
AUSTRALIAN GOVERNMENT DEPARTMENT OF
HEALTH

Implementation Review of the Pharmacy Trial Program

FINAL REPORT

18 NOVEMBER 2019

TABLE OF CONTENTS

ABBREVIATIONS	I		
EXECUTIVE SUMMARY	IV		
PART A	1	PART B	19
CONTEXT		REVIEW FINDINGS	
1	2	4	20
INTRODUCTION		APPROPRIATENESS	
1.1	2	4.1	20
BACKGROUND		EVALUATION QUESTIONS	
1.2	2	4.2	20
OBJECTIVES OF THE IMPLEMENTATION REVIEW		4.2.1	20
1.3	3	Alignment of PTP objectives with 6CPA	
REPORT STRUCTURE		4.2.2	22
		Barriers to expanding pharmacist roles into provision of services	
2	4	4.2.3	23
SITUATION ANALYSIS		Promotion of interdisciplinary collaboration among primary health care professionals through the PTP	
2.1	4	4.2.4	23
PHARMACY TRIAL PROGRAM		Limited existing grant opportunities to address the PTP objectives	
2.2	6	4.2.5	24
POLICY CONTEXT		Achieving the expected outcomes without PTP funding	
2.3	7	4.3	25
CHANGING LANDSCAPE OF PHARMACY IN PRIMARY CARE		CONCLUSION	
2.4	9		
FUNDING OF PRIMARY HEALTH CARE		5	26
		EFFECTIVENESS	
3	14	5.1	26
REVIEW METHODOLOGY		EVALUATION QUESTIONS	
3.1	14	5.2	27
PROGRAM LOGIC AND KEY REVIEW AREAS		5.2.1	27
3.2	16	Stakeholder engagement processes	
DOCUMENTATION REVIEW AND OTHER CONTEXTUAL INFORMATION		5.2.2	28
		Trials Advisory Group	
3.3	16	5.2.3	30
CONSULTATION WITH STAKEHOLDERS		Suitability of the program length	
3.4	18		
SURVEY OF PHARMACISTS			
3.5	18		
TRIANGULATION OF INFORMATION			

5.2.4	Suitability of the application processes	32
5.2.5	Appraisal and selection processes	33
5.2.6	Transparency of decision-making	34
5.2.7	Fostering an outcomes orientation for PTP trials	36
5.2.8	Roles and responsibilities	37
5.2.9	Suitability of record keeping and performance measures	37
5.2.10	Completion of trials within the term of the 6CPA	38
5.2.11	Process for proceeding to health technology assessment	38
5.3	CONCLUSION	39
6	EFFICIENCY	41
6.1	EVALUATION QUESTIONS	41
6.2	ANALYSIS AND FINDINGS	41
6.2.1	Equity of the PTP processes	41
6.2.2	Rigour of the evidence base	42
6.3	CONCLUSION	44
PART C	FUTURE DIRECTIONS	45
7	APPROACH TO EMERGING THEMES: POSSIBLE DIRECTIONS	46
7.1	EMERGING THEME 1: BROADENING THE PTP OBJECTIVES	46
7.1.1	Issue	46
7.1.2	Rationale	46
7.1.3	Options	47
7.2	EMERGING THEME 2: GREATER CONSIDERATION OF CONSUMER VIEWS	48
7.2.1	Issue	48
7.2.2	Rationale	48
7.2.3	Options	49

7.3	EMERGING THEME 3: CHANGED PROGRAM ADMINISTRATION ARRANGEMENTS	50
7.3.1	Issue	50
7.3.2	Rationale	50
7.3.3	Options	50
8	APPENDICES	52
9	REFERENCES	58

ABBREVIATIONS

ABBREVIATION	DEFINITION
6CPA	Sixth Community Pharmacy Agreement
AACP	Australian Association of Consultant Pharmacists
ACCHO	Aboriginal Community Controlled Health Organisation
ACCHS	Aboriginal Community Controlled Health Service
ACRRM	Australian College of Rural and Remote Medicine
ADHA	Australian Digital Health Agency
AHPA	Allied Health Professionals Australia
AIHW	Australian Institute of Health and Welfare
AMA	Australian Medical Association
AMS	Aboriginal Medical Service
Asthma Trial	Getting Asthma Under Control Trial
CGRG	Commonwealth Grants Rules and Guidelines
CHF	Consumers Health Forum of Australia
CPA	Community Pharmacy Agreement

ABBREVIATION	DEFINITION
CVD Trial	Early Detection and Management of Cardiovascular Disease Risk Factors and Chronic Disease Markers in Community Pharmacy Trial
DALY	Disability adjusted life year
Department	The Australian Government Department of Health
Diabetes Screening Trial	Pharmacy Diabetes Screening Trial
EOI	Expressions of Interest
ePIP	Practice Incentives Program eHealth Incentive
ESC	Evaluation Sub-Committee
GP	General practitioner / general practice
Guild	The Pharmacy Guild of Australia
HMA	Healthcare Management Advisors
HMR	Home Medicines Review
HMRO	Health and Medical Research Office
HTA	Health Technology Assessment

ABBREVIATION	DEFINITION
IMeRSe Feasibility Study	Improved Medication Management for Aboriginal and Torres Strait Islanders Feasibility Study
IPAC Project	Integrating Practice Pharmacists into Aboriginal Community Controlled Health Services Project
MBS	Medicare Benefits Schedule
MRFF	Medical Research Future Fund
MSAC	Medical Services Advisory Committee
NACCHO	National Aboriginal Community Controlled Health Organisation
NHMRC	National Health and Medical Research Council
NMHCCF	National Mental Health Consumer and Carer Forum
NMP	National Medicines Policy
NPS	National Prescribing Service
NRHA	National Rural Health Alliance
PA	Pain Australia
PASC	PICO Advisory Sub-Committee
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme

ABBREVIATION	DEFINITION
PharMIbridge Trial	Bridging the Gap between Physical and Mental Illness in Community Pharmacy Trial
PHN	Primary Health Network
PICO	Population, Intervention, Comparator, Outcomes
PLAC	Prostheses List Advisory Committee
PSA	Pharmaceutical Society of Australia
PSML	Pharmacists Shared Medicines List
PTP	Pharmacy Trial Program
QALY	Quality adjusted life year
QUM	Quality Use of Medicines
R&D	Research and Development
RACF	Residential Aged Care Facility
RACGP	The Royal Australian College of General Practitioners
RCT	Randomised controlled trial
ReMInDAR Trial	Reducing Medicine Induced Deterioration and Adverse Reactions Trial
RMMR	Residential Medication Management Review

ABBREVIATION	DEFINITION
SHPA	Society of Hospital Pharmacists of Australia
TAAD	Technology Assessment and Access Division
TAG	Trials Advisory Group
TGA	Therapeutic Goods Administration

EXECUTIVE SUMMARY

BACKGROUND

The Australian Government Department of Health (Department) engaged Healthcare Management Advisors (HMA) to:

‘Review the implementation of the Pharmacy Trial Program (PTP) under the Sixth Community Pharmacy Agreement (6CPA)’

The Pharmacy Trial Program (PTP) is a component (clause 6.1.4) of the Community Pharmacy Programmes of the Sixth Community Pharmacy Agreement (6CPA). This includes an investment of \$50 million for the PTP to trial new and expanded Community Pharmacy Programmes, which seek to improve clinical outcomes for consumers and/or extend the role of pharmacists in the delivery of primary health care services through community pharmacy. [1]

The objective of the PTP was to:

‘Improve clinical outcomes for consumers by extending the role of pharmacists in the delivery of effective and cost-effective primary health care services.’

Implementation review

The objectives of the implementation review were to:

- inform and assess the appropriateness of the PTP including identifying the alignment between the program response (administrative activities and outputs) and the intended outcomes;
- identify early insights into implementation, including lessons learnt, potential design issues and opportunities for program improvement, and
- provide recommendations and/or options for possible enhancements or improvements to the design and implementation of the PTP.

The three key review questions were as follows:

- (1) Is the program the appropriate response for the program’s objectives? (Appropriateness)
- (2) How well is the PTP being delivered and is it working as expected? (Effectiveness)
- (3) What alternative models could be considered to improve clinical outcomes for consumers by extending the role of pharmacists in the delivery of cost effective primary health care services? (Efficiency)

PTP priority areas

The PTP was conducted as three tranches. The priority areas selected for each tranche were:

- **Tranche 1 topics:**
 - pharmacy-based screening and referral for diabetes;
 - improved medication management for Aboriginal and Torres Strait Islander people through pharmacist advice and culturally appropriate services, and
 - improved continuity in the management of patients’ medications when they are discharged from hospital.
- **Tranche 2 priorities:**
 - community pharmacist outreach to residential aged care facilities;
 - medicines management and medicines reconciliation services;
 - disease management for appropriate conditions, and
 - screening and referral by pharmacists for cardiovascular risk.
- **Tranche 3 trials** were targeted grant opportunities.

In addition, it was intended that the Community Pharmacy Programmes, including the PTP, would have a focus on benefits for:

- Aboriginal and Torres Strait Islander people, and
- Consumers in rural and remote areas. [1]

At the time of this review (February to June 2019), seven trials had signed funding agreements, as follows:

- Tranche 1
 - Pharmacy Diabetes Screening Trial (Diabetes Screening Trial)
 - Indigenous Medication Review Service Feasibility Study (IMeRSe Feasibility Study)
- Tranche 2
 - Integrating Practice Pharmacists into Aboriginal Community Controlled Health Services Project (IPAC Project)
 - Getting Asthma Under Control Trial (Asthma Trial)
 - Reducing Medicine Induced Deterioration and Adverse Reactions Trial (ReMInDAR Trial)
 - Early Detection and Management of Cardiovascular Disease Risk Factors and Chronic Disease Markers in Community Pharmacy Trial (CVD Trial), and
- Tranche 3
 - Chronic Pain MedsCheck Trial.

Changing landscape of pharmacy in primary care

Primary health care has an integral role in supporting the health and wellbeing of Australians and can be delivered by a variety of health professionals, including general practitioners, nurses, nurse practitioners, allied health professionals, midwives, pharmacists, dentists, and Aboriginal and Torres Strait Islander health workers.

Medication misadventure has been identified as a key issue for health and wellbeing, with approximately 125,000 Australians admitted to hospital annually for potentially preventable issues relating to medicine safety, including adverse reactions.

Proper medication management requires an interdisciplinary approach with pharmacists as a key member of the primary care team. The scope and range of services provided by pharmacists has expanded over the last 30 years, with the introduction of Community Pharmacy Programmes in successive CPAs. This has also enabled pharmacists to extend services beyond the retail pharmacy outlet into people's homes (Home Medicines Review Program) and residential aged care facilities (Residential Medication Management Review Program).

In addition, advances in e-health impact on the capacity of pharmacists to deliver services to consumers. For example, My Health Record is designed to equip pharmacists with additional information to provide greater patient care, especially during transition of care (from the hospital to the community and vice versa) when medication errors are most likely to occur.

Funding of primary health care

Increasingly, the Australian Government is requiring ongoing evaluation of existing services and an improved evidence base for funding future services. Therefore, new models of care and services delivery must have robust evidence to demonstrate their clinical effectiveness as well as expected economic benefits for implementation. As such, the trials implemented under the PTP are required to include robust clinical evidence and an economic assessment. Evaluations of the trials are expected to estimate costs to implement an ongoing program.

METHOD

The implementation review of the PTP was undertaken in five stages, as follows:

- (1) Development of a program logic and key review areas
- (1) Review of relevant documentation
- (2) Consultation with stakeholders

- (3) Online survey of pharmacists, and
- (4) Triangulation of evidence to identify findings and potential future options for the PTP, should it continue, into a final report.

SUMMARY OF REVIEW FINDINGS

Appropriateness

Key Finding 1: Funding of a program for service delivery trials is an appropriate response for the stated objectives of the PTP, which are to improve clinical outcomes for consumers, and/or extend the role of pharmacists in the delivery of primary health care services through community pharmacy. This is evidenced by the sector support to expand pharmacy service delivery, including greater collaboration with other health care professionals. The PTP is not duplicative of other research funding and aligns with the evidence building approach of the National Strategy for Quality Use of Medicines and the principles of the National Medicines Policy that support the 6CPA. It seems unlikely that the expected outcomes of the PTP could be achieved without the financial support for trials offered by the program.

Evidence suggests that research to validate the clinical and economic effectiveness of new or expanded Community Pharmacy Programmes is appropriate and that there was support for the objectives of the PTP among the community pharmacy and broader pharmacy sector. Many stakeholders expressed interest in a broader interpretation of the PTP objectives to include alternative locations of service delivery within the community and engagement of consultant pharmacists in addition to community pharmacists. Although PTP trials linked into general practice via referral or case conferencing, interdisciplinary collaboration was an area noted by professional and advocacy peak bodies that could be strengthened.

There were mixed views among stakeholders as to whether the expected outcomes of the PTP would be achieved without PTP funding, depending on the nature of the individual trial. Considering the limited funding specifically available for health service research in pharmacy through other research grant programs, it is unlikely that PTP objectives would be achieved without the dedicated funding provided by the PTP. Given the limited capacity of community pharmacy to implement programs without financial incentives for staff time, expanding programs would be challenging without funding for trials.

The review concluded that funding of a program for service delivery trials is an appropriate response for the stated objectives of the PTP, which are to improve clinical outcomes for consumers, and/or extend the role of pharmacists in the delivery of primary health care services through community pharmacy.

Effectiveness

Key Finding 2: Setting of PTP priority areas included reference to expert opinion and stakeholder consultation. Increased engagement of consumer groups from a broader range of health needs perspectives may further enhance trial design in the future. Further focus on the needs of consumers in rural and remote areas could also be considered.

Key Finding 3: Issues that delayed implementation of PTP milestones included the unanticipated time required to refine trial protocols to meet requirements of prospective independent health technology assessment (HTA). Factors that could streamline implementation include increased clarity of application processes to reduce ineligible applications and further documentation of administrative processes associated with decision making.

Key Finding 4: At the time of the evaluation conclusion, seven trials had signed funding agreements, and an additional trial had approval from the Minister for Health to be undertaken in 2019–20 financial year. One trial was completed and five more are scheduled to be completed by the end of the 6CPA. As at June 2019, no trial had undergone an independent HTA. The selected HTA advisory body should consider the service delivery nature and qualitative consumer experience aspects of the PTP trials as part its assessment.

Program development processes

The Department undertook several processes to seek stakeholder input into development and design of the PTP and setting priority areas. This included a stakeholder forum, a ‘call for ideas’ and convening a Trials Advisory Group (TAG). Many professional and advocacy peak bodies would have liked greater engagement in the developmental stages. In addition, stakeholder engagement diminished when the TAG ceased meeting prior to the submission of grant applications under Tranche 2.

Trial design and selection processes

The term of the 6CPA was sufficient time to develop guidelines and processes and implemented at least one tranche of trials. Unexpected delays encountered in protocol development stages led to truncated trial implementation time. Combined with time required for ethics approval, shortened implementation times may have affected trial recruitment and hence potential outcomes that were achievable in the life of the agreement.

Administrative processes

The administrative processes of the PTP were guided by the *Commonwealth Grant Rules and Guidelines*; the PTP grant guidelines met those requirements. There are several areas of the program guidelines that could be strengthened in the future, such as increased clarity of application processes to reduce ineligible applications,

and further documentation of administrative processes associated with decision making.

Program outputs

It is likely that only one PTP trial will undergo an independent HTA during the term of the 6CPA.

Efficiency

Key Finding 5: Implementing RCT methodologies can be challenging in the context of service delivery trials in the community. Approval of PTP study design should be guided by an assessment of whether the proposed method is appropriate and sufficiently robust to enable an independent HTA upon completion.

There is a need for PTP trials to undergo an evaluation of clinical and economic merit before they can justify a submission for a broader rollout. Typically, these evaluations require rigorous evidence, such as that provided by RCTs. The PTP processes generally favoured an approach to trial development that emphasised use of RCTs.

An RCT methodology presented challenges for PTP trials that have a particular focus on interventions which benefit Aboriginal and Torres Strait Islander peoples.

PART A

CONTEXT

1 INTRODUCTION

In response to a greater focus on primary care across the health system and changing consumer expectations surrounding service delivery and access, the Australian Government and the community pharmacy sector recognised an opportunity to expand the role of community pharmacy to meet the needs of the population. This goal was reflected in the design of the PTP funded under the 6CPA.

The Department engaged Healthcare Management Advisors (HMA) to:

‘Review the implementation of the Pharmacy Trial Program (PTP).’

1.1 BACKGROUND

The PTP is a component (clause 6.1.4) of the Community Pharmacy Programmes of the 6CPA. Funding for Community Pharmacy Programmes was approved by the Minister for Health, following consultation by the Department with a range of stakeholders (including the Pharmacy Guild of Australia (the Guild)), and is expected to be up to \$1.26 billion over the term of the 6CPA from 1 July 2015 to 30 June 2020 (Term). The expected allocation is as follows:

- be at a level of \$613 million over the Term as continued investment in a range of Community Pharmacy Programmes;
- be at a level of \$50 million over the Term as funding for the PTP to trial new and expanded Community Pharmacy Programmes, which seek to improve clinical outcomes for consumers and/or extend the role of pharmacists in the delivery of primary health care services through community pharmacy; and
- include access to additional funding of up to \$600 million over the Term to support new and expanded Community Pharmacy Programmes which are intended to be delivered through community pharmacies [1].

In July 2017 a compact to the 6CPA was signed. The amended and restated 6CPA reallocated the \$600 million originally held in a contingency reserve to support new

and expanded Community Pharmacy Programs. As of 1 July 2017, the \$600 million was committed to support the following Community Pharmacy Programmes:

- Dose Administration Aids (\$340 million);
- Staged Supply (\$80 million);
- Expansion of MedsCheck and Diabetes MedsCheck (\$90 million);
- Home Medicines Review (\$60 million); and
- Incorporating medication management programs within Health Care Homes (\$30 million). [1]

1.2 OBJECTIVES OF THE IMPLEMENTATION REVIEW

The objectives of the implementation review were to:

- inform and assess the appropriateness of the PTP, including identifying the alignment between the program response (administrative activities and outputs) and the intended outcomes;
- identify early insights into implementation, including lessons learnt, potential design issues and opportunities for program improvement; and
- provide recommendations and/or options on possible enhancements or improvements to the design and implementation of the PTP.

The three key review questions were as follows:

- (1) Is the program the appropriate response for the program’s objectives? (Appropriateness)
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-
- (3) What alternative models could be considered to improve clinical outcomes for consumers by extending the role of pharmacists in the delivery of cost effective primary health care services? (Efficiency)

1.3 REPORT STRUCTURE

This report presents the findings of the Implementation Review of the PTP and is structured as follows:

- Part A: Context
 - Introduction (this chapter)
 - Situation Analysis (Chapter 2)
 - Review methodology (Chapter 3)
- Part B: Review findings
 - Appropriateness (Chapter 4)
 - Effectiveness (Chapter 5)
 - Efficiency (Chapter 6)
- Part C: Future directions

Approach to emerging themes: possible directions (Chapter 7).

2 SITUATION ANALYSIS

2.1 PHARMACY TRIAL PROGRAM

The PTP aims to:

- (1) improve clinical outcomes for consumers; and/or
- (2) extend the role of pharmacists in the delivery of primary health care services through community pharmacy [1].

The alternative models of care explored through the trials under the PTP are intended to:

- use an integrated care approach to improve health outcomes for consumers or patients;
- support innovation in pharmacy;
- develop activities or programs that could potentially be rolled out nationally, and if so, in what circumstances, subject to an assessment of their comparative safety, clinical effectiveness and cost-effectiveness using best available evidence. The trialed service would also need to satisfy funding priorities as determined by the Minister;
- undergo continued improvement through an iterative process with opportunities for consultation; and
- provide opportunities for the expansion or improvement of existing 6CPA programs and services. [2].

