies.

Pharmaceutical procurement is a multi-disciplinary process requiring medical, pharmaceutical, managerial, financial and often political expertise. An effective pharmaceutical procurement process should ensure availability of the right drugs in the right quantities, at the right time, for the right patients at reasonable prices, and at recognizable standards of quality [5]. Pharmaceutical procurement is very

susceptible to unethical practices. A study undertaken in 2009 demonstrated that transparency, professionalism and equity are some of the major concerning issues related to procurement in healthcare settings [6]. Although a global problem, multiple predisposing factors such as having a weak regulatory authority, lack of regulation enforcement, low staff remuneration, poor procedures and inadequate payment practices, place developing countries at higher risk of corruption [6]. According to Corruption Measurement Tools of the Transparency International, Nepal is vulnerable to corruption with low corruption perceptions index of 31 out of 100 and corruption control score of -0.68 (score ranges from -2.5 to 2.5) [7]. Lack of transparency can have negative health and economic consequences which can lead to loss of credibility and clients' trust in the hospital services [5]. Moreover, this can have greater impact on poorer people, because they can neither afford these consequences nor opt for any alternatives, depriving them of access to medicines [8].

Rational selection of medicines is also considered one of the important factors associated with medicines use [9]. Data from the World Health Organization (WHO) shows that more than half of all medicines prescribed, dispensed or sold are inappropriate [10]. Moreover, medicine selection processes have been influenced by marketing strategies of pharmaceutical industries that manipulate scientific evidence in favor of newer, more expensive, on-patent drugs. For example, pharmaceutical companies can even influence physicians practicing in developed countries like United States of America (USA) to add medicines onto the formulary [11]. Such influential practices have also been seen in Nepalese hospitals [12].

Clinical and pharmaceutical advancements and innovations around the world are causing incremental increases in medicine and total health expenditure [13]. These

increases have greater impact in developing countries like Nepal, which have limited resources and lack of reimbursement for medicines, resulting in the necessity for the general public to pay entirely by themselves [14, 15].

Additionally, the quality of medicines is one of the key components of pharmaceutical procurement because of increasing availability of counterfeit, substandard and contaminated medicines on the market, that have the potential to pose serious health threats [15]. A survey by WHO showed that the majority (63%) of counterfeit medicines came from East Asian countries, with India (which is a neighboring country of Nepal) being the leader of counterfeit medicines production (35%) [16]. Such problems are more common in developing countries like Nepal because of their weak regulatory policies and enforcement capacities as compared to developed countries with strong enforcement of regulatory policies and more transparent supply chains [17]. Counterfeit medicines account for 15-50% of all available medicines in low- and middle-income countries and tend to be more affordable [18]. Counterfeit and substandard medicines can have serious health and economic consequences, creating a never-ending cycle of poverty in the developing world [19].

Medicine shortage is another challenging issue that can have serious implications on healthcare delivery, economy of the hospital and patient's health [20]. There are many contributing factors that can cause medicines shortages, but the major causes that can arise from within healthcare institutions are poor inventory management, lack of information flow and communication, changes in clinical practice, increase in demands, and natural disasters [20]. Health institutions in Nepal often face shortages of essential medicines, especially in remote part of the country [21], and during natural disasters like the devastating earthquakes of April and May 2015 [22]

and health epidemics such as the repeated emergence of Cholera over several years [23].

More than half the population of low-income countries in Africa and Asia do not have regular access to essential medicines, either due to absence of regulatory authorities or limited capacity to regulate medicine distribution [5]. Medicines are the primary vehicle for healthcare delivery and have huge impact on the health and well-being of people around the globe. Therefore, equitable access to medicines is considered one of the fundamental rights of people and vital for achieving several Millennium Development Goals such as minimizing child death, improving maternal health and fighting against diseases like HIV/AIDS and tuberculosis [5, 24]. With increase in adoption of contemporary evidence-based treatment systems, access to medicines has become an important topic for research globally [5, 6]. Since medicines cover large proportions of total health expenditures, ranging from 40% - 60% in developing countries [5, 6], access to health is affected by affordability of medicines [25].

Therefore, accessibility and affordability of essential medicines has also become a growing concern, especially in low and middle-income countries [5, 24, 26]. To promote health globally, WHO has attempted to promote access to essential medicines, especially to people of developing countries through the Essential Medicines List (EML) Programme. Although this programme has been hugely successful in improving accessibility of essential medicines in many low and middle-income countries, access to medicines is still a huge global problem, especially for the underprivileged population [18]. In 2011, a survey conducted on availability of essential medicines found that average availability of medicines is less than 60% in parts of South-East Asia and Africa. Due to poor availability of medicines in the public sector and lack of universal healthcare in many low-income countries,

medicines tend to be unaffordable to the majority of population in these countries [25]. Although a number of barriers and solutions have been researched for promoting access to medicines, ranging from individual to national and international level initiatives, a common element among them has been medicine procurement [18, 25, 27, 28]. Availability of affordable and evidence-based high quality medicines depends on the procurement procedure of medicines and is therefore considered an important aspect of healthcare delivery [5].

Issues of accessibility and affordability of medicines are of paramount importance in Nepal [26], in particular, in light of the earthquakes that struck the country in April and May 2015, inflicting much damage on its infrastructure, finance and healthcare systems. Nepal is a low-income country in South-East Asia and ranks 145th in the Human Development Index [29]. The health status of Nepal is poor with mortality rate of 190 per 100,000 live births and under-five mortality rate of 42 per 1000 live births [30]. Procurement practice in Nepal varies widely depending on whether the health institution is governmental, a non-profit organization or a private institution. Procurement at public hospitals is conducted in three different ways: central push/pull system, district level drug programs, and community drug programs [31]. All public procurements are conducted in accordance with the Public Procurement Act 2007 and the Public Procurement Guidelines 2009 [32, 33], while private hospitals purchase their medicines directly from importers, wholesalers and retailers [31]. Although some information regarding procurement and distribution of some freely distributed essential medicines procured by the government and donor organizations are available [14, 31, 34], procurement practices across all types of health institutions of Nepal are still unknown. Therefore, investigating procurement in hospital pharmacies of Nepal based on international guidelines, namely the Basel

Statements, is both practical and relevant for effectively improving access to affordable high quality medicines.

This study aimed to investigate medicine procurement practices in hospital pharmacies of private and public hospitals of Nepal based on the international hospital pharmacy guidelines (FIP Basel Statements 2008) relating to medicine procurement.

3.3. Method

3.3.1. Ethics

The study was approved by the ethics committee of authors' institution [Project No. 2014/619].

3.3.2. Sampling

Hospital pharmacists or procurement officers at hospital pharmacies in private and public hospitals throughout Nepal were included in the study. Samples were collected using a passive snowballing technique [35].

The Hospital Pharmacists' Association of Nepal, a private company of pharmaceutical products, and prominent figures in the profession such as the Vice President for the Hospital Pharmacy Section of International Pharmaceutical Federation (FIP) in the South East Asian Region were the key contact points for searching and reaching out to prospective participants. The only inclusion criterion was involvement of the participant in the procurement process. Hospital pharmacies that were based inside the premises of a hospital, and were run either by the hospital itself or leased by the hospital to a private organization, were included in the study.

Hospitals from the five major regions in Nepal as well as those in major cities were targeted for inclusion in the study.

3.3.3. Data Collection and Analysis

Semi-structured interviews were conducted with key stakeholders using a standard interview protocol (Appendix 1; Page 173) based on procurement guidelines of the Basel Statements (Table 2) [4] and assessment tools “Measuring Transparency in the Public Pharmaceutical Sector” [5] and “Operational Principles for Good Pharmaceutical Procurement” [36] published by WHO.

Interviews were conducted in either Nepali or English based on the participant’s preference. The recorded interviews were transcribed and translated to English where needed by a bilingual native Nepali speaker. Data collection continued until saturation of themes occurred [37].

Data were analysed thematically utilising the framework analysis approach [38] based on the procurement theme of the Basel Statements [4], with assistance of NVivo10 software [39]. Iterative analysis was conducted with continuous consultation and discussion amongst the research team until consensus was achieved.

3.4. Results

Interviews were conducted with 53 participants; 52 were from hospital pharmacies (40 private, 12 public) in four different regions of Nepal. One participant worked at the Logistic Management Division under the Department of Health Services of the Ministry of Health and Population, and was responsible for procuring free supplies for public hospitals and associated health institutions of Nepal (Table 5).

Table 5: Sample Characteristics of Nepal

Sample	Sample Characteristics/Quantity
Participants	Hospital Pharmacists or Procurement Officers
Inclusion Criteria for Participants	Involvement in the procurement process
Sampling Technique	Passive Snow Balling
Key Contact Points	1. The Hospital Pharmacists' Association of Nepal, 2. A private company of pharmaceutical products, and Prominent figures in the profession such as the Vice President of the Hospital Section of International Pharmaceutical Federation (FIP) for the South East Asian Region
Area Targeted	5 regions of Nepal
Area Covered	4 major regions of Nepal
Public Hospitals	12
Private Hospitals	37+ 3 (INGO*-funded hospitals)
Logistic Management Division, Department of Health Services, Ministry of Health and Population, Nepal	1
Total Sample	53

Our findings showed the existence of two types of hospital pharmacies, irrespective of the type of hospital: 1. those run by the hospital and 2. those run and owned by a private organization under a lease agreement. In first type of hospital pharmacies those run by the hospital, hospital pharmacies were completely regulated by hospital administration/management as a part of hospital's services. On the contrary, in case of privately owned hospital pharmacies, private organization would pay rent for the location of the pharmacy and were allowed to run the pharmacy independently for

business purpose without any control and governance from the hospital administration/governance.

Statements pertaining to the need for pharmacist-controlled procurement, information systems, existence of funding mechanisms, and proper storage conditions were all satisfactorily implemented, however, some guidelines were implemented only partially.

Notably, procurement practices were found to be affected by the nature of ownership of the hospital pharmacy: hospital-regulated hospital pharmacies tended to be more adherent to the Basel guidelines, while privately owned pharmacies deviated.

Utilising the Basel Statements relating to procurement processes, we organised the data under three main themes: Procurement Model, Medicines Selection and Contingency Plans. Below are the details of some important findings; all major findings are listed in Table 6.

Table 6: Major findings of Medicine Procurement in hospital pharmacies of Nepal

	Findings	Frequency	Basel Statements	Implementation Status	Barriers
A.	Theme 1: Procurement Model			Partial	
1)	Direct Procurement Model	Majority	Basel Statements 17&20		
a)	Purchase of medicines directly from wholesalers at a price allocated by the manufacturers or wholesalers.	Majority			
b)	Selection of suppliers based on past relationships, incentives, and/or recommendations of pharmaceutical companies.	Majority			
c)	Absence of suppliers' evaluation system	Majority			

d)	Follows regular procurement procedure but lacks well-defined written procurement procedure.	Majority			
2)	Competitive Procurement Model	Minority	Basel Statements 17&20		Prescription-based selection and frequent change in prescription
a)	<p>Purchase of medicines through either an open bidding process with predefined terms and conditions or competitive negotiations for achieving the best price for the medicines required.</p> <p>Pooled procurement followed by the Logistic Management Division of the Department of Health Services, Ministry of Health and Population, Nepal and the National Tuberculosis Centre (only those supplied by the Global Drug Facilities) for purchase of limited number of medicines that are distributed free-of-cost to patients.</p>	Minority			Requirement of the competitive process such as lengthy and complex administrative process, larger order size, time and cost required for the bidding process.
b)	Selection of suppliers through a separate vendor selection committee on the basis of availability of medicines, assessment of services, quality and price of medicines, whether they were authorised providers, their legal record/status, and past work experiences.	Minority			
c)	Existence of suppliers' evaluation system	Minority			
d)	Existence of well-defined written procurement procedure	Minority			
3)	Appeal System		Basel Statements 17&20	Partial	
a)	Existence of complaints reporting system-Verbal	Majority			

b)	Existence of complaints reporting system-Written	Minority			
c)	Absence of complaints reporting system	Minority			
4)	Expertise Involved		Basel Statement 19	High	
a)	Pharmacists	Majority			
b)	Technically competent staffs (Trained pharmacy staffs)	Majority			
c)	Pharmacy Owner (not necessarily pharmacists/trained)	Minority			
5)	Information System		Basel Statement 23	High	
a)	Existence of information facilities	Majority			
b)	Online sharing of procurement related information by Logistics Management Division of Department of Health Services, Nepal	One			
c)	Absence of any information facilities	Minority			
d)	Telecommunication as a mode of interactions with other procurement officers	Several			
e)	Existence of internal networking facilities	Minority			
6)	Fund Request Mechanism		Basel Statement 24	Full	
	Existence of fund request mechanism	All			
B.	Theme 2: Medicine Selection		Basel Statements 17, 18 & 22	Partial	
a)	Formulary Selection	Minority			Lack of formulary system and Pharmacy & Therapeutics Committee, Authority to

					doctors for medicine selection, and influence of aggressive pharmaceutical marketing
b)	Selection based on doctor's prescription	Majority			
c)	Selection based on national Essential Medicine List (EML)	Majority			
d)	Procurement based on principle of procuring for safety	Minority			
e)	Selection of medicines based on quality and/or price of medicines	Minority			
f)	Influence of Aggressive Pharmaceutical Marketing	Majority			
g)	No influence of pharmaceutical marketing	Minority			
h)	Existence of Pharmacy and Therapeutic Committee	Minority			
i)	Restriction on interactions between health professionals and marketing representatives of pharmaceutical companies	Minority			
j)	Absence of declaration of conflict of interest by health professionals	Almost all			
	Quality Assurance Principle		Basel Statement 21 and 18	Moderate	
a)	Checking registration status of medicine	Majority			
b)	Trusting doctor's prescription and recommendations, and reputations of manufacturers	Minority			
c)	Quality control system comprising of seeking analytical certificates and testing samples	Minority			
d)	Quality assurance based on clinical evidences or results	Minority			
e)	Absence of any quality assurance system	Minority			
f)	Existence of appropriate storage	Minority			

	conditions				
g)	Lack of thermostatically controlled temperature	Almost all			
h)	Availability of unregistered/ substandard/counterfeit medicine	Minority			
C.	Theme 3: Contingency Plans		Basel Statement 25	Moderate	
a)	Existence of strategies to manage medicine shortages which included brand substitution, emergency purchasing (from outside normal supply system, mainly from India), and borrowing from other pharmacies, controlling inventories and gathering prior information from suppliers and manufacturers	Majority			
b)	Existence of funds for emergency purchases	Majority			
c)	Absence of shortage management system	Minority			

3.4.1. Theme 1: Procurement Model

Our study revealed that hospital pharmacies in Nepal tended to use either one or both of two types of procurement models: 1.a direct-procurement model or 2.a competitive-procurement model. In the direct-procurement model, adopted by the majority of hospital pharmacies, medicines were purchased directly from wholesalers based on established business relationships, incentives, and/or recommendations of pharmaceutical companies, at prices allocated by manufacturers/wholesalers.

“If we buy from the supplier allocated by medical representatives, they will provide us with schemes and facilities. I want to maintain relationships and earn profit. Since price is always the same, we negotiate on facilities. When we will buy in bulk quantities they may offer us some extra facilities.

Therefore, while purchasing medicine, bargaining will be done on such things.” [PP40]

On the other hand, some hospital pharmacies operated under the competitive-procurement model, following a well-defined written procedure, through either an open-bidding process with predefined terms and conditions or competitive negotiations for best prices.

“We call for registration of suppliers with predefined criteria. If the applying suppliers meet all those criteria, we will shortlist them through initial screening. Then we will ask for quotation from them and will select who offers us the best price.” [PP53]

These differences in procurement models were directly related to pharmacy ownership: the competitive-procurement model was typically adopted by hospital pharmacies owned by the hospital, while the direct-procurement model was implemented by privately-owned hospital pharmacies.

The study highlighted that pharmacists or trained technical staff were responsible for procurement processes in the majority of hospital pharmacies. In a few hospital pharmacies, the pharmacy owner, (not necessarily a pharmacist or trained) supervised procurement processes.

The study also revealed that procurement officers in most of hospitals utilized the internet, books (e.g. CIMS India; NIDS), company brochures and databases to gather information about medicines.

“We have all sources; primary, secondary and tertiary sources.” [PP18]

Some hospital pharmacies reported not having access to such resources.

Almost all interviewees reported that funds for procurement in their pharmacies were generated by sales of medicines. If hospital pharmacies were regulated by hospitals, surpluses would be added to finances of the hospital whereas it would be of owner of hospital pharmacies in case of privately owned hospital pharmacies. Where medicine sales were low, participants reportedly used credit or returned unused stock.

“We can request from the account section which collects bills of purchased medicine and money collected from the sales. We can also purchase medicine on credit from our regular suppliers.” [PP11]

3.4.2. Theme 2: Medicines Selection

Our study confirmed that the majority of hospital pharmacies did not have a formulary. Of the few that did adopt a formulary list, it was either devised by a formal Pharmacy and Therapeutic (P&T) Committee, or by an informal group of employees. Some procurement officers also mentioned considering the national EML while purchasing medicines.

