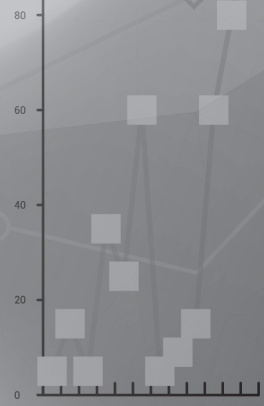




PHARMACEUTICAL SERVICES PROGRAMME
MINISTRY OF HEALTH MALAYSIA

PHARMACY RESEARCH **P R I O R I T I E S** in Malaysia



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MESSAGE BY SENIOR DIRECTOR OF PHARMACEUTICAL SERVICES

The Ministry of Health is committed to transform the health system towards better health services delivery for the rakyat. Pharmaceutical services, being an integral part of the health system, must be able to meet the healthcare needs and expectations of the people. Accordingly, the Pharmaceutical Services Programme recognised that scientific research is the fundamental to aid in policy decision-making and subsequently drive new policies and achieve the goals stipulated in the Pharmacy Programme Strategic Plan 2017-2020. Therefore, setting the priorities for pharmacy research is absolutely crucial to bridge knowledge gaps, maximise resources and support the development of evidence-based policies.



It is with deep satisfaction that the Pharmaceutical Services Programme has conceptualised the research priorities specifically for the pharmacy profession and pharmaceutical services in Malaysia. This is the first officially documented pharmacy research priority areas. Therefore, I would like to congratulate the Director of Pharmacy Policy and Strategic Planning Division, who is also the Chairperson of the Pharmacy Research Priorities Working Committee, for her outstanding leadership and remarkable vision in completing the Pharmacy Research Priorities in Malaysia. On behalf of the Pharmaceutical Services Programme, I would also like to express my heartfelt gratitude to all the committee members and stakeholders for their continuous effort and valuable contributions in the publication of this important document.

With this Pharmacy Research Priorities in Malaysia, we now have clear directions and targets in research. Generating our research priority areas and exploring new ideas certainly sets a momentum towards promoting evidence-based practices and providing excellent pharmaceutical care.

Dr. Salmah binti Bahri, RPh. 783

Senior Director of Pharmaceutical Services
Ministry of Health Malaysia

MESSAGE BY DIRECTOR OF PHARMACY POLICY AND STRATEGIC PLANNING DIVISION



Research entails the backbone towards realising our vision for a seamless healthcare system in Malaysia particularly towards improving health system delivery and work process reengineering. As we progress, research has become an essential part of pharmaceutical services and the culture of conducting research is getting stronger among fellow pharmacists. To ensure that the studies conducted are able to address important national health problems and to avoid duplication of efforts, it is critical to set the right direction and provide appropriate guidance for the researchers.

The Pharmacy Research Priorities in Malaysia enables the Pharmaceutical Services Programme to stipulate a new tone and direction of research for the future. Subsequently, it can strengthen the research ecosystem effectively and efficiently. The publication of the Pharmacy Research Priorities in Malaysia shows the commitment of the Pharmaceutical Services Programme in enhancing the quality of research and implementing evidence-based practice.

Significant effort has been put in to establish the research priority areas for pharmaceutical services in Malaysia. I would like to thank the Senior Director of Pharmaceutical Services for her continuous motivation and support. I would also like to express my utmost appreciation and congratulation to the members and secretariat of the Pharmacy Research Priorities Working Committee for their perseverance and commitment in making this important publication a reality. I sincerely hope that this document will serve as the key reference that guides the planning of research projects and allocation of research grants in the coming years. Hopefully, with the research priorities being clearly laid out, we will be able to generate more high impact research evidence that is feasible to be translated into policy and practice for the strengthening of the health system.

Dr. Hasenah binti Ali, RPh. 1517

Director

Pharmacy Policy and Strategic Planning Division

Ministry of Health Malaysia

EXECUTIVE SUMMARY

The Malaysian National Medicines Policy stipulated the Ministry of Health Malaysia (MOH)'s aim to provide equitable access to quality, safe, effective and affordable medicines and to promote its rational use to improve health outcomes of the population. The Pharmaceutical Services Programme has been tasked to accomplish these goals through the various services it provides amidst the challenges of growing demands for healthcare and increasing costs of pharmaceuticals.

Research provides valuable information and evidence for policy makers to make informed decisions about policies and practices. Research also drives new pharmacy services and is invaluable in monitoring and evaluating them. In the recent years, pharmacy research activities has progressed at a fast pace. Nevertheless, critical gaps in pharmacy knowledge and evidence that are needed in decision making and policy developments still exist and many new frontiers in pharmacy research are yet to be explored. The research topics are often only of interest to the researchers or aim to solve problems at individual facilities and seldom target issues that address national health problems. There is a longstanding commitment of the Pharmaceutical Services Programme to not only strengthen the culture of conducting quality research but also to ensure that the research conducted are relevant and in line with the Pharmacy Programme Strategic Plan and ultimately valuable towards achieving the mission and vision of the MOH.

The main objective of outlining the Pharmacy Research Priorities in Malaysia is to streamline research activities to produce relevant data and evidence needed to fill the critical knowledge gaps to address national problems. The priority setting exercise was systematically carried out and involved a wide representation of stakeholders to gather comprehensive input.

FIVE research priority domains and a number of research scopes/areas have been identified. They are summarised in Table Executive 1.

Individuals and healthcare organisations embarking on research are encouraged to use these research priority areas to design and shape their future research proposals. These research priorities are not only relevant to the Ministry of Health, but all other institutions that conduct pharmacy researches in Malaysia including the universities, Ministry of Defence, pharmaceutical industry, community pharmacies as well as pharmacy students.

Table Executive 1: Pharmacy Research Priorities in Malaysia

Research Priority Domain	Sub-domain	Research Scope/Area
Access to Medicines	Affordability of Medicines	Medicines Pricing
		Generic Medicines Policy
	Availability of Medicines	Essential Medicines
		Procurement and Supply
		Life-saving Medicines
		Medicines Selection
	Health/Medicines Financing	Medicines Reimbursement
		Patient Access Scheme
Monitoring and Evaluation of Outcomes	Pharmacoeconomic Analysis	Economic Evaluation
		Health-related Quality of Life (HRQoL)
		Cost Analysis
	Effectiveness of Care	Pharmacoepidemiology
		Treatment Guidelines
	Drug Safety	Medication Error
		Adverse Drug Reaction (ADR) Management
Quality and Safe Use of Medicine and Sustainability	Sustainability	Medicine Wastage/Medicine Return
		Safe Disposal of Medicines
	Health Behaviour	Vaccination/Immunisation
		Misuse of Medicines
		Smoking
		Adherence
	Quality Use of Medicine	Infectious Disease
		Traditional Medicine
		Halal Medicine

Research Priority Domain	Sub-domain	Research Scope/Area	
		Unregistered/Counterfeit/ Adulterated Medicines	
		Pharmacy Acts and Regulation	
	Community Empowerment	Health Literacy	
		Medicine Literacy	
		Treatment Decision Making	
	Optimisation of Therapy and Pharmacy Services Delivery	Human Resource	Service Efficiency and Productivity of Workforce
Role of Pharmacist			
Capacity Building			
Pharmacy Services Innovation		Extended Services (Public-private Partnership)	
		Antimicrobial Stewardship	
		Home Medication Review	
		Value Added Services	
Information and Communications Technology (ICT)		Pharmacy Information System (PhIS)	
		Pharmacy-related Applications	
		Track and Trace	
National Databases/Big Data Analytics		Medicines Utilisation Study	
		National Patient Outcome Database/Registry	
	Big Data Analytics		
	Medicines Price/Pricing Database Analysis		

Please refer to the relevant chapters for relative ranking of each suggested research scope or area.

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INTRODUCTION



1.0 INTRODUCTION

SETTING THE PHARMACY RESEARCH PRIORITIES IN MALAYSIA

Background

The Pharmaceutical Services Programme of the Ministry of Health Malaysia (MOH) is entrusted to ensure that the public gets access to safe, efficacious and quality pharmaceuticals, protecting their interest via enforcement of the relevant legislations, and ensuring rational use of medicines by both healthcare providers and patients. Fulfilling these responsibilities has become more challenging in the recent years. Demands for healthcare services including medicines have grown exponentially as a result of ageing population, rising prevalence of non-communicable diseases as well as various environmental and communicable threats to health. Costs of pharmaceuticals and medical technologies have also continued to rise. Health budget, however, has not increased proportionately raising the need to optimise available resources.

Pharmaceutical service is vital to the healthcare system and pharmacists play pivotal roles in efficient service delivery to safeguard equitable and timely access to medicines. Due to the changing needs of the population, pharmacists' roles have evolved from regular duties in regulatory, procurement and supply of medicines to providing pharmaceutical care that include clinical pharmacy services and medicine counselling. Research has also become an integral part of pharmacy services to keep pace with the increasing demand for evidence and information to inform healthcare decisions and policies and to continuously improve the quality of services provided for the population. Research could generate innovative ideas and bring about transformation in services delivery in tandem with the changing demands of the population and the advancement of digital technology. Drive-Thru Pharmacy, Medicines Delivery via Postal Service and Locker4U are some of the examples of innovative value-added pharmacy services that need further research to evaluate the performance and effectiveness.

The culture of conducting research in pharmacy services has progressed at a faster pace in the recent years. A large number of small-scaled research are being conducted at hospitals and health facilities by a mixture of trained and novice pharmacy researchers, who sometimes repeat similar researches in different facilities. On the other hand, very few researches are of large-scaled or conducted nationwide to address critical national health concerns. Many frontiers in pharmacy research are also yet to be explored.

Without proper planning and guidance, efforts in research can be incoherent and may not address the current and critical evidence gaps. Hence, there is an urgent need to streamline the research process for the Pharmaceutical Services Programme. The areas of research need to be systematically identified focusing on topics that matter most and those that will significantly impact decisions, aligning them with the Pharmacy Programme Strategic Plan 2017-2020.

The Malaysian National Medicines Policy (MNMP)¹ was established in 2006 in line with the vision and mission of MOH, to meet the current and future healthcare needs of the nation. The MNMP clearly emphasised on the importance of setting research priority areas with the aim to promote evidence-based practices and provide excellent pharmaceutical care¹. Scientific research was identified as one of the platforms for the pharmacists in the public sector to collaborate with those in the private sectors to provide optimal healthcare services to patients.

Setting the priorities for pharmacy research is absolutely crucial to bridge knowledge gaps, maximise resources and to support the development of new policies. The Pharmaceutical Services Programme recognised the fundamental need to set priorities in pharmacy research to streamline pharmacy research in building relevant and useful body of evidence and knowledge that can support decision-making and policies review, and subsequently improve services delivery and the health of the population.

Objectives

The Pharmacy Research Priorities in Malaysia is developed to provide evidence-based and well-planned guidance in conducting pharmacy research in line with the Malaysian National Medicines Policy. The specific objectives of setting the pharmacy research priorities are:

1. To guide researchers to embark on pharmacy research projects that can provide information and evidence that support the primary goals of the 11th Malaysia Plan, Ministry of Health Strategic Plan 2016–2020 and Pharmacy Programme Strategic Plan 2017–2020.
2. To generate useful evidence for policy makers in drawing up new direction or policies in pharmaceutical and health services.
3. To streamline conventional individual research projects towards national researches that are able to address national health priorities.
4. To optimise the time, effort and resources for pharmacy research.

¹ Malaysian National Medicines Policy, 2nd Edition 2012. Ministry of Health Malaysia.