Priority areas of the Pharmacy Trial Program

The PTP has been conducted under three tranches. Priority research areas for the PTP were based on stakeholder consultation including:

- a stakeholder meeting on 26 October 2015 with a large range of peak bodies and representative organisations;
- bilateral meetings with over 20 key stakeholder groups in 2016; and

- 108 submissions to a call for ideas from the release of a discussion paper, 'Supporting pharmacist delivery of primary health care services through the Pharmacy Trial Programme' between 17 March and 29 April 2016 [3].

The PTP priorities areas selected for each tranche were:

- **Tranche 1** topics:
 - pharmacy-based screening and referral for diabetes;
 - improved medication management for Aboriginal and Torres Strait Islander people through pharmacist advice and culturally appropriate services; and
 - improved continuity in the management of patients' medications when they are discharged from hospital.
- **Tranche 2** priorities:
 - community pharmacist outreach to residential aged care facilities (RACFs);
 - medicines management and medicines reconciliation services;
 - disease management for appropriate conditions; and
 - screening and referral by pharmacists for cardiovascular risk.
- **Tranche 3** trials are further targeted grant opportunities.

In addition, it was intended that the Community Pharmacy Programmes, including the PTP, would have a focus on benefits for:

- Aboriginal and Torres Strait Islander people; and
- Consumers in rural and remote areas [1].

A summary of the PTP trials that are the subject of this Review is provided in Table 2.1. A further trial under Tranche 3 was announced in March 2019. The Bridging the Gap between Physical and Mental Illness in Community Pharmacy Trial (PharMIbridge Trial) will commence in the 2019–20 financial year.

Table 2.1 Summary of PTP trials

TRANCHE	RECIPIENT	TRIAL NAME	TRIAL LOCATION SITES	AGREEMENT DATE	VALUE (EXCL. GST)
1	The Pharmacy Guild of Australia (the Guild)	Pharmacy Diabetes Screening (Diabetes Screening Trial)	National	5 May 2016	\$3.05 million
		Improved Medication Management for Aboriginal and Torres Strait Islanders Feasibility Study (IMeRSe Feasibility Study)	QLD, NSW, NT	17 October 2017	\$3.47 million
2	Pharmaceutical Society of Australia (PSA)	Integrating Practice Pharmacists into Aboriginal Community Controlled Health Services (IPAC Project)	QLD, VIC, NT	20 December 2017	\$5 million
	Woolcock Institute	Getting Asthma Under Control (Asthma Trial)	NSW, WA, Tas	3 November 2017	\$2.07 million
	University of South Australia	Reducing Medicine Induced Deterioration and Adverse Reactions (ReMInDAR) Trial	SA, TAS	6 April 2018	\$2.85 million
	Black Swan Health	Early Detection and Management of Cardiovascular Disease Risk Factors and Chronic Disease Markers in Community Pharmacy (CVD Trial)	WA	13 June 2018	\$2.04 million
3	The Guild and PSA	Chronic Pain MedsCheck Trial	National	11 April 2018	\$20.85 million (the Guild) \$500,000 (PSA)
Total value of PTP funds awarded at March 2019					\$39.83 million

Source: Internal Audit Report: Audit of the Management of the Pharmacy Trial Program under the Sixth Community Pharmacy Agreement, page 6 [4]

2.2 POLICY CONTEXT

National Medicines Policy

The National Medicines Policy (NMP) was established in 2000 as a partnership between governments, health educators, health practitioners and other health care providers and suppliers, the medicines industry, health care consumers, and the media [5]. The aim of the NMP is to meet medication and related service needs, so that both optimal health outcomes and economic objectives are achieved. The central objectives of the policy are:

- timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- medicines meeting appropriate standards of quality, safety and efficacy;
- quality use of medicines; and
- maintaining a responsible and viable medicines industry [5].

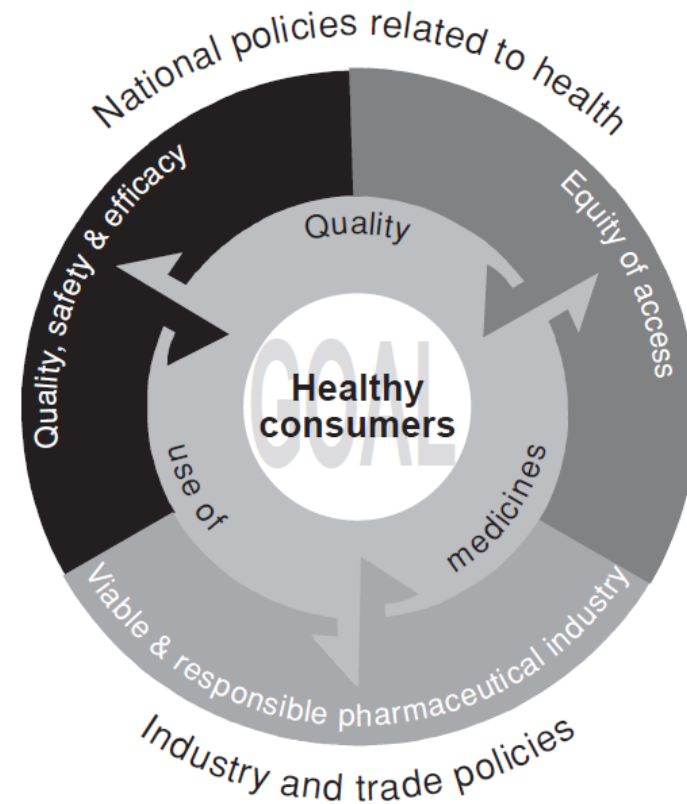
The 6CPA supports the NMP as detailed in Section 3: Pharmaceutical Benefits Scheme (PBS) Access and Sustainability Package¹ that seeks to establish pharmacy funding and medicines pricing arrangements and a range of sector improvements [1]. The funding arrangements noted in the 6CPA seek to:

- ensure consumers can continue to have access to new and innovative PBS subsidised medicines at an affordable price;
- promote and improve the quality use of medicines; and
- ensure a cost-effective and sustainable PBS² [1].

Quality use of medicines

Quality use of medicines (QUM) is one of the four objectives of the NMP. In 2002, the National Strategy for QUM was established and integrates with the strategies for the other NMP objectives as shown in Figure 2.1 [6].

Figure 2.1: Relationship of Quality Use of Medicines to other National Medicine Policy objectives



Source: National Strategy for Quality Use of Medicine, Plain English Version, page 4 [6]

QUM recognises the joint responsibility of key partners, which includes consumers, health practitioners, government and the pharmaceutical industry, for the safe and effective use of medicines in Australia [6]. However, there is an emphasis placed on the pivotal role of practitioners in promoting QUM through:

¹ 6CPA, pages 7–10

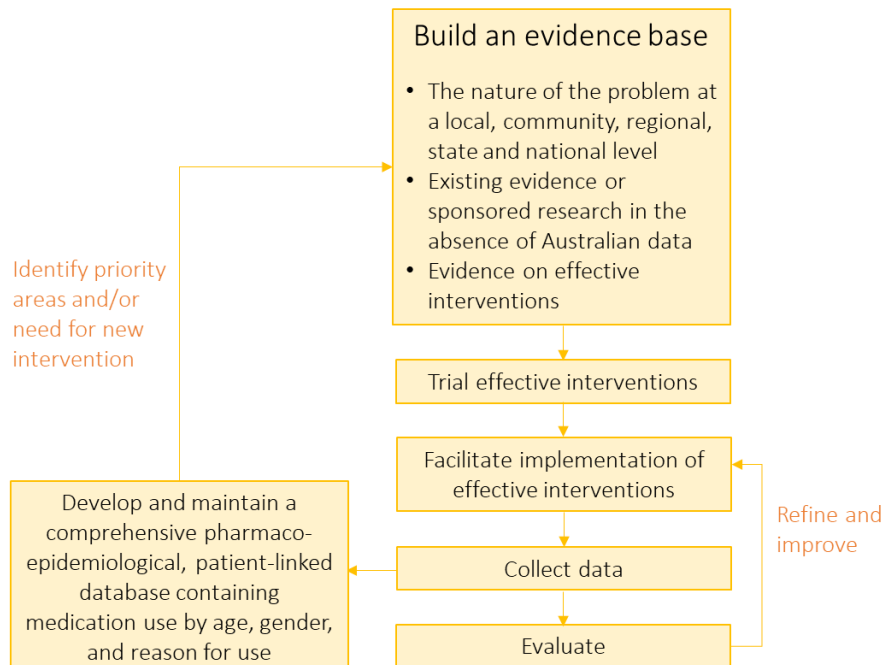
² 6CPA, page 3

- making well-informed choices on treatment;
- communicating with consumers;
- collaborating with other health practitioners outside of their own discipline
- developing and implementing models of best practice; and
- maximising professional roles to provide optimal contribution [5].

The Strategy highlights a need to undertake strategic research for the development of QUM initiatives that includes building the evidence base, trialling evidence-based interventions and the monitoring and evaluation of effective interventions [6].

The relationship between the actions described by the National Strategy are illustrated in Figure 2.2.

Figure 2.2 Strategic research, evaluation and routine data collection to support the development of QUM initiatives



Source: Adapted from Commonwealth Department of Health (2002) 'National Strategy for Quality Use of Medicines'

The principles within the National Strategy for QUM are applicable to the PTP. The focus on research and evaluation is consistent with the intended outcomes of the PTP to provide robust clinical and economic evidence prior to funding ongoing programs.

2.3 CHANGING LANDSCAPE OF PHARMACY IN PRIMARY CARE

In the latest report on Australia's Health (2018), the Australian Institute of Health and Welfare (AIHW) notes that, although Australians are living longer, half are living with at least one chronic condition, which collectively are the leading causes of ill health in Australia [7]. Accordingly, primary health care has an integral role in supporting the health and wellbeing of Australians. Primary health care is typically a person's first contact with the health system [8], and can be delivered by a variety of health professionals, including general practitioners (GPs), nurses, nurse practitioners, allied health professionals, midwives, pharmacists, dentists, and Aboriginal and Torres Strait Islander health workers.

Medicare Benefits Schedule (MBS) and PBS data indicated that in 2018, approximately 148.2 million visits were made to a GP and approximately 283.6 million prescriptions were filled (under the PBS) in Australia [9]. Extrapolation of this information would suggest an average of two prescriptions are filled per GP visit. This demonstrates the important relationship between GP and pharmacist in the management of primary health care.

Medication misadventure and non-dispensing pharmacist roles

It is estimated that approximately 125,000 Australians are admitted to hospital annually for potentially preventable issues relating to medicine safety including adverse reactions [10]. In 2019, the Pharmaceutical Society of Australia (PSA) report on medicines safety identified four key issues related to medicine safety in Australia. These were:

- hospital admissions due to medicine misuse;

- poor hospital discharge processes;
- medication management in residential aged care; and
- adverse medication reactions within the community [10].

Proper medication management requires an interdisciplinary approach with pharmacists as key members of the primary care team. The scope and range of services provided by pharmacists has expanded over the last 30 years, with the introduction of Community Pharmacy Programmes in successive CPAs. This has also enabled pharmacists to extend services beyond the retail pharmacy outlet into people's homes (Home Medicine Reviews) and RACFs (Residential Medication Management Reviews (RMMRs)). This recognises the potential value of extending pharmacy services into active medicines management interventions with the aim of improving consumer health outcomes [11].

The Australian Government recognises the important role that the pharmacy profession plays in primary health care and in improving patient health outcomes. For example, the Community Pharmacy in Health Care Homes Trial Program is an initiative (funded under the 6CPA) to support the incorporation of medication management planning and programs within Health Care Homes [12]. Health Care Homes aims to provide better management of chronic conditions through coordinated, integrated care, provided at the usual GP clinic or Aboriginal Community Controlled Health Service (ACCHS) [13]. Community pharmacy's role in Health Care Homes is to conduct an initial reconciliation of the patient's medications and develop a collaborative Medication Management Plan [12]. Within this trial, community pharmacists provide services in the GP clinic setting. Health Care Homes is being trialled in ten Primary Health Networks (PHNs) across Australia.

Use of non-dispensing pharmacists within GP clinics is supported by the Australian Medical Association (AMA) [14] and the PSA [15]. In addition to the Health Care Homes trials, numerous PHNs across Australia are also investigating the effectiveness of having non-dispensing pharmacists in GP clinics, including North Western Melbourne PHN, Eastern Melbourne PHN, and the Australian Capital Territory PHN.

The PSA also supports the integration of pharmacists into residential aged care due to the high prevalence of medication related issues in this setting [10].

Trialling of non-dispensing pharmacist roles expands the capacity of services that pharmacists could deliver in primary health care in future. The challenge will be to ensure the workforce and funding streams are available, and that the model enhances, but does not compete, with existing community pharmacy models.

Digital Health – My Health Record

The Australian Government has invested in electronic medical records (My Health Record). My Health Record is a secure online summary of an individual's health information [16]. As at February 2019, there was a 90 per cent participation rate for My Health Record and over 15,000 health care provider organisations registered, including 4,609 pharmacies [17].

My Health Record is designed to equip pharmacists with additional information to provide greater patient care, especially during transition of care (from the hospital to the community and vice versa) when medication errors are most likely to occur [18].

For community pharmacy, My Health Record provides new opportunities in service provision through timely access to an individual's key health information. This will:

- enhance delivery of Medication Management services such as MedsCheck; Home Medicines Review, Residential Medication Management Review;
- improve efficiency of professional services, such as medication reconciliation, by reducing time spent gathering information from multiple sources;
- support the provision of tailored advice based on relevant and recent information; and
- support continuity of patient care and inter-professional collaboration [18].

Recent enhancements to the medicines list have been announced for My Health Record. The new medicines list (named the Pharmacists Shared Medicines List (PSML)) will include over-the-counter medicine information for people with a chronic condition as well as prescription medication information.

My Health Record and other digital technology enhancement will change the way pharmacists work to provide services. Streamlining use of the new technologies will enhance uptake and generate more robust information for sharing with other health care providers. Research into mechanisms to integrate and streamline the use of technologies may be required to maximise the potential benefits.

Primary health networks and collaboration

Facilitation and improvement of services through improved coordination and integration of care is another focus of the Australian Government. Through PHNs, the Government seeks to increase the efficiency and effectiveness of medical services for patients and improve coordination of care to ensure patients receive the right care in the right place at the right time [19].

In addition to Health Care Homes and trials of non-dispensing pharmacists in GP clinics (as noted above), PHNs work with pharmacists and other primary health care professionals through provision of education and training sessions and support to implement new technologies such as My Health Record.

Future directions for community pharmacy

In 2018, the Guild released the *Community Pharmacy 2025 Framework for Change*. This recognises nine future growth pathways for community pharmacy to ensure long-term sustainability. Five of these pathways relate to health service provision by or in community pharmacy, as follows:

- (1) **Health services:** provide health services in the pharmacy, including medication management, preventative health, screening and chronic disease support.
- (2) **Community health hub:** enable other health professionals to provide patient services making community pharmacy a health hub.
- (3) **Digital enablement:** integrate digital health into community pharmacy practice and embrace digital technologies as a whole-of-business enabler.
- (4) **In-home care:** provide a range of medication and other health services to patients in their home.
- (5) **Collaboration and partnership:** collaborate and partner with other health providers, local health networks, medicines companies, researchers and government [20].

The Guild notes the support for the stated growth pathways from pharmacy owners and employees, students and patients alike (based on market research of focus group participation and thousands of survey responses) [20].

2.4 FUNDING OF PRIMARY HEALTH CARE

Increasingly, the Australian Government is requiring ongoing evaluation of existing services and an improved evidence base for funding future services. It is vital to consider innovative ways to address health needs and improve the value and cost-effectiveness of all services, whether delivered through pharmacy or other areas of primary health care [11]. Therefore, new models of care and service delivery must have robust evidence to demonstrate their clinical effectiveness as well as expected economic benefits for implementation.

Consistent with this approach, once finalised, the outcomes of all PTP trials will undergo an independent health technology assessment (HTA) to inform decisions about any future funding for trialled services. The recommendation of whether a trialled service should be supported and publicly funded (and if so, its circumstances) will be informed by an assessment of its comparative safety, clinical effectiveness and cost-effectiveness using best available evidence. The service would also need to satisfy funding priorities as determined by the Minister for Health.

Health Technology Assessment

The Australian Government subsidises the cost of health-related goods and services through a range of different funding arrangements. It is not financially viable to support every new health technology that comes onto the market, so the Government aims to direct funding to health services and technologies that are clinically relevant, cost effective and safe [21].

An HTA involves a range of processes and mechanisms that uses scientific evidence to assess the quality, safety, efficacy, effectiveness and cost effectiveness of health services and technologies. An independent HTA enables new services and technologies to be prioritised against existing health care interventions. Common applications for an HTA are pharmaceuticals (including vaccines), diagnostic tests, medical devices, surgically implanted prostheses, medical procedures and public health interventions. The key questions addressed are:

- is it safe?;
- does it improve health outcomes?; and
- is it cost effective? [21]

Several entities provide independent HTA advice including the Medical Services Advisory Committee (MSAC), the Pharmaceutical Benefits Advisory Committee (PBAC), the Therapeutic Goods Administration (TGA) and the Prostheses List Advisory Committee (PLAC) [21].

Of the existing HTA advisory bodies, the Medical Services Advisory committee (MSAC) is the most relevant regarding the objectives of the PTP.

The Medical Services Advisory Committee (MSAC), established in 1998, is an independent scientific committee comprised of individuals with expertise in clinical medicine, health economics and consumer matters.

The principal role of MSAC is to advise the Minister for Health, which informs Australian Government, on medical services including those that involve new or emerging technologies and procedures, in relation to:

- the strength of evidence about the comparative safety, clinical effectiveness, cost-effectiveness and total cost of the medical service;
- whether the medical service should be publicly funded and if so, the circumstances under which this should occur;
- the proposed MBS item descriptor and fee for the service where funding through the MBS is supported; and
- other issues relating to the public funding of health services referred by the Minister [22].

MSAC is supported by two sub-committees:

- **Evaluation Sub-Committee (ESC)**, provides advice to MSAC on the quality, validity and relevance of the evidence presented in applications being considered by MSAC ; and
- **PICO³ Advisory Sub-Committee (PASC) (formally the Protocol Advisory Sub-Committee)**, which oversees the development of a PICO Confirmation intended to:

- capture current clinical practice and reasonably reflect likely future practice with the proposed new service;
- identify all potentially impacted health care resources; and
- present the framework for evidence collection during the assessment phase of the MSAC process [22].

Eligible PTP grant applications were required to undergo consideration by PASC. This process was designed to ensure the necessary level of clinical evidence was available to support an independent HTA upon completion. Applicants were able to resubmit based on the PASC feedback [11] [23].