Participants almost unanimously reported that doctors' prescribing, irrespective of the formulary and EML, drove procurement.

“We have to keep medicines according to doctors' prescriptions.” [PP30]

Additionally, almost all of the participating procurement officers reported that aggressive marketing strategies of pharmaceutical companies affected medicine selection, effectively creating undeclared conflicts of interest.

“Yes, there are influences. If you look at the whole of Nepal, there are influences. Since we don't have Pharmacy and Therapeutic Committee,

medicines are selected based on doctors' prescriptions. Therefore, pharmaceutical companies have become successful in influencing doctors."

[PP25]

One participant stated that some pharmaceutical companies donated to the hospital, and therefore it was desirable for procurement to be conducted through these companies.

We are practising in this way because we want to provide opportunities to all pharmaceutical companies. Sometimes, some companies may have invested in the hospital, and then we can discuss with even directors and can use medicines of such companies... Everyone's interest is met. The pharmaceutical companies are also here for business... They conduct Continuing Medical Education (CME), conferences and other programs. Therefore, we will keep medicines from those companies on rotation basis "

[PP2]

Amidst the prescription-driven and commercially-influenced procurement practices, a small minority of hospital pharmacies confirmed that procurement was conducted in accordance with the Public Procurement Act 2007 without influence of companies.

"It is very transparent; 100% as per the law. Due to this Commission for the Investigation of Abuse of Authority (CIAA), things are very tough now. Public Procurement Act is there and we have to follow each and every step as per guidelines." [PP8]

While the majority of hospital pharmacies showed no regulations or policies for managing influences of pharmaceutical companies.

"This is almost impossible in the context of Nepal because doctors are given more priorities and doctors are controlling the hospital rather than being controlled by hospital... Therefore, it is impossible to regulate doctors. This is more of a national issue rather than a hospital issue. The government has published Medicines Promotional Act for managing this and they can implement this act; then only will there be some control over this promotional strategy... otherwise they are free to continue with their marketing strategy."
[PP4]

A few reported to manage influence by restricting pharmaceutical companies' access to decision-makers.

"Medical representatives are not allowed to visit doctors. We have that rule to restrict medical representatives' visit to our hospital; but meeting outside the hospital might happen." [PP50].

An interesting observation was that such hospital pharmacies tended to be run by the hospital and were often owned by the government or International Non-Governmental Organizations (INGOs).

On the issue of safety, only a few officers mentioned prioritising safety of medicines. Many pharmacists noted that they confirmed the registration status with national regulatory authorities before procuring.

"If medicines are registered in Department of Drug Administration (DDA) then we trust that they are of good quality. We only buy registered medicines."
[PP2]

However, a few hospital pharmacies, especially in cities near the Indian border, admitted that they had to procure unregistered medicines from unauthorised sources if prescribed by doctors or if medicines required were in shortage.

"Some medicines are important to patients and are life-saving medicines. Doctors have to prescribe such medicines and most of them are not available in Nepal. In such conditions when doctors prescribe them, we do purchase from India, even from black market. Such medicines are not kept here in the pharmacy; we stored them separately and even dispense secretly to patients. It is illegal but we are saving patients' lives." [PP44]

When asked about adoption of a quality assurance system for controlling entry of substandard medicines, some respondents answered that they trusted doctors' prescriptions and recommendations, and/or reputations of the manufacturers for ensuring quality of medicines.

"No, we don't do that. If doctors prescribe then it must be of good quality. If they prescribe then we will sell anything, even stones." [PP20]

A few participants had a system in place for quality control, including seeking certificates of analysis and/or testing of samples.

"There is a pre-shipment inspection, post-shipment inspection, checking of Good Manufacturing Practice and analysis certificates. We appoint a third party inspection agency for inspection...It is done for each product and each company that won the bid for supply. There is post-shipment inspection at the time of delivery. We randomly select medicines and send to national medicines laboratories for inspection" [PP15]

The study revealed that medicines in most hospital pharmacies were stored in appropriate conditions. Many had facilities for maintaining room temperature (20-25 °C) and other conditions necessary to preserve the quality of medicines during storage.

3.4.3. Theme 3: Contingency Plans

Our results showed that the majority of pharmacists used brand-substitution, emergency-purchasing (from outside the normal supply system, mainly from India), and borrowing from other pharmacies, as strategies to manage medicine shortages.

"We will borrow from other hospital pharmacies or request suppliers to manage medicines for us. If it is not possible to manage from these sources then we will go for second option. We will discuss with doctors and substitute. We also control inventories and try to manage stock." [PP52]

Several hospital pharmacists also claimed that they had a separate emergency fund, for pricier substitutions needed during emergencies. A few pharmacists stated that they did not have a shortage management system in place.

"If medicines are not available then we have to say no and request patients to search in other places." [PP13]

Some hospital pharmacies managed inventories by stockpiling up to 3 months' worth of medicines based on past consumption or seasonal changes and epidemics, as well as gathering prior information from suppliers/manufacturers to help manage medicine shortages.

"We usually maintain stock for 3 months so shortage does not happen that frequently. Sometimes supplier will inform us about upcoming shortages and

ask whether we want to order in larger quantities. And in such conditions we will order in larger quantity.” [PP14]

3.5. DISCUSSION

To our knowledge, this is the first study to explore procurement practices in hospital pharmacies in Nepal within the framework of the procurement guidelines of the Basel Statements. Our findings revealed mixed results regarding implementation of guidelines, which included partial adoption of guidelines in the majority of hospital pharmacies. This shows that, by and large, Nepalese hospital pharmacies have many good processes in place however there is room for improvement. Accordingly, several recommendations are proposed.

Given the apparent correlation between pharmacy ownership and guidelines implementation, enforcement of the Nepalese National Health Policy 2014 [40] and Hospital Pharmacy Directives 2013 [41] could be an effective way to improve procurement practice and guidelines implementation. These require hospital pharmacies to be run or managed by hospital administrations.

3.5.1. Theme 1: Procurement Model

The study found that the majority of hospital pharmacies followed the direct-procurement model, which is considered one of the most expensive models by WHO [42], and is thus inconsistent with Basel Statement 20 [4] and the Hospital Pharmacy Directives 2013 of Nepal [41]. Moreover, lack of well-defined procurement procedures and transparency in supplier selection is also in contrast to Basel Statements 17 and 20, which demand transparent, professional and ethical procurement practices [4]. According to the WHO, the restricted tender procedure, open for only prequalified suppliers, is considered the best procurement model for

small countries like Nepal [42]. A small minority of hospital pharmacies adopted a competitive-procurement model, similar to other low-and middle- income countries like India and those in the Western Pacific region [43]. However the open tender system without pre-/post-bidding evaluation of suppliers is not in accordance with WHO recommendations [42].

Furthermore, barriers to utilization of the tendering process were identified, such as size of purchase order, stock levels, and administrative workloads, which are similar issues reported by WHO [36] and Arney [44]. To overcome these barriers, pooled procurement which creates buyers' cartel for achieving price reductions, improved quality assurance and minimization of corruption has been recommended [43]. In particular, pooled-procurement with contractual agreements could be adopted [44, 45]; such models are successfully implemented in countries like, Mexico, Chile and within U.S. Department of Veterans Affairs and Department of Defense, and the United Nations Organizations [44]. This achieves competitive uniform pricing through a centralized tender system, allowing decentralized purchasing of medicine at one uniform prices achieved from central bidding by all associated healthcare systems through smaller repeated orders and delivery [44]. Additionally, several other cost containment strategies such as conducting pharmaco-economic evaluation, establishing prescribing guidelines and promoting use of generics could be utilized by procurement officers while purchasing medicines for hospitals [43, 46].

Although the Nepalese National Good Pharmacy Practice Guidelines 2005 [47] insists on pharmacist-controlled procurement, in line with Basel Statement 19, this was not evident in some hospital pharmacies. In contrast, the Nepalese Hospital Pharmacy Directives 2013 [41] do not specify this requirement. Better alignment of directives with guidelines should be ensured in the future. This necessitates

education on the role of pharmacists in the procurement process and inclusion of pharmacist-control in Hospital Pharmacy Directives. Moreover, a multidisciplinary approach involving expertise from clinical pharmacology, pharmacoepidemiology and pharmaco-economics has also been recommended for improving procurement practices [13].

Reliance on unreliable sources of evidence-based healthcare was also a concern. Utilization of readily available online information sources provided by national and international organisations providing evidence-based guidelines [e.g. DDA, and WHO] should be encouraged. Finally, procurement officers should be educated about international guidelines developed by WHO and other international pharmaceutical associations [such as FIP] to improve their procurement practices.

3.5.2. Theme 2: Medicines Selection

Another challenging issue in pharmaceutical procurement was medicine selection. This study found that the majority of hospital pharmacies in Nepal are being operated without a hospital formulary to facilitate patient care and medicine procurement. This finding suggests that the Basel Statements 18, 21 and 22 [4], the WHO [9], American Society of Health System Pharmacists (ASHP) [48] and Nepalese Hospital Pharmacy Directives (2013) [41] regarding adoption of a formulary system, were not followed. Hospital pharmacies in Nepal procured medicines based on prescription, and the majority of doctors did not utilise a formulary system to guide their prescribing behaviour. This is in contrast with medicine selection practices in the USA, Europe and Western Pacific countries that follow a formulary system [49]. Although a few hospital pharmacies reported the existence of a formulary or equivalent list, the selection process was not found to

follow guidelines, possibly due to the absence of a formal pharmacy and therapeutics selection committee. However, while specific formularies were not found to be commonplace in this study, the majority of procurement officers did aim to maintain stock of medicines included on the national EML. National List of Essential Medicines [50] of Nepal developed by Government of Nepal consists of all essential medicines that satisfy health needs and diseases patterns of Nepal and are recommended for availability in all health organizations at adequate amount, appropriate dosage forms, safety and quality, and affordable price. This adoption of national EML indicated some compliance with the procedures recommended by the Nepal Pharmacy Council [47] and WHO [42].

Further, occurrences of undeclared relationships between decision-makers and suppliers/manufacturers were also uncovered in this study. The lack of a Pharmacy and Therapeutic (P&T) Committee, authority of doctors in medicine selection, and influences of aggressive pharmaceutical marketing strategies were reported by interviewees as major barriers for formulary-based selection.

The dominance of doctors driving procurement based on what they prescribe without specific prescribing guidelines could be minimized by establishing a P&T Committee to develop formularies and add additional players in decision making processes [9] with the help of model formularies [national[51] ; international [52]] and guidelines published by the WHO [9] and ASHP [48]. Introduction of hospital formularies can also be actively taken up by hospital pharmacists of Nepal.

The influence of pharmaceutical marketing is a heavily scrutinized topic around the world because of its impact on patient care. Influence of pharmaceutical companies on medicine selection and other procurement-related behaviours evident in Nepal is

in contrast with Basel Statement 17 [4], which demands ethical procurement practice, and the Basel Statement 18 [4] which emphasizes on the safety of medicines. Such influential behaviours to induce prescription and sales of medicines have also been reported to pose enormous challenges in India [53], China [54] as well as developed countries like the US [11]. To address such issues, medical associations in the USA [55] and Australia [56] have attempted to manage relationships between medical professionals and pharmaceutical companies by implementing strict codes of ethics/conduct. Moreover, the American College of Clinical Pharmacy in the USA has developed guidelines for pharmacists to assist in managing ethical interactions with pharmaceutical industry [57]. On the contrary, the Code of Medical Ethics developed by the Nepal Medical Council [58] is yet to include any notes on ethical relationships between healthcare professionals and pharmaceutical companies. Although the DDA has developed guidelines on ethical promotion of medicines [59], our findings suggest that DDA has not been able to effectively enforce them. It is noteworthy that pharmaceutical companies in Australia [60] and the USA [61] also have their own codes of conduct that, among other guidelines, requires declaration of details of promotional activities to be disclosed. Nepalese pharmaceutical companies and regulatory authorities could develop similar codes to further promote ethical medicine use.

Furthermore, undeclared conflicts of interest observed in Nepalese hospital pharmacies suggest that there is room to decrease influence and bias. The WHO actually suggests establishing guidelines for declaration of conflict of interest by people involved in the decision-making processes in order to minimize corruption, favoritism or influence, and to increase transparency in procurement processes [5]. In line with this, Nepal could make regulatory and practical changes based on the

WHO Good Governance for Medicines Medical Framework [62], which has achieved success in countries like Jordan, Thailand and Malaysia [62]. The Nepalese government could also introduce a reward-based system like that in the Philippines [63] and suggested by Ombaka [6] to encourage organizations to follow regulatory guidelines.

Interestingly, many participants did not seem to consider safety issues whilst procuring. Although most procurement officers aimed to procure registered medicines to ensure quality, a few reported procurement of unregistered medicines through unauthorised supply chains, especially from India, one of the leading countries for counterfeit and substandard medicine production [16]. Procurement of medicines from unauthorized sources raises concerns about the safety and efficacy of medicines. While it is understood that such procurement practices may only have been carried out under exceptionally dire circumstances, regulatory authorities should devise a mechanism to tackle this issue.

Although a minority took the extra step of checking analysis certificates and performing analytical testing, trusting doctors' prescriptions and the reputation of pharmaceutical companies in an environment of incentive-based selection and aggressive pharmaceutical marketing may not assure quality of medicine.

Procurement officers could utilize the model and guide of quality assurance system developed by the WHO [64] or the United States Pharmacopeia [65] to develop their own internal quality-assurance systems. Inexpensive and easy-to-use analytical test kits are also available to facilitate testing to minimize entry of substandard/counterfeit medicines [66].

In an attempt to combat counterfeiting globally, the WHO has developed a toolkit named “BE AWARE” [67] in collaboration with World Health Professionals Alliance. The WHO has also established guidelines for the development of measures to combat counterfeit drugs [68], which could be a useful resource. Nepal can also minimize the risk of purchasing poor quality medicines by utilizing the list generated by the WHO prequalification of medicines program [69], especially when purchasing from suppliers from countries with high risk of counterfeit medicine production.

3.5.3. Theme 3: Contingency Plans

The majority of hospital pharmacies reportedly managed medicine shortages through spontaneous workarounds, such as searching for alternatives, emergency purchasing, and borrowing from other hospital pharmacies. Some even stockpiled or tried to acquire prior knowledge about anticipated shortages, to help overcome shortages in epidemics or seasonal demands. These measures were in line with some guidelines recommended by ASHP [20], but possibly not sustainable or sufficient for managing and achieving preparedness for medicine shortages for the long term or times of emergency. The reported lack of shortage management systems in few hospital pharmacies indicated that Basel Statements 25 [4] pertaining to the existence of contingency plans for medicine shortages was not fully addressed. Other countries such as Canada, USA and Europe, have regulatory frameworks, preparedness and strategic approaches in place to address medicine shortages [70]. Hospital pharmacies in Nepal would benefit from utilizing the three-phased approach consisting of identification and assessment, preparation, and contingency phases, proposed by ASHP for managing shortages of critical or essential medicines [20]. This allows for rationing and distributing available medicines ethically and purchasing medicines during emergencies with safety,

quality and cost of medicine under consideration [20, 71]. Moreover, an information system similar to those of developed countries [70] could be utilized, or even made compulsory, as in the USA [72], for sharing information on shortages and management strategies.

Nepal recently endured disastrous earthquakes in April and May 2015 causing major medicines shortages, which was reported to be a crucial issue of concern in the massive aftermath of the tragedy [22]. In such circumstances, adoption of preparedness and strategic contingency plans would be of great significance for providing timely delivery of health services during emergencies. Hospital pharmacies, with active involvement of Ministry of Health and Population, should form a plan to address medicine shortages, as well as emergency management of medicines.

3.6. Conclusions

The findings of this study indicated that procurement guidelines of the Basel Statements are currently implemented to a certain extent in hospital pharmacies of Nepal. This study also found some significant factors that influenced procurement practices in Nepal such as hospital pharmacy ownership, pharmaceutical companies' influences, authority of doctors, and lack of regulatory enforcement. Moreover, purchase of unregistered medicines from unauthorised supply chain reported in the study showed possibility of health threats by counterfeit and substandard medicines. Absence of strategic contingency plans during shortage was also a major concern especially as Nepal could be heavily reliant on other countries for essential and lifesaving medicines in emergency situations such earthquakes, flooding, other natural disasters or health epidemics.

The study reported that existing policies and guidelines comply with the Basel Statements and other international guidelines, and national policies of many countries to a greater extent. However, implementation of these guidelines were in poor practice. Additionally, regulatory constructs were also poor which might provide possible reasons for non-compliance to the national regulations. Therefore, it is recommended to adopt and regulate existing policies in the beginning and gradually amend those policies to meet international standards. Promoting ethical and transparent working culture through educational and awareness programs could be another important step towards responsible and better procurement practice. These recommendations could be helpful in improving accessibility of high-quality, evidence-based and affordable medicines as well as preparedness for health emergencies during natural disasters and health epidemics, achieving patient care goals, and promoting equitable access to health for the general public of Nepal.

