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IPAC PROJECT

Integrating Pharmacists within ACCHSs to improve chronic disease management

Associate Professor Sophia Couzos on behalf of the IPAC Project Team

Community Pharmacy Stakeholder Forum, Sydney, September 2018

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Project Partners

Pharmaceutical Society of Australia	National Aboriginal Community Controlled Health Organisation	College of Medicine and Dentistry, James Cook University
Contract signatory with the Department of Health. Primarily responsible for pharmacist recruitment, training, and support.	Partner responsible for coordinating contracts, relationships and operations involving ACCHSs and Affiliates. Facilitates project governance and leadership.	Partner responsible for trial design and the coordination of project evaluation and analysis of process, outcome, and economic evaluation.
Ms Shelley Crowther	Dr Dawn Casey; Mr Mike Stephens	Associate Professor Sophia Couzos

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Project Managers

Project Manager/Researcher for JCU	**Deborah Smith** Tel: 074781 6861 Email: Deb.smith@jcu.edu.au
Project Managers for PSA	Hannah Loller Tel: 0438 783 432 Email: Hannah.Loller@psa.org.au Megan Tremlett Tel: 0402 253 980 Email: Megan.Tremlett@psa.org.au
Project Coordinators for NACCHO	Fran Vaughan Tel: 0417 826 617 Email: Fran.vaughan@naccho.org.au Alice Nugent Tel: 0439 873 723 Email: Alice.Nugent@naccho.org.au

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Project Operational Teams

Pharmaceutical Society of Australia	National Aboriginal Community Controlled Health Organisation	College of Medicine and Dentistry, James Cook University
Ms Shelley Crowther Ms Hannah Loller Ms Megan Tremlett	Dr Dawn Casey Mr Mike Stephens Ms Fran Vaughan Ms Alice Nugent	Assoc Prof Sophia Couzos, Dr Deborah Smith, Dr Erik Biros

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Project Steering Committee

Independent Chair: Professor Colin Chapman	
Representative: NACCHO	Dawn Casey
Representative: PSA	Deb Bowden
Representative: JCU	Sophia Couzos
Representative: Pharmacy Guild of Australia	Hannah Mann
Independent Pharmacist:	Lindy Swain
Representatives of the Department of Health *(financial sponsors)*	Lloyd Sansom; Natasha Ploenges

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Project Evaluation Team

Assoc Professor Sophia Couzos, Evaluation Lead (JCU)	**Emeritus Professor Rhondda Jones**, Director of Research Development (JCU)
Assoc Professor Emily Callander, Health Economist (JCU)	**Ms Priscilla Page,** Aboriginal Academic and Educator (JCU)
Dr Erik Biros, Biostatistician (JCU)	**Mr Donald Whaleboat,** Torres Strait Islander Academic (JCU)
Dr Deborah Smith, Project Manager/researcher (JCU)	**Ms Nicole Bates,** Research Officer (JCU)
Professor Beverley Glass, Pharmacist Researcher (JCU)	**Mr Mark (Joseph) Thomas,** Research Officer (JCU)
Dr Robyn Preston, Qualitative Researcher (JCU)	**Dr Nadia Lusis,** VACCHO Public Health Medical Officer
Assoc Professor Michelle Bellingan, Head of Pharmacy (JCU)	**Dr Elizabeth Moore,** AMSANT Public Health Medical Officer
Assoc Professor Douglas Iain Ross Boyle, Expert advisor GRHANITE (UniMelb)	**Mr Roderick Wright,** QAIHC Health Information Coordinator
Dr Dawn Casey, Deputy CEO (NACCHO)	**Assoc Professor Katie Panaretto,** Medical Director, Gidgee Healing (JCU)
Mr Mike Stephens, Director, Medicines Policy (NACCHO)	**Ms Shelley Crowther,** Manager Practice Innovation (PSA)

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Project Reference Group

Chair: Wendy Brookman (NACCHO Senior member services officer)	
Representatives of participating ACCHSs	16 ACCHS representatives with further site representatives TBC
Representatives of QAIHC	Roderick Wright; Lucy Morris
Representatives of VACCHO	Nadia Lusis
Representatives of AMSANT	Liz Moore
Representatives of the Project Team	Alice Nugent, Fran Vaughan, Sophie Lawson, Joe Kobier (NACCHO); Shelley Crowther; Megan Tremlett, Hannah Loller (PSA); Deb Smith (JCU).

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Project Sponsor

The financial sponsor of this project is the Australia Government Department of Health, under the Pharmacy Trials Program (Tranche 2) funding as part of the 6th Community Pharmacy Agreement (6CPA). The 6CPA is a five-year agreement (to June 2020) between the Commonwealth of Australia (as represented by the Department of Health) and the Pharmacy Guild of Australia.