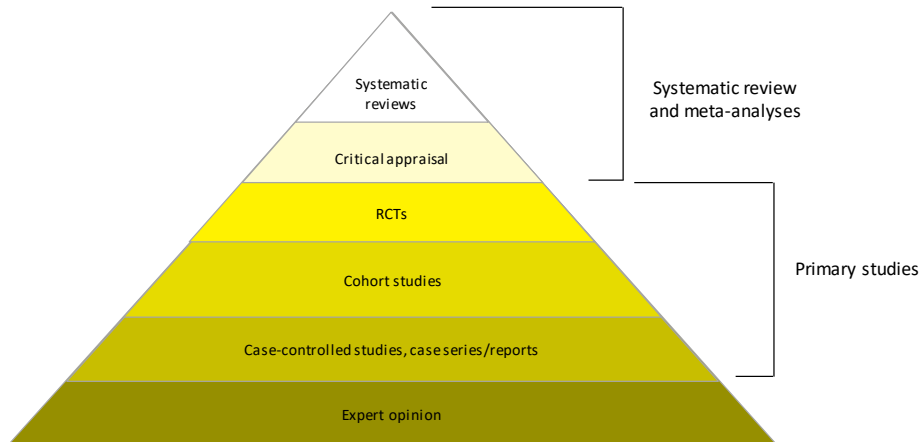
Necessary evidence levels

There are various types of research protocols that provide different levels of evidence strength. The National Health and Medical Research Council (NHMRC) has described a hierarchy of evidence, including:

- Systematic review and critical appraisal: a comparison and analysis of primary studies within a specific study area, providing a meta-analysis;
- Randomised controlled trial (RCT): considered the most rigorous study methodology for determining a cause-and-effect relationship between intervention and patient outcomes by eliminating confounding variables; [24].
- Cohort study: designed to assess if a particular characteristic is associated with the development of a disease or other clinical outcome. Control groups can be included, but allocation is not random;
- Case-controlled study: a form of observational study, i.e. no intervention is provided, and
- Expert opinion: perspectives or predictions provided by individuals who are considered experts in the field of interest.

Further description of the type of research methodologies Appendix A. The evidence hierarchy is depicted in Figure 2.3.

³ PICO: Population, Intervention, Comparator, Outcome

Figure 2.3 Hierarchy of evidence

Adapted from: National Health and Medical Research Council (2009) 'NHMRC Levels of Evidence and Grades for Recommendations for Developers of Clinical Practice Guidelines'

Trials funded through the PTP focused (predominantly) on use of an RCT methodology to ensure robust clinical evidence was available for an independent HTA upon completion.

Systematic reviews of community pharmacy intervention studies in the United Kingdom (UK), the Netherlands, Belgium, Spain, Denmark, Switzerland, Australia, Canada and the United States of America (USA) found that the most common designs used were RCTs, and controlled and uncontrolled 'before and after' studies (a type of cohort study) [25] [26] [27]. The focus of these interventions was chronic disease risk factor management including obesity, smoking cessation, cardiac pulmonary obstructive disorder and heart failure as well as QUM and medication adherence [28] [29].

Peer-reviewed literature from the community pharmacy sector in the USA showed variation in study designs used to explore the expanded scope of pharmacy services. Although RCTs remained a common methodology, controlled cohort studies were also able to produce evidence that is appropriately applied to the general population [30] [31]. Investigation of more novel or innovative services through community pharmacy such as pharmacogenomics and greater use of pharmacy technicians were conducted as feasibility studies [32] [33].

Table 2.2 provides a summary of international community pharmacy primary studies and Australian studies (not part of the PTP) considered in this discussion. This comparison shows that an RCT is a possible study design option for service delivery interventions by community pharmacy. However, controlled and uncontrolled cohort studies are also commonly used.

The scientific rigour of RCTs allows conclusions to be drawn regarding the effectiveness of the interventions including clinical outcomes, scalability and economic viability. However, RCT methodology is relatively costly and should be preceded by feasibility and pilot studies [34] [35]. Preceding trial design may include smaller scale pilot studies or controlled cohort feasibility studies.

MSAC review of existing Continuing Pharmacy Programmes

In 2016–2017, evidence reviews on the clinical and cost effectiveness of Continuing Pharmacy Programmes were undertaken. Programs reviewed included:

- Dose Administration Aids;
- Staged Supply support allowances;
- Clinical Interventions;
- Home Medicines Review (HMR);
- Residential Medication Management Review;
- MedsCheck; and
- Diabetes MedsCheck [36].

MSAC concluded that there was insufficient evidence and a lack of empirical research to determine the clinical and cost effectiveness of the reviewed programs. In addition, MSAC noted that it was difficult to conduct a comparative assessment of the programs as they were now primarily standard of care expected of a pharmacist. MSAC considered that further evidence generation needed to highlight the need for comparative data [37] [36].

Table 2.2 Comparison of primary study designs for community pharmacy service interventions

STUDY NAME	YEAR	STUDY DESIGN	LOCATION	HEALTH AREA
<i>Randomized Trial of the Effect of Pharmacist Prescribing</i> Tsuyuki <i>et al.</i>	2015	RCT (active comparator) – 248 participants	Canada	Chronic Disease – Hypertension
<i>Pharmacist Intervention for Glycaemic Control in the Community</i> AL Hamarneh <i>et al.</i>	2013	Uncontrolled cohort study – 100 participants	Canada	Chronic Disease – Diabetes
<i>Community Pharmacy-Based Medication Assessment Program</i> Beauchesne <i>et al.</i>	2012	Uncontrolled cohort study – 82 participants	Canada	Chronic Disease – Asthma and COPD
<i>Patient case activities by community pharmacists in a capitation funding model mental health and addiction programs</i> Murphy <i>et al.</i>	2018	Uncontrolled cohort study – 182 participants	Canada	Mental Health and Alcohol and Other Drugs/ QUM
<i>Effectiveness of Pharmaceutical Care for Patients with Cardiac Obstructive Pulmonary Disease</i> Tommelein <i>et al.</i>	2014	RCT (active comparator) – 734 participants	Belgium	Chronic Disease – COPD
<i>Effectiveness of a Pharmacist-Led Intervention on Diuretic Compliance in Health Failure Patients: A Randomized Control Study</i> Bouvy <i>et al.</i>	2003	RCT (active comparator) – 152 participants	The Netherlands	Chronic Disease – Heart Failure/ Transition of care/ Medication adherence
<i>Pharmacist Intervention to Improve Medication Adherence in Health Failure</i> Murray <i>et al.</i>	2007	RCT (active comparator) – 314 participants	US	Chronic Disease – Heart Failure/ Medication adherence
<i>Managing minor ailments: The public's preference for attributes of community pharmacies. A Discrete Choice Experiment</i> Porteous <i>et al.</i>	2016	Uncontrolled Cohort Study – 1,049 participants	UK	Access to primary care services/ service gaps
<i>Nicotine Patches in Smoking Cessation: A Randomized Trial among Over-the- Counter Customers in Denmark</i> Sonderskov <i>et al.</i>	1997	RCT (placebo controlled) – 522 participants	Denmark	Chronic Disease Risk Factors – Smoking cessation
<i>Change of body weight and lifestyle of persons at risk of diabetes after screening and counselling in pharmacies</i> Botomino <i>et al.</i>	2008	Uncontrolled Cohort Study – 1,370 participants	Switzerland	Chronic Disease – Weight management
<i>Implementation of an overweight and obese people follow-up program as a previous step to a drug-therapy follow-up</i> De Miguel <i>et al.</i>	2001	Uncontrolled Cohort Study – 168 participants	Spain	Chronic Disease – Weight management

STUDY NAME	YEAR	STUDY DESIGN	LOCATION	HEALTH AREA
<i>Implementation of a weight management pharmaceutical care service</i> Lloyd <i>et al.</i>	2004	Uncontrolled Cohort Study – 288 participants	USA	Chronic Disease – Weight management
<i>Impact of a Pharmaceutical Care Intervention on Blood Pressure Control in a Chain Pharmacy Practice</i> Robinson <i>et al.</i>	2010	Controlled Cohort Study – 376 participants	USA	Chronic Disease – Hypertension
<i>An Integrated Pharmacy-Based Program Improved Medication Prescription and Adherence Rates in Diabetes Patients</i> Brennan <i>et al.</i>	2012	Controlled Cohort Study – 29,247 participants	USA	Chronic Disease – Diabetes/ Medication adherence
<i>Implementation of pharmacogenetics service in a community pharmacy</i> Ferrerri <i>et al.</i>	2014	Feasibility study – 18 participants	USA	Expanded scope of services/point of care testing
<i>Uptake and effectiveness of a community pharmacy intervention programme to improve asthma management</i> Bereznicki <i>et al.</i>	2013	Cluster RCT (active comparator) – 1,483 participants	Australia	Chronic Disease – Asthma
<i>An evaluation of community pharmacy-based rural asthma management service</i> Saini <i>et al.</i>	2008	Controlled Cohort Study – 80 participants	Australia	Chronic Disease – Asthma
<i>The Pharmacy Diabetes Care Program: assessment of a community pharmacy diabetes service model in Australia</i> Krass <i>et al.</i>	2007	Controlled Cohort Study – 289 participants	Australia	Chronic Disease – Diabetes

3 REVIEW METHODOLOGY

The implementation review of the PTP was undertaken from February 2019 to June 2019 in five stages, as follows:

- (1) Development of a program logic and key review areas.
- (2) Review of relevant documentation and other contextual information.
- (3) Consultation with stakeholders.
- (4) Online survey of pharmacists.
- (5) Triangulation of evidence to identify findings and potential future options for the PTP, should it continue, into a final report.

Activities undertaken in each of these stages is described in this chapter.

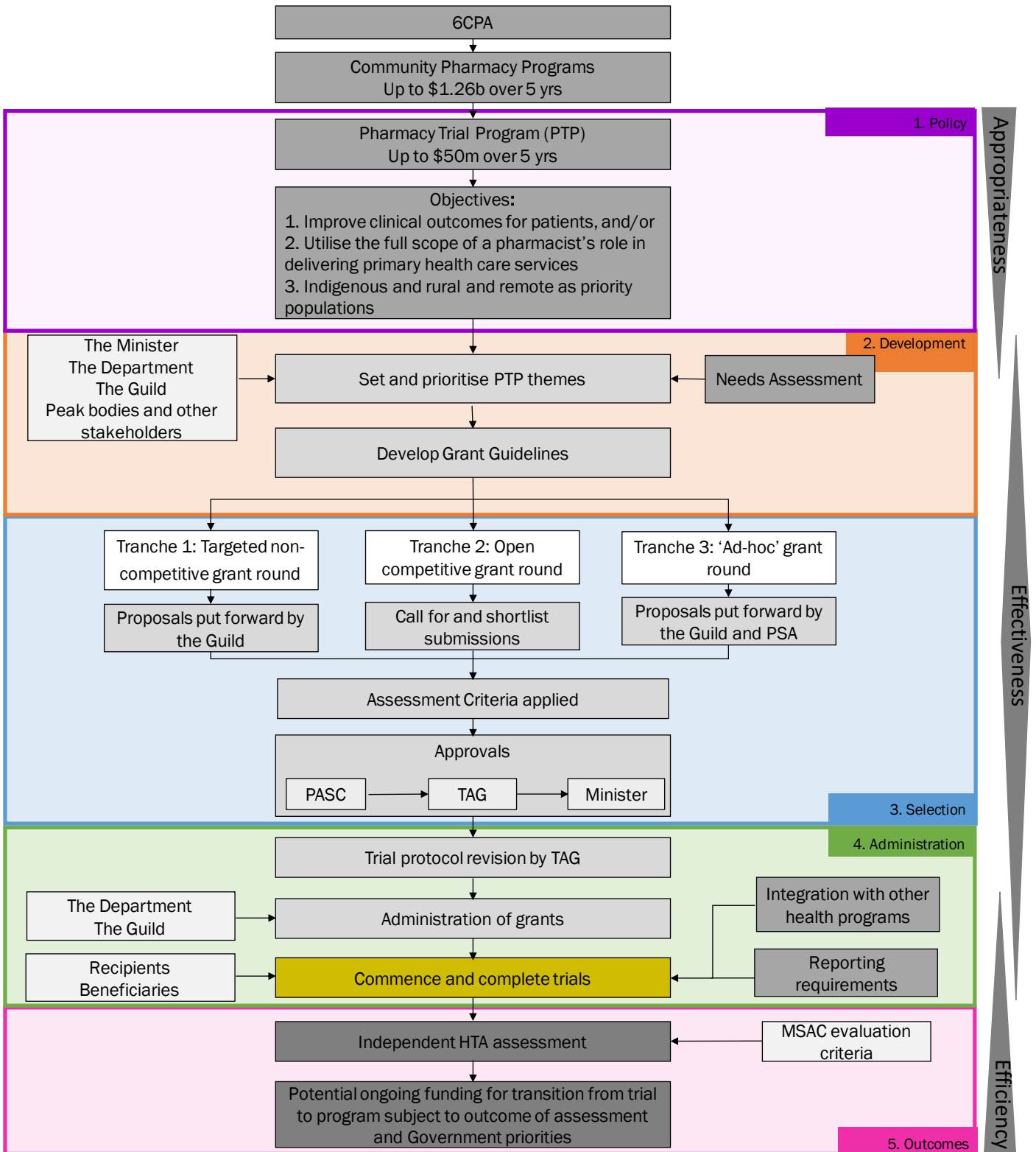
3.1 PROGRAM LOGIC AND KEY REVIEW AREAS

The program logic of any program articulates the reasoning driving the program and highlights the linkages between the different service delivery components of any public sector initiatives. Program logic can also be used to identify key areas for an implementation review. HMA suggested that the following five key review areas for the implementation review:

- (1) Policy.
- (2) Development.
- (3) Selection.
- (4) Administration.
- (5) Outcomes.

The relationship between the program logic and those five key review areas is depicted in Figure 3.1.

Figure 3.1: PTP program logic and implementation review areas



3.2 DOCUMENTATION REVIEW AND OTHER CONTEXTUAL INFORMATION

To inform the evaluation analysis, HMA reviewed documentation related to the PTP and relevant government policy, as well as peer-reviewed and grey literature on the types of research used for service delivery interventions and the robustness of different research models. This analysis was used to examine the broader context in which the PTP operates and to inform consideration of the perspectives put forward by stakeholders during consultations. This section of the report lists the documents that provided that context for the evaluation.

Documentation that was specific to the operations of the PTP trial included:

- “Summary report of the stakeholder consultation forum held on 26 October 2015.” [2]
- “Supporting pharmacist delivery of primary health care services through the Pharmacy Trial Program: Discussion Paper” (2016). [38]
- PTP Principles. [39]
- Terms of reference and membership for the Trial Advisory Group (TAG). [40]
- PTP Grant Guidelines for Tranches 1, 2 and 3. [41] [23] [42] [43]
- PTP applications for successful grants.
- PTP Tranche 2 assessment master list [44].

Policy and related documents relevant to the evaluation context and referred to throughout this final evaluation report are listed below:

- National Medicines Policy (2000). [5]
- National Strategy for Quality Use of Medicines (2002). [6]
- 6CPA.
- The Australian National Audit Office report “Administration of the Fifth Community Pharmacy Agreement.” [45]
- Commonwealth Grants Rules and Guidelines. [46]
- Commonwealth Procurement rules. [47]

Other contextual information considered included:

- Guidance and other published materials produced by health technology assessment bodies providing advice including the Medical Services Advisory Committee (MSAC), the Pharmaceutical Benefits Advisory Committee (PBAC), the Therapeutic Goods Administration (TGA) and the Prostheses List Advisory Committee (PLAC). [21]
- Information on the operations of the Australian Digital Health Agency, My Health Record and the recent research through the Digital Test Beds.
- Medication safety and avoidable hospitalisations caused by medication misadventure.
- Strategic directions for community pharmacy as identified in the “Community Pharmacy 2025 Framework for Change” (2018) published by the Guild. [20]

Literature and evidence from international programs that informed the evaluation analysis included a:

- comparison of trial (also referred to as ‘primary study’) methodologies as described by the hierarchy of evidence developed by the NHMRC; [48] and
- literature scan undertaken by the evaluation project. Findings from the literature scan were used to compare study design protocols for new and innovative health service delivery interventions in Australia and overseas. The search included Australia and countries with similar community pharmacy models, which were defined as the United Kingdom, other parts of Europe, the United States of America, Canada, and New Zealand.

3.3 CONSULTATION WITH STAKEHOLDERS

HMA sought the perspectives of relevant stakeholder groups on their experiences with the PTP and possible future direction for the program. Groups that provided input into the review are listed below, categorised by stakeholder type.

Australian Government and affiliated agencies

- The Australian Government Department of Health, Pharmacy Branch (Department); and

- Australian Digital Health Agency.

Advisory groups

- Representatives of the Trials Advisory Group (TAG)
 - Chair: Emeritus Professor Lloyd Sansom;
 - Shane Jackson (PSA);
 - Grant Martin (Australian Association of Consultant Pharmacy); and
 - Samantha Robertson (NHMRC).⁴

Professional peak bodies with an interest in pharmacy

- The Pharmacy Guild of Australia (Guild);
- Pharmaceutical Society of Australia (PSA);
- Society of Hospital Pharmacists Australia (SHPA); and
- Australian Association of Consultant Pharmacy (AACP).

Professional peak bodies with an interest in primary health care

- Allied Health Professionals Australia (AHPA);
- National Rural Health Alliance (NRHA);
- Australian College of Rural and Remote Medicine (ACRRM); and
- Royal Australian College of General Practitioners (RACGP).

Primary healthcare networks (PHNs)

- Central Queensland, Wide Bay and Sunshine Coast PHN;
- Gippsland PHN; and
- South West Sydney PHN.

⁴ Samantha Robertson was the NHMRC representative on the TAG, however, she has subsequently left the NHMRC

Advocacy peak bodies with an interest in consumer and/or vulnerable populations

- National Aboriginal Community Controlled Health Organisation (NACCHO);
- Consumers Health Forum of Australia (CHF);
- National Mental Health Consumer and Carer Forum (NMHCCF); and
- Pain Australia (PA).

Successful grant applicants

- Pharmacy Diabetes Screening: Guild and Griffith. University;
- Indigenous Medication Management for Aboriginal and Torres Strait Islanders Feasibility Study: the Guild and NACCHO;
- Integrating Practice Pharmacists into Aboriginal Community Controlled Health Services: PSA, NACCHO and James Cook University;
- Getting Asthma Under Control: Woolcock Institute;
- Reducing Medicine Induced Deterioration and Adverse Reactions: University of South Australia;
- Early Detection and Management of Cardiovascular Disease Risk Factors and Chronic Disease Markers in Community Pharmacy: Black Swan Health; and
- Chronic Pain MedsCheck: the Guild and PSA.

Unsuccessful grant applicants

- Top End Health;
- University of Tasmania ; and
- Griffith University.

Consultations occurred as either telephone interviews or face-to-face meetings from 8 April to 13 June 2019. A full list of individuals consulted is provided Appendix B.

3.4 SURVEY OF PHARMACISTS

HMA conducted an online survey of pharmacists to gain their perspective of how research and innovation could be implemented in the pharmacy sector. Although the primary target of the survey was community pharmacists, it was also open to and promoted to hospital and consultant pharmacists and other interested people such as researchers.

The online survey was promoted through the Guild's and PSA's websites, social media and newsletters. In addition, the *Australian Journal of Pharmacy* website promoted the survey in an article published online on 9 April 2019. The survey was open for three weeks from 9 April until 30 April 2019.

There were 124 responses to the survey. Over half were from community pharmacy employees or owners (54%). The remainder comprised universities or researchers (14%), consultant pharmacists (13%), hospital pharmacists (11%) or other (8%), such as administration, peak bodies or Departmental staff.

Survey questions were not compulsory. Therefore, the number of responses to each question varied throughout. Where survey data is presented in this report, the percentages are calculated from the number of responses for each individual question. This information is provided for each example, i.e. x% (n=y of z responses).

A copy of the survey questions is provided at Appendix C.

3.5 TRIANGULATION OF INFORMATION

Information from the previous stages were drawn together as an evidence base to identify findings. Based on the findings, potential future options for discussion are presented in Chapter 7 of this document, the Final Report.

PART B

REVIEW FINDINGS

4 APPROPRIATENESS

Key Finding 1: Funding of a program for service delivery trials is an appropriate response for the stated objectives of the PTP, which are to improve clinical outcomes for consumers, and/or extend the role of pharmacists in the delivery of primary health care services through community pharmacy. This is evidenced by the sector support to expand pharmacy service delivery, including greater collaboration with other health care professionals. The PTP is not duplicative of other research funding and aligns with the evidence building approach of the National Strategy for Quality Use of Medicines and the principles of the National Medicines Policy that support the 6CPA. It seems unlikely that the expected outcomes of the PTP could be achieved without the financial support for trials offered by the program.