3.7. References

1. European Association of Hospital Pharmacists. What Is Hospital Pharmacy? European Association of Hospital Pharmacists. 2012. Available from: <http://www.eahp.eu/practice-and-policy/hospital-pharmacy>. Accessed 2 February 2016.
2. Vermeulen LC, Vulto AG, Zellmer WA. Editorial: The Promise of Basel. Am J Health Syst Pharm. 2009. 66(Suppl 3):S7.
3. American Society of Health System Pharmacists, International Pharmaceutical Federation. Global Conference Proceedings Executive Summary. Am J Health Syst Pharm. 2009. 66(Suppl 3):S1-6. doi: 10.2146/ajhp080664.
4. The Basel Statements on the Future of Hospital Pharmacy. Am J Health Syst Pharm. 2009. 66(5 Suppl 3):S61-6.
5. Baghdadi-Sabeti G, Cohen-Kohler JC, Wondemagegnehu E. Measuring Transparency in the Public Pharmaceutical Sector. World Health Organization. 2009. Available from: <http://apps.who.int/medicinedocs/documents/s16732e/s16732e.pdf>. Accessed 2 February 2016.
6. Ombaka E. Current Status of Medicines Procurement. Am J Health Syst Pharm. 2009. 66(5 Suppl 3):S20-8. doi: <http://dx.doi.org/10.2146/ajhp080604>.
7. Transparency International. Corruption by Country/Territory: Nepal. Transparency International. 2014. Available from: <http://www.transparency.org/country/#NPL>. Accessed 9 February 2016.

8. Mostert S, Sitaresmi MN, Njuguna F, van Beers EJ, Kaspers GJ. Effect of Corruption on Medical Care in Low-Income Countries. *Pediatr Blood Cancer*. 2012. 58(3):325-6.
9. Holloway K, Green T. *Drug and Therapeutic Committees-a Practical Guide*. World Health Organization and Management Sciences for Health. 2003. Available from: <http://apps.who.int/medicinedocs/pdf/s4882e/s4882e.pdf>. Accessed 2 February 2016.
10. World Health Organization. *Promoting Rational Use of Medicines: Core Components*. World Health Organization. 2002. Available from: <http://www.who.int/medicines/publications/policy/perspectives/ppm05en.pdf>. Accessed 3 February 2016.
11. Nguyen NY, Bero L. Medicaid Drug Selection Committees and Inadequate Management of Conflicts of Interest. *JAMA Internal Medicine*. 2013. 173(5):338-43.
12. Thapa BB. Ethical Promotion of Medicine: Benefit to Consumers. *Drug Bulletin of Nepal*. 2007. 19(1):3-4.
13. Milovanovic DR, Pavlovic R, Folic M, Jankovic SM. Public Drug Procurement: The Lessons from a Drug Tender in a Teaching Hospital of a Transition Country. *Eur J Clin Pharmacol*. 2004. 60(3):149-53.
14. Government of Nepal, Ministry of Health and Population. *Nepal Pharmaceutical Country Profile*. Government of Nepal, Ministry of Health and Population and World Health Organization. 2011. Available from: http://www.who.int/medicines/areas/coordination/nepal_pharmaceutical_profile.pdf. Accessed 7 February 2016.

15. Barraclough A, Clark M. Managing Procurement. 2012. In: Managing Access to Medicines and Health Technologies [Internet]. Arlington, VA: Management Science for Health. [18.1-.26]. Available from:
<http://apps.who.int/medicinedocs/documents/s19577en/s19577en.pdf>.
Accessed on 7 February 2016.
16. Wertheimer AI, Santella TM. Counterfeit Drugs: Defining the Problem and Finding Solutions. *Expert Opin Drug Saf*. 2005. 4(4):619-22. doi: 10.1517/14740338.4.4.619.
17. Seiter A. Health and Economic Consequences of Counterfeit Drugs. *Clin Pharmacol Ther*. 2009. 85(6):576-8. doi: 10.1038/clpt.2009.47.
18. Bigdeli M, Jacobs B, Tomson G, Laing R, Ghaffar A, Dujardin B, et al. Access to Medicines from a Health System Perspective. *Health Policy Plan*. 2013. 28(7):692-704. doi: 10.1093/heapol/czs108.
19. Wertheimer AI, Norris J. Safeguarding against Substandard/Counterfeit Drugs: Mitigating a Macroeconomic Pandemic. *Res Social Adm Pharm*. 2009. 5(1):4-16.
20. Mark SM, Mark LK, ASHP Council on Administrative Affairs *Am J Health-Syst Pharm*. ASHP Guidelines on Managing Drug Product Shortages. *Am J Health Syst Pharm*. 2001. 58(15):1445-50.
21. National News Agency. Medicine Shortage Hits Locals in Mugu. *My Republica*. 19 February 2014. Available from:
http://www.myrepublica.com/portal/index.php?action=news_details&news_id=69810. Accessed 6 February 2016.
22. WHO Issues Rapid Health Assessment on Impact of Nepal Earthquake [Internet]. World Health Organization. 1 May 2015. Available from:

- <http://www.who.int/mediacentre/news/releases/2015/health-assessment-nepal/en/>. Accessed on 6 February 2016.
23. Sanyal D. Jajarkot Pandemic and Some Home Truths. *The Rising Nepal*. 25 April 2015. Available from: <http://therisingnepal.org.np/news/3111>. Accessed 6 February 2016.
 24. Hogerzeil HV. Essential Medicines and Human Rights: What Can They Learn from Each Other? *Bull World Health Organ*. 2006. 84(5):371-5.
 25. Cameron A, Ewen M, Auton M, Abegunde D. The World Medicines Situation 2011: Medicines Prices, Availability and Affordability. World Health Organization. 2011. Available from: <http://apps.who.int/medicinedocs/documents/s18065en/s18065en.pdf> Accessed 5 February 2016.
 26. Mendis S, Fukino K, Cameron A, Laing R, Filipe Jr A, Khatib O, et al. The Availability and Affordability of Selected Essential Medicines for Chronic Diseases in Six Low- and Middle-Income Countries. *Bull World Health Organ*. 2007. 85(4):279-88. doi: 10.2471/BLT.06.033647.
 27. Cameron A, Ewen M, Ross-Degnan D, Ball D, Laing R. Medicine Prices, Availability, and Affordability in 36 Developing and Middle-Income Countries: A Secondary Analysis. *Lancet*. 373(9659):240-9. doi: [http://dx.doi.org/10.1016/S0140-6736\(08\)61762-6](http://dx.doi.org/10.1016/S0140-6736(08)61762-6).
 28. Dickens T. The World Medicines Situation 2011-Procurement of Medicines. World Health Organization. 2011. Available from: <http://apps.who.int/medicinedocs/documents/s18769en/s18769en.pdf>. Accessed 5 February 2016.

29. United Nations Development Programme. 2014 Human Development Report. United Nations Development Programme. 2015. Available from: <http://www.undp.org/content/undp/en/home/librarypage/hdr/2014-human-development-report/>. Accessed 8 February 2016.
30. World Health Organization. Nepal: WHO Statistical Profile. World Health Organization. 2014. Available from: <http://www.who.int/gho/countries/npl.pdf?ua=1>. Accessed 3 February 2016.
31. Harper I, Berhlikova P, Subedi MS, Bhattarai S, Basu S, Gupta AD, et al. Drug Procurement in Nepal. The Centre for International Health Policy. 2007. Available from: http://www.csas.ed.ac.uk/_data/assets/pdf_file/0009/38826/DrugProcurementNepal.pdf. Accessed 3 February 2016.
32. Public Procurement Act 2007, Act Number 36 (2007). Government of Nepal.
33. Government of Nepal, Ministry of Health and Population. Public Procurement Guidelines. Government of Nepal, Ministry of Health and Population. 2009. Available from: <http://mohp.gov.np/index.php/publication-1/guideline>. Accessed 3 February 2016.
34. Health Sector Programme, Ministry of Health and Population, Deutsche Gesellschaft für Technische Zusammenarbeit. Essential Drug Procurement and Supply Management System in Nepal: Current Challenges and How to Address Them. GTZ/GFA Consulting Group GmbH and Health Sector Programme, Department of Health Services. 2009. Available from: http://www.ministerial-leadership.org/sites/default/files/resources_and_tools/Essential_Drug_Procurement_Policy_Brief.pdf. Accessed 6 February 2016.

35. Noy C. Sampling Knowledge: The Hermeneutics of Snowball Sampling in Qualitative Research. *Int J Soc Res Methodol*. 2008. 11(4):327-44. doi: 10.1080/13645570701401305.
36. Rankin J, Quick JD, Muziki. S, Woldeyesus K, Fresle DA, Grayston G, et al. Operational Principles for Good Pharmaceutical Procurement. WHO's Department of Essential Drugs and Medicines Policy (EDM). 1999. Available from: <http://www.who.int/3by5/en/who-edm-par-99-5.pdf>. Accessed 6 February 2016.
37. Mason M. Sample Size and Saturation in Phd Studies Using Qualitative Interviews. *Forum Qual Soc Res*. 2010. 11(3).
38. Spencer L, Ritchie J, Connor WO, Morrell G, Ormston R. Analysis in Practice. In: Ritchie J, Lewis J, Nicholls CM, Ormston R, editors. *Qualitative Research Practice: A Guide for Social Science Students and Researchers*. Second edition ed. Los Angeles, California: SAGE; 2014.
39. QSR International. *Nvivo 10 for Windows Getting Started*. QSR International. 2014. Available from: <http://download.qsrinternational.com/Document/NVivo10/NVivo10-Getting-Started-Guide.pdf>. Accessed 5 February 2016.
40. Government of Nepal, Ministry of Health and Population. *National Health Policy 2071*. Department of Drug Administration. 2014. Available from: <http://www.moHP.gov.np/images/pdf/policy/1%20National%20Health%20Policy%202071.pdf>. Accessed 6 February 2016.
41. Government of Nepal, Ministry of Health and Population. *Hospital Pharmacy Directives*. Government of Nepal, Ministry of Health and Population. 2013.

Available from: http://www.slideshare.net/niraj_bartaula/hospital-pharmacy-service-directives-2070-55955345. Accessed 3 February 2016.

42. Levison L. Practical Guidelines on Pharmaceutical Procurement for Countries with Small Procurement Agencies, Manila, WHO, Regional Office for the Pacific, WHO/WPRO, 20002 (Book). *Essent Drugs Monit.* 2003. (33):31-.
43. Nguyen TA, Knight R, Roughead EE, Brooks G, Mant A. Policy Options for Pharmaceutical Pricing and Purchasing: Issues for Low- and Middle-Income Countries. *Health Policy Plan.* 2015. 30(2):267-80. doi: 10.1093/heapol/czt105.
44. Arney L, Yadav P, Miller R, Wilkerson T. Strategic Contracting Practices to Improve Procurement of Health Commodities. *Glob Health Sci Pract.* 2014. 2(3):295-306. doi: <http://dx.doi.org/10.9745/GHSP-D-14-00068>.
45. Hussain Z, Tukai M, Adu JA, Khan AI. Workshop on Framework Agreement and Two-Year Procurement Cycle at Proshika Hrdc, Koitta, Manikgonj, March 6–8, 2012. Arlington, VA: USAID, SIAPS, MSH; 2012.
46. Tordoff JM, Norris PT, Reith DM. Managing Prices for Hospital Pharmaceuticals: A Successful Strategy for New Zealand? *Value Health.* 2005. 8(3):201-8.
47. Nepal Pharmacy Council. National Good Pharmacy Practice Guidelines. Nepal Pharmacy Council. 2005. Available from: http://nepalpolicy.net/images/documents/publichealth/regulations/DoDA_2005_National%20Good%20Pharmacy%20Practice%20GuidelineseDraft.pdf. Accessed 6 February 2016.

48. Linda S. Tyler, Cole SW, May JRe, Millares M, Valentino MaA, Jr. LCV, et al. ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System. *Am J Health Syst Pharm*. 2008. 65:1272-83.
49. Penm J, Chaar B, Dechun J, Moles R. Formulary Systems and Pharmacy and Therapeutics Committees in the Western Pacific Region: Exploring Two Basel Statements. *Am J Health Syst Pharm*. 2013. 70(11):967-79. doi: 10.2146/ajhp120396.
50. Government of Nepal, Ministry of Health and Population, Department of Drug Administration. National List of Essential Medicines. Department of Drug Administration, Nepal. 2011. Available from: <http://www.dda.gov.np/druglist/nlem2011.pdf>. Accessed 11 February 2016.
51. Kafle KK, Thapa BB. Nepalese National Formulary 2nd Edition. Government of Nepal, Ministry of Health and Population, and Department of Drug Administration 2010. Available from: https://www.researchgate.net/publication/262562432_Nepalese_National_Formulary_2010. Accessed 16 February 2016.
52. World Health Organization. WHO Model Formulary. World Health Organization. 2014. Available from: <http://apps.who.int/medicinedocs/documents/s16879e/s16879e.pdf>. Accessed 6 February 2016.
53. Roy N, Madhiwalla N, Pai SA. Drug Promotional Practices in Mumbai: A Qualitative Study. *Indian J Med Ethics*. 2007. 4(2):57.
54. Penm J, Li Y, Zhai SD, Hu YF, Chaar B, Moles R. The Impact of Clinical Pharmacy Services in China on the Quality Use of Medicines: A Systematic

- Review in Context of China's Current Healthcare Reform. Health Policy Plan. 2014. 29(7):849-72. doi: 10.1093/heapol/czt067.
55. American Medical Association. AMA's Code of Medical Ethics. American Medical Association. 2015. Available from: <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics.page>. Accessed 4 February 2016.
 56. Medical Board of Australia. Good Medical Practice: A Code of Conduct for Doctors in Australia. Medical Board of Australia. 2014. Available from: <http://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code-of-conduct.aspx>. Accessed 4 February 2016.
 57. Hatton RC, Hutchison LC, Matzke GR, Noviasky JA, Rospond RM, Kelloway JS, et al. Pharmacists and Industry: Guidelines for Ethical Interactions. Pharmacotherapy. 2008. 28(3):410-20. doi: 10.1592/phco.28.3.410.
 58. Nepal Medical Council. NMC-Code of Ethics. Nepal Medical Council. 2016. Available from: <http://www.nmc.org.np/information/nmc-code-of-ethics.html>. Accessed 16 February 2016.
 59. Department of Drug Administration. Guidelines on Ethical Promotion of Medicine, 2007. Department of Drug Administration. 2007. Available from: <http://www.dda.gov.np/guidlines/Ethical%20Promotion%20Guidelines%202007.pdf>. Accessed 2015 April 17.
 60. Medicines Australia. Code of Conduct. Medicines Australia. 2015. Available from: <https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/01/20150617-PUB-Code-Edition-18-FINAL.pdf>. Accessed 2 February 2016.

61. Pharmaceutical Research and Manufacturers of America. Code on Interactions with Healthcare Professionals. Washington. Pharmaceutical Research and Manufacturers of America. 2008. Available from: http://www.phrma.org/sites/default/files/pdf/phrma_marketing_code_2008.pdf. Accessed 5 February 2016.
62. World Health Organization. Good Governance for Medicines: Model Framework. World Health Organization. 2014. Available from: http://www.who.int/medicines/areas/governance/ggm_modelframe_updated/en/. Accessed 5 February 2016.
63. Baghdadi-Sabeti G, Serhan F. WHO Good Governance for Medicines Programme: An Innovative Approach to Prevent Corruption in the Pharmaceutical Sector. World Health Organization. 2010. Available from: <http://www.who.int/healthsystems/topics/financing/healthreport/25GGM.pdf>. Accessed 5 February 2016.
64. World Health Organization. A Model Quality Assurance System for Procurement Agencies. World Health Organization. 2007. Available from: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf>. Accessed 5 February 2016.
65. United States Pharmacopeia Drug Quality and Information Program and collaborators. Ensuring the Quality of Medicines in Resource-Limited Countries: An Operational Guide. The United States Pharmacopeial Convention. 2007. Available from: http://www.usp.org/sites/default/files/usp_pdf/EN/dqi/ensuringQualityOperationalGuide.pdf. Accessed 5 February 2016.

66. Hall C. Technology for Combating Counterfeit Medicine. *Pathog Glob Health*. 2012. 106(2):73-6. doi: 10.1179/204777312X13419245939485.
67. International Council of Nurses, International Pharmaceutical Federation, World Dental Federation, World Medical Association. *Be Aware: Helping to Fight Counterfeit Medicines, Keeping Patients Safer*. The World Health Professions Alliance. Available from: http://www.whpa.org/Toolkit_BeAware.pdf. Accessed 5 February 2016.
68. World Health Organization. *Guidelines for the Development of Measures to Combat Counterfeit Drugs*. 1999. Available from: http://whqlibdoc.who.int/hq/1999/WHO_EDM_QSM_99.1.pdf. Accessed 5 February 2016.
69. WHO Prequalification of Medicines Programme. *WHO Drug Information*. 2012. 26(2):99.
70. Dill S, Ahn J. Drug Shortages in Developed Countries—Reasons, Therapeutic Consequences, and Handling. *Eur J Clin Pharmacol*. 2014. 70(12):1405-12. doi: 10.1007/s00228-014-1747-1.
71. Manolakis M. Ethical Integrity in Managing Drug Shortages. *Am J Health Syst Pharm*. 2012. 69(1):17. doi: 10.2146/ajhp110640.
72. The White House Office of Press Secretary. *Fact Sheet: Obama Administration Takes Action to Reduce Prescription Drug Shortages in the U.S.* The White House President Barack Obama. 2011. Available from: <https://www.whitehouse.gov/the-press-office/2011/10/31/fact-sheet-obama-administration-takes-action-reduce-prescription-drug-sh>. Accessed 5 February 2016.