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METHOD



2.0 METHOD

Working Committee

Since year 2016, setting the Pharmacy Research Priorities became the central agenda of the National Pharmacy Research and Development (R&D) Committee (more commonly known as *Jawatankuasa R&D Farmasi* or JKR&D). The JKR&D is tasked to look into national level streamlining of all research activities conducted under the Pharmaceutical Services Programme. The aim was to promote and guide research efforts to generate relevant information and evidence for service improvement and expansion. The JKR&D committee members, consisting of pharmacists from 15 states/Federal Territories and 4 health institutions, formed the Pharmacy Research Priorities Working Committee. These pharmacists are highly engaged with research activities in their own state or institution and deemed capable of providing holistic and cross-departmental view of pharmacy research activities and needs. The Working Committee is chaired by the Director of Pharmacy Policy and Strategy Planning Division of the Pharmaceutical Services Programme, Ministry of Health Malaysia (MOH). To spearhead this research areas prioritisation project, the Deputy Director of the Pharmacy Research and Development Branch of the Pharmacy Policy and Strategy Planning Division was appointed to head the Secretariat of the Working Committee that was responsible to drive and implement the project as well as to monitor the timeline by which key milestones are to be achieved. The Pharmacy Research Priorities Working Committee members are listed in Table 2.1.

Table 2.1: Members of the Pharmacy Research Priorities Working Committee

Chairperson	
<p>Dr. Hasenah binti Ali Director Pharmacy Policy and Strategic Planning Division</p>	
Working Committee Members	
<p>Pn. Basariah binti Naina Chief Pharmacist Hospital Tuanku Ja'afar</p>	<p>Pn. Aishah binti Hamzah Chief Pharmacist Hospital Hulu Terengganu</p>
<p>Pn. Saidatul Raihan binti Ibrahim Chief Pharmacist Hospital Melaka</p>	<p>Pn. Norazlin binti Abd. Kadir Senior Principal Assistant Director Pharmacy Practice and Development Division</p>
<p>Pn. Soo Bee Kuan Pharmacy Enforcement Division Federal Territory of Labuan</p>	<p>Mr. Ridhwan bin Abdullah Chief Pharmacist Hospital Sentosa, Kuching</p>
<p>Pn. Norharlina binti Sulaiman Pharmacist Klang District Health Office</p>	<p>Dr. Norkasihah Ibrahim Pharmacist Hospital Kuala Lumpur</p>
<p>Dr. Jannatul Ain binti Jamal Pharmacist Hospital Tengku Ampuan Afzan</p>	<p>Dr. Abdul Haniff bin Mohd Yahaya Pharmacist Hospital Teluk Intan</p>
<p>Pn. Ida Syazrina binti Ibrahim Senior Principal Assistant Director National Pharmaceutical Regulatory Agency</p>	<p>Ms. Rohaizan binti Mohd Hanafiah Senior Principal Assistant Director Pulau Pinang State Health Department</p>
<p>Mr. Manzatul Azrul Azrie bin Sulaiman Senior Principal Assistant Director Pharmacy Enforcement Division, MoH</p>	<p>Pn. Norazila binti Abd. Ghani Pharmacist Hospital Sultanah Bahiyah</p>
<p>Pn. Zahrina binti Abdul Kadir Senior Principal Assistant Director Johor State Health Department</p>	<p>Pn. Nazmi Liana binti Azmi Pharmacist Hospital Raja Perempuan Zainab II</p>

Pn. Yuzlina binti Mohd Yahaya
Chief Pharmacist
Hospital Rehabilitasi Cheras

Pn. Hazlin Syafinar binti Hussein
Senior Principal Assistant Director
Perlis State Health Department

Pn. Bibi Faridha binti Mohd Salleh
Senior Principal Assistant Director
Pharmacy Policy and Strategic Planning
Division

Mr. Jerry Liew Ee Siung
Pharmacist
Hospital Queen Elizabeth

Mr. Azmi Nor Mohd Farez bin Ahmat
Pharmacist
National Cancer Institute

Secretariat

Dr. Azuana binti Ramli
(Head of Secretariat)
Deputy Director (Pharmacy Research and Development)
Pharmacy Policy and Strategic Planning Division

Ms. Mary Chok Chiew Fong
Senior Principal Assistant Director
Pharmacy Policy and Strategic Planning
Division

Mdm. Chan Pui Lim
Senior Principal Assistant Director
Pharmacy Policy and Strategic Planning
Division

Mdm. Chan Lai Yue
Principal Assistant Director
Pharmacy Policy and Strategic Planning
Division

Ms. Ho See Wan
Principal Assistant Director
Pharmacy Policy and Strategic Planning
Division

Ms. Safura binti Sa'ad
Research Officer
Pharmacy Policy and Strategic Planning
Division

Ms. Noor Atiqah binti Mat Yusoff
Research Officer
Pharmacy Policy and Strategic Planning
Division

Mr. Mohd Faiz bin Abdul Manan
Research Officer
Pharmacy Policy and Strategic Planning
Division

Implementation

The main method and work flow employed in establishing the Pharmacy Research Priorities in Malaysia was based on the methodology used in the 10th Malaysia Plan Health Research Priority Setting² and 11th Malaysia Plan Health Research Priority Areas³. Both the 10th and 11th Malaysian Plan Health Research Priority settings were conducted by the National Institutes of Health Malaysia (NIH) and Institute of Health Systems Research (IHSR), MOH. For the prioritisation process, the scoring and ranking method employed in the previous research priorities setting projects was adapted after consultation with the NIH Secretariat who has vast experience in conducting research prioritisation projects for the MOH.

Stage 0: Pre-Prioritisation

In 2016 and 2017, several brainstorming sessions among the members of the Pharmacy Research Priorities Working Committee were conducted to identify and discuss the current gaps in knowledge and research evidence relevant to the pharmacy services. Several more workshops were held to determine the domains and priority areas for pharmacy research, based on the knowledge and evidence gaps established with reference to health priority areas of the 10th Malaysia Plan. Subsequently, the secretariat summarised and streamlined the areas identified and FIVE research domains (Figure 1) were conceptualised as below:

1. Access to Medicines
2. Monitoring and Evaluation of Outcomes
3. Quality and Safe Use of Medicine and Sustainability
4. Optimisation of Therapy and Pharmacy Services Delivery
5. National Databases/Big Data Analytics

Stage 1: Research Areas Identification

To identify research areas and topics to be incorporated into each research domain, a survey involving multiple stakeholders were conducted. A survey form was developed based on the 10th Malaysia Plan Health Research Priority Setting project (Annex 1). The survey was then sent to the Institute of Health Systems Research (IHSR), Clinical Research Centres (CRC), Ministry of Defence, Traditional and Complementary Medicine Division, Malaysian Pharmaceutical Society (MPS), Malaysian Organisation of Pharmaceutical

² 10th Malaysian Plan Health Research Priority Setting (HRPS-10).

³ 11th Malaysia Plan Health Research Priority Areas (unpublished).

Industries (MOPI), Pharmaceutical Association of Malaysia (PhAMA) and all higher learning institutions with established School of Pharmacy across Malaysia. A list of the respondents can be found in Annex 2. Subsequently, all the research areas and research topics suggested by the respondents were incorporated into a master list and arranged according to the five research domains.

Stage 2: Scoring and Ranking

In November 2017, the list of research areas identified in Stage 1 was distributed to the members of the Pharmacy Research Priorities Working Committee for scoring. Scores were awarded to the research areas and suggested research topics according to three main criteria:

- Answerability and Feasibility
- Importance and Potential Impact
- Magnitude/Severity

Under each of the criteria, the working committee members have to answer three simple questions. Some questions have dichotomous response and the others have to be answered using a scale of 1 to 5 as illustrated in Annex 3. The working committee members were advised to evaluate each research scope and research topic that are of importance to address critical knowledge/evidence gaps and/or relevant to current and future national health problems.

For every suggested research topic, the scores given by the working committee members were added and the overall average scores were calculated for each research topic. The suggested research topics were then ranked within respective research domains according to their average scores. The main objective of this process is to gain consensus about the research areas that are more relevant and have higher potential in meeting the healthcare needs.

Stage 3: Ratification

The research priorities were presented to the Director of Pharmacy Policy and Strategic Planning Division for ratification and endorsement. Subsequently the final document will be published on the website of Pharmaceutical Services Programme. Involvement of policy makers in the process offers a greater likelihood of translation of research evidence into policies and practice in the future.

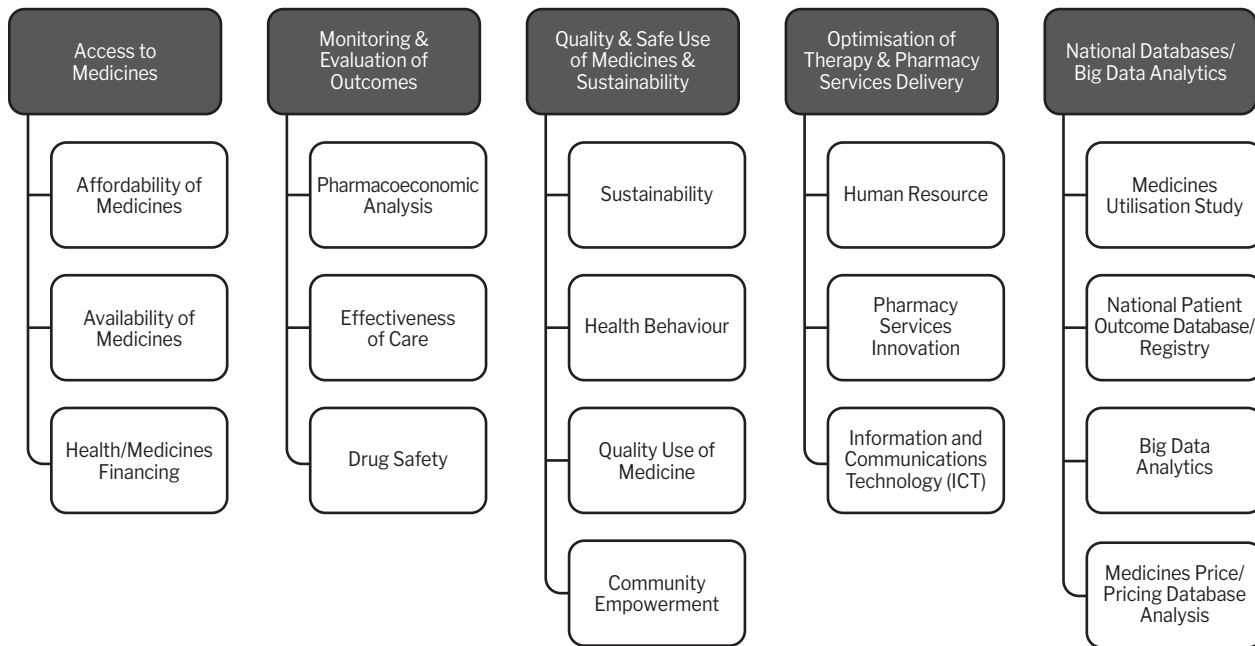


Figure 2.1: Five Research Domains and their Priority Areas in Pharmacy Research

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RESULTS



3.0 RESULTS

3.1. ACCESS TO MEDICINES

3.1.1 Introduction

Access to Medicines is a new component in the second edition of the Malaysian National Medicines Policy (MNMP), formed by combining the Medicines Availability and Medicines Affordability components from the previous edition of MNMP. The aim of this component is to ensure adequate, continuous and equitable access to quality, safe, effective and affordable medicines towards achieving optimal health outcomes through effective and efficient medicines selection, procurement and financing mechanisms⁴. In line with the MNMP, improving accessibility of pharmaceutical products through implementation of price setting mechanism and patient access scheme (PAS) is one of the strategies under the Operational Excellence Thrust of the Pharmacy Programme Strategic Plan 2017 to 2020. Guided by the MNMP, this research domain was organised into three main areas, namely Availability of Medicines, Affordability of Medicines and Health/Medicines Financing.