4.1 EVALUATION QUESTIONS

The implementation review of the PTP sought to assess the appropriateness of the program. The key evaluation question for appropriateness was:

Is the program the appropriate response for the program's objectives?

Review of the appropriateness of the PTP included analysis of the following detailed review questions:

- (1) How does the PTP align with the objectives of the Community Pharmacy Programme in the 6CPA?
- (2) Does the community pharmacy sector have the capacity to be able to expand service provision to address the PTP objectives?
- (3) Does the PTP promote appropriate links with other health professionals (interdisciplinary collaboration)?

- (4) Is the PTP duplicative of efforts being undertaken by any other government grant programs?
- (5) Could the expected outcomes be achieved without PTP funding?

The detailed analysis of these questions is discussed in the remainder of this chapter.

4.2 ANALYSIS AND FINDINGS

4.2.1 Alignment of PTP objectives with 6CPA

The PTP sits within Section 6 of the 6CPA, Community Pharmacy Programmes, which describes the provision of funding for 'evidence-based, patient-focused professional pharmacy programmes and services (Community Pharmacy Programmes) over the Term' of the 6CPA.

The intent of the PTP is to trial new and expanded Community Pharmacy Programmes, with the following objectives:

- (1) improve clinical outcomes for consumers; and/or
- (2) extend the role of pharmacists in the delivery of primary health care services through community pharmacy [1].

Considering the research and evaluation focus of the National Strategy for QUM (see Section 2.2) [6], it is appropriate for the 6CPA to implement a mechanism to test and evaluate initiatives prior to committing ongoing funding. In addition, the increasing requirement of the Australian Government to have a robust evidence base for programs demonstrating the improved value and cost-effectiveness of services, makes a program such as the PTP an essential component in establishing new, or expanding existing, Community Pharmacy Programmes.

Observation 1: Research to validate the clinical and economic effectiveness of new or expanded Community Pharmacy Programmes is appropriate. It aligns with the evidence-based requirements of the National Strategy for QUM, and to the overarching NMP that is supported by the 6CPA.

Regarding the specific objectives of the PTP as stated above, responses to the pharmacist survey indicated that the majority of respondents felt the PTP objectives were suitable and effective in advancing pharmacy practice in Australia (83%, n=87 of 105 responses to this question). Further to this, approximately two thirds of pharmacists responding to the survey indicated that a grants program was a suitable mechanism to achieve the aims of the PTP (68%, n=71 of the 104 responses).

Likewise, the Guild's strategic plan (*Community Pharmacy 2025 Framework for Change*) identifies health services (including medication management, preventative health, screening and chronic disease management) as one of nine growth pathways for community pharmacy [20], demonstrating further support for the PTP objectives.

Observation 2: The objectives of the PTP were supported by the pharmacy sector. This is evidenced by market research by the Guild, which indicates support for ongoing development of community pharmacy health services including medication management, preventative health, screening and chronic disease management. Health service provision is noted as one of nine growth pathways for community pharmacy identified by the Guild and survey responses by individual pharmacists.

Consultation with the Guild and the Department showed that interpretation of the PTP objectives differed between the two stakeholders:

- The Guild interpreted the program to be specific to community pharmacy and /or community pharmacists with the development of programs that would expand community pharmacy service options.

- The Department interpreted the program objectives more broadly and saw improved clinical outcomes of consumers as independent from service delivery setting.

Stakeholder consultation indicated many stakeholders supported a broader interpretation of the role that should be undertaken by the PTP in order to promote a consumer-centric and inter-disciplinary approach for the management of chronic conditions.

There was a general view among professional and advocacy peak bodies (including the PSA, SHPA, AACP, AHPA, NACCHO, and CHF), that restrictions placed around delivering trial activities through community pharmacies, or pharmacists employed by a community pharmacy, limited the potential of what the program had set out to achieve. These groups expressed concern that continued investment in the delivery of pharmacy services through a retail pharmacy model would not reflect the future needs of consumers nor integrate into changing primary care systems.

Stakeholders said that, as implementation of the program progressed, there was a growing disparity between the sector's vision for the PTP and the grant activity that eventuated. This perspective is summarised in the following stakeholder statement responding to a question on the appropriateness of the PTP.

'The PTP has been a program of lost opportunity; it could've been research that could have seriously impacted practice. It could've given us evidence around new programs... This was a once-in-a-lifetime investment in community pharmacy that will result in very little.'

Peak professional body comment

Observation 3: Interpretation of the PTP objectives differed between stakeholders. The Guild maintains that the PTP objectives are to focus on community pharmacy and community pharmacists. There was general support among other stakeholders interviewed for the review, including professional and advocacy peak bodies, for a broader interpretation of the PTP objectives in regard to the type of pharmacist engaged in trials and the location of trial service provision beyond community pharmacy settings.

4.2.2 Barriers to expanding pharmacist roles into provision of services

The changing needs and expectations of consumers in primary care is changing the environment in which pharmacy services need to operate. Furthermore, as discussed in Section 2.3, inter-disciplinary approaches to health care and issues such as preventable medication misadventure resulting in hospitalisation highlight the need to expand pharmacist services to maximise the use of pharmacist expertise.

In response, the Guild has identified nine future growth pathways for community pharmacy to ensure long-term sustainability, five of which relate to health service provision by or in community pharmacy. These include provision of pharmacy-related health services, establishing community health hubs, digital enablement, provision of in-home care, and collaboration and partnership with other health professionals [20].

Supporting these broad directions, three quarters of pharmacist survey respondents (76%, n=92 of 121 responses) agreed that the community pharmacy sector had the capacity to provide an expanded range of primary care services such as chronic disease monitoring and patient education.

One respondent commented:

'Pharmacists are currently underutilised. A greater utilisation of pharmacists will offer consumers greater choice and improved medication management.'

Survey respondent

However, many survey respondents also noted barriers to expanding services. The main barriers identified by approximately one quarter of respondents each were:

- the lack of funding structures to support the expanded delivery of services (26%, n=23 of 87 responses); and
- the lack of time and access to staffing support (23%, n=20 of 87 responses).

The following comment from a community pharmacy employee highlights several barriers to the implementation of new pharmacy service delivery programs.

'[There is a] conflict of interest between the retail offering with the owner's need for profitability and delivering an authentic health service. Pharmacists are positioned more so as shop or business managers. The bread-and-butter task of being a true pharmacist becomes an automated constant background task.'

Current industry structure regarding location rules and traditional pharmacy models [is a barrier]. These stores are overworked and under supported – and the constant blame is either PBS cuts or discount competitors.'

Community pharmacist – employee

Very few survey respondents noted existing enablers for expanded services, although the accessibility and existing skill set of pharmacists was mentioned as enablers by 9% of respondents (n=10 of 87 responses).

Another confounding factor to expanded service delivery models identified by survey respondents was the lack of incentive payments for pharmacists to engage with emerging technologies such as My Health Record. GPs can apply for the Practice Incentives Program eHealth Incentive (ePIP), which aims to encourage GPs to keep up to date with the latest developments in digital health and adopt new digital health technology as it becomes available [49]. Consultation with PHNs indicated there are no equivalent incentive payments for pharmacists.

4.2.3 Promotion of interdisciplinary collaboration among primary health care professionals through the PTP

Primary health care involves many health professions. Increasingly a coordinated interdisciplinary approach is required to optimise consumer care. There was a perception among most stakeholders that opportunities to collaborate between pharmacy and other health professions through the PTP were limited. Collaboration in many PTP trials focused mostly on case conferencing with or referral to a GP. Three of the seven approved PTP trials were provided in a location other than a community pharmacy (RACF or ACCHS).

Many professional and advocacy peak bodies expressed a desire for community pharmacy to be better integrated into the primary health sector and other settings such as RACFs. The AHPA noted a need for greater involvement of allied health professionals in PTP trials relating to the management of chronic conditions.

The perception that PTP trials were pharmacy-led also raised concerns about the lack of collaboration and the danger of duplicating services already being offered by other health professions. These concerns were raised by professional groups such as the RACGP and AHPA, and grant applicants.

'We're trying to do fixes around the edges but what is the outcome for the consumer?'

Professional peak body comment

'The rules set out in the trials are highly restrictive and innovation is hampered by this. Because of the 6CPA...the trials have to go through community pharmacy...'

Professional peak body comment

'Funding is siloed, which makes it difficult for pharmacists to be doing multidisciplinary or collaborative work with other health professions.'

PTP grant applicant comment

It was also noted by one grant recipient that study design using only community pharmacists may have been prohibitive in rural areas where there is only one community pharmacist.

'In some [areas], there was not a good relationship between the pharmacist and the community so this would not have worked. The community would have walked away from participating in the trial.'

PTP trial grant recipient comment

Through the online survey, pharmacists were asked how they considered collaboration between pharmacists and other health professions could be encouraged. The pharmacist survey received 78 responses to this question, with five key themes identified:

- better communication between professions and understanding of each other's roles and capabilities (25%, n=19);
- more opportunities for structured interactions such as inter-professional education and training events and networking evenings (24%, n=18);
- integration of pharmacists into general practices or other health care settings outside of the community pharmacy (16%, n=12);
- specific funding for multidisciplinary service delivery (14%, n=11); and
- better relationships between peak professional bodies (9%, n=7).

The survey responses suggest that ongoing efforts to enhance education and training of health professionals across disciplines is beneficial. This agenda could be progressed through greater involvement of PHNs and peak professional bodies in trial design in a future PTP.

Observation 4: Professional and advocacy peak bodies felt that interdisciplinary collaboration could have been strengthened in the PTP trials.

4.2.4 Limited existing grant opportunities to address the PTP objectives

The *Commonwealth Grants Rules and Guidelines* (CGRG) aim to promote value for money and accountability for use of public funds and outline the legislative rules for grant agreements as well as best practice principles for management of public funds [47]. One consideration under the CGRG is that officials should determine whether

an existing grant opportunity may be expanded or modified to meet the objectives, rather than establishing an additional grant opportunity and duplicating administrative efforts and costs⁵ [47].

Many stakeholders stated that there is little funding available for pharmacy research, particularly for service delivery interventions, other than the funding made available through the PTP. Access to research funding in the broader health sector is otherwise provided through NHMRC grants. NHMRC is an independent statutory agency within the portfolio of the Australian Government Minister for Health.

However, many stakeholders felt that components of the NHMRC processes were incompatible with the PTP. This includes (in their opinion):

- the lack of accountability as grant payments are not tied to achievement of outcomes and are not monitored;
- low success rate for service delivery intervention research (an average of only 4% of NHMRC funding was provided to health services delivery from 2000 to 2016 [50]); and
- the NHMRC focus on acute care medical research.

Stakeholders were concerned that if funding for pharmacy research was incorporated into the NHMRC pool of funding, there was a danger the allocation for pharmacy-related initiatives would be absorbed by other research areas.

'Almost every other profession goes through NHMRC for the proof of concept research funding. But to date this has been very medically focused. If there [were] a focus on service delivery, then pharmacy could then be part of this.'

Grant applicant comment

In addition to the administration and management of medical research funding, NHMRC manages grant funding administration for numerous agencies including the Cancer Council and the Medical Research Future Fund (MRFF). These funds are administered separately to NHMRC funds. Grant rounds and funding application assessments are core business for the NHMRC, with processes in place

to facilitate assessment. This includes specific criteria to ensure the suitability of research with Aboriginal and Torres Strait Islander populations, i.e. *NHMRC Indigenous Research Excellence Criteria*, which assess community engagement, benefit, sustainability and building capacity [51].

Regarding the administration of the PTP, NHMRC felt that they would have been ideally placed to manage the PTP. NHMRC commented that application review is the core business of the NHMRC. It has skilled employees and panels for review, a comprehensive knowledge of expected timeframes, resources and salaries for research, and other established criteria (such as that for Indigenous research) to support assessment of grants.

Another potential funding source for research is the MRFF, established in 2015. MRFF is guided by 'Research Missions', to which the aim of the PTP aligns. A MRFF Research Mission is defined as:

a program of work with ambitious objectives that are only possible through significant investment, leadership and collaboration [52].

The aims are to bring together key researchers, health professionals, stakeholders, industry partners and patients to tackle significant health challenges [52].

Currently there are two MRFF Research Missions – the Australian Brain Cancer Mission and the Million Minds Mental Health Research Mission [52]. Neither of the existing missions address the objectives of the PTP, so there is no duplication with this funding source.

4.2.5 Achieving the expected outcomes without PTP funding

Investment in the PTP was highly valued by the pharmacy sector. As stated in Section 4.2.4 above, other research funding sources do not specifically target the objectives of the PTP. Therefore, it is unlikely that the innovative research undertaken by the PTP trials would have occurred otherwise.

⁵ CGRG Section 11.4, page 30

NACCHO expressed the view that without PTP, the positive health outcomes being observed in the Aboriginal and Torres Strait Islander communities through the PTP-funded trials could not have been achieved.

Observation 5: The expected outcomes of the PTP are unlikely to be achieved without PTP funding.

4.3 CONCLUSION

Evidence collected during the review suggests that research to validate the clinical and economic effectiveness of new or expanded Community Pharmacy Programmes is appropriate and that there was support for the objectives of the PTP among the community pharmacy and broader pharmacy sector. Many stakeholders expressed an interest in a broader interpretation of the PTP objectives to include alternative locations of service delivery within the community and engagement of consultant pharmacists in addition to community pharmacists.

Although PTP trials linked into general practice via referral or case conferencing, interdisciplinary collaboration was an area noted by professional and advocacy peak bodies that could be strengthened. There were mixed views among stakeholders as to whether the expected outcomes of the PTP would be achieved without PTP funding, depending on the nature of the individual trial. Considering the limited funding availability for health service research in pharmacy through other research grants, it is unlikely that PTP objectives would be achieved without the funding. Furthermore, noting the limited capacity of community pharmacy to implement programs without financial incentives for staff time, expanding existing programs would be challenging without funding for trials.

Therefore, the review concluded that funding of a program for service delivery trials is an appropriate response for the stated objectives of the PTP.

5 EFFECTIVENESS

Key Finding 2: Setting of PTP priority areas included reference to expert opinion and stakeholder consultation. Increased engagement of consumer groups from a broader range of health needs perspectives may further enhance trial design in the future. Further focus on the needs of consumers in rural and remote areas could also be considered.

Key Finding 3: Issues that delayed implementation of PTP milestones included the unanticipated time required to refine trial protocols to meet requirements of prospective independent HTA. Factors that could streamline implementation include increased clarity of application processes to reduce ineligible applications and further documentation of administrative processes associated with decision making.

Key Finding 4: At the time of the evaluation conclusion, seven trials had signed funding agreements, and an additional trial had approval from the Minister for Health to be undertaken in 2019–20 financial year. One trial was completed and five more are scheduled to be completed by the end of the 6CPA. As at June 2019, no trial had undergone an independent HTA. The selected HTA advisory body should consider the service delivery nature and qualitative consumer experience aspects of the PTP trials as part of its assessment.

5.1 EVALUATION QUESTIONS

The implementation review of the PTP sought to assess the effectiveness of the program. The key evaluation question for effectiveness was:

How well is the PTP being delivered and is it working as expected?

Review of the effectiveness of the PTP included analysis of the following detailed review questions:

Program development processes

- (1) Were stakeholders adequately engaged in the development of the PTP?
- (2) Was the TAG membership appropriate for its Terms of Reference (TOR) and was the TOR realised?
- (3) Was the lead-in time for PTP development, appraisal and selection process timely and did it allow for the delivery of grant activities within the 6CPA?

Trial design and selection processes

- (1) Were competitive, merit-based selection processes used?
- (2) Were application and decision-making processes suitably transparent to grant applicants?
- (3) Did selection processes foster an outcomes orientation for the grants?

Administrative processes

- (1) Were decision makers and advisors (and their roles) identified and transparently communicated among stakeholders?
- (2) Is the record keeping relevant to the PTP grant process satisfactory?

Program outputs

- (1) In the term of the 6CPA, how many trials were completed and evaluated by a relevant independent health technology assessment (HTA) body?
- (2) Were processes developed for finalising the trials, including a process to proceed to an appropriate independent HTA evaluation?

The detailed analysis of these questions is discussed in the remainder of this chapter.

5.2 ANALYSIS AND FINDINGS

PROGRAM DEVELOPMENT PROCESSES

5.2.1 Stakeholder engagement processes

The Department took several approaches to ensure stakeholders were engaged in the development of the PTP, including its underlying rules and priority setting. This included a stakeholder forum, a written call for ideas and the establishment of a TAG of professional and advocacy peak body representatives.

The stakeholder forum was held at the end of October 2015 [2]. The forum was facilitated by the Department with attendees addressed by the Minister, the Deputy Secretary of the Health Benefits Group and Special Advisor Emeritus Professor Lloyd Sansom, Chair of the TAG. Executive personnel from the Guild, PSA, AACP, AMA and CHF also made presentations [53].

HMA was informed that over 100 attendees from invited stakeholder organisations were in attendance and were asked to:

- identify priority health areas to be addressed by the trials; and
- discuss potential design principles.

Examples of PTP targets emerging from this discussion included medication management for older Australians in both the community and in residential aged care, integration of care across the health system including eHealth and PHNs, and QUM and reducing medication related harm [53].

Stakeholders attending the forum emphasised the need to consider a range of issues in the design and delivery of PTP trials, including:

- performing a needs analysis to identify appropriate target groups, health areas or service gaps and ensure a patient focus;
- innovative service design with applicability to various locations/settings;
- application of co-design principles and extensive stakeholder engagement; and

- capacity and capability of current community pharmacy workforce to deliver on individual trial objectives [2].

Following the stakeholder forum, a discussion paper was produced and circulated to a wider range of stakeholders over a six-week period from March to April 2016. This discussion paper included a ‘call for ideas’ from stakeholders to aid in the prioritisation of PTP themes [11].

Although they participated in the stakeholder forum, the RACGP and ACRRM still indicated that they had little involvement in the design and development of the PTP. The NRHA, AHPA, NMHCCF and PA were not involved in the stakeholder forum and said they had no other engagement in the PTP design processes. The representative PHNs consulted in this review also indicated they were not involved in development of the PTP.

Many stakeholders consulted felt that a future program would benefit from broader stakeholder input in the design phase. The RACGP commented that, despite having a representative on the TAG, it was unable to provide adequate input to the PTP considering the importance of interactions between GPs and community pharmacists in consumer care.

‘The RACGP could and should be engaged with community pharmacy. We sometimes sense that various projects get the go-ahead without enough discussion.’

RACGP comment

Observation 6: The Department undertook several approaches to seek stakeholder input into the development and design of the PTP and setting of priority areas. This included a stakeholder forum, a ‘call for ideas’ and convening a Trial Advisory Group. Many professional and advocacy peak bodies would have liked greater engagement in the developmental stages, beyond the activities described.

Co-design of trials with relevant stakeholders

Peak bodies with a focus on vulnerable population groups noted a lack of engagement in the design of individual trials. In particular:

- the NMHCCF was not consulted in the development of the Bridging the Gap between Physical and Mental Illness in Community Pharmacy Trial (PharMIbridge Trial protocol has yet to be approved). It commented:

'While intent of the program was good, all the programs are 'doing to' not 'doing with' consumers.'
- NACCHO was not initially involved in the design of the IMeRSe Feasibility Study, although it has subsequently been engaged in the trial.

These stakeholders felt increased co-design with consumers from the start of the design process would improve potential trial uptake and hence the ultimate outcomes of trials.