Chapter 4

How do we procure medicines? A comparative study between Australia and Nepal based on the Basel Statements

Chapter 4: How do we procure medicines? A comparative study between Australia and Nepal based on the Basel Statements

This chapter is presented in the form of a manuscript that has been submitted to a peer reviewed journal and is currently under review.

4.1. Abstract

Accessibility, affordability, safety and quality of medicines are highly influenced by medicine procurement. Different countries have different regulatory policies and medicine supply management systems resulting in different procurement practices. Therefore, we aimed to compare medicine procurement practices of Australia and Nepal using framework analysis in the context of international guidelines, namely the Basel Statements. Semi-structured interviews were conducted with 22 participants from different public hospitals of Nepal and Australia. For the most part, procurement practices and their compliance with the Basel Statements in hospital pharmacies at public hospitals of Nepal varied from those of Australia in several aspects. Nevertheless, a few similarities were also found. Additionally, procurement practices that are implemented better in Australia were identified. Adoption and amendment of current procurement policies are recommended for improving access to affordable and high-quality medicines in Nepal and other developing countries with similar medicine access problems and procurement issues.

4.2. Introduction

Hospital pharmacy practice has evolved over the decades from traditional product-centred practice models to contemporary patient-oriented models of services. Today, hospital pharmacists in many countries actively engage in patient care services, clinical services, promotion of rational use of medicines, assessment and monitoring of therapy, individualized medicine therapy, medicine-use evaluation, and cost-effective analysis [1, 2]. However, from a global perspective, advancement of hospital pharmacy practice still has not been achieved equally in all parts of the world. Hospital pharmacy in many countries, especially low and middle-income developing countries, has traditional medicine distribution practices and is still struggling to establish basic clinical practice [3-5]. For instance, Nepal, a developing country [6] has very basic hospital pharmacy practice models focused on drug distribution functions [7, 8] whereas Australia, a developed country [9] has advanced hospital pharmacy practice models focused on individualized and specialty clinical pharmacy services [10].

The Basel Statements are the international consensus statements developed by the Hospital Pharmacy Section of International Pharmaceutical Federation (FIP) in 2008 for standardizing hospital pharmacy practices around the globe [11-14]. The Basel Statements 2008 consisted of 75 statements on six key elements of hospital pharmacy practice [12]. Medicine Procurement is one of the six themes included in the Basel Statements [12] (Table 2).

Table 2: Procurement Guidelines of the Basel Statements 2008

STATEMENT NUMBER	STATEMENTS
17	The procurement process must be transparent, professional, and ethical to promote equity and access and to ensure accountability to relevant governing and legal entities.
18	Procurement should be guided by the principle of procuring for safety.
19	Procurement of pharmaceuticals is a complex process that requires pharmacist control and technically competent staff.
20	Operational principles for good procurement practice should be regularly reviewed and procurement models adapted to fit different settings and emerging needs in the most appropriate and cost effective way.
21	Procurement must be supported by strong quality assurance principles to ensure that poor quality medicines are not procured or allowed into the system. Proper storage to ensure maintenance of quality in the whole supply pipeline is mandatory.
22	Procurement should not occur in isolation, but rather be informed by the formulary selection process.
23	Good procurement must be supported by a reliable information system that provides accurate, timely, and accessible information.
24	A formal mechanism must be in place for pharmacists to request designated funds to procure medicines for their patients.
25	Each pharmacy should have contingency plans for medicines shortages and purchases in emergencies.

According to WHO, more than half of the population in low-income countries in Africa and Asia were deprived of regular access to essential medicines, due to lack of efficient regulatory authority and medicines distribution system [15]. As medicines

are the primary vehicle for medical intervention in the modern era, providing access to medicines to patients from all backgrounds is an important issue. Medicine procurement has huge impact on total health expenditure which ranges from 40% - 60% in developing countries and has direct influence on availability, affordability, safety and quality of medicines [15, 16]. Therefore, exploring the basic yet very crucial theme of “Procurement” from the Basel Statements is both practical and relevant to developed and developing countries.

In low-income countries like Nepal, availability of medicines in public hospitals is lower than that in private hospitals whereas prices are 66.3% higher in private hospitals [17]. Due to poor availability and higher prices of medicines along with lack of universal healthcare in many low-income countries, medicines tend to be unaffordable for the majority of the population in these countries [18]. The government of Nepal has been distributing few selected essential medicines to the general public through public health institutions as a part of a free basic health program. However, public procurement and the availability of essential medicines in public institutions has been reported to be poor [19]. Increasing availability of affordable and quality medicines in public health institutions would be beneficial in achieving equitable access to medicines to the general public of all background. Therefore, this study is focused on exploring medicine procurement in public hospitals of Nepal and compare that to public hospitals of Australia.

Nepal is a low-income developing country in South-Asia [6] ranking 145th position in the Human Development Index (HDI) with the HDI value of 0.540 [20, 21]. With 25.2% of the population living under poverty lines [6], the Gross National Income (GNI) per capita (Atlas Method) is US\$730 and Gross Domestic Product (GDP) is US\$19.64 billion [22]. With 5.69% of Nepal’s GDP spent on health, the health status

of Nepal is poor and has life expectancy at birth of 68 years [22], adult mortality rate of 176 per 1000 population [23] and under-five mortality rate of 35.8 per 1000 live births [24]. People in Nepal can access health services through three types of healthcare facilities: governmental institutions, non-governmental and non-profit organizations, and private health institutions [25]. Government institutions provide 39.04% of total health expenditure and the remaining 60.96% is provided by private institutions. External resources from donor organizations accounted for 10.92% of total health expenditure of Nepal [26]. The government and donor organizations are responsible for funding selected healthcare services and freely distributed medicines. People must pay for all other healthcare facilities and medicines [27, 28]; which sums up to 48.68% out-of-pocket expenditure of total health expenditure [26].

Australia is a high-income developed country in the Western Pacific region [9] with the second highest HDI of 0.933 [21], GNI per capita of US\$64,620 and GDP of US\$1.455 trillion [29]. With 9.36% of GDP spent on health, life expectancy at birth of Australian people is 82 years [29], adult mortality rate of 61 per 1000 population [23], neonatal mortality rate of 2.2 per 1000 live births and under-five mortality rate of 3.8 per 1000 live births [24]. Health services in Australia are provided by public health institutions, which contribute 67.01% of total health expenditure and private health institutions which cover the remaining 32.99% of total health expenditure. Out-of-pocket expenditure in Australia is only 18.83% of total health expenditure with 25.36% of private health expenditure contributed by private prepaid plans [26].

Public hospitals of Nepal procure medicines in accordance to the Public Procurement Guidelines [30] following the Public Procurement Act 2007 [31]. Medicine procurement in Nepal is funded completely by sales of medicines. This

implies that the costs of medicines are fully paid for by the general public, except for a few selected freely distributed essential medicines funded by the government [27]. On the other hand, public hospitals in Australia purchase medicines as per supply contracts set by their states which are funded by the Australian government [32]. And medicines are provided to the general public at affordable government-subsidized prices [33-35].

4.3. Aim

To compare medicine procurement practices in hospital pharmacies of public hospitals of Australia and Nepal.

4.4. Ethics

Ethics approval for conducting this study was obtained from the Human Research Ethics Committee of author's institution [Project No. 2014/619].

4.5. Method

4.5.1. Sampling

Hospital pharmacists or procurement officers at hospital pharmacies of public hospitals of Nepal and Australia were contacted using a passive snowballing sample collection technique. In snowballing sample collection technique, participants were contacted through information provided by other informants or previous participants [36]. The only inclusion criterion for participants was involvement in procurement procedures. Hospital pharmacists or procurement officers that serviced public hospitals in all five regions of Nepal, and the six states and two territories of Australia were targeted for inclusion in this study. Hospital pharmacies were selected regardless of whether the hospital pharmacy was run by the hospital itself or whether

the public hospital leased its pharmacy service from a private organization. In Nepal, the Hospital Pharmacists' Association of Nepal, a private pharmaceutical company, and the Vice President for the Hospital Section of International Pharmaceutical Federation (FIP) in the South East Asian Region were contacted to assist with recruitment of prospective participants. In Australia, the Society of Hospital Pharmacists of Australia assisted in the recruitment process. Detailed information about sample characteristics is presented in Table 7.

Table 7: Sample Characteristics of Australia and Nepal

Sample	Sample Characteristics/Quantity
Participants	Hospital Pharmacists or Procurement Officers
Inclusion Criteria for Participants	Involvement in the procurement process
Sampling Technique	Passive Snow Balling
Key Contact Points	<p>1. Nepal</p> <ul style="list-style-type: none"> a. The Hospital Pharmacists' Association of Nepal, b. A private company of pharmaceutical products, and c. Prominent figures in the profession such as the Vice President of the Hospital Section of International Pharmaceutical Federation (FIP) for the South East Asian Region <p>2. Australia</p> <ul style="list-style-type: none"> a. The Society of Hospital Pharmacists of Australia b. Academics of author's institution
Area Covered	<p>Nepal: 4 major regions of Nepal</p> <p>Australia: 4 states and 2 territories of Australia</p>
Hospitals	Public Hospitals of both countries Logistic Management Division, Department of Health Services, Ministry of Health and Population, Nepal
Number of Sample	<p>Nepal: 12+1</p> <p>Australia: 9</p>
Total Sample	22

4.5.2. Data Collection and Analysis

For collecting data, a standard semi-structured interview protocol (Appendix 1; Page 173) was developed based on the procurement guidelines of the Basel Statements (Table 2). Additionally, assessment tools “Measuring Transparency in the Public Pharmaceutical Sector” [15] and “Operational Principles for Good Pharmaceutical Procurement” [37] published by World Health Organization (WHO) were also used to assess different aspects of the procurement statements of the Basel Statements 2008. This interview protocol was utilized for interviewing participants in both Australia and Nepal. All interviews in Australia were conducted in English whereas participants in Nepal were interviewed either in Nepali or English based on interviewees’ choice of language. All interviews were audio-recorded and then transcribed verbatim. Transcripts in Nepali language were then translated to English by a bilingual native Nepali speaker. Interviews continued until no new concepts emerged i.e. saturation of themes [38].

The framework analysis approach [39] was used for thematically analysing data, based on the procurement theme of the Basel Statements [12]. Framework analysis is an analytical approach developed by Ritchie and Spencer which organises data based on key themes, concepts and categories, making the process systematic and transparent facilitating retrieval and tracking of data [39, 40]. The framework analysis approach is used for analysing data with predetermined concepts such as those of semi-structured interviews [40]. It is suitable for data covering similar topics or key issues that can generate themes capable of providing full description on the phenomenon under investigation [40, 41]. The NVivo10 software [42] was used for organising data to develop a framework required for analysis. The consensus of the

research team was achieved through continuous involvement and discussion in iterative analysis.

4.6. Results

Interviews conducted with 22 participants from 12 public hospitals and 1 national Logistic Management Division of Nepal, and 9 public hospitals of Australia reported similarities and differences in procurement practices. Results were thematically categorised into four different themes (Table 8) based on nine statements of the procurement theme of the Basel Statements 2008.

Table 8: A comparative study between Australia and Nepal

	Similarities	Frequency	Differences	Frequency
1.	Operational Principles			
a)	Pharmacy Ownership		Pharmacy Ownership-Hospital	All (Australia); Some (Nepal)
			Pharmacy Ownership-Private	Some (Nepal) None (Australia)
b)	Procurement Method			
	Mixed type procurement method	All (Australia) Minority (Nepal)	Direct Procurement Method	Almost All (Nepal) None (Australia)
	Competitive Procurement Method in combination with Direct/Negotiation Procurement Method	All (Australia) Minority (Nepal)	Competitive Procurement Procedure Australia -State Tender Nepal -Hospital Tender; Central tender for selected free supply medicines	All (Australia) Minority (Nepal)
	Presence of well-defined procurement procedure	All (Australia)	Outsourcing of Imprest Supply System	One (Australia)

		Minority (Nepal)		None (Nepal)
c)	Supplier Selection			
	Supplier Selection by hospital/hospital pharmacies	All (Nepal) Minority (Australia)	Supplier Selection by state government	Majority (Australia) None (Nepal)
	Selection Criteria: - Price and Availability of Medicines - Services provided by suppliers	All (Australia and Nepal)	Evaluation of Suppliers- Documented	All (Australia) Minority (Nepal)
d)	Expertise Involvement			
	Pharmacist and technically competent staff involvement in procurement process	All (Australia) and Majority (Nepal)	Pharmacy owner managed procurement	Minority (Nepal)
e)	Funding			
	Funding Source-Government and/or International Non-governmental Organization	All (Australia) Minority (Nepal)	Funding Source-Sales of Medicines	Majority (Nepal)
f)	Information System			
	Information Resources- Internet and web-based resources	Majority (Australia and Nepal)	Information Resources- Research/Survey	One (Australia)
			Information resources- Books and Consultation with Doctors	Minority (Nepal)
			Information System-Not Available	One (Nepal)
2.	Evidence-Based Practice			
a)	Selection of Medicines		Formulary Selection of Medicines; Cost-effective, safety and clinical evidences based Medicines Selection	All (Australia) Minority (Nepal)
			Medicines Selection based on Prescription	Majority (Nepal)

			Medicines Selection based on national EML	Majority (Nepal)
			Medicines Selection based on Patient's Need (Non-Formulary\One-Off Medicines	A couple (Australia)
b)	Quality Assurance			
	Quality Check Criteria-Registration Status with national regulatory authorities	Majority (Australia and Nepal)	Availability of Unregistered Medicines	Few (Nepal)
			Checking compliance to International Good Manufacturing Guidelines	Majority (Nepal)
			Analytical Quality Testing of Medicines	Some (Nepal)
			Quality Check Criteria-Risk/Safety Assessment	Some (Australia)
c)	Storage Facilities			
	Appropriate storage conditions	All (Australia and Nepal)	Storage Security System - Australia-Highly controlled manual and electronic security system - Nepal-Manual security and scheduled monitoring system	
3.	Professionalism and Ethics			
a)	Pharmacy And Therapeutic Committee		Pharmacy and Therapeutic Committee	Majority (Australia) Minority (Nepal)
			COI Declaration by PTC Members	Majority (Australia) One (Nepal)
b)	Influence Of Pharmaceutical Companies		Influence of Pharmaceutical Companies	Majority (Nepal) None (Australia)
			Approved promotional activities of	Few (Australia)

			pharmaceutical companies	
c)	Presence of Influence Management System	All (Australia) Some (Nepal)	Absence of Influence Management System	Some (Nepal)
4.	Shortage Management			
	Workarounds - Substitution - Emergency Purchasing - Searching and Borrowing Stock Management	Majority (Australia and Nepal)	Preparedness and Strategic Approach - Information Circulation - Controlled Usage/ Supply - Regular Fortnightly Meeting for assessing availability of medicines, probability of upcoming shortages, stock watch and preparedness.	Many (Australia)
			Absence of Shortage Management Procedures	Few (Nepal)

4.6.1. Operational Principles

The study conducted in hospital pharmacies of public hospitals in Australia and Nepal reported a significant difference in the type of hospital pharmacies in these two countries. Hospital pharmacies in Australian public hospitals are regulated by hospital administration, whereas hospital pharmacies of Nepalese public hospitals were found to be regulated either by the hospital or leased by the hospital to private organizations. Under lease agreement, the location/s designated for pharmacy are rented to private organizations which are then allowed to run their pharmacies on their own, independent from the governance/control of hospital administration/management. This type of hospital pharmacy is similar to a retail pharmacy; the only difference is that it is within the premises of hospitals.

In regard to the type of procurement methods used for procuring medicines, Nepalese public hospitals reportedly utilized either or both competitive or direct procurement methods, with the majority following the direct procurement method. With direct procurement methods, medicines were purchased directly from wholesalers at prices allocated by manufacturers.

“We buy directly from wholesalers.” [Nep_PP7]

Public hospitals of Nepal which followed competitive procurement method reportedly conducted their own tendering process at hospital level.

“We purchase every year through tender process. ... We will select suppliers that have offered us the lowest price.” [Nep_PP12]

An exception existed for the purchase of some selected essential medicines that were purchased by the central government for free distribution to all public health institutions. An interesting finding was that public hospitals of Nepal which regulated their own hospital pharmacies reportedly utilized competitive procurement method whereas hospital pharmacies that were leased to private organizations were more likely to use direct procurement method.

On the contrary, Australian public hospitals followed competitive procurement methods in combination with direct procurement or negotiation methods.

“That’s mainly done by the state contracts.” [Aus_PP8]

Public hospitals of Australia either utilized state tenders conducted by state government, where all state hospitals were allowed to buy medicines at the price negotiated by the state, or called for tender on their own.