Pharmaceuticals expenditure in 2016 was reported at RM4,600 million or 8.89% of total health expenditure⁵. Private pharmacy expenditure was RM2,756 million, which accounted for 14% of out-of-pocket healthcare expenditure (by function, sales through community pharmacies)⁶. Therefore, it is estimated that around 60% of pharmaceuticals use in 2016 was paid by out-of-pocket. On the other hand, the 2015 National Health and Morbidity Survey (NHMS) reported that the population in poorest household income quintile (Q1) have higher out-of-pocket health expenditure⁷ compared to other quintiles except the richest quintile (Q5)⁸. These figures highlight the importance to continuously ensure the affordability of pharmaceuticals to prevent impoverishment due to high spending of medicines. In addition, while the utilisation of pharmaceuticals to treat NCDs and other conditions in Malaysia from 2006 to 2014 has been increasing, it is still lower than the rates observed in OECD countries although the prevalence of these conditions

⁴ Malaysian National Medicines Policy, 2nd Edition 2012. Ministry of Health Malaysia.

⁵ MNHA Health Expenditure 1997-2016. MNHA Steering Committee Meeting 2017.

⁶ MNHA OOP Health Expenditure 1997-2016. MNHA 2017.

⁷ NHMS 2015 reported that health expenditure made up about 4.6% of total household monthly spending.

⁸ NHMS 2015. Volume III HCDA.

exceed the prevalence rates in many of the comparator countries⁹. Therefore, there is a need to further investigate factors hindering the access to required treatment and establish policies to improve the access to medicines.

Based on the prioritisation exercise for research topics under this Access to Medicines domain, Medicines Pricing under the sub-domain Affordability of Medicines received the highest attention among the research areas identified. As medicines pricing in Malaysia is not regulated, there could be profound concern that this may impede the accessibility to affordable medicines. Examples of research topics in the area of medicine pricing that can be explored include medicines price transparency and fair pricing, pricing disparities, the effect of medicine prices on affordability and access, and mechanisms for price regulation. On the other hand, implementation of generic medicines policy could potentially create a positive impact on medicines price and studies in this area have also been prioritised. Another research area which is also high in the list is Procurement and Supply under the sub-domain Availability of Medicines, which mainly focuses on medicines logistics management in the public sector. Efficiency in the procurement and supply chain management directly impact timely access to medicines. There is a paucity of information in this area in making good procurement decisions and improving the supply chain. The area of medicine reimbursement under the sub-domain Health Financing, which looks at issues surrounding co-payment and out-of-pocket payment for medicines, also tops the list. Research that looks into a more sustainable medicine financing mechanism that combines contributions from both the provider and patients will be valuable.

The National Essential Medicine List (NEML) was gazetted in 2000¹⁰ but its use and impact on the population's access to essential medicines particularly in the private health sector has never been evaluated. It is also a high time to review the NEML and research on the most reliable framework of medicine evaluation and selection for the NEML will support this process.

⁹ Malaysia Health Systems Research Volume I. Contextual Analysis of the Malaysian Health System, March 2016. Ministry of Health of Malaysia and Harvard T.H. Chan School of Public Health, Harvard University.

¹⁰ National Essential Medicines List 4th Edition. Pharmaceutical Services Division, MOH 2014.

3.1.2 Research Priority Framework

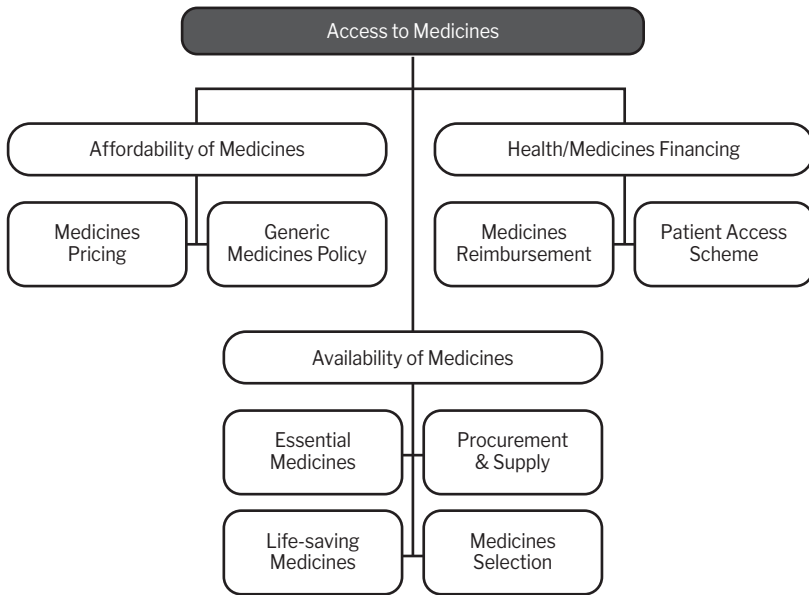


Figure 3.1: Research Priority Framework for ‘Access to Medicines’

3.1.3 Research Priority: Access to Medicines

National Problem	Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
Affordability of Medicines	Medicines Pricing	Medicines price regulation has been a long debated issue in Malaysia. It was believed that regulation of medicines price will be able to help improve affordability and accessibility of medicines. More evidence is needed to guide the establishment of effective medicine price interventions.	<ul style="list-style-type: none"> • To evaluate the effect of price on access to medicines among the Malaysia population. • To understand the accessibility & affordability of medicines from the users' perspective. • To analyse out-of-pocket spending on pharmaceuticals by population group and identify incidents of catastrophic payment and impoverishment due to medicine expenditure. • To study suitable mechanisms for collection of up-to-date and reliable information on medicine prices, % mark-ups for comparisons and benchmarking. 	<ul style="list-style-type: none"> • Identifying the disparities in medicine pricing and thus serve as an evidence to constitute a good medicine pricing policy. • Understanding of whether unregulated medicines prices impede access. • Evidence to guide medicine pricing policy e.g. whether medicine price regulation will be effective. • Medicine price databank. 	1

National Problem	Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
		Unaffordability of medications may lead to non-adherence and lead to increased direct and indirect costs of treatment. This is especially important for essential medicines. Information about the affordability of essential medicines is needed to ensure the access to these medications is not affected.	<ul style="list-style-type: none"> To collect information about prices of essential medicines in the private sector and compare to international benchmark. To investigate whether spending on essential medicines has resulted in any catastrophic household expenditure. 	Information about affordability of essential medicines.	2
		It was reported that around 50% of medicine products (by expenditure) in the public sector were procured at more than two times of the international reference pricing (IRP) (MHSR 2016) ¹¹ . It is necessary to continue monitoring the medicine procurement prices in the public sector, especially high-cost but low volume products that have a substantial impact on the budget for medicines.	<ul style="list-style-type: none"> To compare MOH and other public health facilities medicines procurement prices to the IRP. To identify measures to ensure reasonable pharmaceutical procurement prices in the public sector. 	Improved medicines price negotiations in the public sector.	9

¹¹ Malaysia Health Systems Research Volume I. Contextual Analysis of the Malaysian Health System, March 2016. Ministry of Health of Malaysia and Harvard T.H. Chan School of Public Health, Harvard University.

National Problem	Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
	Generic Medicines Policy	Better understanding about generic medicines among consumers and healthcare providers could result in enhanced access to affordable medicines.	<ul style="list-style-type: none"> To collect evidence about equivalence of generic medicines. To evaluate adoption, perception and identify barriers to generic medicines policy. To investigate factors affecting generic medicines production and performance in Malaysia, e.g. regulatory and/or tender requirements. To develop a national level generic medicines use guidelines. 	<ul style="list-style-type: none"> Evidence to support and promote generic medicines policy. Development and adoption of generic medicine use guideline. 	3
Availability of Medicines	Essential Medicines	NEML ¹² was implemented in Malaysia but the adoption in the private sector is yet to be assessed.	<ul style="list-style-type: none"> Awareness about NEML among private healthcare providers. Adoption of NEML by private healthcare providers. 	Information on the availability (and affordability) of selected medicines in the NEML.	2

¹² National Essential Medicines List.

National Problem	Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
	Procurement & Supply	<p>Incidents of pharmaceutical products not supplied within the specified delivery lead time have been reported in the MOH facilities. However, no studies were conducted to investigate this problem.</p>	<ul style="list-style-type: none"> • To evaluate performance of medicine suppliers, especially concession and central contract suppliers, in terms of delivery lead time. • To document the incidents and impact of products not supplied within the stipulated delivery lead time. • To investigate factors and prevention of delays in medicine delivery. 	Improved medicine delivery lead time.	3
		<p>Medicine shortages in MOH facilities were often deemed due to the wrong estimation of central contract volume.</p>	<ul style="list-style-type: none"> • To document the incidents and factors of medicine shortages in MOH facilities. • To identify factors contributing to inaccurate forecast of central contract volume. • To identify factors affecting medicines utilisation in MOH facilities and establish tools to predict medicines usage for upcoming year(s). 	A methodology or tool to accurately forecast medicine utilisation and central contract volume in MOH facilities.	4

National Problem	Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
		Variation between the government procurement policy and procurement procedures for MOH local purchase (LP) products has been reported.	<ul style="list-style-type: none"> To evaluate barriers or problems in the procurement of products via LP. To audit the compliance to government procurement policy in the purchase of LP products. 	More efficient medicine procurement system.	7
		The General Guidelines on Shariah-based Governance or <i>Garis Panduan Umum Tadbir Urus Berteraskan Syariah</i> (GTU-s) was launched in 2017. There is no <i>Shariah</i> compliant pharmacy practice yet.	To identify the feasibility of GTU-s in pharmaceuticals procurement chain.	More efficient medicine procurement system.	13
	Life-saving Medicines	The access to orphan medicines and certain expensive life-saving medicines that have low utilisation volume are often affected or limited by their high prices. In addition, the supply of these medicines is often affected by other issues such as stringent regulatory requirements and no ready supplier. The same applies to low volume (utilisation) essential medicines with low prices and low profit margins.	To investigate the barriers in access to orphan medicines and other life-saving medicines.	Improved access to orphan medicines and other life-saving medicines.	8

National Problem	Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
		Antivenom ¹³ is listed as one of the essential medicines by WHO. However, the supply is limited, it is rarely used and is relatively more expensive than common non-biologics. Therefore, there is a need to determine the most suitable locations and types of antivenoms that need to be stored for timely treatment and minimise wastage.	Mapping study for the placement of suitable types and amount of antivenoms.	<ul style="list-style-type: none"> • More timely treatment of snake bites. • Better estimation of types and amount of antivenoms to facilitate procurement. • Improved alertness of the public and prevention of snake bites. 	11
	Medicines Selection	Newer medicines are often more expensive but may be more effective with less adverse effects. Cost-effectiveness of drugs are considered during the medicine selection process in the public sector, but information on cost-effectiveness of medicines is not made available to private healthcare providers.	<ul style="list-style-type: none"> • Cost-effectiveness evaluation on new and more expensive medicines. • To forecast the overall long term savings with the utilisation of cost-effective new medicines. 	<ul style="list-style-type: none"> • Evidence-based medicines selection and NEML medicines listing. • Guidance in medicines selection process for private practitioners and insurance providers. 	10

¹³ Snake antivenom immunoglobulins.

National Problem	Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
		The NEML consists of medicines deemed essential for addressing the most important healthcare needs of the population (WHO, 2017) ¹⁴ . These were medicines proven to be efficacious, safe and cost-effective. Nevertheless, the number of innovative medicines in the NEML is limited. Therefore, there is a need to find out whether it is feasible and affordable for Malaysia to include more innovative medicines into the NEML.	Comprehensive review of the NEM utilising cost-effectiveness evaluation of innovative medicines	<ul style="list-style-type: none"> Improved access to and utilisation of cost-effective medicines. 	12
Health/ Medicines Financing	Medicines Reimbursement	Co-payment is introduced in many countries to prevent medicine wastage and prescription of non-essential medicines. However, it may reduce the adherence to medicines especially among the vulnerable population such as the elderly and low income groups.	<ul style="list-style-type: none"> To assess medicine adherence by source of financing i.e. fully subsidised, out-of-pocket and partially subsidised at different levels of co-payment or co-insurance. To evaluate patients' perception of free, subsidised and self-paid medicines. To identify potential benefits of co-payment and the suitable mechanism and level of co-payment. 	Proposals on appropriate co-payment mechanism and level for pharmaceuticals.	3

¹⁴ Essential medicines selection. http://www.who.int/selection_medicines/list/en/.