5.2.2 Trials Advisory Group

The TAG was formed to provide expert and technical advice to the Minister and the Department throughout the development and implementation of the PTP. The TAG consisted of fourteen members including clinicians and policy experts. This included representatives from community, consultant and hospital pharmacy, primary health care, consumer advocacy, health research and evidence, health technology assessment and quality use of medicines. The potential appointment of a rural and remote health practitioner to the TAG was indicated, but this did not occur [40]. The membership of the TAG is presented in Table 5.1.

Table 5.1 TAG Membership

Member	Area of expertise
Emeritus Professor Lloyd Sansom AO (Chair)	Pharmacy and national medicine policy
Dr Ian Coombes	Hospital pharmacy
Mr Mark Douglass	Community pharmacy (the Guild)
Dr Tony Hobbs	Primary health care
Dr Shane Jackson	Community pharmacy (PSA)
Mr Grant Martin	Pharmacy (Australian Association of Consultant Pharmacy)
Dr Vlad Matic	Clinician and Indigenous representative
Ms Samantha Robertson	Evidence health and governance
Dr Rashmi Sharma	General Practice
Mr Brett Simmonds	Pharmacy
Mr Ian Todd	Community pharmacy (the Guild)
Ms Diane Walsh	Health care consumer
Dr Claire O'Reilly	Health Technology Assessment
Dr Lyn Weekes	Quality Use of Medicines and pharmacy education
Not appointed	Rural and remote health representative

Composition of the TAG was widely considered representative by stakeholders. The NMHCCF did not consider there was adequate Aboriginal and Torres Strait Islanders or consumer representation stating:

'You can tick a box and say well we've had input but if they are not part of the group that is providing advice to the Minister, then they are relying on others and essentially that input can be lost.'

NMHCCF comment

HMA notes that, although not stated in the public information on the TAG membership, Dr Vlad Matic is an Aboriginal man and acted as the Indigenous representative for the TAG.

Observation 7: The TAG was formed to provide expert and technical advice throughout the PTP. The membership was suitable for this narrowly defined purpose but may have benefited from additional representation from vulnerable consumer populations, including consumers in rural and remote areas and Aboriginal and Torres Strait Islander communities.

The TAG met five times throughout the PTP, with the first of these meetings being held in January 2016, consistent with the requirements outlined in the terms of reference (TOR) [40].

The role of the TAG as described by the TOR can be grouped into three main categories:

- setting priority areas for PTP trials;
- assessing submissions and trial protocols; and
- providing input into the evaluation and transition of trials to longer term community pharmacy programs.

Issues relating to TAG involvement in each of these main areas of activity are described below.

Setting priority areas

The TAG was involved in the setting of priority areas for Tranches 1 and 2 of the PTP but was not directly involved in providing advice on Tranche 3 trials.

At the initial meeting of the TAG in January 2016, the group discussed priority areas for trials and potential trial themes that emerged from the stakeholder forum. This was used to prepare a discussion paper to support the public ‘call for ideas’. The submitted ideas were discussed and prioritised in the third meeting of the TAG, held in April 2016. Prioritised topics were submitted to the Minister for approval as Tranche 2 priority areas [54].

Tranche 1 topics were reviewed by the TAG at the second meeting (March 2016), based on the proposals submitted by the Guild [54].

The setting of priority areas for the PTP was primarily based on expert opinion via invited stakeholder groups. Peak professional bodies, advocacy groups, PHNs and grant applicants felt the priority areas were important and expressed areas of need. Some professional and advocacy peak bodies (such as the SHPA, RACGP, CHF and the ADHA) felt that the finalised priority areas failed to address areas of opportunity such as interventions that integrate pharmacists into general practice or community health centres, or use of emerging technologies. Greater communication about the priority area setting processes and the ranking of priority areas may have alleviated stakeholder concerns.

Assessment of submissions and trial protocols

The TAG was heavily involved in the assessment of Tranche 1 trial protocols, which formed the majority of the discussion for TAG meetings 2, 3 and 5.

The last TAG meeting occurred in September 2016, several months prior to submissions for Tranche 2 in December 2016. The TAG was not involved in the assessment of Tranche 2 trials. The TAG was not directly involved in the assessment of submissions or trial protocols for Tranche 3 trials.

A subsequent assessment committee (comprising Departmental staff and advisors, including the chair of the TAG) was established for the appraisal and selection of Tranche 2 and 3 trials. These advisors were:

- Director, Program Assessment Section, National Delivery Branch, Health Services Network (Chair);
- Director, Pharmacy Policy and Stakeholder Engagement Section, Pharmacy Branch (then Pharmacy Programs Section, Pharmaceutical Access Branch); and
- Technical Expert, Sansom Institute for Health Research.

Stakeholders consulted for the review indicated that there was a lack of transparency about the decision-making process for Tranche 2 trials. Stakeholders felt that assessment by a panel of three advisors may have been insufficient. Broader representation of stakeholders, such as the TAG, would have provided stakeholders with greater confidence in the assessment process. Several stakeholders including the PSA, AACP and grant applicants, commented that reliance on one expert advisor was insufficient to provide a balanced and informed view about applications under Tranches 2 and 3.

Observation 8: Greater communication about the decision-making processes for all tranches would have been appreciated by stakeholders.

Evaluation and sustainability of trials

The TOR for the TAG noted a requirement to consider evaluation methodologies including data collection and key performance indicators, and to provide advice on the translation of trial outcomes to establish long-term community pharmacy programs. The TAG provided guidance on protocol refinement, including key performance indicators to inform assessment of program sustainability for Tranche 1 trials.

This function was performed by internal Departmental staff and an expert advisor for Tranches 2 and 3 (as discussed above).

5.2.3 Suitability of the program length

Lead-in times for developmental processes and unexpected delays

The PTP sought to expend the full \$50 million on trial activity within the term of the 6CPA (5 years). In order for the outcomes of the trials to inform future negotiations of the 7CPA, the period for program activities should have been completed before negotiations commenced. Clause 10.4 of the 6CPA advises that negotiations for a new agreement would commence 12 months prior to the end of the 6CPA and conclude by March 2020.

Consistent with these broad program timelines, the grant guidelines developed for each Tranche of the PTP specified that trials were expected to be implemented over

⁶ TAG made recommendations for priority areas for both Tranches 1 and 2, however the processes for setting priority areas for Tranches 1 and 2 varied – Tranche 1 priority areas were set in response to proposal submissions submitted by The Guild, while Tranche 2 priority areas were set based on the stakeholder forum and call for ideas, taking care to not duplicate Tranche 1 priority areas.

three years [41] [23] [42] [43]. This would allow for up to 18 months from commencement of the 6CPA to identify priority areas and develop the appropriate processes to administer the grant program.

There was extensive activity to support program implementation both in the early stages and as PTP implementation continued to progress. Within the first 18 months of the PTP (July 2015 to December 2016), the following developmental activities had been completed:

- PTP principles established;
- priority areas for Tranches 1 and 2 approved;⁶
- grant guidelines for Tranches 1 and 2 developed;⁷
- three Tranche 1 proposals submitted, and one approved with funding agreement signed; and
- Tranche 2 approach to market closed. [55] [4].

A further four months were required for:

- assessment of Tranche 2 applications for eligibility and compliance;
- PASC review of the 29 eligible submissions;
- invitations to eligible submissions to resubmit based on PASC feedback; and
- re-assessment of resubmitted applications.

The level of revision required for some PTP application protocols was not anticipated. For example, an additional three to four months was required to negotiate protocols with the IMeRSe Feasibility Study under Tranche 1, and three of the four trials under Tranche 2 (IPAC Project, ReMInDAR Trial and CVD Trial) [41] [23]. Similarly, the Bridging the Gap between Physical and Mental Illness in

⁷ Tranche 2 grant guidelines were developed in October 2016. Tranche 1 Grant Guidelines were developed in December 2016 (after the original Tranche 1 proposals were submitted).

Community Pharmacy Trial (PharMIbridge) protocol was submitted in May 2018 under Tranche 3 [43] and was still to be finalised as at May 2019.

The NHMRC commented that the scientific rigour of applications could be strengthened if applications are submitted to their respective University Research Offices prior to submission to the PTP. The role of University Research Offices is to provide support to researchers to ensure grant applications have the maximum chance of success. NHMRC commented that ensuring applications follow scientific methodology and rigour prior to submission would decrease the time required for refinement post submission.

Observation 9: The timing objectives of the PTP processes did not allow for staggered tranches throughout the term of the 6CPA, nor did it allow time to assess and review applications in the open grant round (Tranche 2). Future program implementation planning should allow time to refine trial protocols to meet the required level of rigour expected by program administrators. Alternatively, University Research Offices could be engaged by applicants to ensure the quality of submissions.

Suitability of the length of grants for trials to realise the intended outcomes

During the review process some grant recipients commented on the delays between approval and signing of the funding agreements. The period for signing of PTP trial funding agreements varied between one to eight months, as shown in Table 5.2.

Table 5.2 Summary of PTP trials elapsed time between approval and funding agreement dates

TRANCHE	TRIAL	APPROVAL	FUNDING AGREEMENT SIGNATURE DATE	ELAPSED TIME
1	Diabetes Screening Trial	March 2016	May 2016	2 months

TRANCHE	TRIAL	APPROVAL	FUNDING AGREEMENT SIGNATURE DATE	ELAPSED TIME
	IMeRSe Feasibility Study	June 2017	October 2017	4 months
2	Asthma Trial	July 2017	November 2017	4 months
	IPAC Project	October 2017	December 2017	2 months
	ReMInDAR Trial	October 2017	April 2018	6 months
	CVD Trial	October 2017	June 2018	8 months
3	Chronic Pain MedsCheck Trial	March 2018	April 2018	1 month

With the exception of the Tranche 1 Diabetes trial, PTP trials did not commence until between October 2017 and June 2018.

Implementation timeframes for some trials were further prolonged due to extended periods of time required to obtain ethics approval in order for the trial to proceed. NHMRC felt that seeking ethics approval prior to PTP application would also increase the scientific rigour of applications.

To accommodate the reduced timeframes in which trials needed to be conducted, researchers had to modify their recruitment processes. For example:

- the Woolcock Institute (Asthma trial) had to increase the number of participating pharmacies; and
- the University of SA (ReMInDAR trial) had to increase the number of participating RACFs.

Ultimately, both these trials had to request an extension to ensure that sufficient participants could be enrolled in their trials to ensure statistical power (all extension requests were approved by the Department).

Observation 10: Time to obtain ethics and difficulties in recruiting sufficient participants to provide statistical power necessitated extensions of trial timeframes until the end of the 6CPA term in June 2020.

5.2.4 Suitability of the application processes

Suitability of the grant guidelines

Consistent with the requirements of the CGRG, grant guidelines were developed for all three tranches of the PTP, specific to their operations.

Tranche 1 grant guidelines were developed retrospectively after the initial submissions from the Guild. This was due to the decision by the Department to change from a contract for services to a grant program in June 2016. Tranche 1 grants were resubmitted after the release of the Guidelines in December 2016.

Tranche 2 guidelines were developed prospectively and made publicly available for eight weeks, from 20 October 2016 up until the due date for submissions on 15 December 2016.

Tranche 3 grant guidelines were prepared so they could be used to deal with unsolicited proposals. The Tranche 3 guidelines were tailored to the specific nature of the individual projects selected for ad hoc submission.

In step with the CGRG, the guidelines for all three tranches included details of how funds could be used. This included provision to prevent inappropriate cost-shifting from other levels of government to the Australian Government.

Observation 11: Grant guidelines developed for all three tranches were consistent with the Commonwealth Grant Rules and Guidelines.

Assessment criteria and rating scales differed between the tranche guidelines. Tranche 1 guidelines gave very little detail on the assessment criteria. Tranches 2 and 3 provided additional information for respondents for all assessment criteria.

Assessment criteria in Tranche 2 guidelines created a level of duplication in responses. For example:

- criteria 1, 2 and 3 sought information on the trial methodology and target patient cohorts; and
- both criteria 1 and 3 sought information on the supporting evidence and the intended outcomes.

Tranche 3 assessment criteria had less duplication with the PICO information being required under the trial design criterion. Tranche 3 guidelines were also suitably adapted to the specific needs of the individual proposals they were seeking.

Both Tranches 1 and 3 grant guidelines used a three-tier rating scale, while Tranche 2 guidelines used a five-tier rating scale. This may reflect the proportionality of the grant rounds and the need for a more detailed rating scale for an open tender round, but comparability between the tranches was reduced.

Observation 12: Assessment criteria and rating scales in the PTP grant guidelines differed between the three tranches, reducing comparability of the assessment processes across the tranches.

Suitability of Tranche 2 application process (open round)

In addition to advertising the PTP approach to market for Tranche 2 on the GrantConnect website, the PTP was also advertised through the Department's website, as well as the Guild and 6CPA websites.

Of the 90 pharmacist survey respondents aware of the PTP prior to the survey, approximately half had learned about the program through the Guild website, newsletters or social media (56%, n=50 of 90 respondents) or the 6CPA website (48%, n=43 of 90 respondents). Other common sources of information regarding the PTP were other pharmacists, and the Department of Health website or media release. A few respondents recalled hearing of the program through researchers, other peak body websites and conferences.

Observation 13: Advertising of the open round of PTP grants (Tranche 2) via official websites, media releases and word-of-mouth is appropriate and appears to have been effective.

The approach to market for Tranche 2 allowed applicants approximately two months to prepare and apply through the GrantConnect website.

Grant applicants commented that the application processes for the PTP was time-intensive and onerous compared to other grant application processes such as the NHMRC. For example:

- the PTP applications were considered to be very large (100 plus pages) in comparison to other grant process (an average of nine pages for the NHMRC applications research proposal component [56]);
- applications were resource intensive (many required multiple staff over six to eight weeks to complete); and
- the application time was short (approximately eight weeks from invitation to apply to closing date) for the level of work required.

Several applicants also commented that the response criteria were duplicative, and it was often unclear where to present information in the application.

Given the level of information requested in the PTP full application process, all stakeholders agreed that the two-step process of calling for an expression of interest (EOI) prior to inviting applicants to submit a full application was a good process. This narrowed down over 100 EOIs to 46 full applications, of which 29 were considered eligible and assessed. Some stakeholders queried if the selection process should include another pre-selection round before the full application is completed, i.e. a three-step process.

Observation 14: PTP grant applications were considered by applicants to be onerous compared to other grant application processes such as NHMRC. The time available to complete the applications (approximately two months) was considered short by consulted applicants.

Suitability of non-competitive grant rounds

Tranches 1 and 3 of the PTP were non-competitive grant rounds, open only to the Guild (Tranche 1) or the Guild in collaboration with the PSA (Tranche 3).

The decision-making process for implementing closed rounds was not communicated as part of the PTP, but may have considered *the need for timeliness and cost-effectiveness in the decision-making process while maintaining rigour, equity and accountability*, as noted in the CGRG [57].

One of the Tranche 3 topics was the subject of four grant applications under Tranche 2 (interventions for pharmacist-led management of pain/chronic pain). None of the Tranche 2 applications for pain/chronic pain were successful, and the quality of the applications and proposed methodologies varied [44]. The broader interest in the topic may have warranted an open or invited round.

TRIAL DESIGN AND SELECTION PROCESSES

5.2.5 Appraisal and selection processes

For all three tranches, grants guidelines specified assessment criteria and rating scales, which were used to assess the suitability of the grant applications. In all three tranches, the Departmental assessment committee was responsible for assessing the applications and making recommendations to the decision maker. In Tranche 1, the TAG also provided advice to the assessment committee. The decision maker for each of the tranches was as follows:

- Tranche 1: The Minister for Health or the Departmental delegate – the First Assistant Secretary, then Pharmaceutical Benefits Division (now Technology Assessment and Access Division (TAAD)) [41];
- Tranche 2: The Minister for Health and Aged Care [23]; and
- Tranche 3: The Assistant Secretary, then Private Health Insurance and Pharmacy Branch (now Pharmacy Branch), TAAD. [42] [43].

Application appraisals were merit-based and assessors scored applications against each of the specified criteria using the agreed scoring scale (three-point scale for Tranches 1 and 3 and a five-point scale for Tranche 2) [44] [41] [23] [42] [43].

The Internal Audit of the PTP noted that the mechanism to progress from application assessment to grant approval required improvement. The Internal Audit report observed that the Minister was invited to choose from the higher rated proposals, inconsistent with the assessment report conclusion that none of the trials fully achieved all of the assessment criteria⁸ [4].

Grant applicants suggested that adoption of a scoring threshold (i.e. grants must score above a set value in order to be funded), similar to the process used by NHMRC for assessment, would provide greater rigour to the assessment process.

In addition, the Internal Audit noted that negotiated protocol amendments should have documented endorsement by Departmental expert technical advisor(s) prior to the approval of the trial and the signing of the trial funding agreement⁹ [4].

Observation 15: The assessment process for the PTP trials was merit-based. The process could be strengthened to ensure an agreed level of readiness and endorsement by Departmental expert advisors prior to approval of grant funding.

5.2.6 Transparency of decision-making

Professional and advocacy peak bodies consulted had concerns about the lack of transparency of the PTP key decision-making processes. It was felt that the rationale for selecting priority areas or approved trials was not communicated more broadly to interested stakeholders. This resulted in a level of scepticism among stakeholders about how decisions were made about which organisations were approved to receive funds.

‘Communication...on the PTP on the whole has not been great.’

Advocacy peak body comment

‘The tender process was secretive and opaque.’

Pharmacist survey respondent

Many professional peak bodies (including the PSA, SHPA, RACGP) commented on the levels of transparency regarding Tranches 1 and 3 of the PTP. Stakeholder scepticism of processes for these tranches was increased by the large number of approved trials led by the Guild (four of seven trials), including the Chronic Pain MedsCheck trial, which received notably higher funding (at approximately \$21 million) than the other PTP trials (at an average of \$3.2 million per trial). In response to this observation by HMA, the Guild commented that, although they were the lead-organisation from a contract perspective, the engaged universities and researchers were in charge of the trials and leading the day-to-day implementation.

There was a perception among many stakeholders that the Guild was the administrator of the PTP as they had been for the R&D program under previous CPAs. While this perception is incorrect (see Section 5.2.8 below for further comment), the confusion added to general scepticism in the sector, as reported to the review team.

Most professional peak bodies, advocacy groups, grant applicants and TAG members consulted felt that PTP tranches should not be non-competitive rounds. Limited communication on the rationale for the non-competitive tranches was also expressed by stakeholders. Professional peak bodies commented that the non-competitive grant round in Tranches 1 and 3 were announced without consultation and associated documentation appeared to some of those interviewed to be discouraging of applications from others in the profession.

⁸ Internal Audit of the Management of the PTP, page 10

⁹ Internal Audit of the Management of the PTP, page 17

Observation 16: Stakeholders reported being sceptical about the PTP decision-making processes. They sought greater information on the reasons for decision making about which grants were successful in gaining a PTP grant.

Clarity of grant eligibility and assessment criteria

Despite the comprehensive grant guidelines for Tranche 2 trials that met the requirements of the CGRG, grant applicants interviewed for the review indicated that more guidance was required throughout the application process to address queries. Approximately one third of submitted applications were considered ineligible [58], suggesting additional guidance may have been helpful.

Similarly, the relatively low scores of eligible applications suggest that the criterion requirements were not well understood by applicants. Tallied application scores of the 29 eligible applications ranged from 10 to 28, with an average score of 20 (out of a possible score of 50) [44].

Given the value of the grants (average of \$3.2 million per trial), it was not unreasonable to expect a minimum level of rigour for trial protocols. However, the need for further information on trial requirements also appears to have translated to additional effort in protocol refinement to increase the robustness of the trial protocols prior to signing-off funding agreements.

Observation 17: Clarity of Tranche 2 eligibility criteria could have been improved to reduce the proportion of ineligible applications. The relatively low application scores suggested that the assessment criteria were not well understood.