“In New South Wales, if a drug is listed on the government tender, then we are bound to buy that specific brand from the tender... So generally it’s the price that’s on tender that will be the cheapest that you can get.” [Aus_PP3]

Both methods allowed Australian public hospitals to purchase medicines in a cost-effective manner.

Hospital pharmacies of both countries had pharmacists and technically competent staff involved in the procurement process. However, some of the hospital pharmacies in Nepal that were run by a private organization were managed by a pharmacy owner who may or may not be a pharmacist/trained person.

In regard to funding sources for purchasing medicines, all Australian hospitals reported being funded entirely by state government; whereas majority of hospital pharmacies in Nepal were funded directly by the sale of the medicines. The surpluses generated from sales of medicines would then belong to the hospital administration if a hospital pharmacy was regulated by the hospital, or belong to the owner of the hospital pharmacy if it was privately owned. Procurement of a few selected essential medicines, that were included in free distribution list, was however funded by the government. Additionally, a couple of hospital pharmacies were funded by international non-governmental organizations.

The main sources of gathering information in hospital pharmacies of Australia were the Internet and other Internet-based resources. A few examples included databases and direct access to websites of suppliers for obtaining information about product prices and availability. Additionally, a few Australian participants reported the use of national/state-wide price comparison surveys conducted by an external organization for gathering information about price of medicines paid by different hospitals. The

majority of hospital pharmacies in Nepal utilized Internet and medicine information books like CIMS of India (mainly) and NIDS of Nepal. In addition, a few procurement officers of Nepal consulted doctors for any necessary information. One participant reported lack of information resources in one of the public hospitals of Nepal.

4.6.2. Evidence-based Practice

All public hospitals in Australia followed formulary processes for selecting medicines. Participants also reported that public hospitals might use a formulary list formulated by the state government, or develop their own formulary for their specific hospitals. Regardless of whether they used a state or hospital developed formulary list, patient safety, price and quality of medicines, and clinical evidences were major selection criteria.

“We have the formulary list and we purchase and stock medicines according to that list...HPV will meet and look at 1. price, 2. availability, and 3. the product itself, that there is no risk. There is big emphasis on medication safety to make sure that any products are assessed for risk.” [Aus_PP9]

In addition to medicines listed in a formulary, some participants stated that occasionally they had to procure non-formulary and one-off medicines based on clinical needs of patients with approval from Pharmacy and Therapeutics (P&T) Committee.

On the other hand, the majority of procurement officers in hospital pharmacies in Nepal selected medicines based on doctors' prescription. One of the respondents added that they had to select medicines based on prescription because they did not have P&T Committee and hospital formulary.

“We haven’t had a hospital formulary till now. That’s why we keep medicines based on doctors’ prescription. We may not be able to keep all prescribed brands and so we will keep most commonly prescribed brands.” [Nep_PP9]

Only a few hospital pharmacies that were managed by hospitals reported to have a formulary list of their own. However, the majority of procurement officers in Nepal claimed to take into consideration the National Essential Medicines List while procuring medicine for their hospital pharmacies.

“Department of Drug Administration has published narcotic medicines list and essential medicines list. We keep all these medicines. We try to keep all necessary emergency medicines as well.” [Nep_PP7]

Sales and price of medicines were other frequently considered selection parameters in Nepal.

In regard to quality of medicines, hospital pharmacies of both countries trusted registration of medicines with national regulatory authorities of their respective countries. Moreover, the majority of procurement officers in hospital pharmacies of Nepal also considered checking whether medicines were manufactured following international manufacturing standard.

“We usually observe whether they are Good Manufacturing Practice (GMP) certified or not; most of the medicines available here are from GMP certified company.” [Nep_PP12]

The study reported that some Australian hospital pharmacies prioritized safety of medicines and took extra measures to assess safety, minimizing risk and evaluating clinical evidences of medicine.

“There is big emphasis on medication safety to make sure that products are assessed for risk ...Everything that's new is looked and tested by Med-safe team.” [Aus_PP9]

On the contrary, a few hospital pharmacies in Nepal, especially those situated near the Indian border, admitted to purchasing of unauthorized medicines when prescribed by doctors and when no alternatives were available.

“Department of Drug Administration should do something on this matter. Some medicines are not authorised for entry in Nepal but since doctors have prescribed them, such medicines have to be bought illegally.” [Nep_PP10]

However, some hospital pharmacies in Nepal reported to ensure quality of medicines through quality control testing procedure.

“There is a pre-shipment inspection, post-shipment inspection, documentation and GMP certification check. ...It is done for each product and each company that won the bid for supply.” [Nep_PP6]

It was found that hospital pharmacies of Nepal that were managed by the hospital were more stringent about quality assessment compared to those controlled by private organizations. However, a number of procurement officers in Nepal reportedly relied completely on doctors' prescriptions trusting their judgment for ensuring quality of medicines.

All hospital pharmacies in Australia claimed to maintain required storage facilities such as appropriate storage conditions, continuous monitoring of storage facilities, and highly controlled electronic and manual security systems. Similar facilities were reported by the majority of hospital pharmacies in Nepal. However, hospital

pharmacies in Nepal did not have provision of continuous monitoring and electronic security systems, instead had scheduled manual monitoring and manual security systems for controlling unauthorised access.

4.6.3. Professionalism and Ethics

All hospital pharmacies in Australia reported to have a Pharmacy and Therapeutic Committee (P&T Committee) for selecting medicine and handling medicine-related issues in hospital. In contrast, only a minority of hospital pharmacies in Nepal had P&T Committee and the majority did not have any committee as such. The study also reported that hospital pharmacies that were managed by hospitals had P&T Committees.

Procurement and medicine selection processes in the majority of hospital pharmacies of Nepal were reported to be heavily influenced by marketing strategies of pharmaceutical companies.

“Due to influences of these pharmaceutical companies, medicine selection process has been affected by incentives. Since same doctors are working in both private and public hospitals, they even tell public hospitals to procure medicines of their chosen company.” [Nep_PP7]

While some participants admitted absence of policies, others claimed existence of local and national policies for managing such influences which included restricting interactions of doctors and pharmacists with pharmaceutical companies.

“We don’t have rules.” [Nep_PP10]

“There is a law by CIAA (Commission for Investigation of Abuse of Authority), which says that there should be no influence and corruption; there is no need

for any additional rules. If anyone does, then they will be charged by CIAA.”

[Nep_PP6]

There was no system for declaring conflicts of interest in the majority of hospital pharmacies of Nepal to ensure that the health professionals did not have any conflicting relationship with pharmaceutical companies. Furthermore, it was found that policies for managing relationships between doctors and pharmaceutical companies were likely to exist in hospital pharmacies that were managed by hospitals.

Unlike Nepal, public hospitals of Australia reported that their selection and procurement processes were not influenced by pharmaceutical companies; and that all decision makers and P&T Committee members have to declare any conflicting relationship with pharmaceutical companies.

“We get some good deals from drug companies, outside the state contract.

They come in as a deal that if we buy their product, they’ll give us bonus or a better price, different things like that will happen……. Sometimes companies might give it away for a period of time so that the doctors can get used to using it……. but then that still has to be approved by the drug committee.”

[Aus_PP8]

Moreover, procurement officers in Australia claimed that their hospitals had necessary policies., system and working environment for managing relationships between pharmaceutical companies and decision makers.

“We have a code of conduct for medical representatives which are formulated by the drug and therapeutic committee and it is based on the fairly clear

guidelines of how they should conduct their business when they are in the hospital.... based on the code of ethics created by medicines Australia.”

[Aus_PP6]

“We cannot control the world but we try to have policies in our hospitals to control such issues. We have review processes where we examine these issues closely.... We educate staff about faults, give presentation about tricks used by pharmaceutical companies, try to raise alerts, create awareness and explain about negotiating...all actions are quite transparent.” [Aus_PP2]

Furthermore, it was found that participants had a great sense of responsibilities and accountability of any decisions taken by them as decision makers.

“You have a lot of power in being able to decide so you really have to be careful as a director that you are doing everything ethically and are very transparent with the process... you just have to make sure you can justify your decision to the board and that there is no perceived conflict of interest.”

[Aus_PP3]

4.6.4. Shortage Management

Substituting unavailable medicines with other available brands or similar type of medicines, and supplying medicine through emergency purchasing was a commonly used strategy for managing medicine shortages in public hospitals of both countries. Other frequently used approaches by procurement officers of both countries were workarounds such as borrowing and managing inventories. However, a couple of hospital pharmacies in Nepal reported not having any system for managing medicine shortages.

A significant difference reported between these countries in managing shortages was adoption of strategic approaches for handling shortages. Hospital pharmacies in Australia had strategic approaches such as gathering prior information, assessing and managing availability of medicines, controlling supply and usage, circulating information and avoiding stockpiling.

“One of the meetings we have at our hospital is drug availability meetings every two weeks. Basically there is an agenda about stock level, availability and usage of medicine. We discuss strategies on what to do... We look at many options proactively, try to reduce the risk or manage the product during the shortage period by meeting every two weeks, and looking in advance what’s happening.” [Aus_PP9]

Moreover, the majority of participants from Australia reported that they received information about medicine shortages through different sources such as the State Government, Therapeutic Goods Administration (TGA) (a national regulatory body of Australia), and pharmaceutical companies or suppliers. On the contrary, hospital pharmacies of Nepal did not always have such strategic plans or resources at hand. Information sharing services were also not reported in public hospitals of Nepal.

4.7. Discussion

This comparative study is the first study to compare procurement practices in public hospitals of Nepal and Australia. This study, conducted in hospital pharmacies of public hospitals in Nepal and Australia, showed that there are similarities and differences in how medicines are purchased. The study found that public hospitals in Australia procure medicines in their hospital pharmacies in accordance with their state and national policies, and their procurement procedures comply with those of

the Basel Statements. It is a well-known fact that high-income countries like Australia have advanced hospital pharmacy practice and well-established professional standards [5, 43] and this was also reflected in this study. On the other hand, national policies and adoption of the Basel Statements in public hospitals of Nepal was found to be enforced only to a certain extent.

4.7.1. Operational Principles

Hospital pharmacies of public hospitals in Nepal and Australia both had similarities and differences in terms of their operational principles. An interesting finding of this study is the difference in ownership between hospital pharmacies of Nepal and Australia. Generally, hospital pharmacies in public hospitals of Australia are managed by hospitals. However, in the case of Nepal, some public hospitals managed their own hospital pharmacies whereas others provided lease to private organizations to run hospital pharmacies in their hospitals. This is in contrast to National Hospital Pharmacy Directives of Nepal which demand hospital pharmacies be managed by the hospital [27]. Existence of privately controlled hospital pharmacies in public hospitals reported in this study suggested that there is lack of enforcement and monitoring of national guidelines. An earlier study by Harper et.al. in 2007 [44] reported that medicine procurement in Nepal differs according to type of health institutions. Our findings indicated that even within the same health institution procurement procedures varied depending on types of hospital pharmacies. Hospital pharmacies that were controlled by hospitals had one type of procurement procedure and those run by private organizations had another type of procurement procedure. Moreover, the influences of the ownership of hospital pharmacies on procurement procedures observed in this study suggested that compliance to guidelines is more

likely to occur if hospital pharmacies are controlled by hospitals rather than if owned by private organizations.

Hospital pharmacies of Australia followed mixed type procurement methods, which included a combination of competitive and direct/negotiation procurement procedures. Utilization of competitive procurement methods by all public hospitals of Australia suggested that all public hospitals of Australia utilized the method that complies with the National Medicine Policy [34] and the Commonwealth Procurement Rules [45] of Australia which demand utilization of procurement methods for achieving value for money, and the Basel Statement 20 which advocates for cost-effective procurement model [12]. This was also the same for some hospital pharmacies of Nepal, especially those managed by hospital administration. But for the majority of hospital pharmacies of Nepal, it was through the direct procurement method. This direct procurement method is considered an expensive method by WHO [46] and does not comply with the National Drug Policy 1995 of Nepal [47] and the Procurement Act 2007 [31] recommending competitive processes to be in place and the Basel Statement 20 [12] emphasising the notion of cost-effectiveness. This choice of procurement method suggested that this could be one of many causes of the higher prices of medicines in Nepal compared to international reference pricing [17].

Alternatively, the study found that the government of Nepal had adopted pooled procurement for purchasing a few selected essential medicines marked for free distribution to all public health institutions. This pooled procurement is considered successful in providing competitive prices, by pooling volumes of medicines from each institution within the group [48]. This method is similar to that used by India, a neighbouring country of Nepal [49], and New Zealand [50].

Another significant difference between Australian and Nepalese public hospitals was the tendering process. Reported utilization of state-wide contracts by public hospitals of Australia, which allowed all public hospitals to purchase medicines at the price negotiated by the state, is considered to be effective in achieving best prices as well as reducing time and resources required for procurement procedures [51, 52]. This is similar to group contracting strategies utilized by the U.S. Department of Veterans Affairs and Department of Defense, and international organizations like United Nations Children's' Fund, United Nations Population Fund and Global Fund. In group contracting strategies, a central body within the group will negotiate for price through bidding and organizations within the group can purchase individually from the selected supplier at that negotiated price [51, 52]. Although similar group contracting strategies also have been recommended for low and middle-income countries like Nepal [53], public hospitals of Nepal still reportedly utilized individual tendering processes.

In addition to pooled procurement and group contracting strategies, other cost-effective strategies such as use of formularies, rational prescribing guidelines, stocking up on less expensive generics, and price regulation [50, 53] have also been recommended for low and middle-income countries like Nepal for improving access to affordable medicines to the general public.

Hospital pharmacies of both countries operated in line with the Basel Statement 19 [12] requiring pharmacists' control, Statement 23 [12], recommending the existence of evidence based information to be at hand, and Statement 24 [12] about funding facilities. However, funding sources of these two countries were different.

Procurement in public hospitals of Australia was funded by the government whereas

procurement in public hospitals of Nepal completely relied on sales of medicines except for some selected essential medicines that are freely distributed by the government. The reason for this difference is due to variations in healthcare funding policies of these countries. Australia provides free/subsidized healthcare facilities, including medicines, to its public [32] through Medicare [33] and the PBS system [35]. On the contrary, Nepal does not have any public healthcare coverage facilities and people have to pay for their medicines [27]. The equity and affordability in medicines access could be increased if the government of Nepal might consider providing some healthcare subsidization in medicines prices similar to that adopted in Australia, especially to poor and needy people who can't afford medicines and may be deprived of basic health needs.

In regard to information facilities, the use of a national price comparison survey by a few public hospitals in Australia is expected to strengthen negotiation power for achieving better medicine prices [16]. Governments of both countries should consider promoting public accessibility and utilization of such reference prices and other medicine-related information in all hospital pharmacies for improving access to affordable medicines [54].

4.7.2. Evidence-based Practice

The study showed a clear variation in medicine selection process of hospital pharmacies of these two countries. Formulary selection processes on the basis of patient safety, price and quality of medicines, and the clinical evidence available were adopted by public hospitals of Australia. This practice complies with the National Medicines Policy [34] and practice standards of Society of Hospital Pharmacists of Australia [55], the international WHO guidelines [56], the ASHP

guidelines [57] and the Basel Statements 18, 20, 21, and 22 advocating for formulary selection, safety, quality and cost-effectiveness [12].

Many hospital pharmacies of public hospitals of Nepal on the other hand did not have any formularies and selected medicines based on doctor's prescriptions. This prescription-based medicine selection practice is in contrast with the Basel Statement 22 [12] and Hospital Pharmacy Directives 2070 of Nepal [27] which recommended formulary selection processes. As formularies have proven to improve rational and cost-effective prescribing practices [58], hospitals of Nepal should develop their own formularies by utilizing either Nepalese National Formulary [59] developed by Department of Drug Administration or model formularies formulated by WHO [60]. However, the consideration of a National List of Essential Medicines, by some hospital pharmacies for selecting medicines was in line with these guidelines to a certain extent. The National List of Essential Medicines [61] is a list of all essential medicines required for Nepal and is developed on the basis of diseases patterns and health needs of people of Nepal.

A lack of P&T Committees as a reason for the absence of formularies and use of prescription-based medicine selection correspond to one of the three reasons for non-utilization of formularies reported by Penm et.al [58]. Additionally, Penm et.al [58] did highlight in their study that hospitals' funding models influenced formulary adoption, with public hospitals more likely to have these system in place [58].

Interestingly in this study which only focused on public hospitals, we found it was the actual funding model of the pharmacy- not that of the hospital that seemed to influence formulary use in Nepal. Hospital pharmacies that were funded and managed by hospitals tended to utilise a formulary process for selecting medicines

whereas those pharmacies that were contracted by the hospital had limited use of formularies.

We also found that hospital pharmacies of both countries had similar quality assurance principles which are on the basis of registration status of medicines. This shows that both countries complied with the requirement of the Basel Statement 21 [12] of having quality assurance principles to ensure purchase of high-quality medicines. A comparative multi-country study conducted in 2002 reported that the national regulatory authority, Therapeutic Goods Administration (TGA), of Australia has well-developed regulatory framework for quality assurance of registered medicines [62]. Moreover, special safety and risk minimization strategies adopted by public hospitals of Australia for ensuring entry of safe and quality medicines in hospital pharmacies reflect strong safety and quality driven working cultures. This is in line with the country's National Medicines Policy 2000 [34] and the Basel Statements 18 and 21 [12].