National Problem	Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
		<p>The access to new health technologies in the public healthcare sector may be delayed due to the non-affordability of the treatment. To accelerate the access to expensive treatment for terminal illnesses, many patients have to pay out-of-pocket at the private facilities or subscribe to private health insurance.</p>	<ul style="list-style-type: none"> • To investigate the willingness to pay for private medical insurance to allow access to expensive new medicines or treatment of terminal illnesses. • To investigate the willingness to pay for cost-sharing to improve or accelerate access to expensive new medicines or treatment of terminal illnesses. • To identify the suitable level of co-payment or co-insurance for cost-sharing of expensive treatment. • To study the feasibility of setting co-insurance level by tier of medicines (e.g. France and Singapore). 	<p>Understanding of patients or publics' level of willingness to pay for cost-sharing or insurance.</p>	5
	Patient Access Scheme	<p>Patient Access Schemes (PAS) are offered by the pharmaceutical industry to help improving the access to expensive new treatments. There is a need to document the types of PAS established to date and evaluate their impact to the health system.</p>	<ul style="list-style-type: none"> • To document existing PAS such as types of PAS (e.g. outcome-based or volume based), number of beneficiaries, value of treatment received and cost savings achieved (if any). • To evaluate the performance, short and long term financial impact to the government and issues of PAS. • To study and compare with PAS in other countries. 	<p>Guidelines for PAS and PAS negotiation.</p>	6

3.2. MONITORING AND EVALUATION OF OUTCOMES

3.2.1 Introduction

Healthcare systems around the world have been facing increasing pressure to improve the quality of healthcare while containing costs. Accordingly, there has been greater reliance on outcomes research to help identify the most effective interventions to be incorporated into practices. Health outcomes research generally refers to research that studies the effectiveness of medical interventions, public-health interventions and health services¹⁵. In simple term, it studies what works and what does not work in healthcare. In outcomes research, the end results of healthcare services are studied to provide evidence on the value of specific medicines or interventions that can be used to guide decision making¹⁶. Unlike clinical trials, health outcomes research considers a broader view to incorporate real life clinical outcomes, financial impact and other functional measures such as patient satisfaction. The focus of outcomes research can be on individual level such as quality of life and preferences, or on the effectiveness of healthcare delivery such as cost-effectiveness, health status, disease burden, cost, appropriateness and access. It has been applied in area such as disease prevention, screening, drug treatment, medical procedures, medical practices, diagnostic tests, guidelines and healthcare policy.

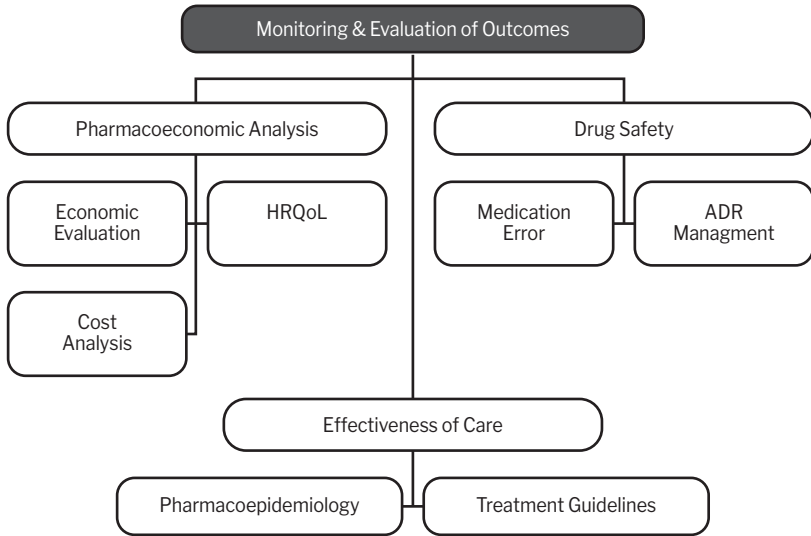
As the Malaysian health system is constantly facing budgetary and cost containment pressure, outcomes research has gained increasing popularity with measures to improve the efficiency in healthcare delivery receiving particular interest. Consequently, health technology assessment and budget impact analysis are already being implemented in the management of the Ministry of Health Medicines Formulary. Nevertheless, the potential of economic analysis to improve the efficiency of health resources utilisation is still largely unexplored in Malaysia. Therefore, among the research areas proposed under the Monitoring & Evaluation of Outcomes domain, the highest research priority is given to economic evaluations such as cost-effectiveness or budget impact analysis for the treatment of high disease burden conditions and expensive medicines (Economic Analysis sub-domain). In relation, researches on health-related quality of life (HRQoL) are also given high priority to establish information on patients' preferences and to support cost-utility analysis using local data.

¹⁵ Jefford, M. et al. 2003. Outcomes research: what is it and why does it matter? *Internal Medicine Journal* 33, pp. 110-118.

¹⁶ Ellis, L.D. 2017. *The Value of Applying Health Outcomes Research to Improve Treatment Results*. Boston: Harvard T.H. Chan School of Public Health. <https://www.hsph.harvard.edu/ecpe/value-of-health-outcomes-research/>.

Within the Effectiveness of Care sub-domain, highest attention is paid to the geographical disparities in the management of communicable diseases and producing evidence for standard treatment guidelines to improve management in selected disease areas. On the other hand, medication error in paediatric and medicine, supplement and disease associated renal conditions in the Medicine Safety sub-domain received equally high priority.

3.2.2 Research Priority Framework



Abbreviation: HRQoL, Health-Related Quality of Life; ADR, Adverse Drug Reaction

Figure 3.2: Research Priority Framework for ‘Monitoring and Evaluation of Outcomes’

3.2.3 Research Priority: Monitoring and Evaluation of Outcomes

National Problem	Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
Pharmacoeconomic Analysis	Economic Evaluation	To achieve the maximum health benefit from the limited healthcare resources, it is necessary to ensure that only the most cost-effective treatments are used.	To conduct economic evaluation such as cost-effectiveness or budget impact analysis for:	<ul style="list-style-type: none"> Health economics tool to aid selection of medicines. Identification of cost-effective medicines. 	1
			<ul style="list-style-type: none"> Treatment for the conditions with the highest disease burden such as hypertension, diabetes and mental illnesses. 		2
			<ul style="list-style-type: none"> Expensive medicines, especially those with cheaper options. 		2
			<ul style="list-style-type: none"> Other medicines or conditions such as: <ol style="list-style-type: none"> Arthritis 		13
			<ol style="list-style-type: none"> Imatinib for gastrointestinal stromal tumour 		14
			<ol style="list-style-type: none"> Interferon for multiple sclerosis 		16
			<ol style="list-style-type: none"> Antimuscarinic agents for overactive bladder 		

National Problem	Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
		Current evidence suggests that antibiotic de-escalation therapy is safe and effective for most infections ¹⁷ . However, the economic impact is unknown.	<ul style="list-style-type: none"> To identify current practice of antibiotic de-escalation in Malaysia. To evaluate the clinical and economic impact of antibiotic de-escalation approach. 	Review of antibiotic use policies and guidelines.	7
	HRQoL	There is a lack of local data on outcomes and quality of life of infectious diseases such as HIV/ AIDS, TB, Dengue, HFMD etc.	HRQoL of infectious disease patients.	Local HRQoL data.	3
		The quality of life of cancer patients and caretakers, and factors affecting the quality of life are not well documented in Malaysia.	HRQoL of cancer patients and their caretakers using established instruments such as EQ5D and EORTC QLQ-C30.	<ul style="list-style-type: none"> Improved social support for cancer patients and their families. Local HRQoL data for health economic studies. Pharmacists as subject matter expert in oncology researches. 	10

¹⁷ Ohji, J. et al. 2016. Is de-escalation of antimicrobials effective? A systematic review and meta-analysis. International Journal of Infectious Diseases 49, pp. 71-79.

National Problem	Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
	Cost Analysis	Current state budget for cancer treatment is not allocated according to cancer burden of each state. As the burden of cancer (e.g. types of cancer) differs between states, the cancer treatment budget needed by each state varies.	<ul style="list-style-type: none"> To map the cancer burden by states. To determine the disparity in cancer burden, budget allocation and standard of cancer care across the states in Malaysia. To estimate cost of illness, financial burden of patients or caretaker and cost of cancer treatment in all states. 	Fair allocation of cancer drug budget and better planning of health programmes.	7
		The ASEAN Costs in Oncology Study (Action) reported that cancer treatment has resulted in financial catastrophe (spending 30% or more of household income on cancer treatment) in 45% of cancer patients in Malaysia ^{18, 19} . There is a need to further investigate the causes of catastrophic treatment and financial impact of cancer on the patients and their families.	<ul style="list-style-type: none"> Cost analysis of cancer treatment from the patient and caregiver's perspective. Financial impact of cancer on patients and their caretakers. 	Guide to improve financing mechanism for cancer care.	10

¹⁸ The ACTION Study Group. 2015. Catastrophic health expenditure and 12-month mortality associated with cancer in Southeast Asia: results from a longitudinal study in eight countries. *BMC Medicine* 13:190.

¹⁹ Tan Shioh Chin. November 22, 2015. The economic impact of cancer on families in Asia. <https://www.star2.com/health/2015/11/22/the-economic-impact-of-cancer-on-families-in-asia/#uGrzilAxRbSGHuid.99>.

National Problem	Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
Effectiveness of Care	Pharmacoepidemiology	The prevalence of infectious diseases in Malaysia such as HIV/AIDS, TB and Dengue is still significant despite the rising of non-communicable diseases. Therefore, as the country is moving towards a high income status, there is a need to step up the standard of care for infectious conditions.	To determine the geographical variations in the incidence/prevalence, standards of care and outcomes of infectious diseases.	Improved care for infectious diseases.	3
		The prevalence of Multi-drug-resistant tuberculosis (MDR TB) in Malaysia has been increasing with Sabah having one of the highest prevalence. Without knowing the predictors of MDR TB, it is difficult to implement targeted intervention to reduce the burden of TB.	To find out the predictor of MDR TB.	<ul style="list-style-type: none"> • Guidance for intervention for MDR TB. • Reduction of burden and prevalence of MDR TB. 	9

National Problem	Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
	Treatment Guidelines	Budget impact of expensive medicines are evaluated during formulary listing but economic evaluation is not conducted after listing, to guide selection of medicines at clinical level. For example, Tenecteplase is 3-4 times more expensive than streptokinase but there is no guideline to guide their usage.	<ul style="list-style-type: none"> To review decisions on choices of medicines, e.g. among fibrinolytics. Economic evaluation of high cost medicines, such as tissue plasminogen activator (e.g. tenecteplase). 	Revision of prescribing policies and treatment guidelines for antifibrinolytics.	5
		Standard treatment guidelines (STG) involving high cost medicines are not readily available or are not reviewed routinely in all facilities.	<ul style="list-style-type: none"> To review existing STG or medicine use protocol. To develop STG especially for treatment involving high cost medicines. 	Streamlining of medicines management and medicines budgeting at facility level.	6
		Comprehensive clinical and pharmaceutical care for nephrology patients are provided by the MOH. It is timely to review the quality and effectiveness of care.	To review and assess the adequacy of treatment, quality of pharmaceutical care, occurrence of side effects, etc. among nephrology patients.	<ul style="list-style-type: none"> New evidence to guide pharmacists in the development of guidelines for renal care. Improved care for renal patients. 	7