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Project Governance Structure

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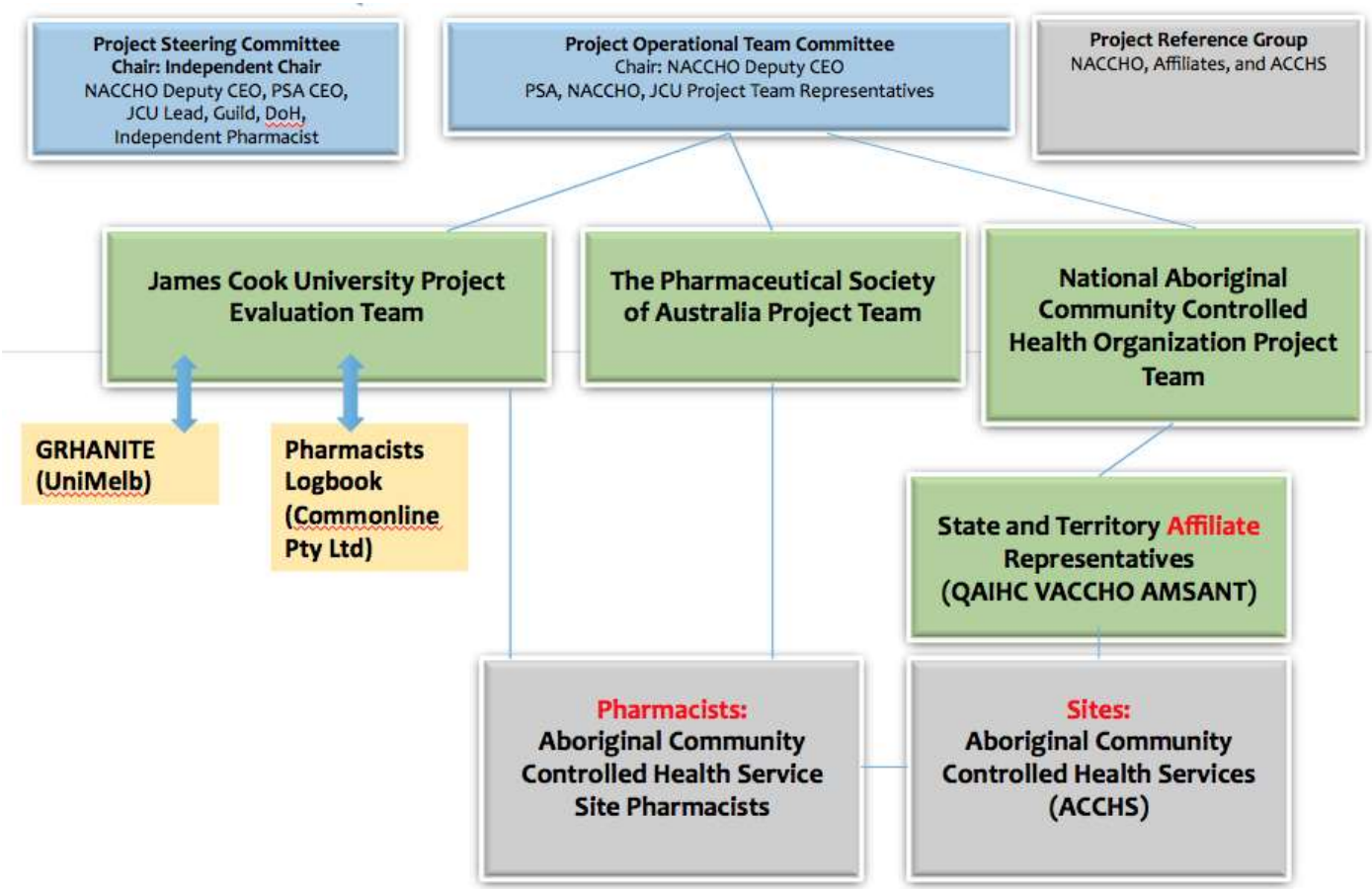

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MOU- Project Partners - Signed: Nov 2017

JAMES COOK UNIVERSITY AUSTRALIA

Pharmaceutical Society of Australia

NACCHO

Memorandum of Understanding

Between the National Aboriginal Community Controlled Health Organisation, the Pharmaceutical Society of Australia and James Cook University

28Th November 2017

Pharmacy Trial Program: Integrating Pharmacists into Aboriginal Community Controlled Health Services

Introduction

This is a Memorandum of Understanding (MoU) for the joint Pharmacy Trial Program Tranche 2 trial known as 'Integrating Pharmacists into Aboriginal Community Controlled Health Services' and will be known as the Project, hereafter. The MoU is between the three intended Project Partners - The National Aboriginal Community Controlled Health Organisation (NACCHO), The Pharmaceutical Society of Australia (PSA) and the College of Medicine and Dentistry within James Cook University (JCU) – known as the Partners.