On the contrary, this study reported incidents of purchase of unauthorised medicines in a few hospital pharmacies of Nepal near the Indian border, suggesting lack of effective regulatory monitoring of medicine registration. India, a neighbouring country to Nepal and the source of many life-saving and essential medicines for Nepal, is considered home to counterfeit and substandard medicines [63], and as such can increase the possibility of purchasing counterfeit and substandard medicines. Although this unauthorised purchase may be the last resort for fulfilling the demand for some medicines, this can pose serious health threats - which might add economic and health costs burdens to a poor country like Nepal and its poverty stricken people. While such malpractice was evident only in a few areas of Nepal during certain difficult situations, the study also reported that few hospital

pharmacies analytically tested quality of medicines to ensure that all purchased medicines were of high quality.

The Australian regulatory framework and its success in providing high-quality medicines to its people could be an example for Nepal to follow for improving its current regulatory and monitoring practices. Also, safety and risk minimization programs, and systematic working culture that promote safety and quality of medicines could be something that can be incorporated in hospitals of Nepal gradually in practice. Moreover, Nepal can adapt the WHO recommended model [64] and guide [65] for improving its current regulatory policies and work on enforcing its current policies and monitoring practices. Hospital pharmacies can also benefit from available and affordable analytical test kits that can be used in their own in-house laboratories for testing quality of medicines [66]. In addition to this, regulatory authorities in Nepal should stringently focus on controlling purchase of poor quality and counterfeit medicines, including in adverse situations of medicines shortages, by following WHO guidelines on fighting against counterfeiting [67]. And, with the correlation reported between hospital pharmacies' ownership and quality assurance procedures, it appears that controlling privatisation could be a good start towards quality purchasing procedure.

4.7.3. Professionalism and Ethics

Hospital pharmacies of Australia and Nepal differ in terms of professionalism and ethics in practice. The Basel Statement 17 states that procurement should be conducted in a professional and ethical manner complying with national policies and guidelines [12]. Complying with this statement, all public hospitals of Australia had P&T Committee whereas majority of hospital pharmacies of Nepal operated without

P&T Committee. The Hospital Pharmacy Directives 2070 [27] of Nepal requires the establishment of P&T Committees in all hospital pharmacies of Nepal. However, this evidence of lack of P&T Committee in Nepal demonstrates that hospital pharmacies of Nepal do not operate in accordance with national practice guidelines. P&T Committees are considered responsible for handling all medicine-related matters, developing formularies and treatment protocols, and promoting rational and cost-effective use of medicines [56]. Therefore, in a developing country like Nepal establishing P&T Committees could improve access of evidence-based medicine at an affordable price to patients of all economic and social background. To assist hospitals in establishing P&T Committees, WHO has published a practical guide [56] which can be useful for public hospital of Nepal.

Moreover, this study revealed that, unlike Australian hospital pharmacies, medicine selection and procurement processes in the majority of hospital pharmacies of Nepal were highly influenced by marketing strategies of pharmaceutical companies. These processes, along with undeclared relationships between decision-makers and pharmaceutical companies are in contrast to the Basel Statements 17 [12]. While such influential practices are common in developing countries such as India [68] and China [69], this has also been of concern to developed countries like US [70].

Therefore, the United States have developed necessary policies for overseeing promotional activities of pharmaceutical companies and relationships between pharmaceutical companies and decision makers [71, 72]. Similar policies have been developed by Australia [73-75] and well-controlled relationships and promotional strategies evident in this study suggested their enforcement. Moreover, perspectives of participants on relationship with pharmaceutical companies reflected a deeply rooted ethical and responsible working culture and decision making process in

Australia. Although, the government of Nepal has also developed guidelines for ethical promotion for pharmaceutical companies [76], such influential promotions on practice evident from this study suggest that these policies have not been implemented in hospital pharmacies of Nepal. Moreover, the code of ethics for doctors [77] developed by Nepal Medical Council does not include guidelines on how to maintain ethical relationship with pharmaceutical companies.

4.7.4. Shortage Management

Hospital pharmacies of both countries have similar strategies for managing medicine shortages majorly through substitution, borrowing, emergency purchasing and managing inventories. These strategies are closely related with recommendations suggested by ASHP guidelines [78]. Existence of shortage management plans evident in both countries also indicated that the Basel Statement 25 [12] has been adopted. However, unlike hospital pharmacies of Australia, Nepalese hospitals did not have any strategic plans for preparedness and shortage minimization; instead overstocked medicines - which further created medicine shortages. Moreover, this study reported information sharing initiatives taken by hospitals, state government, TGA, and suppliers of Australia which was similar to those of other developed countries [79]. Nepal did not have any type of information sharing strategies at either local or national levels. Another concerning issue was lack of contingency plans in few hospital pharmacies. This can be crucial for countries like Nepal where medicines shortages are common due to various reasons like difficult geographical areas [80], earthquakes [81], health epidemics [82] and political instability [83] making existence of strategic plans even more important.

The success stories of Australian hospital pharmacies revealed in this study might be useful for Nepal. Alternatively, hospital pharmacies can utilize ASHP guidelines [78] for managing shortages strategically. Additionally, the government of Nepal could take national initiatives similar to those of Australia and the United States [84] for improving availability of medicines especially.

4.8. Conclusions

Procurement practices of majority of public hospitals of Nepal varied from those of public hospitals of Australia in several aspects however there were a few similarities. Wide adoption of national policies and the Basel Statements was reported in hospital pharmacies of Australia, whereas it was reported only to some extent in hospital pharmacies of Nepal. However, it is to be noted that this study was conducted with the assumption and findings that high-income countries like Australia have better procurement practices; and its procurement procedures could be utilized to propose first-hand practical recommendations to improve current procurement practices of Nepal.

Privatization of hospital pharmacies, lack of cost-effective procurement method, prescription-driven medicine selection processes, the influence of pharmaceutical companies in undeclared relationships between decision-makers and pharmaceutical companies, the availability of unregistered medicines, and lack of preparedness and strategic plans for handling medicine shortages were all major concerns reported in this study. These issues suggest that current procurement practices of hospital pharmacies of Nepal still need to implement its own national policies and guidelines in practice. However, this partial compliance reported in Nepal suggested that Nepal is heading in right direction and its current procurement practice could be improved to meet international standards.

Adoption and regulation of national policies and guidelines are therefore recommended for improving procurement practices of public hospitals of Nepal. International policies and guidelines, and successful strategies from other countries could be utilized to amend and update existing national policies and guidelines in a way to suit health needs and priorities, regulatory and administrative framework, and financial capabilities of Nepal. In particular, competitive procurement methods like pooled procurement with group contracting strategies, price-subsidization, ethical work culture, and formulary selection process based on safety, quality and cost-effective principles, which are successfully implemented in Australia, are recommendations for improving access to affordable and high-quality medicines in Nepal. While adopting international guidelines and strategies, further studies are recommended to research the suitability and feasibility of those guidelines in the context of Nepal and also identify necessary adaptation steps required. Moreover, working on promoting ethical, transparent and professional work culture and developing systematic operational principles in Nepal could be helpful in achieving procurement goals.

Efforts are ongoing at both national and international levels to improve equity in medicine access in Nepal and other developing countries. To that end, these recommendations based on evidence from Australian procurement systems and national and international guidelines should be highly useful for improving access to affordable and quality medicines in Nepal and other developing countries.

4.9. References

1. Pearson GJ. Evolution in the Practice of Pharmacy--Not a Revolution. CMAJ. 2007. 176(9):1295-96. doi: 10.1503/cmaj.070041.
2. Abramowitz PW. The Evolution and Metamorphosis of the Pharmacy Practice Model. Am J Health Syst Pharm. 2009. 66(16):1437.
3. Vermeulen LC, Vulto AG, Zellmer WA. Editorial: The Promise of Basel. Am J Health Syst Pharm. 2009. 66(Suppl 3):S7.
4. American Society of Health System Pharmacists, International Pharmaceutical Federation. Global Conference Proceedings Executive Summary. Am J Health Syst Pharm. 2009. 66(Suppl 3):S1-6.
5. Doloresco F, Vermeulen LC. Global Survey of Hospital Pharmacy Practice. Am J Health Syst Pharm. 2009. 66(5 Suppl 3):S13-9.
6. The World Bank. Nepal. The World Bank Group. 2015. Available from: <http://data.worldbank.org/country/nepal>. Accessed 16 February 2016.
7. LeBlanc JM, Dasta JF. Scope of International Hospital Pharmacy Practice. Ann Pharmacother. 2005. 39(1):183-91.
8. Thapa RK, Bajracharya KS, editors. Hospital Pharmacy Practice in Nepal, Present Situation and Future Vision. NPSA-NPSS Workshop – Paradigm Shift in Pharmacy Profession; 2010; Kathmandu: Nepal Pharmacy Students' Society (NPSS); 2010.
9. World Health Organization. Australia: WHO Statistical Profile. World Health Organization. 2013. Available from: <http://www.who.int/gho/countries/aus.pdf?ua=1>. Accessed 12 February 2016.
10. The Society of Hospital Pharmacists of Australia. Fact Sheet: The Society of Hospital Pharmacists of Australia. The Society of Hospital Pharmacists of

- Australia. 2013. Available from: <http://www.shpa.org.au/About>. Accessed 16 February 2016.
11. Gray A, Vermeulen L. The Basel Statements Moving the Hospital Pharmacy Agenda Forward. *IPJ*. 2008. 23(2):10-3.
 12. *The Basel Statements*. The Basel Statements on the Future of Hospital Pharmacy. *Am J Health Syst Pharm*. 2009. 66(5 Suppl 3):S61-6.
 13. Gray A, Tredree R. Implementing the Basel Statements on the Future of Hospital Pharmacy. *IPJ*. 2010. 26(2):32-4.
 14. Penm J, Chaar B, Moles R. Validating a Hospital Medicines Formulary Survey in the Western Pacific Region--a Global Hospital Pharmacy Initiative Based on the Basel Statements. *Res Social Adm Pharm*. 2012. 8(4):298-308.
 15. Baghdadi-Sabeti G, Cohen-Kohler JC, Wondemagegnehu E. Measuring Transparency in the Public Pharmaceutical Sector. 2009. Available from: <http://apps.who.int/medicinedocs/documents/s16732e/s16732e.pdf>. Accessed 2 February 2016.
 16. Ombaka E. Current Status of Medicines Procurement. *Am J Health Syst Pharm*. 2009. 66(5 Suppl 3):S20-8. doi: <http://dx.doi.org/10.2146/ajhp080604>.
 17. Mendis S, Fukino K, Cameron A, Laing R, Filipe Jr A, Khatib O, et al. The Availability and Affordability of Selected Essential Medicines for Chronic Diseases in Six Low- and Middle-Income Countries. *Bull World Health Organ*. 2007. 85(4):279-88. doi: 10.2471/BLT.06.033647.
 18. Cameron A, Ewen M, Auton M, Abegunde D. The World Medicines Situation 2011: Medicines Prices, Availability and Affordability. World Health Organization. 2011. Available from:

- http://www.who.int/medicines/areas/policy/world_medicines_situation/WMS_ch6_wPricing_v6.pdf. Accessed 15 February 2016.
19. Health Sector Programme, Ministry of Health and Population-Nepal, Deutsche Gesellschaft für Technische Zusammenarbeit. Essential Drug Procurement and Supply Management System in Nepal: Current Challenges and How to Address Them. GTZ/GFA Consulting Group GmbH, Health Sector Programme, Department of Health Services. 2009. Available from: http://www.ministerial-leadership.org/sites/default/files/resources_and_tools/Essential_Drug_Procurement_Policy_Brief.pdf. Accessed 6 February 2016.
 20. Government of Nepal, National Planning Commission, United Nations Development Programme. Nepal Human Development Report 2014. Government of Nepal, National Planning Commission, United Nations Development Programme. 2014. Available from: <http://www.un.org.np/sites/default/files/Nepal-HDR-2014.pdf>. Accessed 3 February 2016.
 21. United Nations Development Programme. Human Development Reports. United Nations Development Programme. 2014. Available from: <http://hdr.undp.org/en/composite/HDI>. Accessed 16 February 2016.
 22. The World Bank. World Development Indicators: Nepal. World Bank Group. 2015. Available from: <http://databank.worldbank.org/data/reports.aspx?source=2&country=NPL&series=&period=>. Accessed 16 February 2016.
 23. World Health Organization. Adult Mortality Data by Country. World Health Organization. 2015. Available from:

- <http://apps.who.int/gho/data/view.main.1360?lang=en>. Accessed 12 February 2016.
24. World Health Organization. Probability of Dying Per 1000 Live Births: Data by Country. World Health Organization. 2015. Available from: <http://apps.who.int/gho/data/node.main.ChildMort-2?lang=en>. Accessed 12 February 2016.
25. Dixit H. The Quest for Health: The Health Services of Nepal. 2nd ed. Kathmandu: Educational Enterprise (P) Limited; 1999. 291 p.
26. World Health Organization. Health Expenditure Ratios, All Countries, Selected Years Estimates by Country. 2013. Available from: <http://apps.who.int/gho/data/node.main.75?lang=en>. Accessed 12 February 2016.
27. Government of Nepal, Ministry of Health and Population. Hospital Pharmacy Directives 2070. Government of Nepal, Ministry of Health and Population. 2013. Available from: http://www.slideshare.net/niraj_bartaula/hospital-pharmacy-service-directives-2070-55955345. Accessed 3 February 2016.
28. Ministry of Health and Population, Government of Nepal. Current Status of MoHP's Annual Work Plan and Budget. Ministry of Health and Population, Government of Nepal. 2013. Available from: <http://www.moHP.gov.np/images/pdf/publication/Budget-Analysis-2070-71.pdf>. Accessed 16 February 2016.
29. The World Bank. Australia. World Bank Group. 2014. Available from: <http://data.worldbank.org/country/australia>. Accessed 12 February 2016.
30. Government of Nepal, Ministry of Health and Population. Public Procurement Guidelines. Government of Nepal, Ministry of Health and Population. 2009.

Available from: <http://moHP.gov.np/index.php/publication-1/guideline>.

Accessed 3 February 2016.

31. Public Procurement Act 2007, Act Number 36 (2007). Government of Nepal.
32. McLachlan AJ. Cost Shifting and the Quality Use of Medicines: Is It Time for National Medicines Policy 2.0? Australian Prescriber. 2014. 37(4):110-11. doi: 10.18773/austprescr.2014.045.
33. Australian Government, Department of Health Services. Medicare Services. Department of Health Services. 2015. Available from: <http://www.humanservices.gov.au/customer/subjects/medicare-services#a3>. Accessed 16 February 2016.
34. Australian Government, Department of Health. National Medicines Policy. Commonwealth of Australia. 2000. Available from: <http://www.health.gov.au/internet/main/publishing.nsf/Content/national-medicines-policy>. Accessed 16 February 2016.
35. Australian Government, Department of Health. The Pharmaceutical Benefits Scheme. Commonwealth of Australia. 2015. Available from: <http://www.pbs.gov.au/info/about-the-pbs>. Accessed 16 February 2016.
36. Noy C. Sampling Knowledge: The Hermeneutics of Snowball Sampling in Qualitative Research. Int J Soc Res Methodol. 2008. 11(4):327-44. doi: 10.1080/13645570701401305.
37. World Health Organization. Operational Principles for Good Pharmaceutical Procurement. WHO's Department of Essential Drugs and Medicines Policy (EDM). 1999. Available from: <http://www.who.int/3by5/en/who-edm-par-99-5.pdf>. Accessed 6 February 2016.

38. Mason M. Sample Size and Saturation in Phd Studies Using Qualitative Interviews. *Forum Qual Soc Res.* 2010. 11(3).
39. Ritchie J, Spencer L, O'Connor W. Carrying out Qualitative Analysis In: Ritchie J, Lewis J, editors. *Qualitative Research Practice: A Guide for Social Science Students and Researchers.* London: Sage Publications; 2003.
40. Spencer L, Ritchie J, Connor WO, Morrell G, Ormston R. Analysis in Practice. In: Ritchie J, Lewis J, Nicholls CM, Ormston R, editors. *Qualitative Research Practice: A Guide for Social Science Students and Researchers.* Second edition ed. Los Angeles, California: SAGE; 2014.
41. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the Framework Method for the Analysis of Qualitative Data in Multi-Disciplinary Health Research. *BMC Medical Research Methodology.* 2013. 13(1):117. doi: 10.1186/1471-2288-13-117.
42. QSR International. *Nvivo 10 for Windows Getting Started.* QSR International 2014. Available from: <http://download.qsrinternational.com/Document/NVivo10/NVivo10-Getting-Started-Guide.pdf>. Accessed 5 February 2016.
43. The Society of Hospital Pharmacists of Australia. *SHPA Practice Standards.* The Society of Hospital Pharmacists of Australia. 2014. Available from: <http://www.shpa.org.au/Practice-Standards>.
44. Harper I, Brhlikova P, Subedi MS, Bhattarai S, Basu S, Gupta AD, et al. Drug Procurement in Nepal. 2007. Available from: http://www.csas.ed.ac.uk/data/assets/pdf_file/0009/38826/DrugProcurementNepal.pdf. Accessed 3 February 2016.