National Problem	Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
		There are mixed evidence in the choice of medicines in Dual Antiplatelet Therapy (DAPT). No assessment has been done on current practice/CPG on the local population.	To generate local evidence on the outcome of treatment such as effectiveness and bleeding complications.	<ul style="list-style-type: none"> Local evidence on treatment regime to guide clinicians. Revision of local Standard Treatment Guidelines (STG). 	8
		Despite the availability of national guidelines for perinatal care, the management of anaemia in pregnancy remains suboptimal, with underutilisation of parenteral iron therapy. There is a need to evaluate the standards of care for anaemia among pregnant women in Malaysia.	<ul style="list-style-type: none"> To evaluate anaemia management in pregnancy and to compare the management across obstetric teams and primary care practitioners. To identify impacts of under-management of anaemia during pregnancy. To identify key factors for underutilisation of intravenous iron in the management of anaemia in pregnancy. To review STG for anaemia in perinatal care. 	Improved anaemia management during pregnancy.	10

National Problem	Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
Drug Safety	Medication Error	Medication errors are more common in children compared to adults due to the chances of dosage calculation error based on age, weight or body surface area and clinical condition. Pharmacists play an important role in identifying and preventing medication errors, and therefore the ability to detect errors is very important.	<ul style="list-style-type: none"> To assess the competency of pharmacy personnel in detecting medication errors in paediatric care. To identify factors of missed or near-missed in detecting medication errors. 	<ul style="list-style-type: none"> Improved medication safety in paediatric care. Better pharmaceutical care for paediatric patients. 	4
		Latest evidence highlighted the safety concern of long term use of proton pump inhibitors (PPI). Moreover, unnecessary prolonged use and overprescribing of PPI will incur more cost to the health system. Local guideline on appropriate prescribing of PPI is not available.	<ul style="list-style-type: none"> To audit the prescribing pattern of PPI. To develop guideline for PPI use. 	<ul style="list-style-type: none"> Improved PPI prescribing guideline. Reduction of unnecessary adverse events and more efficient use of health budget. 	5
	ADR Management	Chronic kidney disease (CKD) and acute kidney injury (AKI) may be caused by other morbidities (e.g. dengue) or medicines (e.g. losartan). Recently, there are increasing reports on supplements-associated AKI or CKD. Nevertheless, the exact prevalence of AKI/CKD by causes is not studied.	<ul style="list-style-type: none"> To identify factors causing AKI and CKD. To determine the prevalence of medicine, supplement and disease associated AKI and CKD. 	Improved prevention of AKI and CKD.	7

National Problem	Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
		Current standard of management of drug-related problems (DRP) is not evaluated. More evidence is needed to improve prevention and interventions of DRPs.	<ul style="list-style-type: none"> To identify the frequency, factors, classifications and severity of DRPs requiring primary care management and hospitalisation. To evaluate the management of DRPs in primary, secondary and tertiary care. 	Improved prevention and management of DRPs.	11
		Local epidemiology data on drug-related fall injuries among geriatric population is not available.	<ul style="list-style-type: none"> To identify high-risk medicines related to fall injuries among geriatric population. To evaluate pharmaceutical care/interventions targeted at geriatric patients taking high-risks medicines related to fall injuries. 	Prevention of drug-related fall injuries among geriatric population.	12
		There is a lack of data on psychotropic dependence in Malaysia.	<ul style="list-style-type: none"> Prescribing trends of benzodiazepine and other psychotropics. Prevalence of psychotropic dependence among patients with mental illnesses and other diseases. To monitor the occurrence of adverse events among patients with psychotropic dependence. 	<ul style="list-style-type: none"> Better management and prevention of psychotropic dependence. Reduction of adverse events caused by psychotropics. 	15

3.3. QUALITY AND SAFE USE OF MEDICINES AND SUSTAINABILITY

3.3.1 Introduction

In Malaysia, Quality Use of Medicine (QUM) is one of the 5 components stipulated in the Malaysian National Medicines Policy, highlighting its importance to the health system. The aim of QUM implementation is to ensure medicines are used judiciously, appropriately, safely and cost-effectively towards promoting better health outcomes²⁰. According to the National Medicines Policy of Australian Government Department of Health, QUM means (i) selecting management options wisely, (ii) choosing suitable medicines if a medicine is considered necessary and (iii) using medicines safely and effectively²¹.

Over the past few decades, higher education level and better standards of living among Malaysians have impacted patient perceptions and expectations on health. A large increase in health-seeking behaviour has resulted in congestion in the public hospitals and irrational use of medicines. More than 70% of patients expect the doctor to prescribe them with antibiotics when they suffer from common cold symptoms and more than 50% thinks that antibiotics do not cause side effects²². Inadequate knowledge on medicine literacy can have negative impacts on patient care. As a consequent, Malaysia is now experiencing a rising trend of antibiotics utilisation which might pose a risk of antibiotic resistance in the country.

A study conducted among students in Universiti Sains Malaysia (USM) revealed that most female students are likely to store medicine in their room. Majority of the medicines were found to have expired, and unused medicines were disposed into rubbish bins²³. Medicines disposed through domestic rubbish bins can cause pollution to the soils and expose the general population to unknown risks or side effects that may affect public health.

Findings from these researches might be just the tip of an iceberg of inappropriate use of medicine and mismanagement medicine waste in Malaysia. Inappropriate use medicine and medicine wastage is a great concern

²⁰ Malaysian National Medicines Policy, 2nd Edition 2012. Ministry of Health Malaysia.

²¹ Australian Government. The Department of Health. <http://www.health.gov.au/internet/main/publishing.nsf/Content/nmp-quality.htm>.

²² Lim KK and Teh CC. Dec 2012. A Cross Sectional Study of Public Knowledge and Attitude towards Antibiotics in Putrajaya, Malaysia. *South Med Rev.*; 5(2):26-33.

²³ Ali SE, Ibrahim MIM, Palaian Subish. 2010. Medication storage and self-medication behavior amongst female students in Malaysia. *Pharmacy Practice*; 8(4): 226-232.

to the Ministry of Health because of the scarcity of financial resources. Issues related to inappropriate medicine use rarely becomes the topic of interest among researchers even though the prevention of medicine wastage can provide highly positive economic impact to the health financing system. Behavioural studies related to medicine use are very limited and stakeholders are demanding evidence to support new interventions to prevent medicine wastage. Research on medicine wastage, particularly on the effect as well as the identification of root causes of the problems tops the list of research areas in this third domain Quality and Safe Use of Medicine & Sustainability.

Majority of QUM activities revolve around educational and awareness campaigns that cover topics such as unregistered products, counterfeit medicine, antibiotics use, vaccination, medicine adherence, health literacy, smoking cessation and substance abuse. It is high time that researchers performs more evaluation studies on the impact of these activities on patients' or population's change in behaviour following these activities and the improvements that can be made to improve the impact. In this prioritisation exercise, evaluation on quality use of antibiotics and vaccines, and safe use of traditional and complementary medicines (TCM) were specifically highlighted.

Under this domain, patients' and carers' empowerment and how it may affect quality use of medicines, safe self-care and consequently ease provider financing and congestion at health facilities, is also another research area waiting to be explored.

3.3.2 Research Priority Framework

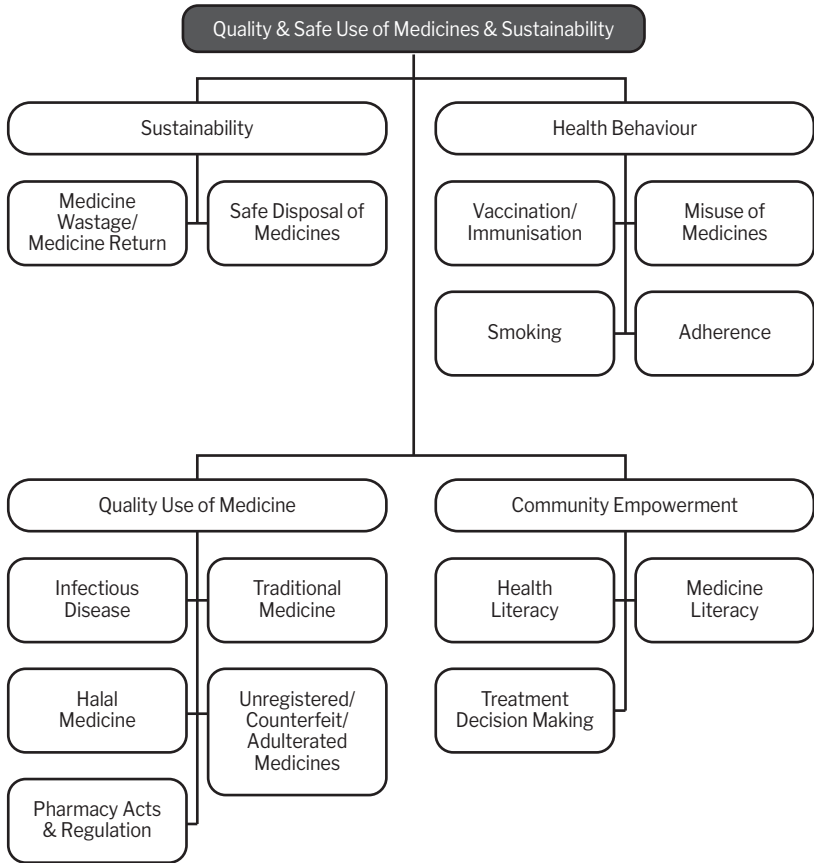


Figure 3.3: Research Priority Framework for ‘Quality and Safe Use of Medicines and Sustainability’.

3.3.3 Research Priority: Quality and Safe Use of Medicines and Sustainability

National Problem	Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
Sustainability	Medicine Wastage/ Medicine Return	High amount of medications returned to pharmacy and low awareness among patients about the cost and wastage of subsidised medicines.	<ul style="list-style-type: none"> To identify and evaluate factors that contributes to medicine return/medicine wastage. To quantify the value of medicine wasted. To evaluate whether interventions to reduce medication wastage are effective. 	<ul style="list-style-type: none"> Improved patient compliance (counselling given when patient is found to be non-compliant). Reduced expenditure of medication due to wastage. 	1
		The extent of medication wastage at patients' home is unknown.	To quantify the value (RM) of unused/damaged/expired medications at patients' home.	<ul style="list-style-type: none"> Understanding the extent of medication wastage at patients' home. Review of the policy of medicine supply duration. 	2
	Safe Disposal of Medicines	Lack of understanding about proper disposal methods of medication and its use among Malaysians poses potential threat to the environment and ultimately to the safety of human.	To study the awareness of patients/carer on proper and safe disposal of medicines.	Formulation of education programme for safe disposal of medicines.	7

National Problem	Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
Health Behaviour	Vaccination/ Immunisation	Prevalence of anti-vaccination group and a series of outbreak of preventable diseases such as measles. There is a need to explore parents' views on immunisation in children and to explore the reasons against vaccination.	To explore and identify the reasons for non-vaccination in children.	Identification of reasons for non-vaccination and appropriate intervention to improve vaccination acceptance.	3
		Missed immunisations among paediatric patients in rural areas (e.g. Sabah) still occurs. The reasons of our patients missing immunisations is undocumented,	<ul style="list-style-type: none"> • To determine the prevalence and factors causing missed immunisations among children rural areas. • To compare the knowledge, awareness and perception (KAP) on immunisation programmes by geographical areas. 	<ul style="list-style-type: none"> • Prevalence of non-immunised patients. • Identification of barriers to immunisations. • Increased awareness of the importance immunisation among parents. • Increased acceptance of immunisation programmes. 	6