Feedback on selection processes

Feedback and communication on assessment and selection processes was highlighted as an area for improvement by Tranche 2 applicants.

The feedback process involved notification of unsuccessful applicants with an invitation to contact the Department for feedback. Unsuccessful applicants who

contacted the Department were provided verbal feedback based around the assessment criteria. This met the obligations under the grant guidelines.

Unsuccessful applicants commented that there was limited feedback provided on their grants. Researchers had different expectations on the level of feedback they would receive, based on experiences with NHMRC and similar funding bodies. Researchers expected detailed peer-reviewed feedback that would enable improvement in their approach for future funding rounds.

Observation 18: Researchers expected additional detail in their feedback, based on their experiences with NHMRC grant application processes.

Public dissemination of information on trial activities

Under the terms of the standard grant agreements [59], publication of PTP trial activities required prior approval from the Department. This was in order to manage consumer/public expectations prior to completion of an independent HTA assessment.

Departmental approval prior to publication throughout the trial process was considered by some grant recipients to limit the opportunity for peer review and contribution to the evidence base. The Guild felt that not allowing researchers to publish results throughout the trials would hinder the evaluations to be undertaken by the independent HTA, which will make assessments based on the existing body of evidence for a service.

Grant recipients for the two trials focused on Aboriginal and Torres Strait Islander communities also said that general promotion of trial activities among communities or to consumers would be beneficial for recruitment and consumer engagement.

The Department commented that at the time of this review (July 2019), all but one PTP request for journal publication, newsletter communication, conference presentation and/or community engagement promotional material had been approved, albeit sometimes with minor edits. Typical edits included:

- acknowledgement of the Australian Government as funders of the trials, or

- ensuring wording did not imply that trial activities were considered best practice in Australia prior to completion, as the role of the trial is to find evidence for or against this.

Observation 19: Grant recipients felt that the rules for publication relating to the PTP trials were restrictive and could limit consumer engagement, or available evidence for an independent HTA assessment. The Department worked closely with grant recipients to approve publication requests quickly with minimal edits. To date (July 2019) only one publication request had been refused.

5.2.7 Fostering an outcomes orientation for PTP trials

Clinical outcomes

The assessment criteria of the grant guidelines for all three tranches had a focus on demonstrating a need for the intervention and ensuring scientific rigour for the trial protocol. Trial protocols were reviewed by:

- the TAG for Tranche 1;
- the PASC of MSAC for Tranche 2; and
- Department's special advisor, Emeritus Professor Lloyd Sansom, for Tranches 2 and 3.

The nature of the advice provided was how researchers could strengthen the scientific rigour of their trial protocol to ensure clinical outcomes could be achieved and measured.

Observation 20: Assessment criteria supported a clinical outcome focus of trials. Additional supports provided, including review by PASC, TAG and an expert advisor, fostered a focus on clinical outcomes.

Cost-effectiveness

The need for cost-effectiveness analysis of trial outcomes was clearly stated in the grant guidelines for Tranches 2 and 3. Tranche 3 was the only tranche to specifically request a methodology for the cost-effectiveness analysis to be undertaken in the grant assessment criteria [41] [23] [42] [43].

Other supports such as the review of trial protocol by PASC, TAG and the Department's special advisor, considered and advised on the cost-effectiveness methodology and data inputs. In addition, PTP grant recipients all included health economic expertise on their teams – typically partnering with a health economics department from a university.

Observation 21: Use of PASC, TAG and Departmental Advisors, plus engagement of health economic expertise in researcher teams, all fostered an outcomes focus for cost-effectiveness analysis. This could have been strengthened by inclusion of cost-effectiveness methodology in the assessment criteria for all tranches as it was done for Tranche 3.

Focus on Aboriginal and Torres Strait Islanders and people living in rural and remote areas

Consistent with the 6CPA Continuing Pharmacy Programmes, interventions providing benefit to Aboriginal and Torres Strait Islanders and people living in rural and remote areas were to be focus areas for the PTP [38]. However, only one of the nine topics/priority areas identified for the PTP (see Table 5.3), had a specific focus on Aboriginal and Torres Strait Islander peoples, and none of the trials had a specific emphasis on the needs of people living in rural and remote areas.

Table 5.3: Topics / priority areas for PTP trials by tranche

TRANCHE 1 TOPICS	TRANCHE 2 PRIORITIES	TRANCHE 3 TOPICS
(1) Pharmacy-based screening and referral for diabetes	(4) Community pharmacist outreach to	(8) Chronic Pain MedsCheck

TRANCHE 1 TOPICS	TRANCHE 2 PRIORITIES	TRANCHE 3 TOPICS
(2) Improved medication management for Aboriginal and Torres Strait Islander people through pharmacist advice and culturally appropriate services, and	residential aged care facilities	(9) Mental health support in community pharmacy
(3) Improved continuity in the management of patients' medications when they are discharged from hospital.	(5) Medicines management and reconciliation services	(6) Disease management for appropriate conditions, and
	(6) Disease management for appropriate conditions, and	(7) Screening and referral by pharmacists for cardiovascular risk

Assessment criteria in Tranches 1 and 3 did not mention Aboriginal and Torres Strait Islanders and people living in rural and remote areas as a focus of the PTP [41] [42] [43]. Tranche 2 assessment criterion 3 included the focus of PTP initiatives on these areas [23], and these were considered in the assessment of Tranche 2 grant applications [44].

Two of the seven funded PTP trials had a specific focus on Aboriginal and Torres Strait Islander people. No trial had a specific focus on rural and remote areas, although remoteness may have been considered in trial site selection for some trials.

NHMRC expressed disappointment that research applications focused on Aboriginal and Torres Strait Islander populations did not consider the *Indigenous Research Excellence Criteria* in their initial submissions to the PTP.

Inclusion of remoteness as an assessment criterion may have been insufficient to drive this PTP focus area.

ADMINISTRATIVE PROCESSES

5.2.8 Roles and responsibilities

The grant guidelines for all tranches clearly state the roles and responsibilities of the Department, the Minister, the assessment committee, the TAG (in Tranche 1), and the applicants [41] [23] [42] [43].

The TAG spent several meetings refining Tranche 1 protocols but its activities ceased before the assessment of Tranche 2 trial applications commenced.

As co-signatory to the 6CPA, the Guild expressed a desire to be jointly involved in the PTP development and decision-making processes. The Department viewed the Guild to be a potential applicant for funding and therefore considered involvement of the Guild in the PTP decision processes to be a conflict of interest.

HMA observed some confusion among broader stakeholders about the role of the Guild in relation to the PTP. Many professional peak bodies incorrectly thought the Guild was both a program administrator and grant recipient.

5.2.9 Suitability of record keeping and performance measures

Record keeping

The Internal Audit noted that the complete written records, including in minutes of relevant meetings, were not maintained¹⁰ [4]. Lack of documentation possibly contributed to a reduced ability to recall and communicate the reasons for decisions.

Performance measures and reporting requirements

All three tranche guidelines outline the PTP objectives and note the expectation of an independent HTA evaluation upon completion, to determine suitability for

¹⁰ Internal Audit of the Management of the PTP, page 19

ongoing program funding [41] [23] [42] [43]. In addition, the funding agreements for each trial are milestone-based and describe the expected deliverables for each trial.

Grant recipients indicated that once the funding agreements were signed, the reporting requirements were straightforward and proportional to the value of the grants and level of work to be undertaken. One grant recipient noted that reporting and administration of the grant would be challenging without dedicated administration personnel in their grant team.

PROGRAM OUTPUTS

5.2.10 Completion of trials within the term of the 6CPA

At the time of this review (June 2019), the status of the PTP trials was as follows:

- two applications under review (one in Tranche 1 and one in Tranche 3)
 - one of these applications (Tranche 3) had been approved by the Minister for Health, but had not yet signed a funding agreement;
- seven trials had signed funding agreements and had commenced;
- one of the seven trials had been completed
 - five of the remaining six were due for completion by the end of the 6CPA term; and
 - one trial anticipated it would need to apply for an extension beyond the term of the 6CPA); and
- no trial had undergone an independent HTA evaluation.

Observation 22: It is likely that only one PTP trial will undergo an HTA evaluation during the term of the 6CPA.

¹¹ Tranche 2 grant guidelines, page 8

5.2.11 Process for proceeding to health technology assessment

Grant recipients were aware that trial outcomes were required to be submitted to an appropriate independent HTA advisory body (such as MSAC). Grant guidelines for Tranche 2 provided an *example of the handling strategies for the review of evidence*, via a pdf link to ‘Guidelines for preparing assessment reports for the MSAC – Service Type: Investigative’¹¹ [23].

To meet the economic requirements of the PTP, most grant recipients partnered with university health economic departments familiar with HTA processes.

As only one trial has been completed to date – the Diabetes Screening Trial – this has been provided as an example of PTP completion processes. As lead-organisation for the Diabetes Screening Trial, the Guild commented on trial finalisation processes compared to the structure employed for the R&D program under the 5CPA and prior CPAs.

The finalisation processes for the R&D program included the following steps:

- preparation of final report (based on a template format) and presentation to the Trial’s Expert Panel;
- review of final report by Expert Panel, with comments and requested edits then provided back to the researchers;
- researchers to re-submit amended report; and
- before the project can be finalised.

The Guild indicated that, in order to finalise the Diabetes Screening Trial, it had undergone several review and re-submission cycles for the final report.

This may reflect the need to provide additional detail on patient-focused trial activities and outcomes in the final report compared to interim reports (as noted in the Internal Audit report). [4]

Preparation of a monitoring and evaluation framework for endorsement by the appropriate independent HTA (once selected), as recommended in the Internal Audit¹² [4], would help ensure data collection processes are appropriate for subsequent HTA evaluation. This may streamline trial finalisation processes in future.

Suitability of health technology assessment bodies

An independent HTA advisory body has not yet been formally identified for the PTP. MSAC is referred to as an example in multiple PTP documentation, including the discussion paper, which called for ideas on priority areas and grant guidelines. [11] [23]

Due to the service delivery nature of projects trialled under the PTP, several stakeholder organisations expressed concerns that the MSAC evaluation process will not adequately capture information on qualitative and quantitative outcomes needed to make a comprehensive assessment of each trial's effectiveness.

In addition, peak advocacy bodies such as the CHF and NACCHO highlighted the need to consider consumer experience and increased awareness of medication safety and consumer-related quality use of medicines issues as part of an evaluation of PTP trials. The implication was that some peak bodies felt that this not a core component of an MSAC assessment. However, consumer engagement through public consultation and consumer representation on MSAC and its sub-committees is demonstrably an important part of the MSAC process and considerations. [60]

Pharmacy peak body groups expressed concern about the appropriateness of existing independent HTA advisory bodies to undertake assessment of a service delivery intervention within current protocols. It was suggested that a new protocol for service delivery interventions may be required, to be implemented by experts with sufficient knowledge of pharmacy services in the community. One peak body commented:

'There is a need for greater input from pharmacy as well as representation within the organisation from pharmacists with real-world service delivery experience.'

Professional peak body comment

To support its consideration of pharmacy service assessments, MSAC specifically appointed a member with expertise in community pharmacy services.

Observation 23: Stakeholders expressed concern regarding the ability of existing independent HTA advisory bodies to address the service delivery nature and qualitative consumer experience aspects of the PTP.

5.3 CONCLUSION

Program development processes

The Department undertook several approaches to seeking stakeholder input into the development and design of the PTP and setting priority areas. This included a stakeholder forum, a 'call for ideas' and convening the TAG. Many professional and advocacy peak bodies would have liked greater engagement in the developmental stages. In addition, stakeholder engagement reduced when the TAG ceased meeting prior to the submission of grant applications under Tranche 2.

Trial design and selection processes

The term of the 6CPA was sufficient time to develop guidelines and processes and implement at least one round of trials. Unexpected delays encountered in protocol development stages, combined with the processes required for ethics approval, led to reduced time to conduct trials. There is evidence this affected the time available for trial site selection and patient recruitment and hence potential outcomes from the PTP achievable in the life of the agreement.

¹² Internal Audit of the Management of the PTP, page 14

Administrative processes

The administrative processes of the PTP were guided by *the Commonwealth Grant Rules and Guidelines*. The PTP grant guidelines met those requirements. There are several areas that could be strengthened in the future, such as increased clarity of application processes to reduce ineligible applications and further documentation of administrative processes associated with decision making.

Program outputs

It is likely that only one PTP trial will undergo an independent HTA during the term of the 6CPA.

6 EFFICIENCY

Key Finding 5: Implementing RCT methodologies can be challenging in the context of service delivery trials in the community. Approval of PTP study design should be guided by an assessment of whether the proposed method is appropriate and sufficiently robust to enable an independent HTA upon completion.

6.1 EVALUATION QUESTIONS

The implementation review of the PTP sought to assess the efficiency of the program. The key evaluation question for efficiency was:

What alternative models could be considered to improve clinical outcomes for consumers by extending the role of pharmacists in the delivery of cost effective primary health care services?

Review of the efficiency of the PTP included analysis of the following detailed review questions:

- (1) Did the PTP promote equitable access to funding for pharmacists and researchers, and to services for intended beneficiaries?
- (2) Are rigorous clinical trials the most suitable method to generate the desired outcomes? Could alternative trial models be used?

6.2 ANALYSIS AND FINDINGS

6.2.1 **Equity of the PTP processes**

Pharmacists and researcher access to funding

There were mixed views among stakeholders as to whether the use of a grant program such as the PTP provided equal access to researchers and pharmacists.

Approximately half the pharmacist survey respondents (57%, n=57 of 100 responses to this question) felt that the PTP provided equitable access to both researchers and pharmacists, and half did not (43%, n= 43 of 100 responses).

From the 52 comments provided by respondents, 37% (n=19 of 52 responses) indicated that the PTP favoured researchers and that pharmacists would not have the expertise to write a successful grant application. Other respondents expressed the view that this bias was necessary to provide high-quality evidence.

‘Competitive research grants underpin our research sector. It’s a reasonable and fair way to distribute funds.’

Pharmacy survey respondent

A small proportion of respondents felt that trial selection was not merit-based and (15%, n=8 of 52 responses). Comments included:

'It is not equitable when you have people who have received grants who have not gone through the original tendering process'

Pharmacist survey respondent

'It seems to be advantageous if applicants are politically and personally connected.'

Pharmacist survey respondent

A few respondents commented that trials were difficult to access or that the focus of funding should be rolling-out services rather than investing in a large grants program.

Stakeholder consultation reflected many of these views. Stakeholders considered that the rigour of the methodology required by the grant rules restricted both the type of organisation that could apply for grant funding as well as the pharmacies that were able to participate in the trial. At the grant applicant level, many felt that only large academic institutions would have the capacity and expertise to make a successful submission.

Observation 24: The level of scientific rigour required to ensure PTP trials are able to undergo an independent HTA may favour academic researchers. This was considered appropriate by many stakeholders consulted and surveyed.

Intended beneficiaries (consumers) access to services

The PTP trial priorities were based on areas of greatest need, and therefore vulnerable populations were appropriately targeted for the trials. A focus on regional/rural areas was not explicitly listed as a priority area or referred to in assessment criteria, except for Tranche 2 applications [44].

The Guild commented that the focus on rigorous trial protocols such as RCT methodology may have favoured participation from larger, better resourced pharmacists. This may have inadvertently excluded many rural and remote

pharmacies, especially sole-pharmacist pharmacies which have limited capacity to direct their staffing resources to activities not associated with dispensing and running a small business.

However, it must be noted that approved trials that have commenced implementation have included rural / remote pharmacies in the selection of participating pharmacies.

Implementing RCT methodology was also challenging for the two trials focused on Aboriginal and Torres Strait Islander communities (IMeRSe and IPAC). NACCHO and James Cook University commented that RCTs are challenging in the context of Aboriginal and Torres Strait Islander Health as they do not promote a culturally sensitive approach because of the method reliance on randomising patients to control and intervention groups. Conducting these trials as feasibility studies was regarded as a positive step by both NACCHO and James Cook University. NACCHO considered feasibility and implementation trials are more appropriate in the context of developing medicine-related services for Aboriginal and Torres Strait Islander communities. There was recognition that the flexibility afforded in changing the two trials involving Aboriginal and Torres Strait Islander populations to feasibility studies has had a positive impact in the community. James Cook University considered the pragmatic research methods were beneficial and expressed desire to see even more value placed on these methods in future.

6.2.2 Rigour of the evidence base

The grant guidelines for PTP trials specify that trial design must be valid and include scientific rigour, but do not specify that an RCT methodology must be employed. In contrast, the perception among stakeholders and grant applicants interviewed for the review was that an RCT methodology was preferred. This may have been influenced by the preference of RCT derived evidence for MSAC evaluations.

The Guild commented that refinement of trial protocols with the TAG and assessment committee in Tranches 1 and 3 preferentially focused on RCT methodologies.

An RCT methodology is considered the most rigorous study methodology for determining a cause and effect relationship between an intervention and patient outcomes, based on the elimination of confounding variables [24].

Stakeholders including the Guild and the PSA questioned the generalisability of trial results due to the eligibility criteria restrictions required to implement an RCT. The ADHA noted that RCT methodology may be appropriate for some trials but commented that most service delivery interventions did not require evidence that is as rigorous as an RCT. The NMHCCF felt that use of RCT methodology is not appropriate for trials in a service delivery setting; they argued that the collection of qualitative data is very important in this context and often not collected in RCT study design. The RACGP felt that evaluation of the PTP trials needed to be broader than an assessment focused on health economics and health outcomes, and should include assessment of societal impacts. One grant recipient said that the MSAC guidelines provided for reporting purposes were tailored for RCT methodology; they felt that some of the reporting criteria specified were not relevant for the trial they were implementing.

Many stakeholders felt that other study designs could have yielded adequate results, sufficient for clinical and economic assessment, and should have also been considered within the scope of the PTP. There is some support for this view in literature which notes that other study design methods can be more suitable for assessing the effectiveness of public health interventions where there are considerable extraneous or potentially confounding variables that are difficult to control for in study design [35].

However, the key focus for the PTP is to assess whether pharmacy services do improve clinical outcomes for consumers. Independent HTA reviews of existing pharmacy services already considered by MSAC showed that the evidence base was consistently weak across the services that they had examined. Furthermore, the MSAC reviews of existing pharmacy services indicated that there were either insufficient evidence to show an effect in improving clinical outcomes for consumers, or showed that these effects were small [37]. On this basis, it is reasonable to assume that a rigorous design is warranted in order to minimise the biases and confounding factors that are likely to hinder the detection of the expected effect of the program or service on the clinical outcomes for patients.

Independent HTA advisory bodies such as MSAC consider other study design type in addition to RCT. However, other study designs increase the risk of biases or confounding factors that may reduce the ability to determine the true effect of the initiative.

Independent HTA evaluation such as those undertaken by MSAC will consider any type of clinical outcome that is relevant to patients or consumers including quality adjusted life years (QALYs) to support cost-utility analysis [61].

Based on the feedback provided by stakeholder groups consulted during the evaluation, we concluded that greater understanding of the MSAC evaluation process is needed, to reduce stakeholder concerns regarding the suitability of RCTs.

Pilot and feasibility studies

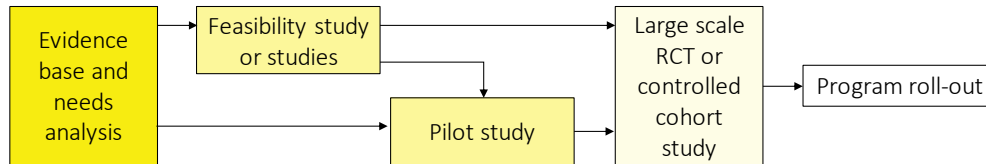
In the United Kingdom potential new programs are required to undergo a feasibility or piloting process, to determine whether it is possible to conduct the study as it has been designed [34]. This occurs prior to investment in large scale RCT studies. Other Australian Government grant opportunities also use this model, such as the Business Research and Innovation Initiative. This funds applicants to first complete a feasibility study before they can apply for a larger proof-of-concept grant [62].