45. Commonwealth Procurement Rules, S105B(1) (2014). Australian Government, Department of Finance.
46. Levison L. Practical Guidelines on Pharmaceutical Procurement for Countries with Small Procurement Agencies, Manila, WHO, Regional Office for the Pacific, WHO/WPRO, 20002 (Book). *Essent Drugs Monit.* 2003. (33).
47. Department of Drug Administration. National Drug Policy 1995. Department of Drug Administration. 1995. Available from: http://www.dda.gov.np/files/National_Drug_Policy.pdf. Accessed 16 February 2016.
48. Barraclough A, Clark M. Managing Procurement. 2012. In: *Managing Access to Medicines and Health Technologies* [Internet]. Arlington, VA: Management Science for Health. Available from: <http://apps.who.int/medicinedocs/documents/s19577en/s19577en.pdf>. Accessed on 7 February 2016.
49. Kotwani A, Ewen M, Dey D, Iyer S, Lakshmi P, Patel A, et al. Prices & Availability of Common Medicines at Six Sites in India Using a Standard Methodology. *Indian J Med Res.* 2007. 125(5):645-54.
50. Tordoff JM, Norris PT, Reith DM. Managing Prices for Hospital Pharmaceuticals: A Successful Strategy for New Zealand? *Value Health.* 2005. 8(3):201-08.
51. Hussain Z, Tukai M, A. J, Adu A, Khan I. Workshop on Framework Agreement and Two-Year Procurement Cycle at Proshika Hrdc, Koitta, Manikgonj, March 6–8, 2012. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: MSH, 2012.

52. Arney L, Yadav P, Miller R, Wilkerson T. Strategic Contracting Practices to Improve Procurement of Health Commodities. *Glob.* 2014. 2(3):295-06. doi: <http://dx.doi.org/10.9745/GHSP-D-14-00068>.
53. Nguyen TA, Knight R, Roughead EE, Brooks G, Mant A. Policy Options for Pharmaceutical Pricing and Purchasing: Issues for Low- and Middle-Income Countries. *Health Policy Plan.* 2015. 30(2):267-80. doi: 10.1093/heapol/czt105.
54. Hinsch M, Kaddar M, Schmitt S. Enhancing Medicine Price Transparency through Price Information Mechanisms. *Global Health.* 2014. 10:34. doi: 10.1186/1744-8603-10-34.
55. O'Leary K, Burke R, Kirsa S. SHPA Standards of Practice for the Distribution of Medicines in Australian Hospitals. *JPPR.* 2006. 36(2):143-49. doi: 10.1002/j.2055-2335.2006.tb00592.x.
56. Holloway K, Green T. Drug and Therapeutic Committees-a Practical Guide. World Health Organization and Management Sciences for Health. 2003. Available from: <http://apps.who.int/medicinedocs/pdf/s4882e/s4882e.pdf>. Accessed 2 February 2015.
57. Linda S. Tyler, Cole SW, May JRe, Millares M, Valentino MaA, Jr. LCV, et al. ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System. *Am J Health Syst Pharm.* 2008. 65:1272-83.
58. Penm J, Char B, Dechun J, Moles R. Formulary Systems and Pharmacy and Therapeutics Committees in the Western Pacific Region: Exploring Two Basel Statements. *Am J Health Syst Pharm.* 2013. 70(11):967-79.
59. Kafle KK, Thapa BB. Nepalese National Formulary 2nd Edition. Government of Nepal, Ministry of Health and Population & Department of Drug

- Administration. 2010. Available from:
https://www.researchgate.net/publication/262562432_Nepalese_National_Formulary_2010. Accessed 16 February 2016.
60. World Health Organization. WHO Model Formulary. World Health Organization. 2014. Available from:
<http://apps.who.int/medicinedocs/documents/s16879e/s16879e.pdf>. Accessed 12 February 2016.
61. Department of Drug Administration. National List of Essential Medicines. Department of Drug Administration. 2011. Available from:
<http://www.dda.gov.np/druglist/nlem2011.pdf>. Accessed 1 June 2014.
62. Ratanawijitrasin S, Wondemagegnehu E. Effective Drug Regulation: A Multicountry Study. World Health Organization 2002. Available from:
<http://apps.who.int/medicinedocs/pdf/s2300e/s2300e.pdf>. Accessed 16 February 2016.
63. Wertheimer AI, Santella TM. Counterfeit Drugs: Defining the Problem and Finding Solutions. *Expert Opin Drug Saf.* 2005. 4(4):619-22. doi: 10.1517/14740338.4.4.619.
64. World Health Organization. A Model Quality Assurance System for Procurement Agencies. World Health Organization. 2007. Available from:
<http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf>. Accessed 5 February 2016.
65. United States Pharmacopeia Drug Quality and Information Program and collaborators. Ensuring the Quality of Medicines in Resource-Limited Countries: An Operational Guide. The United States Pharmacopeial Convention. 2007. Available from:

- http://www.usp.org/sites/default/files/usp_pdf/EN/dqi/ensuringQualityOperationalGuide.pdf. Accessed 5 February 2016.
66. Hall C. Technology for Combating Counterfeit Medicine. *Pathog Glob Health*. 2012. 106(2):73-6. doi: 10.1179/204777312X13419245939485.
 67. World Health Organization. Guidelines for the Development of Measures to Combat Counterfeit Drugs. 1999. Available from: http://whqlibdoc.who.int/hq/1999/WHO_EDM_QSM_99.1.pdf. Accessed 5 February 2016.
 68. Roy N, Madhiwalla N, Pai SA. Drug Promotional Practices in Mumbai: A Qualitative Study. *Indian J Med Ethics*. 2007. 4(2):57.
 69. Penm J, Moles R, Wang H, Li Y, Char B. Factors Affecting the Implementation of Clinical Pharmacy Services in China. *Qual Health Res*. 2014. 24(3):345-56. doi: 10.1177/1049732314523680.
 70. Nguyen NY, Bero L. Medicaid Drug Selection Committees and Inadequate Management of Conflicts of Interest. *JAMA Internal Medicine*. 2013. 173(5):338-43.
 71. Hatton RC, Hutchison LC, Matzke GR, Noviasky JA, Rospond RM, Kelloway JS, et al. Pharmacists and Industry: Guidelines for Ethical Interactions. *Pharmacotherapy*. 2008. 28(3):410-20. doi: 10.1592/phco.28.3.410.
 72. Pharmaceutical Research and Manufacturers of America. Code on Interactions with Healthcare Professionals. Pharmaceutical Research and Manufacturers of America. 2008. Available from: http://www.phrma.org/sites/default/files/pdf/phrma_marketing_code_2008.pdf. Accessed 5 February 2016.

73. Medicines Australia. Code of Conduct. Medicines Australia. 2015. Available from: <https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/01/20150617-PUB-Code-Edition-18-FINAL.pdf>. Accessed 2 February 2016.
74. Medicines Australia. Code of Conduct Guidelines. Medicines Australia. 2015. Available from: <https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/01/20150513-PUB-E18-Guidelines-FINAL-V1a.pdf>. Accessed 12 February 2016.
75. Medical Board of Australia. Good Medical Practice: A Code of Conduct for Doctors in Australia. Medical Board of Australia. Available from: <http://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code-of-conduct.aspx>. Accessed 4 February 2016.
76. Department of Drug Administration. Guidelines on Ethical Promotion of Medicine, 2007. Department of Drug Administration. 2007. Available from: <http://www.dda.gov.np/guidlines/Ethical%20Promotion%20Guidelines%202007.pdf>. Accessed 17 April 2015.
77. Nepal Medical Council. NMC-Code of Ethics. Nepal Medical Council. 2016. Available from: <http://www.nmc.org.np/information/nmc-code-of-ethics.html>. Accessed 12 February 2016.
78. Fox ER, Birt A, James KB, Kokko H, Salverson S, Soflin DL. ASHP Guidelines on Managing Drug Product Shortages in Hospitals and Health Systems. *Am J Health Syst Pharm*. 2009. 66(15):1399.
79. Dill S, Ahn J. Drug Shortages in Developed Countries—Reasons, Therapeutic Consequences, and Handling. *Eur J Clin Pharmacol*. 2014. 70(12):1405-12. doi: 10.1007/s00228-014-1747-1.

80. National News Agency. Medicine Shortage Hits Locals in Mugu. My Republica. 19 February 2014. Available from:
http://www.myrepublica.com/portal/index.php?action=news_details&news_id=69810. Accessed 16 February 2016.
81. WHO Issues Rapid Health Assessment on Impact of Nepal Earthquake [Internet]. World Health Organization. 1 May 2015. Available from:
<http://www.who.int/mediacentre/news/releases/2015/health-assessment-nepal/en/>. Accessed on 6 February 2016.
82. Sanyal D. Jajarkot Pandemic and Some Home Truths. The Rising Nepal. 25 April 2015. Available from: <http://therisingnepal.org.np/news/3111>. Accessed 6 February 2016.
83. Post Report-Parsa. Shortage of Medicines Hits Health Services. The Kathmandu Post. 9 November 2015. Available from:
<http://kathmandupost.ekantipur.com/news/2015-11-09/shortage-of-medicines-hits-health-services.html>. Accessed 6 February 2016.
84. The White House Office of Press Secretary. Fact Sheet: Obama Administration Takes Action to Reduce Prescription Drug Shortages in the U.S. The White House President Barack Obama. 2011. Available from:
<https://www.whitehouse.gov/the-press-office/2011/10/31/fact-sheet-obama-administration-takes-action-reduce-prescription-drug-sh>. Accessed 5 February 2016.

Chapter 5

Conclusions and Recommendations

Chapter 5: Conclusions and Recommendations

5.1. Conclusions

The aim of this study was to explore how medicines are purchased in hospital pharmacies of Nepal and Australia, and study whether these practices comply with international guidelines, namely the Basel Statements. Additionally, this study also aimed to identify barriers and facilitators regarding implementation of guidelines and to provide evidence-based recommendations to improve the current medicine procurement practice in Nepal. This was the first study to explore medicine procurement practices of Australia and Nepal based on the Basel Statements.

A literature review on the procurement theme of the Basel Statements revealed that many aspects of medicine procurement were unexplored and a thorough study to include all aspects of procurement practice was needed. This review revealed that studies were focused mainly on corruption, transparency, counterfeiting, price control, quality of medicines, and medicine selection process. Quality assurance principles, information facilities, financing/funding systems and storage facilities were factors that had not received adequate coverage. The review identified some other factors such as marketing strategies of pharmaceutical companies, undeclared conflict of interests, unethical practices, and contingency plans that could influence procurement practices, especially in developing countries like Nepal. This study also revealed that selection of medicines and procurement methods was crucial for improving access to affordable and quality medicines. The observed lack of information about medicine procurement practices in Nepal suggested that there was a need to conduct comprehensive studies and publish information about medicine procurement in Nepal from individual, organizational and national perspectives.

A qualitative study on medicine procurement practice in hospital pharmacies of Nepal was conducted to study current procurement practices, explore implementation of the Basel Statements, identify facilitators and barriers, and propose recommendations to improve current procurement practices. Semi-structured interviews were conducted and data were analysed thematically using the framework analysis method. The results of this study showed that procurement guidelines of the Basel Statements were adopted to a certain extent by a majority of hospital pharmacies and to a greater extent by select hospital pharmacies of Nepal. However, some aspects of medicine procurement such as expertise, information resources, storage facilities and availability of funds, complied with the Basel Statement to a greater extent. Some barriers that affected implementation of national guidelines and the Basel Statements, as reported by study participants, were: leasing provision of hospital pharmacies to private organizations, influences of pharmaceutical companies, full authority of doctors on medicine selection, lack of formulary systems, and lack of regulatory enforcement. The procurement method utilized by the majority of hospital pharmacies was found to be the “direct” procurement method, which is comparatively more expensive than other competitive methods. However, there were a few exceptions, in which pharmacies utilized a competitive tendering process to achieve the lowest possible price. While medicine selection should follow a formulary process, only a small number of hospital pharmacies had a formulary system in place and the majority of hospital pharmacies selected medicines completely based on doctors’ prescriptions. Nonetheless, the National List of Essential Medicines was found to be taken into consideration by most pharmacies. In addition to this, prescription-driven selection processes, undeclared conflicts of interests and influential medicine selection process was one

of the concerning issues about ethical and transparent procurement procedure in the majority of hospitals of Nepal. However, procurement procedures of a few hospitals were under national scrutiny by CIAA and other regulatory departments.

Although few hospitals in Nepal undertook quality-testing procedures for ensuring quality of medicines purchased, the majority relied on testing undertaken by national regulatory authorities. It has been debated whether reliance on national regulatory authorities is an effective and strong quality assurance principle for developing countries like Nepal that are susceptible to the entry of counterfeit and substandard medicines across their borders. The findings of this study suggested that such reliance on national authorities is not effective, as unregistered medicines were evident in a few hospitals of Nepal near the Indian border.

And while shortage management plans were prevalent, lack of strategic contingency plans was identified as a point of concern for Nepal, given that Nepal has to import most life-saving medicines and is prone to natural disasters, health epidemics, political instabilities, and geographical difficulties that make medicine shortages almost unavoidable. Collectively, these findings indicate that hospital pharmacies in Nepal are taking steps along the right path, but the country needs changes in order to achieve greater compliance with its own national standards and be on a par with international standards.

Furthermore, our comparative study between medicine procurement practices of Nepal and Australia based on the Basel Statements, revealed variations in the extent to which procurement guidelines of the Basel Statements were implemented in these two countries. As expected, Australian practice was found to comply with the Basel Statements to a greater extent compared to Nepalese practice. However, quality

assurance principles, information sources, shortage management plans, and expertise involvement were some aspects of Nepalese procurement practices that were comparable to those of Australian practice and consistent with the Basel Statements. However, factors such as ownership/management of hospital pharmacy, procurement methods, medicine selection processes, regulatory frameworks, and financing systems were areas in which Nepal differed from Australian practices and failed to comply with the Basel Statements.

A significant difference between the two countries was how relationships between key stakeholders and pharmaceutical companies were perceived and managed. Strong policy-based enforcement of ethical relationships and pharmaceutical marketing were evident in Australia, whereas heavy industry influences on procurement practices, due to a lack of policies to manage conflicts of interest, were found in Nepal. Although Nepal did not have specific policies for managing ethical relationships between health professionals and pharmaceutical industries), public procurement procedures were subject to scrutiny by CIAA and governmental regulatory bodies for assessing corruption and abuse of authority. Moreover, drug regulatory authorities were found to make efforts to ensure ethical promotion of medicines by pharmaceutical companies, which could be considered a good start. In addition to ethical policies, this study also found self-awareness and perceptions of accountable and justifiable decision-making ingrained in Australian practice, which may serve as a good lesson for policy and decision makers of Nepal. Moreover, safety and quality principles were found to be incorporated in routine practice in public hospitals of Australia, which were lacking in the majority of hospital pharmacies of Nepal. Such principles are urgently needed in Nepal, especially given the evidence of purchasing of unregistered medicines of dubious quality from

unauthorized suppliers. Furthermore, despite Nepal being susceptible to medicine shortages due to the country's vulnerability to natural disasters, as well as health epidemics, and political instabilities, there was a clear lack of preparedness to deal with medicine shortages. Strategies for minimizing shortages should be considered an urgent issue requiring immediate action.

Although the above-mentioned description of hospital pharmacies in Nepal were applicable to the majority of hospital pharmacies, it is noteworthy that a few were found operating in accordance to national policies and guidelines to procure cost-effective, high-quality and safe medicines by following a competitive procurement method and formulary selection process, and making a clear effort to ensure that the purchased medicines were of good quality.

In conclusion, our findings indicated that medicine procurement practices in Nepal differed from that of Australia in many aspects and exhibited poor compliance to the Basel Statements. Nevertheless, some aspects of Nepalese medicine procurement procedures were on par with those of Australia and complied with the Basel Statements in a few key areas. Although compliance to national and international guidelines were relatively poor and their procurement practices appeared to be in need of major improvements, hospital pharmacies of Nepal were found to be generally progressive and on the right path towards meeting international standards.

5.2. Recommendations

This study successfully examined the medicine procurement practices of Australia and Nepal, compared them, and proposed evidence-based recommendations to improve current medicine procurement practices in Nepal. Although this qualitative study did not cover all hospitals of Nepal and Australia and may not be completely

generalizable, major hospitals from most regions of Nepal and several states of Australia were included and therefore provide meaningful insights into medicine procurement practices in Nepal and Australia. The study was restricted to public hospitals of Australia and Nepal, so inclusion of private hospitals from the two countries in future studies is recommended. This study involved interviews with hospital pharmacists and procurement officers however, perspective of policy makers, national regulatory authorities and hospital administrators could have provided in-depth and first-hand idea on practical challenges on guidelines adoption, regulation and implementation, and providing recommendations that were feasible and applicable to Nepal. Further studies are recommended to conduct research with the explore these key stakeholders and explore these above mentioned issues.