National Problem	Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
	Misuse of Medicines	Common complications of inappropriate use of analgesics include gastrointestinal disturbances, cardiovascular effects, kidney failure and liver failure. Without knowing the patients' knowledge, attitude and practice towards painkillers, it is difficult to prevent complications due to misuse of painkillers.	To assess patients' knowledge and behaviour in the use of analgesics.	Reduced unnecessary use of analgesics that can endanger patients' health.	13
		The extent and types of medicines used for unlicensed/off-label indications are worrying.	<ul style="list-style-type: none"> To study unlicensed and off-label use of medicines especially in children. To study the stability of extemporaneous preparation (for off-label use). 	Safer use of medicines.	17
		Lack of data on the long term use of opioid in non-cancer pain.	To determine the long term effects and the risks of abuse and misuse in long term opioid users with chronic non-cancer pain.	Details on the outcomes/ consequences of long term use of opioid.	21

National Problem	Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
		Greatest factor that influences improper use of medicine (include inhaler, GTN, insulin pen, etc.) is the lack of education on the proper use. Little is known about how patients manage self-administration of medicine.	To assess patients knowledge on medicines that need counselling on technical advice e.g. inhaler, GTN and insulin pen.	Safer use of medicines.	22
	Smoking	Best model for smoking cessation at workplace.	<ul style="list-style-type: none"> To identify the type of smoking cessation intervention at work place. To evaluate smoking cessation intervention at workplace. 	New module for smoking cessation at workplace.	18

National Problem	Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
	Adherence	Number of patients with psychiatric problems is increasing yearly. There are lack of studies associating self-stigma to adherence and treatment discontinuation in Malaysia. Most treatment and counselling modules do not address the issue of self-stigma among these group of patients which leads to non-adherence and treatment discontinuation. This increases the rate of relapse and increases the health care burden though increasing number of readmissions.	Determine the level of self-stigma among psychiatric patients in Sabah and its association with adherence and discontinuation of medication.	Improvement in patient compliance and treatment continuation.	19
Quality Use of Medicine	Infectious Disease	The yearly antibiotic usage review reported high usage in Sabah. This might increase the rate of antimicrobial resistance in the state.	To evaluate the success of antimicrobial stewardship in promoting appropriate use of antibiotics and preventing antibiotic resistance.	Development of a coordinated program that promotes the appropriate use of antimicrobials.	4

National Problem	Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
	Traditional Medicine	A series of National Health Morbidity Surveys (NHMS) have identified an increasing trend in self-medication among Malaysian. The use of traditional medicine is of current interest to be explored. The factors that influence the use of TCM are not known.	To explore the factors affecting the general public decision making in using traditional medicine.	Added information and evidence for future educational programme and relevant policy development.	5
		Standards on herbal products are needed for regulatory and quality control.	To establish standards for herbal products.	Standardisation of herbal products.	16
	Halal Medicine	There is a market for halal medicines and halal active pharmaceutical ingredient (API) and excipients (Ref: MS2424:2012 Halal Pharmaceutical Guidelines).	To identify the pro and cons in adopting the halal guidelines.	Taking Muslim's and special population's needs into account.	10
	Unregistered/ Adulterated/ Counterfeit Medicines	There is a wide use of unregistered health products that may be adulterated, of sub-standard quality and/or unsafe.	To explore the reasons/factors that cause public consuming unregistered/adulterated/ counterfeit health products.	Public protection against potential harm that can be caused by unregistered/ adulterated/sub-standard quality or unsafe products.	11

National Problem	Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
	Pharmacy Acts and Regulation	General practitioners who handle psychotropic substances lack knowledge about laws governing it.	To assess the level of knowledge regarding laws governing medicines/psychotropic substances in Malaysia.	Improved knowledge of pharmacy acts and laws that govern psychotropic substances in Malaysia.	20
Community Empowerment	Treatment Decision Making	There is a potential in healthcare cost savings via patient empowerment, e.g. in the management of minor ailments.	<ul style="list-style-type: none"> Percentage of patients seeking treatment for minor ailments in primary healthcare facilities and community pharmacy. To compare the cost of management of minor ailments in primary healthcare facilities and community pharmacy. 	<ul style="list-style-type: none"> Optimisation of healthcare spending. Establishment of new model of minor ailment management. 	8
		Low level of patient involvement in treatment decision making among patients with chronic diseases/cancers.	<ul style="list-style-type: none"> To determine level of involvement in treatment decision making. To identify adherence and factors influencing adherence. 	Towards shared decision making and improvement in adherence to treatment.	15

National Problem	Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
	Medicine Literacy	Lack or inadequate knowledge among parents/caregivers may cause higher risk of medication error in children or elderly. No local data on the prevalence of medication error and health literacy level among parents/ caregiver in local setting.	<ul style="list-style-type: none"> To assess medicine literacy among specific population, e.g. paediatric, geriatric, carer and nurses. Types of medication error e.g. measurement error, labelling, route of administration, etc. 	Prevalence of measurement error among parents/caregiver, then to identify strategies to reduce the error.	9
		To assess the handling and administration of children's medications among parents/ caregivers.	Improved compliance to proper administration of medication in paediatric patients and help to formulate counselling approach.	13	
There is a need to assess the impact of Home Medication Review (HMR) on the knowledge, attitude and perception (KAP) of rural villagers on medicines.		To assess KAP of rural villagers with chronic diseases on multiple medicines pre-and post-HMR.	Improved KAP on medicines and adherence among rural villagers.	15	

National Problem	Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
		There is a risk of overdose or under-dose of antibiotic suspensions due to incorrect reconstitution and administration of antibiotics suspension by parents. Pharmacist counselling can improve patients' antibiotics reconstitution technique and understanding on administration i.e. dose, frequency and storage of antibiotics.	To assess parents/caregivers' antibiotic reconstitution technique and their understanding on dose, frequency, duration and storage of antibiotics pre- and post-counselling by pharmacist.	Improved parents/ caregivers' antibiotic reconstitution technique and understanding on dose, frequency, duration and storage of antibiotics.	17
	Health Literacy	To determine the association between health literacy and medication adherence.	<ul style="list-style-type: none"> To assess health literacy and medication adherence among patients with chronic diseases on multiple medications. 	Improvement in health literacy and medication adherence through appropriate interventions.	10
		The high prevalence of medication errors in Malaysia justifies the needs for more effective, life changing intervention approach. It is therefore timely to review current interventions and routine clinical practices such as High Alert Medications (HAM) and tablet splitting practices.	<ul style="list-style-type: none"> To review the impact of HAM in MOH facilities (including wards). To review practice of tablet splitting and the clinical outcome of patient. 	Enhanced awareness about medication safety among nurses and other clinical staffs.	12

National Problem	Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
		<p>There is a need to scale up the efforts in improving health literacy among the public. Therefore, it is important to assess the feasibility and suitability of various programmes for improving health literacy.</p>	<ul style="list-style-type: none"> • To assess current practice, knowledge and attitude towards health literacy among healthcare professional in public hospitals. • To evaluate the feasibility of educational intervention or introduction of health literacy programme in curriculum of healthcare professionals. • To assess health literacy among patients with chronic diseases patients in self-disease management (including the validation of the standard health literacy tool). 	<ul style="list-style-type: none"> • Introduction of standard health literacy tool to be used in identification of low health literacy patients. • Enhanced role of healthcare professionals on improving health literacy. 	14

3.4. OPTIMISATION OF THERAPY AND PHARMACY SERVICES DELIVERY

3.4.1 Introduction

Pharmaceutical care and pharmacy services play an integral role in the healthcare system. It offers a wide range of services spanning from primary and secondary care to patients and enforcement of the relevant acts and regulations pertaining to pharmaceutical products and cosmetics. Many research questions could arise as the pharmacy profession strives to improve the services provided. Throughout the years, pharmacy services in Malaysia have expanded tremendously from basic product-based dispensing services to various innovative patient-oriented services such as clinical (ward) pharmacy services, integrated medicine dispensing system and home medication review. Nevertheless, limited studies were conducted to evaluate the health and economic impact of these services.

As we are striving to expand the pharmacy services and improve the quality of service delivery, we are also confronted with constant constraints in healthcare resources. Therefore, it is indispensable to ensure that valuable healthcare resources are optimised. As a result, 'Optimisation of Therapy and Pharmacy Services Delivery' was chosen as one of the five research priority domains. The research areas in this domain were arranged in three sub-domains, namely Human Resource, Pharmacy Services Innovation, and Information and Communications Technology (ICT). Overall, the research areas in these sub-domains aim to raise innovative ideas to improve pharmacy services delivery and to provide evidence of current programmes effectiveness and recommendations for their improvements. Moreover, the suggested research areas are largely in-line with the plan of actions or strategies under the four strategic thrusts²⁴ in the Pharmacy Programme Strategic Plan 2017-2020. It is hoped that the research findings can serve as evidence and information that are crucial to support the implementation of the strategic plan.

In this prioritisation exercise, extended services through public-private partnership under the sub-domain Pharmacy Services Innovation received the highest attention. While the public-sector pharmacists are overwhelmed with the increasing patient load, the community pharmacists could explore new and innovative services that can be provided through community pharmacies to fill the current gaps in providing patient care. The extended pharmacy services with huge potential to consider include home medication

²⁴ The four strategic thrusts are Customer engagement, Innovation driven, Operational excellence and Capacity building.

review, medicine counselling and home delivery. At the same time, it is critical to assess the performance of value added pharmacy services (VAS) currently provided in the public sector and to devise more innovative ideas in improving the delivery of pharmacy services.

Considering that pharmacy personnel plays a key part in pharmaceutical care and constitutes a significant portion of health expenditure, the efficiency and productivity of the pharmacy workforce under the sub-domain Human Resource scored second place in terms of research priority. This is followed by the assessment of user acceptance of the Pharmacy Information System (PhIS) under the sub-domain Information and Communications Technology (ICT). As PhIS is meant to improve the delivery of pharmacy services, it is crucial to evaluate user’s perception and allow for continuous improvement accordingly. As innovation is increasingly becoming multidimensional, multidisciplinary and collaborative research approach is needed to constantly adapt and align our services to meet societal needs.

3.4.2 Research Priority Framework

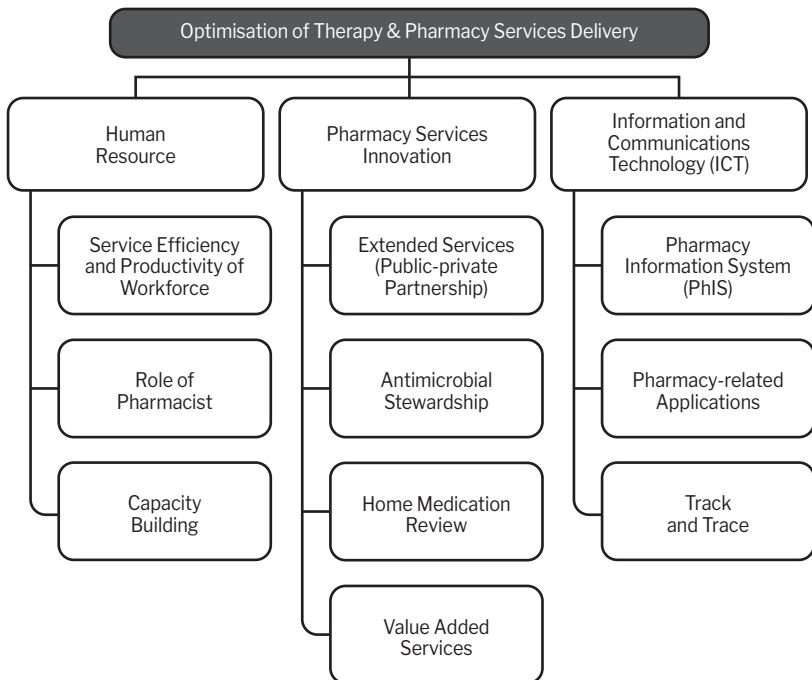


Figure 3.4: Research Priority Framework for ‘Optimisation of Therapy and Pharmacy Services Delivery’

3.4.3 Research Priority: Optimisation of Therapy and Pharmacy Services Delivery

National Problem	Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
Pharmacy Services Innovation	Extended Services (Public-private Partnership)	Recent study revealed that polypharmacy is prevalent in around 46% of Malaysian older adults who are on chronic medications ²⁵ . International evidence has shown the role of pharmacists in preventing and managing polypharmacy-associated negative consequences by providing extended services such as medication review, patient education and pharmacist outreach programmes ²⁶ . In Malaysia, the potential of community pharmacists in extended pharmacy services is still largely unexplored.	<ul style="list-style-type: none"> To evaluate patients' view on extended pharmacy services by community pharmacists (e.g. medication review) including their willingness to pay for these services. To design a mechanism to involve community pharmacists (through public-private partnership) in the provision of extended pharmacy services. 	Improved patient outcome with more community pharmacists delivering extended pharmacy services.	1

²⁵ Lim et al. 2017. Prevalence, risk factors and health outcomes associated with polypharmacy among urban community-dwelling older adults in multi-ethnic Malaysia. PLoS One 12(3) e0173466.