Feasibility studies are used to determine whether it is possible to conduct the study as it has been designed. In feasibility studies, outcomes are generally not assessed and participants do not require randomisation [34].

Pilot studies are a small-scale version of a potential larger study. The same methodological protocols including reporting and assessment of outcomes should be used for both the pilot and the potential future study. The purpose of a pilot study is to ensure that the components of the study design can work together.

Figure 6.1 illustrates potential steps that could be used in the development of new public health service interventions.

Figure 6.1 Potential pathway for researching public health service interventions



Observation 25: Implementing RCT methodology can be challenging in the context of service delivery trials in the community. However, a rigorous design is warranted in order to minimise the biases and confounding factors that are likely to hinder the detection of the expected effect of the program or service on the clinical outcomes for patients.

Other considerations in trial design

The Guild noted that logistical challenges were created by running several large trials simultaneously, given the limited pool of pharmacies willing or able to participate. The Guild was also concerned that trial burn-out among pharmacists / pharmacies could further contribute to reduced levels of engagement in a future PTP.

The PSA felt that commissioned research through open tender contracting processes may have been appropriate for some priority areas where there is existing evidence to support a specified approach.

Observation 26: Investigator-initiated grants were useful to drive innovative approaches to service delivery models. Where a need or service gap is known, and there is sufficient existing evidence to support a model of care, directed commissioned research could also be appropriate.

6.3 CONCLUSION

There is a need for PTP trials to undergo an evaluation of clinical and economic merit before they can justify a submission for a broader rollout. Typically, these evaluations require rigorous evidence, such as that provided by RCTs. The PTP processes generally favoured an approach to trial development that emphasised use of RCTs.

PART C

FUTURE DIRECTIONS

7 APPROACH TO EMERGING THEMES: POSSIBLE DIRECTIONS

Based on the assessment of the appropriateness, effectiveness and the efficiency of the implementation of the PTP (as discussed in Part B), HMA identified areas where the program could be strengthened in the future. The RFQ for the review stated that it should:

provide recommendations and/or options on possible enhancements or improvements to the design and implementation of the PTP [63].

The Department's Internal Audit of the Management of the PTP conducted in 2018 [4] highlighted several options for better practice around grant administration processes. This review has not sought to replicate these issues. Rather, we have identified five broader emerging themes that could contribute to an enhancement of the program's operations. These are:

- **Emerging theme 1:** broadening the PTP objectives;
- **Emerging theme 2:** greater consideration of consumer views; and
- **Emerging theme 3:** changed program administration arrangements.

Redevelopment options underlying these themes are examined further in the remainder of this chapter.

7.1 EMERGING THEME 1: BROADENING THE PTP OBJECTIVES

7.1.1 Issue

As discussed in our analysis of appropriateness (Section 4.2.1), some stakeholders such as the Guild, felt that the PTP should be limited to initiatives involving community pharmacy/community pharmacists. However, many other stakeholders felt that constraining the focus of PTP trials to community pharmacy/community pharmacists would restrict innovation in the primary health care sector and other

settings such as ACCHS and RACFs, limit exploration of roles for consultant or non-dispensing pharmacists, reduce opportunities for collaboration with other health professionals, and limit the consumer-centred approach to new service design.

7.1.2 Rationale

The landscape for pharmacy in primary health care and other non-acute settings is changing; so too are consumer needs and expectations. The discussion in Section 2.3 highlights the need for inter-disciplinary approaches to primary health care and potential to use emerging models of non-dispensing pharmacists in locations other than a community pharmacy. Reviewing how the objectives of the PTP were interpreted indicated that there was general support for a broader interpretation of the program among stakeholders, other than the Guild. (See the discussion in Section 4.2.1 for more detail).

From the perspectives of professional peak bodies (such as the PSA, SHPA, AHPA and RACGP), innovative consumer-centric services in primary care cannot be driven through pharmacy alone. The PTP could be strengthened through greater engagement of the wider primary health sector, including settings such as ACCHS and RACFs, to promote co-design of services from a holistic, cross-service setting perspective. Pharmacist expertise in primary health care and other settings is required to ensure medicines are used appropriately to minimise harm. Enabling enhanced integration of medicines information into multidisciplinary primary care is a critical step to improving consumer outcomes and minimising medication misadventure. This is supported by the emerging models of care being trialled for non-dispensing pharmacists in GP clinics, ACCHS and RACFs (see Section 2.3 for background information).

Professional and advocacy peak bodies expressed a desire for community pharmacy to be better integrated into the primary health sector (as discussed in Section 4.2.3). Broadening the interpretation of the PTP objectives to focus on the *quality use of*

medicines in primary health care may promote greater collaboration among health professionals to drive innovative service delivery models.

In developing new models of service delivery to be trialled, it is also important to acknowledge the existing pharmacy workforce and business arrangements. Community pharmacies must be able to generate a sustainable income and support their workforce. Consideration should be given to ensuring a degree of consistency with exiting payment arrangements and reporting requirements to minimise the burden on participating pharmacies. Design of future trials should maintain an approach that works with and enhances the existing system and does not compete against it.

7.1.3 Options

Potential future options include:

- (1) **Status quo:** Maintain the current interpretation of the PTP objectives of improving health outcomes for consumers by the delivery of new and extended existing, cost-effective pharmacy programs.
- (2) **Minor adjustment:** Expand the interpretation of PTP objectives to include a broader range of community settings including GP clinics, ACCHS and RACFs.
- (3) **Significant adjustment:** Broaden the interpretation of the PTP objectives to focus on quality use of medicines in primary health care and other settings such as ACCHS and RACFs.

Benefits and challenges of these options are discussed below.

Option 1.1 status quo: Maintain the current interpretation of the PTP objectives of improving health outcomes for consumers by the delivery of new and extend existing, cost-effective pharmacy programs.

BENEFITS	CHALLENGES
<ul style="list-style-type: none"> • Increased options of service delivery for consumers. • Increased access to services / referral through community pharmacy. • Supports existing business models for community pharmacy. 	<ul style="list-style-type: none"> • Limited collaboration with other health professionals. • Can cause friction with other health professions if it appears pharmacists are attempting to move into the roles of other disciplines. • Limited access for consumers in RACFs, ACCHOs, and other primary care settings outside of community pharmacy.

Option 1.2 minor adjustment: Expand the interpretation of PTP objectives to include a broader range of community settings including GP clinics, ACCHS and RACFs

BENEFITS	CHALLENGES
<ul style="list-style-type: none"> • Increased access to pharmacist expertise for consumers and health professionals in locations outside of community pharmacy. • Promotes new roles for pharmacists in alternative locations, e.g. RACFs, GP clinics, workplaces. • Promotes new workforce options for the pharmacy workforce. • Promotes a broader use of pharmacist expertise. 	<ul style="list-style-type: none"> • Maintains a pharmacist-led approach, which may reduce collaboration or holistic design. • Impact on existing community pharmacy remuneration models could be challenging. • Maintains alignment with CPA community pharmacy programme objectives.

Option 1.3 significant adjustment: Broaden the interpretation of the PTP objectives to focus on quality use of medicines in primary health care and other settings such as ACCHS and RACFs

BENEFITS	CHALLENGES
<ul style="list-style-type: none"> • Promotes increased access to pharmacist expertise for consumers and health professionals in locations outside of community pharmacy. • Promotes full collaboration with primary health professions to provide a holistic consumer-centred approach. • Promotes innovative models of care to best address consumer healthcare needs. • Promotes new workforce options for the pharmacy workforce. • Promotes new roles for pharmacists in alternative locations. • Promotes use of pharmacist expertise. • Enables the program to address a range of newly emerging issues that do not have translational research support, e.g. impact of community pharmacy on personalised medicine therapies, pharmacotherapy and genetic testing, implementation of digital health technologies into standard work practice. 	<ul style="list-style-type: none"> • Impact on existing community pharmacy remuneration models could be challenging. • Maintains alignment with CPA community pharmacy programme objectives.

7.2 EMERGING THEME 2: GREATER CONSIDERATION OF CONSUMER VIEWS

7.2.1 Issue

As discussed in the assessment of PTP implementation effectiveness, the needs assessment for setting priority areas was driven largely by expert opinion (see Section 5.2.1 for more details). Barriers to service delivery uptake may be overlooked if perspectives from a variety of consumer groups are not considered. Co-design of service models with consumers and other health professionals, leads to approaches more likely to succeed in the long-term.

7.2.2 Rationale

The assessment of need and priority setting for the PTP sought views of experts and key opinion leaders in the field (Section 5.2.1). This is a necessary part of a needs assessment process, but it lacked perspectives of consumers and carers on current barriers or issues within the health system. Priority setting for the PTP made efforts to seek consumer input through engagement of representatives from the CHF at the stakeholder forum and their membership of the TAG. However, other consumer advocacy groups felt that the inclusion of just one consumer group was insufficient to reflect the diverse needs of the community. For example, the NMHCCF and PA commented that the specific needs of vulnerable groups may have been overlooked in trial design, e.g. the risk of medication interactions when people taking anti-psychotic medication are prescribed new medications for co-morbidities, or issues of over-prescribing or poly-pharmacy for chronic pain sufferers.

Ensuring greater consumer co-design in the development of trial protocols may contribute to improved consumer outcomes and program sustainability. It would provide a greater understanding of the current gaps / priorities in the system and could broaden the scope of health technology assessment.

Additionally, the needs assessment could be broadened to include systemic development priorities. The current needs assessment for priority area setting has

largely focused on medication management and health needs of population sub-cohorts (for example, a Tranche 1 priority area was to ‘improve continuity in the management of patients’ medications when they are discharged from hospital’, although a trial under this area is yet to be approved).

Expanding the priority area focus to include existing and emerging technological advances in primary health and pharmacy presents further opportunities to investigate new ways to streamline integration of technology into day-to-day practice for pharmacists. For example, the introduction of My Health Record and enhancements to the included medicines list provide new opportunities and challenges for pharmacists and coordinated health care (see Section 2.3 and Section 4.2.2 for further discussion on this topic). Any efforts in this area would need to be done in consultation with the Australian Digital Health Agency to ensure that trials are not duplicative.

7.2.3 Options

Potential future options include:

- (1) **Status quo:** Maintain existing priority areas derived from the workshop process and the ‘call for submissions.’
- (2) **Minor adjustment:** Include an emphasis on consumer co-design in the development of trial protocols.
- (3) **Moderate adjustment:** Conduct a comprehensive needs assessment and consumer experience study to identify the barriers and service gaps prior to setting new priority areas.
- (4) **Significant adjustment:** Apply a systemic development assessment process to address a broader range of priority areas.

Benefits and challenges of these options are discussed below.

Option 2.1 status quo: Maintain existing priority areas derived from the workshop process and the ‘call for submissions’

BENEFITS	CHALLENGES
<ul style="list-style-type: none"> Maximises use of the work already undertaken to set Priority Areas 	<ul style="list-style-type: none"> Priority Areas may not be as comprehensive as they could be.

Option 2.2 minor adjustment: Include an emphasis on consumer co-design in the development of trial protocols

BENEFITS	CHALLENGES
<ul style="list-style-type: none"> Maximises use of the work already undertaken to set Priority Areas Ensures a consumer perspective is applied to trial design 	<ul style="list-style-type: none"> Priority Areas may not be as comprehensive as they could be. Area of researcher interest may not align with consumer perceived needs.

Option 2.3 moderate adjustment: Conduct a comprehensive needs assessment and consumer experience study to identify the barriers and service gaps prior to setting new priority areas.

BENEFITS	CHALLENGES
<ul style="list-style-type: none"> Robust evidence will be gathered to inform the development of trial priorities that address an identified need within the community and better align with consumers’ perceptions of need. Information collected for the comprehensive needs assessment compiled by the PHNs could be used to inform the process. 	<ul style="list-style-type: none"> May be a time consuming and costly process that will extend the development stages of the program. The detail of information on quality use of medicines, access to medicines and pharmacy services may vary between PHN needs assessments, which have a broader primary health care focus.

Option 2.4 significant adjustment: Apply a systemic development assessment process to address a broader range of priority areas

BENEFITS	CHALLENGES
<ul style="list-style-type: none"> Ensure the service development needs of pharmacy (including community pharmacy) are considered in the changing landscape, such as the integration of digital health technology into standard work practices and personalised medicine Could be conducted quickly as information would come largely from expert opinion and service providers. 	<ul style="list-style-type: none"> Will increase the complexity of determining the appropriate weighting for different priority areas.

7.3 EMERGING THEME 3: CHANGED PROGRAM ADMINISTRATION ARRANGEMENTS

7.3.1 Issue

Traditional grants administration structures are core business of the Department¹³ [4]. As noted in the Internal Audit of PTP management, the Department assumed administrative responsibility for the PTP without any additional resources¹⁴ [4].

Implementing changes to strengthen the PTP administration is likely to require additional resource investment from the Department (see Section 5.2 for a discussion on effectiveness of PTP implementation). It may be more efficient and cost-effective to use the resources and expertise of existing grant administration programs that specialise in health service development.

¹³ Internal Audit of the Management of the PTP, page 7

7.3.2 Rationale

The Internal Audit noted that the clinical research focus of the PTP meant the structures and processes required for administration have much in common with those processes required by NHMRC.

There are concerns among stakeholders that if PTP funding were added to the existing pool of NHMRC funds, the focus on community pharmacy development would be reduced (see Section 4.2.4 for further discussion).

Another potential funding administrator is the MRFF. The Australian Medical Research Advisory Board offers advice to government about MRFF research priorities and funding [64]. Implementation of MRFF programs is overseen by the Health and Medical Research Office (HMRO) in the Department of Health. HMRO uses the grants expertise of the NHMRC and the government's Business Grants Hub to assist with administration [65].

Further consultation with NHMRC and MRFF is needed to determine if either of these organisational options are suitable for future administration of an ongoing PTP.

7.3.3 Options

Potential future options include:

- (1) **Status quo:** Maintain administration of the PTP by the Department within a CPA framework.
- (2) **Moderate adjustment:** Transfer administration of the PTP to the NHMRC.
- (3) **Significant change:** Establish a new MRFF Research Mission to administer the program.

Benefits and challenges of these options are discussed below.

¹⁴ Internal Audit of the Management of the PTP, page 7

Option 3.1 status quo: Maintain administration of the PTP by the Department within a CPA framework

BENEFITS	CHALLENGES
<ul style="list-style-type: none"> • Maintains a connection to establishment of new Community Pharmacy Programmes through the CPA. 	<ul style="list-style-type: none"> • As trials have not yet gone through the full requirements of the trial program including the independent HTA process, the PTP has not fully demonstrated its capacity as an appropriate mechanism for exploring alternative models of care. • Could require additional resources from the Department because of growing administrative requirements. • Restrictions of the CPA may limit the scope and timeframes of research. • Does not align with some stakeholder views.

Option 3.2 moderate adjustment: Transfer administration of the PTP to the NHMRC

BENEFITS	CHALLENGES
<ul style="list-style-type: none"> • Established grant administration body with well recognised processes. • Ability to increase scope of trials to include innovation, digital technology implementation and collaboration among health professionals. • Peer review system matches researcher expectations. 	<ul style="list-style-type: none"> • Funding could become absorbed in the general NHMRC funding pool. • Limits the accessibility of non-academic institutions as NHMRC recipients need to be affiliated with an approved institution (AI) (e.g. universities listed in the Higher Education Support Act 2003.) <ul style="list-style-type: none"> – NHMRC is updating processes for non-university organisations to become AIs. The new process is expected for release in mid-2019.

BENEFITS	CHALLENGES
	<ul style="list-style-type: none"> • Connection to the independent HTA assessment for ongoing Community Pharmacy Programmes may be decreased.

Option 3.3 significant change: Establish a new MRFF Research Mission to administer the program

BENEFITS	CHALLENGES
<ul style="list-style-type: none"> • Established health related grant administration body with well recognised processes. • Ability to increase scope of trials to include innovation, digital technology implementation and collaboration among health professionals. • Peer review system matches researcher expectations. • Potential to include greater consumer and carer perspectives (including vulnerable populations) in advisory groups. • As MRFF is managed within the Department there is a connection to the independent HTA process. 	<ul style="list-style-type: none"> • Requires support from the Australian Medical Research Advisory Board.

8 APPENDICES

APPENDIX A DESCRIPTION OF RESEARCH METHODOLOGY TYPES

Systematic review and critical appraisal

Systematic reviews provide a comparison and analysis of primary studies within a specific study area. This results in an assessment of the comparative strengths and weaknesses of study design and implementation.

Critical appraisals provide systematic reviews of a single primary study and assessment of its strengths and weaknesses.

However, systematic reviews and critical appraisals provide a meta-analysis and are not themselves a primary study.

Randomised controlled trials

Randomised controlled trials (RCTs) are considered the most rigorous study methodology for determining a cause-and-effect relationship between intervention and patient outcomes as the design seeks to eliminate confounding variables [24]. Regarding primary study methodologies, RCTs are considered the least susceptible to bias and, therefore, produce the strongest evidence of treatment effectiveness. In addition, evidence from RCTs with larger sample sizes is considered stronger than from those with small sample sizes. Key features of an RCT include:

- random allocation of patients/consumers to an intervention group;
- ‘blinding’ of participants and/or researchers to which group is receiving the intervention;
- both groups are treated identically, apart from the intervention protocol

- data is analysed based on the group to which the participant is allocated regardless of intervention non-compliance, withdrawal or protocol deviation, according to intention to treat principles; and
- analysis is focused on estimating the size of the difference in predefined outcomes between intervention groups.

Double blind RCTs (i.e. neither participants nor researchers know the intervention group) are preferred to minimise bias, including overestimation of trial effectiveness. However, in service delivery interventions, it is not possible to blind the researcher delivering the intervention. In these instances, the risk of bias can be overcome by blinding the evaluator. [24]

Cohort studies

A cohort study is designed to assess if a particular characteristic is associated with the development of a disease or other clinical outcome. Features of a cohort study include:

- a longitudinal approach that follows groups of individuals with a common characteristic, e.g. demographic characteristics, exposure, disease risk factor, over a period of time;
- assessment of the association of characteristic to the development of a disease or other clinical outcome; and
- can be conducted retrospectively or prospectively. [66]

A well-designed cohort study with large participant numbers can produce more reliable results than an RCT with low participation rates. [67]

Case-controlled studies

Case-controlled studies are a form of observational study, i.e. no intervention is provided. Features include:

- observational only, no intervention;

- can be conducted retrospectively or prospectively;
- resulting evidence can be used to prove an association but is not able to establish cause and effect; and
- uncontrolled observational studies are termed case-series studies.

Expert opinion

Perspectives or predictions provided by individuals who are considered experts in the field of interest. The strength of expert opinion is reinforced through a consensus of multiple experts. However, it cannot be considered a form of primary study and is the least robust form of evidence collection, and subject to the most bias.