Owing to the influence of ownership of hospital pharmacies on different aspects of procurement, strict monitoring and enforcement of national policy against privatisation of hospital pharmacies is the simplest starting step for Nepal. Although, the government of Nepal has already started legal actions and monitoring initiatives against leasing agreements of hospital pharmacies, enforcement is still poor.

Hospital pharmacies of Nepal should utilize appropriate procurement methods that are transparent and free of any influences and corruption, allowing purchase of cost-effective and evidence-based high quality medicines to maximize utilization of the limited resources available. Group-contracting strategies utilized by Australian public hospitals and many other countries and international organizations could offer one solution for Nepal.

Strong regulatory framework, efficient operational principles, well-managed procurement processes, ethical and professional organisational culture, and safety and quality principles ingrained deeply in policies and practice are some

recommendations that have been drawn from Australian practice for improving both national and international guidelines implementation in Nepal. Also, this study highly recommends changing perceptions of key stakeholders in Nepal through education and creating suitable working environments that foster ethical and safe practices.

Being a relatively poor country, Nepal is in dire need of ethical and safe practices to maximize utilization of limited resources, particularly in cases of medicine shortages. Assessing availability, managing inventories, circulating information to alert upcoming or existing medicine shortages, and rationing usage/ distribution of available medicines, in conjunction with existing shortage management plans, could be the suitable strategy for tackling repeated occurrences of medicine shortages in Nepal, especially in light of recent earthquakes and blockades of the India-Nepal border.

It is a well-known fact that it is impossible to simply transplant the practices of developed countries to developing countries. Nepal needs to carefully scrutinize its own situation and with awareness and a will for change, should implement incremental changes towards improving affordability and availability of high-quality medicines, patient safety, ethical working habits, and preparedness for health emergencies. Therefore, strengthening its own national policies and guidelines to meet international standards and working efficiently on their enforcement would be an effective approach for overcoming existing barriers and improving accessibility and affordability of high-quality medicines in Nepal. Moreover, developing efficient work cultures, changing perceptions of key stakeholders through educational and awareness programs, and strengthening policy enforcements are all important for achieving these goals.

Table 10 below summarizes procurement issues reported in Nepal and recommendations to improve the current procurement practice of Nepal based on evidence-based procedures of Australia and other international guidelines:

Table 9: Summary of Procurement Issues and Recommendations

	Procurement Issues	Recommendations
1	Hospital pharmacies operated by private organizations on lease agreements	- Strengthening national regulatory enforcement against leasing provision of hospital pharmacies
2	Utilization of the expensive direct procurement method	- Use of group contracting strategies such as pooled procurement to facilitate individual purchase while still receiving group-negotiated prices.
3	Prescription-driven selection of medicines	- Implementation of a formulary system and P&T Committee system and breaking the monopoly of an individual or biased group over decision-making.
4	Lack of transparency in practice; undeclared conflict of interest and influential decision making and procurement practice	- Strengthening regulatory policies and their enforcement - Policy amendment to include policies for ethical relationship between decision makers and pharmaceutical companies - Creating ethical working habits; promoting ethical work environment; and educating and creating awareness for making the decision-making process accountable.
5	Weak quality assurance principles	- Strengthening national regulatory authorities for making the quality testing procedure more effective. - Adoption of pre- and post-qualification process by hospital pharmacies or a group before purchasing medicines, especially from a new or suspicious supply chain.
6	Purchase of unregistered medicines in few hospital	- Strong regulatory monitoring of distribution and marketing of medicines to avoid entry of

	pharmacies near Indian border, especially during medicine shortages	<p>unregistered medicines.</p> <ul style="list-style-type: none"> - Checking quality of medicines before purchasing to avoid counterfeit and substandard medicines, especially during emergency purchase.
7	Lack of strategic contingency plans	<ul style="list-style-type: none"> - Adoption of preparedness strategies such as assessment of medicine availability, managing inventories, information circulation about upcoming shortages and managing strategies at national and local levels. - Rational use and distribution of the available stock of medicines.

Appendices

Appendix 1: Interview Protocol

Step 1

Introduction and greeting

Step 2

Reiteration of participation options (withdrawal etc), organise consent form signing and ask for permission to start audio-taping

Step 3

Start interview- allow participant to speak without prompts. Use prompts only if the flow lulls somewhat.

Interview Questions

1. How do you procure medicines in your hospital?

Prompts:

- a. Does your hospital have Standard Operating Procedure for the procurement?
- b. Are the decisions made by selection committee publicly disseminated?
If yes, where?
- c. Is the procurement of medicines based on evidence of safety? National essential medicines list or hospital formularies?
- d. Are pharmacists involved in the procurement procedure? If not, who is the responsible person for handling the procurement process?

2. Are there competitive procedures for the procurement of medicines?

If yes, prompts:

- a. Are the contract specifications publicly available and distributed with tender documents?
- b. Are tenders and tender results publicized?
- c. Are there specific criteria for tender committee membership? Is the membership permanent?

3. Does your hospital have Pharmacy & Therapeutics Committee [PTC], formulary list, standard treatment guidelines and formulary manual?

If yes, prompt:

- a. If a PTC is present, who are the members of the committee?
- b. Are there clear criteria for selection committee membership? If yes, what are they?
- c. Do terms of reference exist which describe the purpose of the selection committee, its composition, processes and duration?
- d. Are there clear rules for decision-making for the committee decisions? Is the decision made in a democratic manner?
- e. Is there a conflict of interest form that members of the selection committee and tender committee are obliged to complete? Are there clear sanctions for breach of these regulations?
- f. Is there a law or regulation prohibiting members of the drug selection committee from accepting support in kind or in cash from pharmaceutical companies?

4. Are there clear written criteria for adding and removing medicines for formulary list? If yes, what are they?
 - a. Is the inclusion of medicines in the formulary list based on evidence of cost-effectiveness and health needs?
 - b. Is there a clear algorithm, based on utilization of services and health needs to determine quantity and type of medicines purchased?

5. Is quality of medicines tested as a part of procurement procedure? If yes, which method do you follow? Prequalification or Post-qualification or both? Does your have own in-house quality control laboratories? Where are they tested?

6. Is supplier performance monitored annually?

7. Do your hospital storage facilities satisfy the desired storage conditions of all medicines? Are storage facilities accessible to all? If no, who is/are the authorized person/s for access?

8. What type of security system is present in your storage facilities? Manual or Electronic?

9. Does your hospital have information system for tracking the procurement procedure, communication exchange, international reference pricing and other useful resources?

10. Is there a management information system used to report product problems in procurement?

- a. Is the information obtained from monitoring used to influence future procurement decisions?
- b. How are medicines shortages managed in the hospital and how are they purchased during emergencies?

11. How is procurement of medicines funded in the hospital? Is there existence of any funding mechanism for requesting funds?

Thank the participant and ask if they wish for feedback in the form of a summary of findings.

Appendix 2: Ethics Approval



Research Integrity
Human Research Ethics Committee

Friday, 15 August 2014

Dr Bouad Betty Chaar
Pharmacy; Faculty of Pharmacy
Email: betty.chaar@sydney.edu.au

Dear Bouad Betty

I am pleased to inform you that the University of Sydney Human Research Ethics Committee (HREC) has approved your project entitled **"Exploring procurement through the lens of the Basel Statements: A comparative study between Australia and Nepal"**.

Details of the approval are as follows:

Project No.: 2014/619
Approval Date: 12 August 2014
First Annual Report Due: 12 August 2015
Authorised Personnel: Chaar Bouad Betty; Moles Rebekah; Shrestha Mina;

Documents Approved:

Date Uploaded	Type	Document Name
15/06/2014	Interview Questions	INTERVIEW PROTOCOL
15/06/2014	Participant Consent Form	PCF
15/06/2014	Participant Info Statement	PIS
6/08/2014	Recruitment Letter/Email	Email to potential participants

HREC approval is valid for four (4) years from the approval date stated in this letter and is granted pending the following conditions being met:

Special Condition/s of Approval

- It will be a condition of approval that independently certified translations of the public documents are forwarded to the HREC. The translations must be certified by a person who is not associated with the research project (either an applicant or other persons identified in the application) and has no conflict of interest. They need to indicate that the translated documents are a true and accurate representation of the English language versions submitted to the HREC. A statutory declaration to this effect (if not a registered translator or a staff member with the appropriate expertise) would be acceptable if they are not an official translator. A statutory declaration form can be found at <http://www.ag.gov.au/STATDEC>

Condition/s of Approval

- Continuing compliance with the National Statement on Ethical Conduct in Research Involving Humans.

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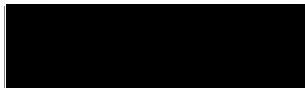
- Provision of an annual report on this research to the Human Research Ethics Committee from the approval date and at the completion of the study. Failure to submit reports will result in withdrawal of ethics approval for the project.
- All serious and unexpected adverse events should be reported to the HREC within 72 hours.
- All unforeseen events that might affect continued ethical acceptability of the project should be reported to the HREC as soon as possible.
- Any changes to the project including changes to research personnel must be approved by the HREC before the research project can proceed.
- Note that for student research projects, a copy of this letter must be included in the candidate's thesis.

Chief Investigator / Supervisor's responsibilities:

1. You must retain copies of all signed Consent Forms (if applicable) and provide these to the HREC on request.
2. It is your responsibility to provide a copy of this letter to any internal/external granting agencies if requested.

Please do not hesitate to contact Research Integrity (Human Ethics) should you require further information or clarification.

Yours sincerely



Dr Stephen Assinder
Chair
Human Research Ethics Committee

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research (2007), NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007) and the CPMP/ICH Note for Guidance on Good Clinical Practice.

Appendix 3: Participant Information Statement



Faculty of Pharmacy

ABN 15 211 513 464

CHIEF INVESTIGATOR

Dr Betty Chaar

Senior Lecturer in Pharmacy Practice

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Exploring procurement through the lens of the Basel Statements: a comparative study between Australia and Nepal

PARTICIPANT INFORMATION STATEMENT

(1) What is this study about?

You are invited to take part in a research study comparing procedures of procurement of medicines in hospitals in Australia and Nepal. Hospital pharmacies are generally responsible for medicines procurement, and practices differ around the world. We would like to ask you about procedures of medicine procurement in your practice.

You have been invited to participate in this study because we have found, or have been told by the relevant Hospital Pharmacy Association in Australia or Nepal, that you are the Pharmacist in charge of procurement in your department or hospital.

This Participant Information Statement tells you about the research study. Knowing what is involved will help you decide if you want to take part in the study. Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.

Participation in this research study is voluntary. So it's up to you whether you wish to take part or not.

By giving consent to take part in this study you are telling us that you:

- ✓ Understand what you have read
- ✓ Agree to take part in the research study as outlined below
- ✓ Agree to the use of your personal information as described.

You will be given a copy of this Participant Information Statement to keep.

(2) Who is running the study?

The study is being carried out by the following researchers from the Faculty of Pharmacy, University of Sydney:

- Dr Betty Char
- Dr Rebekah Moles
- Ms Mina Shrestha

Ms Mina Shrestha is conducting this study as the basis for the degree of Master of Philosophy at The University of Sydney. This will take place under the supervision of Dr Betty Char and Dr Rebekah Moles

(3) What will the study involve for me?

You will be asked to participate in an interview at a location of convenience for you. We are seeking your perspective on procurement of medicines procedures in your institution. We are interested in whether procurement processes follow any specific guidelines or carried out in a different manner, and what that manner may be. These interviews will be conducted in English in both Australia and Nepal.

The interview will be tape recorded with your permission, to enable us to transcribe later. We will send you the transcript for confirming its accuracy and any emendations you wish to make, if you agree.

(4) How much of my time will the study take?

We anticipate the interview to take no longer than half an hour.

(5) Do I have to be in the study? Can I withdraw from the study once I've started?

Being in this study is completely voluntary and you do not have to take part. Your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at the University of Sydney.

If you decide to take part in the study and then change your mind later, you are free to withdraw at any time. You can do this by notifying us at any time, with no consequence whatsoever.

You are free to stop the interview at any time. Unless you say that you want us to keep them, any recordings will be erased and the information you have provided will not be included in the study results. You may also refuse to answer any questions that you do not wish to answer during the interview.

(6) Are there any risks or costs associated with being in the study?

Aside from giving up your time, we do not expect that there will be any risks or costs associated with taking part in this study.

(7) Are there any benefits associated with being in the study?

We cannot guarantee or promise that you will receive any direct benefits from being in the study.

(8) What will happen to information about me that is collected during the study?

By providing your consent, you are agreeing to us collecting only a minimal amount of personal information about you for the purposes of this research study. Your information will only be used for the purposes outlined in this Participant Information Statement.

All data collected from the recordings of interviews will be de-identified – allocating only a number to the interview to allow us to analyse the data. No one other than the researchers will have access to the data.

Your information will be stored securely in the supervising researcher's office and your identity/information will only be disclosed with your permission, except as required by law. Transcripts and recordings will be destroyed completely after 7 years. Study findings may be published, but you will not be identified in these publications.

(9) Can I tell other people about the study?

Yes, you are welcome to tell other people about the study.

(10) What if I would like further information about the study?

When you have read this information Ms Mina Shrestha [mobile number: 0450229179] will be available to discuss it with you further and answer any questions you may have. If you would like to know more at any stage during the study, please feel free to contact **Dr Betty Chaar** [Work Phone Number: +61290367101, Mobile:+61 425210547; Email: betty.chaar@sydney.edu.au]

(11) Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by ticking the relevant box on the consent form. This feedback will be in the form of a one page lay summary]. You will receive this feedback after the study is finished.

(12) What if I have a complaint or any concerns about the study?

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the University of Sydney [Project No. 2014/619]. As part of this process, we have agreed to carry out the study according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect people who agree to take part in research studies.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number.

The Manager, Ethics Administration, University of Sydney:

- **Telephone:** +61 2 8627 8176
- **Email:** ro.humanethics@sydney.edu.au
- **Fax:** +61 2 8627 8177 (Facsimile)

For the Nepalese arm of the study, if you have any concerns or wish to make a complaint, please contact:

Nepal Health Research Council
Ramshah Path; P.O.Box 7626
Telephone No.: 977-1-4254220/4227460
Fax: 977-1-4262469/4268284
Email: nhrc@nhrc.org.np

This information sheet is for you to keep

Appendix 4: Participant Consent Form



Faculty of Pharmacy

ABN 15 211 513 464

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Exploring procurement through the lens of the Basel Statements: a comparative study between Australia and Nepal

PARTICIPANT CONSENT FORM

I, [PRINT NAME], agree to take part in this research study.

In giving my consent I state that:

- ✓ I understand the purpose of the study, what I will be asked to do, and any risks/benefits involved.
- ✓ I have read the Participant Information Statement and have been able to discuss my involvement in the study with the researchers if I wished to do so.
- ✓ The researchers have answered any questions that I had about the study and I am happy with the answers.
- ✓ I understand that being in this study is completely voluntary and I do not have to take part. My decision whether to be in the study will not affect my relationship with the researchers or anyone else at the University of Sydney now or in the future.
- ✓ I understand that I can withdraw from the study at any time.
- ✓ I understand that I may stop the interview at any time if I do not wish to continue, and that unless I indicate otherwise any recordings will then be erased and the information provided will not be included in the study. I also understand that I may refuse to answer any questions I don't wish to answer.

- ✓ I understand that personal information about me that is collected over the course of this project will be stored securely and will only be used for purposes that I have agreed to. I understand that information about me will only be told to others with my permission, except as required by law.

I understand that the results of this study may be published, but these publications will not contain my name or any identifiable information about me unless I consent to being identified using the “Yes” checkbox below.

- Yes, I am happy to be identified.
- No, I don’t want to be identified. Please keep my identity anonymous.

I consent to:

- **Audio-recording** YES NO
- **Reviewing transcripts** YES NO

Would you like to receive feedback about the overall results of this study?

- YES NO

If you answered **YES**, please indicate your preferred form of feedback and address:

Postal: _____

Email: _____

.....
Signature

.....
PRINT name

.....
Date

Appendix 5: Invitation Email for Participation

Wording for Email/Facebook

Subject: Invitation for Participation in the Research Interview

Dear _____

I am a post graduate student at **The University of Sydney** and I am currently undertaking a research project for the completion of my **Master of Philosophy (Pharmacy)** under the supervision of Dr Betty Chaar and Dr Rebekah Moles.

The title of my research project is "**Exploring Procurement through the lens of the Basel Statements: A Comparative Study Between Australia and Nepal**"

The objective of this research project is to explore and compare the implementation of the procurement guidelines based on the Basel Statements in Australia and Nepal and we are hoping to interview hospital pharmacists or procurement officers regarding current practice.

Attached are the Participant Information Statement and Consent Form. We request that you consider participation in our research and would also be grateful if you could forward this information to other parties you think may be interested. If you have any queries concerning the nature of the research or are unclear about the extent of your involvement please contact me at mina.shrestha@sydney.edu.au or Betty Chaar at betty.chaar@sydney.edu.au or Rebekah Moles at rebekah.moles@sydney.edu.au

Finally, we would like to thank you for taking the time to consider our request and we look forward to your reply.

Yours sincerely,

Mina Shrestha | M.Phil Candidate

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