²⁶ Koshy, S. 2016. The Practice of Polypharmacy: Do Pharmacists Have A Role? Journal of Pharmaceutical Care and Health System 3:153.

National Problem	Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
		Currently, community pharmacists are under-utilised in the Malaysian health system. There is a need to explore their roles especially in the optimisation of medicine use in the community. In addition, most community pharmacists in the country have not expanded their role in extended services such as providing community liaison pharmacy service to ensure continuity of care in the transitional care setting (e.g. patients discharged from secondary care to primary care).	<ul style="list-style-type: none"> • To identify and evaluate services provided by public and community pharmacists including extended pharmacy services. • To evaluate the outcome of extended pharmacy services in the public sector. • To survey the readiness community pharmacists to provide extended pharmacy services. • To design a framework for community liaison pharmacy service in both public and community pharmacies. 	<ul style="list-style-type: none"> • Expansion of community pharmacists' function in national healthcare system. • Improved continuity of patient care across the primary-secondary care interface through community liaison pharmacy service. 	4
	Antimicrobial Stewardship	Implementation of antimicrobial stewardship program (AMS) is an essential practice element for healthcare institutions in gate-keeping judicious antimicrobial use. The acceptance rates of AMS in healthcare settings have not been evaluated.	<ul style="list-style-type: none"> • To identify level of acceptance of AMS intervention among healthcare professionals. • To identify factors associated with the level of acceptance of AMS intervention among healthcare professionals. • To identify the challenges in embedding AMS among healthcare professionals. 	Improved level of acceptance of AMS pharmacists' intervention among healthcare professionals.	7

National Problem	Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
	Home Medication Review	Home Medication Review (HMR) has been shown to be effective in improving patients' compliance but at the same time it is very resource consuming. The cost-effectiveness of HMR has yet to be explored.	<ul style="list-style-type: none"> To evaluate the cost-effectiveness of HMR. To explore a mechanism to implement HMR that can maximise outcomes with limited budget and manpower. 	Evidence to guide implementation of HMR.	10
	Value Added Services	Pharmacy Value Added Services (VAS) such as Integrated Drug Dispensing System (IDDS), Drive Through Pharmacy, Postal Medicine, SMS and Collect and Locker4U have been implemented in MOH facilities for years. However, the impact of VAS on patients' outcome is not evaluated. There is also a lack of data on patients' response/preference towards VAS.	<ul style="list-style-type: none"> To evaluate the impact and performance of pharmacy VAS and identify areas improvements. To evaluate VAS uptake among the patients and understand patient's perception on VAS. 	Improved implementation of VAS.	11
Human Resource	Service Efficiency and Productivity of Workforce	Factors that influence efficiency of pharmacy profession workforce have yet to be explored. With the constraints in healthcare resources, it is imperative to optimise available human resources towards better health quality and outcome.	<ul style="list-style-type: none"> To evaluate the efficiency and productivity of pharmacy workforce. To identify challenges that affects the efficiency and productivity of pharmacy workforce. 	<ul style="list-style-type: none"> Identification of efficient facilities that can become role model in improving the performance of pharmacy workforce. Improved efficiency of pharmacy services delivery. 	2

National Problem	Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
		Lean management is adopted in MOH hospitals to improve the efficiency in service delivery and reduce waiting time. Nevertheless, the potential of lean management in improving pharmacy services has not been explored.	<ul style="list-style-type: none"> To identify potential work process in pharmacy services for the implementation of lean management. To explore interventions that can improve the efficiency of pharmacy services. 	Improved efficiency of pharmacy services.	5
	Role of Pharmacists	The role of pharmacist has transformed over the years from product to patient oriented services in many countries including Malaysia. Nonetheless, the lack of understanding on the roles of pharmacists among general public and other healthcare professionals defers the pharmacy practice transition.	To evaluate patients' view and knowledge/understanding on the role of pharmacists in Malaysia (e.g. community & hospital pharmacists).	<ul style="list-style-type: none"> Improved public perceptions on role and image of pharmacists. Better understanding of consumers' and providers' perceptions towards roles of pharmacists and enhancement of the roles and image in the community as well as in the healthcare settings. 	6

National Problem	Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
	Capacity Building	Currently, there is a growing demand from pharmacists in the private sector for specific career pathway in different pharmacy fields or in various healthcare settings (e.g. hospital, primary care, policy, industry, etc.). In addition, there are initiatives by the pharmacists in private sector to deliver pharmacy services established in the public sector such as MTAC, drug reconciliation, methadone clinic etc.	<ul style="list-style-type: none"> • To develop specific career pathway and training framework for pharmacists in different settings or career options. • To develop capacity building framework (of education and training) for pharmacists in the private sector to deliver pharmacy services implemented in public sector. 	<ul style="list-style-type: none"> • Development of career pathway and training framework. • Improved quality and standard of pharmacy services in the private sector. 	8
		Subject Matter Expert (SME) is a form of recognition to an individual pharmacist who is an expert in a particular area or field. To support the establishment of SME, there is a need to look into current challenges, benefits and potential impact of the implementation of SME programme in pharmacy services.	<ul style="list-style-type: none"> • To evaluate the appropriate qualifying criteria for recognition of SME. • To study current challenges, benefits and potential impact of the implementation of SME programme. 	Framework for establishment of SME programme in pharmacy services.	13

National Problem	Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
Information and Communications Technology (ICT)	Pharmacy Information System (PhIS)	PhIS was implemented to provide a better and more efficient pharmacy system to improve delivery of pharmacy services. However, the acceptance of PhIS among users in healthcare facility was unknown.	<ul style="list-style-type: none"> To identify the level of acceptance of PhIS among users in healthcare facility. To identify the factors contributing to the acceptance/unacceptance of PhIS among users. 	<ul style="list-style-type: none"> Understanding of the factors contributing to users' acceptance/unacceptance of PhIS. Interventions to improve users' acceptance to PhIS. 	3
	Pharmacy-related Applications	There are various mobile or web-based applications (apps) that are designed to help improving patients' adherence to medication. It is therefore important to understand the utilisation of these apps among the patients and evaluate the impact of these technologies on patients' medication taking behaviour.	<ul style="list-style-type: none"> To evaluate the utilisation of mobile or web-based apps among the patients or carer. To determine patients' perception on the use of pharmacy-related apps. To identify the potential and feasibility of using mobile or web-based apps to improve medication adherence. 	Improved medication adherence or compliance using suitable mobile or web-based apps.	9

National Problem	Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
		The usage of mobile medical apps among healthcare providers is gaining popularity but the effectiveness and impact of this technology advancement is unknown.	To determine the usage pattern of mobile medical apps among pharmacists and other healthcare providers.	Understanding of the usage pattern and impact of medical mobile apps among healthcare professionals.	14
		Health information technology (IT) is having increasingly important role in current medical practices. However, majority of healthcare providers including pharmacists have limited capacity in health IT development. It is therefore necessary to strengthen the capacity of healthcare providers in health IT.	<ul style="list-style-type: none"> • To assess the capacity of health IT development among pharmacy personnel. • To develop health IT capacity building framework for pharmacy personnel. 	Health IT capacity building framework for pharmacy personnel.	15
	Track and Trace	The Pharmaceutical Track & Trace System is an initiative to improve patient safety and optimisation of logistic management. To guide the design and establishment of this project, more information and evidence is needed.	<ul style="list-style-type: none"> • To conduct feasibility study and impact analysis (e.g. regulatory and economic impact) for the Track & Trace project. • To identify the challenges and potential benefits in the implementation of Track & Trace system. 	<ul style="list-style-type: none"> • Evidence to guide the development of the Track and Trace project. • Improved transparency and safety in medicine distribution system. 	12

3.5. NATIONAL DATABASES/BIG DATA ANALYTICS

3.5.1 Introduction

In this fifth research domain, the importance of establishing national pharmacy databases and harnessing big data is emphasised. National databases and big data analytics may provide population statistics such as medicines utilisation, adverse drug events and patient outcomes that can be useful for health decision making and planning.

The top priority in this domain is the national study on medicines utilisation. This study is vital to explore the pattern and trend of medicines used by Malaysians over the years. Results obtained are invaluable in fields related to disease prevalence and burden, disease treatment, medicines pricing and financing, as well as in investigation for new medicines. With the availability of new and more sophisticated data analysis methods, the methodology of this on-going study on medicine utilisation can be reviewed and strengthened to produce more accurate, representative and quality results that can be reported in a timely manner.

The research that utilise and optimise valuable healthcare database particularly big data should be planned and carried out more extensively. Due to the advancement in information technology, large amount of data on healthcare including patient outcomes can now be easily and rapidly collected. A big volume of statistics and indicators are also being collected regularly and stored at the national level, waiting to be studied. The analysis of these datasets may provide valuable information and evidence to decision makers. Data from various sources owned by individual health departments in the country can be integrated and harmonised to generate a single digitalised database which can be advantageous for research purposes. Data obtained can also be used to conduct research targeting specific population, such as special need patients, paediatric, geriatric, or specific diseases. The use of national patient registries to collect outcome data should also be explored. In addition, efforts should also be made to promote collaboration between different practices and ministries as well as public and private sectors in order to form comprehensive databases that can provide evidence that represents the entire population of the country.

Big data refers to datasets that are so massive and complicated that traditional computing methods and conventional data analysis tools are not capable of handling the information in a timely manner. The advancement of information technology and technology innovations had enabled the generation of huge amount of data. Major sources of big data include electronic patient medication record, insurance claims, medicines financing and purchasing records and national surveys. It is envisaged that big data analytics will contribute in accelerating clinical

trials, strengthening pharmacovigilance, advancing pharmaceutical care services, providing clinical decision support and predicting patient outcomes. Nevertheless, the lack of big data analytical skills among healthcare professional such as knowledge in big data technologies and platforms, mathematics and statistics, predictive analytics and decision-making models pose a major challenge to the advancement of big data analytics in the Malaysian health system^{27,28}. Moreover, it is necessary to keep up with the recent trends of big data analytics technology including the shift from static terminal environment to cloud-based big data, and from structured data to semi-structured data (e.g. telehealth, sensor-based wireless devices and home monitoring) and unstructured data (e.g. transcribed notes, images and video)²⁹. Therefore, more focus shall be paid to big data analytics from now on to harness the benefits of big data in health system improvement.

Studies related to medicines prices are ranked third, fourth and fifth in this domain. Medicines prices need to be monitored closely as well as factors that can affect them in both private and public health sectors. It is also essential to investigate the impact of medicine prices on the healthcare budget and system. Methodology of on-going studies and data collection related to medicines prices need to be strengthened from time to time to ensure the results obtained are robust and relevant to the current needs of decision makers.

3.5.2 Research Priority Framework

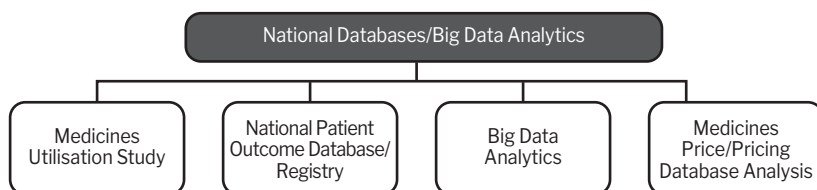


Figure 3.5: Research Priority Framework for ‘National Databases/Big Data Analytics’

²⁷ Stokes et al. 2016. Big Data: Implications for Health System Pharmacy. *Hospital Pharmacy* 51 (7), pp. 599-603.