APPENDIX B STAKEHOLDER CONTACTS

Individuals and organisations consulted

ORGANISATION	CONTACT(S) CONSULTED
AACP	• Mr Grant Martin
ACRRM	• Ms Jenny Johnson
ADHA	• Mr Darnel Murgatroyd • Ms Vandana Chandnani • Mr Andrew Matthews
AHPA	• Ms Claire Hewat
Black Swan Health	• Ms Sarah Tadier
CHF	• Ms Jo Root
Central Queensland, Wide Bay and Sunshine Coast PHN	• Ms Jodie Sargent
Department	• Mr Ben Sladic • Ms Natasha Ploenges • Ms Jane Ranson-Smith • Ms Min Ma

ORGANISATION	CONTACT(S) CONSULTED
Gippsland PHN	• Ms Stephanie Germano • Ms Sarah Clarke
Griffith University	• Professor Amanda Wheeler
Guild	• Ms Fiona Mitchell • Ms Erica Vowels • Ms Michelle Quester • Ms Marsha Gomez
James Cook University	• Associate Professor Sophie Couzos
NACCHO	• Mr Mike Stephens • Dr Dawn Casey
NHMRC	• Ms Samantha Robertson
NMHCCF	• Ms Lorraine Powell • Ms Eileen McDonald • Ms Lyn English
NRHA	• Mr Mark Diamond
PA	• Ms Priyanka Rai
PSA	• Dr Shane Jackson
RACGP	• Mr Roald Versteeg • Dr Mark Morgan
SHPA	• Ms Kristin Michaels
South West Sydney PHN	• Ms Dina Malak • Mr Samuel Sio
TAG	• Emeritus Professor Lloyd Sansom
Top End Health	• Dr Bhavini Patel
University of South Australia	• Dr Bruce Chadwick

ORGANISATION	CONTACT(S) CONSULTED
	<ul style="list-style-type: none">• Dr Rebecca Bilton• Associate Professor Nicole Pratt• Dr Renly Lim• Ms Annette Pashke
University of Tasmania	<ul style="list-style-type: none">• Dr Juanita Westbury
Woolcock Institute	<ul style="list-style-type: none">• Professor Carol Armour• Ms Sarah Serhal

APPENDIX C SURVEY TOOL

Survey tool for online survey of pharmacists

SURVEY QUESTION	ANSWER OPTIONS	SURVEY LOGIC
(1) Please indicate the pharmacy setting in which you work the largest proportion of your regular hours.	(a) Community pharmacy – owner	Proceed to Question 2
	(b) Community pharmacy – employee	Skip to Question 3
	(c) Consultant pharmacist	
	(d) Hospital pharmacy	
	(e) Research or university	
	(f) Other (<i>please specify</i>)	
(2) How long have you been practicing as a registered pharmacist?	(a) Less than five years	Proceed to Question 3
	(b) Between five and ten years	
	(c) Between ten and fifteen years	
	(d) Over fifteen years	
(3) Please indicate the primary location in which you work?	(a) Major cities	Proceed to Question 4
	(b) Regional	
	(c) Remote	
Under the 6CPA, pharmacists are funded to provide a range of health services including medication adherence (e.g. dose administration aids) and medical management (e.g. HMR / RMMRs, MedsChecks) programs.	(a) Yes (<i>please explain your answer</i>)	Proceed to Question 5
(4) In your opinion, do community pharmacies currently have capacity to expand the range of these services for consumers, e.g. chronic disease monitoring, patient education?	(b) No (<i>please explain your answer</i>)	
(5) What are the potential barriers and enablers of expanding these types of services in pharmacies?	<i>Free text</i>	Proceed to Question 6
The aims of the PTP are to improve clinical outcomes for consumers and/or extend the role of pharmacists in the delivery of primary health care services through community pharmacy.	(a) Yes	Proceed to Question 7
(6) Were you aware of the PTP prior to completing this survey?	(b) No	Skip to Question 9
(7) How did you become aware of the PTP? Please select all that apply	(a) Department of health website, media release	Proceed to Question 8

SURVEY QUESTION	ANSWER OPTIONS	SURVEY LOGIC
	(b) The Pharmacy Guild of Australia website, newsletters, social media	
	(c) The Pharmaceutical Society of Australia website, newsletters, social media	
	(d) 6CPA website	
	(e) Other pharmacists	
	(f) Other researchers	
	(g) Other (<i>free text</i>)	
(8) Were you or your pharmacy involved in a funding application for a trial?	(a) Yes	Proceed to Question 9
	(b) No	
(9) Do you think the PTP aims are suitable and/or effective to advance pharmacy practice in Australia?	(a) Yes (<i>please explain your answer</i>)	Proceed to Question 10
	(b) No (<i>please explain your answer</i>)	
(10) In your opinion, is a research grant program a suitable mechanism to achieve the aims of the PTP?	(a) Yes (<i>please identify any enablers</i>)	Proceed to Question 11
	(b) No (<i>please identify any barriers and possible solutions</i>)	
(11) Do you believe that funding of research grants provides equitable access to researchers or pharmacists?	(a) Yes (<i>Please explain your answer</i>)	Proceed to Question 12
	(b) No (<i>Please explain your answer</i>)	
(12) Are you currently, or have you previously, participated in research for pharmacy-led health service delivery models?	(a) I am/was involved in a PTP trial	Proceed to Question 13
	(b) Other – Randomised controlled trial (RCT) – this includes cluster randomisation of participants, e.g. by pharmacy or geographic location	
	(c) Cohort study with or without comparator group	
	(d) Other	
	(e) Not sure (<i>Please provide a brief description</i>)	
	(f) None	
(13) If yes – what service delivery setting was your research focused in?	(a) Hospital	Skip to Question 14
	(b) Community	
		Proceed to Question 14

SURVEY QUESTION	ANSWER OPTIONS	SURVEY LOGIC
	<p>(c) Transitional care (e.g. between hospital and community)</p> <hr/> <p>(d) Residential aged care facility</p> <hr/> <p>(e) Aboriginal Community Controlled Health Organisation / Aboriginal Medical Service</p> <hr/> <p>(f) Other (<i>please specify</i>)</p>	
<p>(14) What type of research protocol(s) should a research grant program such as the PTP have a focus on?</p> <p>Select all that apply</p>	<p>(a) RCTs</p> <hr/> <p>(b) Small scale pilot studies</p> <hr/> <p>(c) Proof of concept / feasibility studies</p> <hr/> <p>(d) Grass roots research (i.e. small-scale test of novel concepts)</p> <hr/> <p>(e) Other (please provide a brief description)</p>	<p>Proceed to Question 15</p>
<p>(15) Please describe some new ways in which pharmacists can develop and deliver consumer-centric models of care in the community setting?</p>	<p><i>Free text</i></p>	<p>Proceed to Question 16</p>
<p>(16) How can collaboration between pharmacists/pharmacy and other primary health care professionals be enhanced?</p>	<p><i>Free text</i></p>	<p>End of survey – participants directed to acknowledgement page and invited to leave final comments</p>

9 REFERENCES

- [1] Australian Government Department of Health, “Amended and Restated Sixth Community Pharmacy Agreement,” Australian Government, Canberra, 2017.
- [2] Australian Government Department of Health, “Pharmacy Trial Programme: Summary report of the stakeholder consultation forum held on 26 October 2015,” Canberra, 2015.
- [3] Australian Government Department of Health, “Pharmacy Trial Program,” 27 September 2018. [Online]. Available: <http://www.health.gov.au/internet/main/publishing.nsf/Content/pharmacy-trial-programme#Stakeholder>. [Accessed 2019].
- [4] Australian Government Department of Health, “Audit of the Management of the Pharmacy Trial Program under the Sixth Community Pharmacy Agreement,” Department of Health, Canberra, 2018.
- [5] Australian Government Department of Health and Ageing, “National Medicines Policy,” Australian Government, Canberra, 2000.
- [6] Commonwealth of Australia, “The National Strategy for Quality Use of Medicines,” Commonwealth of Australia, Canberra, 2002.
- [7] Australian Institute of Health and Welfare, “Australia's Health 2018: in brief – How Healthy Are We?,” AIHW, Canberra, 2018.
- [8] Australian Government Department of Health, “Primary care,” 14 July 2015. [Online]. Available: <http://www.health.gov.au/internet/main/publishing.nsf/Content/primarycare>. [Accessed 2019].
- [9] Australian Institute of Health and Welfare, “Australia's Health 2018: in brief - On an average day in our health system,” AIHW, Canberra, 2018.
- [10] Pharmaceutical Society of Australia, “Medicine Safety: Take Care,” PSA, Canberra, 2019.
- [11] Australian Government Department of Health, “Supporting pharmacist delivery of primary health care services through the Pharmacy Trial Program,” Australian Department of Health, Canberra, 2016.
- [12] Sixth Community Pharmacy Agreement, “Community Pharmacy in Health Care Homes Trial Program,” [Online]. Available: <http://6cpa.com.au/medication-management-programs/community-pharmacy-in-health-care-homes-trial-program-interim/>. [Accessed 2019].
- [13] Australian Government Department of Health, “Health Care Homes,” [Online]. Available: <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-care-homes>. [Accessed 2019].
- [14] Australian Medical Association, “Bringing Pharmacists into the Fold,” [Online]. Available: <https://ama.com.au/ausmed/bringing-pharmacists-fold>. [Accessed 2019].
- [15] Australian Journal of Pharmacy, “Four GP Clinics Get Integrated Pharmacists,” [Online]. Available: <https://ajp.com.au/news/four-gp-clinics-get-integrated-pharmacists/>. [Accessed 2019].
- [16] Health Direct, “My Health Record,” February 2019. [Online]. Available: <https://www.healthdirect.gov.au/my-health-record>. [Accessed 2019].

-
- [17] Australian Digital Health Agency, “My Health Record Statistics: Dashboard Statistics,” February 2019. [Online]. Available: <https://www.myhealthrecord.gov.au/statistics>. [Accessed 2019].
- [18] Australian Digital Health Agency, “My Health Record Information Fact Sheet for Pharmacists,” Department of Health.
- [19] Australian Government Department of Health, “Primary Health Networks,” 15 May 2019. [Online]. Available: <https://www.health.gov.au/internet/main/publishing.nsf/Content/PHN-Home>. [Accessed 2019].
- [20] Pharmacy Guild of Australia, “Community Pharmacy 2021: Framework for Change,” Canberra, 2018.
- [21] Australian Government Department of Health, “Health Technology Assessment,” 27 February 2017. [Online]. Available: <http://www.health.gov.au/internet/hta/publishing.nsf/Content/about-1>. [Accessed 2019].
- [22] Australian Government Department of Health, “MSAC and its Sub-committees,” Australian Government of Australia, 21 July 2017. [Online]. Available: <http://www.msac.gov.au/internet/msac/publishing.nsf/content/factsheet-05>. [Accessed 2019].
- [23] Australian Government Department of Health, “Pharmacy Trial Program Tranche 2 Grant Guidelines,” Australian Government Department of Health, Canberra, 2016.
- [24] B. Sibbald and M. Roland, “Understanding controlled trials: Why are randomised controlled trials important?,” *British Medical Journal*, vol. 316, no. 201, 1998.
- [25] Canadian Pharmacists Association, “A Review of Pharmacy Services in Canada and the Health and Economic Evidence,” Canadian Pharmacists Association, 2016.
- [26] T. J. Brown, A. Todd, C. O. O'Malley, H. J. Moore, A. K. Husband, C. Bambra, A. Kasim, F. F. Sniehotta, L. Steed, S. Smith, L. Nield and C. D. Summerbell, “Community pharmacy-delivered interventions for public health priorities: a systematic review of interventions for alcohol reduction, smoking cessation and weight management, including meta-analysis for smoking cessation,” *British Medical Journal*, vol. 6, 2016.
- [27] J. L. Chapman, A. Zechel, C. Y. H and S. Abbott, “Systematic review of recent innovations in service provision to improve access to primary care,” *British Journal of General Practice*, vol. 502, p. 54, 2004.
- [28] J. Gordon, M. Watson and A. Avenell, “Lightening the load? A systematic review of community pharmacy-based weight management interventions,” *Obesity Reviews*, vol. 12, pp. 897-911, 2011.
- [29] D. Brown, J. Portlock and P. Rutter, “Review of services provided by pharmacies that promote healthy living,” *International Journal of Clinical Pharmacy*, vol. 34, no. 3, pp. 399-409, 2012.
- [30] J. D. Robinson, L. L. M. Segal R and D. R. E, “Impact of a Pharmaceutical Care Intervention on Blood Pressure Control in a Chain Pharmacy Practice,” *Annals of Pharmacotherapy*, vol. 44, pp. 88-96, 2010.
- [31] M. D. Murray, J. Young, S. Hoke, W. Tu, M. Weiner, D. Morrow, K. T. Stroupe, J. Wu, D. Clark, F. Smith, I. Gradus-Pizlo, M. Weinberger and C. Brater, “Pharmacist Intervention to Improve Medication Adherence in Heart Failure,” *Annals of Internal Medicine*, vol. 146, pp. 714-725, 2007.
- [32] S. P. Ferrari, A. J. Greco, N. M. Michaels, S. K. O'Connor, R. W. Chater, A. J. Viera, H. Faruki, H. L. McLeod and Roederer, “Implementation of a pharmacogenomics service in a community pharmacy,” *Journal of the American Pharmacy Association*, vol. 54, pp. 172-180, 2014.

-
- [33] J. E. Bailey, S. Surbhi, P. C. Bell, A. M. Jones, S. Rashed and M. O. Ugwueke, “SafeMed: Using pharmacy technicians in a novel role as community health workers to improve transitions of care,” *Journal of the American Pharmacists Association*, vol. 56, no. 1, pp. 73-81, 2016.
- [34] National Institute for Health Research, “Feasibility and Pilot Studies,” National Health Service, London, 2017.
- [35] P. Criag, P. Dieppe, S. Macintyre, S. Michie, I. Nazareth and M. Petticrew, “Developing and evaluating complex interventions: the new Medical Research Council guidance,” *British Medical Journal*, vol. 337, 2008.
- [36] The Pharmaceutical Benefits Scheme, “2017 Community Pharmacy Stakeholder Forum: Topic 2: Outcomes of the Pharmacy Programs Cost Effectiveness Review,” 2017. [Online]. Available: <http://www.pbs.gov.au/info/general/sixth-cpa-pages/community-pharmacy-stakeholder-forum#forum2017>. [Accessed 2019].
- [37] Medical Services Advisory Committee, “MEDICAL SERVICES ADVISORY COMMITTEE (MSAC) MINUTES - November 2016,” Medical Services Advisory Committee, Canberra, 2016.
- [38] Australian Government Department of Health, “Supporting pharmacist delivery of primary health care services through the Pharmacy Trial Program: Discussion Paper, page10,” Canberra, 2016.
- [39] Australian Government Department of Health, “Pharmacy Trial Program: Principles,” 2016. [Online]. Available: <https://www.health.gov.au/internet/main/publishing.nsf/Content/pharmacy-trial-programme>. [Accessed 2019].
- [40] Australian Government Department of Health, “Pharmacy Trial Program Trials Advisory Group: Terms of Reference,” Canberra, 2016.
- [41] Australian Government Department of Health, “Pharmacy Trial Program Tranche 1 Grant Guidelines,” Australian Government Department of Health, Canberra, 2016.
- [42] Australian Government Department of Health, “Pharmacy Trial Program Tranche 3 Grant Guidelines - Chronic Pain MedsCheck,” Australian Government Department of Health, Canberra, 2018.
- [43] Australian Government Department of Health, “Pharmacy Trial Program Tranche 3 Grant Guidelines - Mental Health Support in Community Pharmacy,” Australian Government Department of Health, Canberra, 2018.
- [44] PTP Tranche 2 Assessment Team, *PTP Tranche 2 assessment documentation, Master List, provided by the Department of Health*, 2017.
- [45] The Auditor-General, “ANAO Report: No.25 Administration of the Fifth Community Pharmacy Agreement,” Australian National Audit Office, Canberra, 2014-15.
- [46] Australian Government Department of Finance, “Commonwealth Grant Rules and Guidelines,” Australian Government, Canberra, 2017.
- [47] Australian Government Department of Finance, “Commonwealth Procurement Rules,” Commonwealth Government, Canberra, 2014.
- [48] National Health and Medical Research Council, “Levels of Evidence and Grades for Recommendations for Developers of Clinical Practice Guidelines,” 2009.
- [49] Australian Digital Health Agency, “My Health Record: ePIP,” [Online]. Available: <https://www.myhealthrecord.gov.au/for-healthcare-professionals/practice-incentives-program>. [Accessed 2019].
- [50] National Health and Medical Research Council, “NHMRC Grants Funding 2000 - 2016 Summary Tables,” NHMRC, Canberra, 2017.
- [51] National Health and Medical Research Council, “Funding rules involving Aboriginal and Torres Strait Islander People,” [Online]. Available: <https://www.nhmrc.gov.au/funding-rules-involving-aboriginal-and-torres-strait-islander-people>. [Accessed 2019].
-

-
- [52] Australian Government Medical Research Future Fund, “Research Mission,” [Online]. Available: <https://beta.health.gov.au/initiatives-and-programs/medical-research-future-fund/about-the-mrff/research-missions>. [Accessed 2019].
- [53] Australian Government Department of Health, “Pharmacy Trial Programme: Summary report of the stakeholder consultation forum held on 26 October 2015,” Department of Health, Canberra, 2015.
- [54] Australian Government Department of Health, “Pharmacy Trial Program,” 27 September 2018. [Online]. Available: <http://www.health.gov.au/internet/main/publishing.nsf/Content/pharmacy-trial-programme#AdvisoryGroup>. [Accessed 22 March 2019].
- [55] Australian Government Department of Health Pharmacy Trial Program, “Trial Advisory Group,” [Online]. Available: <https://www.health.gov.au/internet/main/publishing.nsf/Content/pharmacy-trial-programme-tag>. [Accessed 2019].
- [56] National Health and Medical Research Council, “Development Grant Scheme 2019 Guidelines,” NHMRC, Canberra, 2018.
- [57] Australian Government Department of Finance, “Commonwealth Grants Rules and Guidelines 2017 Information Sheet,” Commonwealth Government of Australia, Canberra, 2017.
- [58] National Health and Medical Research Council, “NHMRC funding averages from 2000 to 2016,” [Online]. Available: <https://www.nhmrc.gov.au/funding/data-research/research-funding-data>. [Accessed 2019].
- [59] Australian Government Department of Health, “Commonwealth Standard Grant Agreement, clause 15.1 confidentiality,” Department of Health, Canberra.
- [60] Medical Services Advisory Committee, “About MSAC / Frequently Asked Questions,” 20 July 2016. [Online]. Available: <http://www.msac.gov.au/internet/msac/publishing.nsf/Content/Factsheet-08>. [Accessed 2019].
- [61] Medical Services Advisory Committee, “Technical Guidelines for preparing assessment reports for the Medical Services Advisory Committee – Service Type: Therapeutic Version 2,” Australian Government Department of Health, Canberra, 2016.
- [62] Australian Government: Business , “Business grants and assistance programs,” [Online]. Available: <https://www.business.gov.au/assistance/business-research-and-innovation-initiative>. [Accessed 2019].
- [63] Australian Government Department of Health, “Request for quotation for Implementation Review of Pharmacy Trial Program (PTP) under the Sixth Community Pharmacy Agreement (6CPA) (the Review), page 2,” Department of Health, Canberra, 2018.
- [64] Australian Government Medical Research Future Fund, “How is the MRFF governed?,” [Online]. Available: <https://beta.health.gov.au/initiatives-and-programs/medical-research-future-fund/about-the-mrff/how-is-the-mrff-governed>. [Accessed 2019].
- [65] Australian Government Medical Reserach Futures Fund, “About MRFF - how does funding work?,” [Online]. Available: <https://beta.health.gov.au/initiatives-and-programs/medical-research-future-fund/about-the-mrff/how-does-mrff-funding-work>. [Accessed 2019].
- [66] J. W. Song and C. K. C, “Observational Studies: Cohort and Case-Control Studies,” *Plastic Reconstructive Surgery*, vol. 126, no. 6, p. 2234–2242, 2010.
- [67] S. K. Gupta, “Intention-to-treat concept: A review,” *Perspectives in Clinical Research*, vol. 2, no. 3, pp. 109-112, 2011.