²⁸ Hui-Qi See et al. 2018. Advancing Pharmacy Service using Big Data – Are We Fully Utilising the Big Data’s Potential Yet? *Journal of Pharmacy and Pharmaceutical Sciences* 21, pp. 217-221.

²⁹ Wang et al. 2018. Big data analytics: Understanding its capabilities and potential benefits for healthcare organizations. *Technological Forecasting & Social Change* 126, pp. 3–13.

3.5.3 Research Priority: National Databases/Big Data Analytics

National Problem/ Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
Medicines Utilisation Study	High quality reports from medicines utilisation study should be published in a timely manner. Currently, this is a challenge to the investigators.	<ul style="list-style-type: none"> Methodology of the study should be reviewed and improved to allow timely completion of the study. The most effective data collection methods should be applied, in particular to review data collection methods using data at dispensing level. 	<ul style="list-style-type: none"> Timely publications of results to be achieved in shorter duration of time. Availability of most up-to-date results to support decision making and promote research in other domains or scopes. More accurate results. 	1
National Patient Outcome Database/ Registry	It is a challenge to conduct research that requires huge and detailed patient data, for example study that explores the relationship between medicines utilisation and clinical outcomes, and epidemiology studies. This is largely due to the unavailability of comprehensive patients' clinical data. Furthermore, data from private sector are not accessible to researchers from public sector and vice versa.	<ul style="list-style-type: none"> All databases from different sources should be identified and assessed to determine data quality and consistency. Databases can be integrated to establish a national patient database. Researchers in academic field, community service, pharmaceutical industry and health authority can collaborate to conduct research that optimises the use of healthcare data. With the availability of healthcare databases, methodology of study on medicines utilisation can be revised to include more specific objectives. 	<ul style="list-style-type: none"> Findings obtained can be generalised to population. Results to guide planning for healthcare services and consequently optimise utilisation of healthcare resources. Outcomes of treatment using new and expensive medicines can be evaluated swiftly following the launch of new medicines and including effectiveness of medicines that cause high impact on budget. Commonly used medicines in paediatric, geriatric and on other diseases can be identified and findings will direct other researchers to conduct study on the clinical aspect of medicines. 	2

National Problem/ Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
Big Data Analytics	Enormous amount of data is generated in our health system through various information technology systems and health databases. In addition, the increasing use of health-related applications and even social media is also bringing about countless data on the people's health outcome, lifestyle and preferences. It is therefore imperative to embrace big data analytics to transform these data into useful information in real-time to support timely decision making and improve pharmaceutical care in Malaysia.	<ul style="list-style-type: none"> • To identify and analyse current and past big data projects in healthcare in Malaysia and in the region. • To evaluate big data capability³⁰ and gaps within the Pharmaceutical Services Programme and Ministry of Health Malaysia. • To evaluate existing databases in terms of sources, reliability, availability, fitness of the data and format of data (structured, semi-structured and unstructured form). • To identify potential big data projects that will be beneficial to the health system and population health outcome. • To evaluate ethical, legal, and regulatory challenges with data governance in big data analytics. 	<ul style="list-style-type: none"> • Proposals for policies, standards, and compliance requirements for big data analytics. • Strategies and implementation plans for the success of big data analytics. 	2

³⁰ Big data capability is the ability to acquire, store, process and analyse large amount of health data in various forms, and deliver meaningful information to users that allows them to discover business values and insights in a timely fashion (e.g. analytical capability, unstructured data analytical capability, decision support capability, predictive capability and traceability) (Wang et al. 2018, p.6).

Wang et al. 2018. Big data analytics: Understanding its capabilities and potential benefits for healthcare organizations. *Technological Forecasting & Social Change* 126, pp. 3–13.

National Problem/ Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
Medicines Price/ Pricing Database Analysis	Expenditure on medicines, both in public and private sectors, has escalated over the past years and caused huge burden to the government and patients.	<ul style="list-style-type: none"> • To monitor current medicine prices both in public and private sectors. • To determine variation of medicine prices, compare to international reference prices, and determine the margin of profit in private sector. • To compare medicine prices over years to identify pattern of price changes in different sectors, healthcare settings, by diseases and other factors. 	<ul style="list-style-type: none"> • Information about variation of medicine prices, differences by sectors, regions, years, origin, and other factors. • Determination of availability and affordability of medicines by diseases and patient groups. 	3
	Price variation across the entire market observed. Medicine prices vary not only between sectors, but also across the same type of practices in private sector.	<ul style="list-style-type: none"> • To identify characteristics of medicine price setting in private sector. • To identify factors related to medicines price variations in private practice. • To determine profit margins or mark-up of medicines prices and its associated factors, by private healthcare practitioners in various setting. 	<ul style="list-style-type: none"> • Factors that affect medicines price at different practices in private sector, in particular in community pharmacies and approaches to monitor or control medicines prices. • Information to support decision making by policy maker in medicines price setting or price negotiation. • Improved transparency in medicine prices. Patients and the healthcare industry will be better informed of medicines prices. 	4

National Problem/ Research Scope	Gaps & Needs (Rationale)	Suggested Research Area	Expected Output	Relative Rank
	Monitoring of medicines cost, in particular cost per prescription had been conducted. There is a need to study on factors that influence cost of medicines prescribed in both public and private sector and the financial impact to the patients.	<ul style="list-style-type: none"> • To review the methodology of current study on cost per prescription to answer more specific objectives such as cost per prescription in different patient groups, diseases, geographical regions and types of facility. • To investigate factors affecting cost of medicines per prescription in both public and private sector. • To identify the financial impact of prescription costs on the patients. 	<ul style="list-style-type: none"> • Information about cost per prescription in different patient groups, diseases, geographical regions and types of facility. • Factors affecting cost of medicines per prescription and the financial impact of prescription costs on the patients. • Information to support decision-making related to medicines price, mark-up, co-payment, dispensing fee, etc. 	5

PHARMACY RESEARCH
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CONCLUSION



4.0 CONCLUSION

The Pharmacy Research Priorities in Malaysia aspires to provide clear guidance for pharmacy research activities towards generation of useful evidence that is relevant to the national health priorities. Individuals and healthcare organisations are encouraged to refer to the outlined research priority areas when planning and designing their researches. These research priorities are applicable to all institutions that conduct pharmacy researches in Malaysia including the Ministry of Health, universities, Ministry of Defence, pharmaceutical industry, community pharmacies as well as pharmacy students.

The research priorities stipulated in this document shall be the key focus for pharmacy research in the next few years, depending on the pace of the profession's evolution, national health problems and global challenges in pharmacy services. The Pharmaceutical Services Programme will continue to be vigilant on the relevance and applicability of these priority areas. Whenever necessary, the Pharmacy Research Priorities in Malaysia will be reviewed accordingly, incorporating new domains that emerge in the future.

ACKNOWLEDGEMENT

The secretariat would like to express our appreciation to the Senior Director of Pharmaceutical Services, Director of National Pharmaceutical Regulatory Agency, Director of Pharmacy Practice and Development and Director of Pharmacy Policy and Strategic Planning for their continuous support in setting the Pharmacy Research Priorities in Malaysia. We would also like to thank the members of the Pharmacy Research Priorities Working Committee, all stakeholders and everyone who have contributed in the publication of this document.

PHARMACY RESEARCH
P R I O R I T I E S
— in Malaysia

ANNEX



ANNEX 1: Format of Survey Form for Identification of Areas Requiring Research

1. Please classify your proposed and planned research project(s) by your organization according to the most appropriate RESEARCH DOMAINS as listed in the Section A of this questionnaire.

(Note: Please refer Figure 1 on Section A)

No.	Research Domain	A	B	C	D	E	F
		National Problems (Document referred to)	What do you need to know?	Research Scope	Gaps & Needs (Rationale)	Suggested Research Areas	Expected Outputs
1							
2							
3							
4							

References

1.	
2.	

Guide to complete this form:

- For each of the five research domains (Figure 1), identify issues of concerns that requires research/evidence to help in achieving the goals for that research domain in the future.
- Please make sure that ALL columns are completed.
- Please insert the references you have referred to in the References table.

Note: If the research does not fall in any of the existing domains, a new domain can be suggested, if appropriate, and marked (new).

2. Please classify your current and on-going research project(s) in your organization according to the most appropriate RESEARCH DOMAINS as listed in the Section A of this questionnaire.

(Note: Please refer Figure 1 on Section A)

No.	Research Title	A	B	C	D	E
		National Problems (Document referred to)	Expected Outputs	Research Domain	Research Scope	Gaps & Needs (Rationale)
1						
2						
3						
4						

References

1.	
2.	

Guide to complete this form:

1. For column C, select one out of the five research domains from Figure 1 that suits best, otherwise write your suggestion of research domain that is applicable.
2. Please make sure that ALL columns are completed.
3. Please insert the references you have referred to in the References table.

Note: If the research does not fall in any of the existing domains, a new domain can be suggested, if appropriate, and marked (new).

ANNEX 2: List of Stakeholders Who Contributed to List the Research Areas

Bil.	Institution/ Organization	Stakeholders	Public/ Private
01	Pharmaceutical Services Programme	Deputy Director of Pharmacy Practice and Development (Pharmacy Logistics)	Public
02	Pharmaceutical Services Programme	Deputy Director of Pharmacy Practice and Development (Management of Medicine Price)	Public
03	Pharmaceutical Services Programme	Deputy Director of Pharmacy Policy and Strategic Planning (Research and Development)	Public
04	Hospital Kuala Lumpur	Pharmacists	Public
05	Hospital Pulau Pinang	Pharmacists	Public
06	Hospital Seberang Jaya	Pharmacists	Public
07	Hospital Sibu	Pharmacists	Public
08	Hospital Miri	Pharmacists	Public
09	Hospital Simunjan	Pharmacists	Public
10	Selangor State Health Department	Pharmaceutical Services Division	Public
11	Sabah State Health Department	Pharmaceutical Services Division	Public
12	Bahagian Perubatan Traditional & Komplementari	Pharmacists	Public
13	Ihsr	Pharmacists	Public
14	Health Technology Assesment Moh	Pharmacists	Public
15	Higher Education	Universiti Sains Malaysia	Public
16	Higher Education	Universiti Kebangsaan Malaysia	Public
17	Higher Education	International Islamic University Malaysia	Public
18	Higher Education	Asian Institute of Medicine, Science & Technology (Aimst) University	Private

Bil.	Institution/ Organization	Stakeholders	Public/ Private
19	Clinical Research Centre	Pharmacists	Public
20	Ministry of Defense	Brigadier General Dato' Dr. A Halim Bin Basari	Public
21	NGO	Malaysia Pharmaceutical Society (Mps)	Private
22	NGO	Pharmaceutical Association of Malaysia (Phama)	Private

ANNEX 3: Criteria for Scoring and Ranking

Criteria	Answerability & Feasibility	Importance/ Potential Impact	Magnitude/ Severity
Clarification/ Explanation	1. Can a study(ies) be designed to provide a practical solution/outcome?	1. Will the results of this research fills an important knowledge gap in achieving national goal?	1. Is the problem common in terms of burden to the healthcare system/ community?
	2. Will there be sufficient capacity to carry out this research?	2. Are the results from this research likely to shape future planning and implementation (e.g. policy, programme)?	2. Is the problem severe to the healthcare system/ community?
	3. Is the cost and time required for this research reasonable?	3. Are the results of the research likely to be beneficial?	3. Is data urgently needed for decision making?

**This criteria is adopted from National Institutes of Health (NIH) Malaysia*