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Project Objective:

To explore if quality of care outcomes for Aboriginal and/or Torres Strait Islander adult patients with chronic disease can be improved by integrating a practice pharmacist within the primary health care team of Aboriginal Community Controlled Health Services (ACCHSs), when compared with prior care.

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Study Intervention:

- Registered practice pharmacist integrated within the primary health care team of an ACCHS
  - 15-month intervention period (aggregated to represent 0.57 FTE pharmacist per site)
  - Up to 22 ACCHS sites in Queensland, Northern Territory, Victoria.
  - Sites geographically spread (urban, regional, remote)

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Study design:

- Interventional, pragmatic, non-randomised, pre and post study with a cost-effectiveness analysis, where the pharmacist intervention will be added to standard primary health care practice within ACCHSs.
- Adhering to community-based participatory research (CBPR) principles.

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CBPR principles:

- "A partnership approach to research that equitably involves, for example, **community members**, organizational representatives, and researchers in all aspects of the research process and in which **all partners contribute expertise and share decision making and ownership.**" *[Israel BA, et al. Ann Rev Public Health, 1998]*
- The CBPR principles for this project have been adapted from the WHO guiding principles for Indigenous CBPR. http://www.who.int/ethics/indigenous_peoples/en/index1.html

[For more information: see https://www.mja.com.au/journal/2015/202/10/talking-about-smokes-large-scale-community-based-participatory-research-project]

2 Condensed framework: guiding principles for participatory health research involving research institutions, Indigenous peoples and their representative bodies*

Theme	Subsection	The guiding principles refer to:
1. Consultation and approval	1.1–1.3	Initiation of research and making contact
	1.4–1.5	Approval for the research to proceed
2. Partnerships and research agreements	2.1–2.4	Equality of research relationships, joint preparation of a research agreement and research proposal
	2.5–2.6	Development of agreed research processes
	2.7–2.8	Joint obligations towards the research
3. Communication	3.1	Clarification of, and respect for, the lines of authority of the partners
	3.2	Committee selection by Indigenous peoples (for communication, facilitation and promotion); the committee should represent all relevant community-controlled organisations
	3.3–3.4	Maintenance of communication, including progress reports, results and implications of the research
4. Funding	4.1–4.2	A joint commitment to fund seeking, and agreement of sources in advance
	4.3	Research institutions' obligation to ensure Indigenous peoples are involved where resources or capacity are lacking
5. Ethics and consent	5.1–5.2	Respect for ethical guidelines, approval from human research ethics committees and Indigenous-controlled ethics committees
	5.3	Research commencing only after ethics approval is received and signed agreements are finalised
	5.4	Research conforming to additional protocols of the Indigenous peoples involved
	5.5	Consent for research at various levels: individual (study participants), representatives of Indigenous peoples, and the umbrella Indigenous organisation
	5.6	A jointly agreed consent-seeking process
	5.7	Umbrella Indigenous organisation demonstrating the collective consent of Indigenous peoples
6. Data	6.1–6.2	Intellectual property rights, benefit sharing and boundaries pertaining to information use
	6.3	Confidentiality and limiting access to research data
	6.4	Joint review and interpretation of data before publication
	6.5	Authorship or acknowledgement of participants in joint research
	6.6	Formatting data and reports for independent use by Indigenous peoples
	6.7	Indigenous ownership of data and authorisation for further use
7. Benefits of the research	7.1	Obligation for research to provide short-term and long-term benefits for Indigenous peoples, including provision of health care where lacking
	7.2	Disclosure of potential economic benefits of the research
	7.3	Research benefits including training, employment, general capacity building and improved health status or services (or prospects for such improvement)

* Adapted from the World Health Organization, 2003.[7] See Appendix 1 for the full framework. ◆

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Pragmatic design

- Pragmatic trials seek to determine if interventions work *under usual conditions* rather than under ideal conditions. Examples shown below:

Domain	IPAC Study design example:
Site eligibility	Criteria reflect usual ACCHS scope of activity
Patient eligibility	Minimally restrictive
Intervention	Core roles, but flexible. Pharmacist eligibility consistent with usual skills.
Comparator	Usual practice pre-intervention
Follow-up intensity	Usual intervals c/w MBS rules, and patient-centred care
Data sources	Data extracted from existing CIS with minimal intrusion. Logbook designed for pragmatism. HSA simplified for sites.
Adherence to study protocol	Initial training. Audit is minimally intrusive from the logbook.
Trial outcomes	Assessed from pragmatic data sources

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Clinical claim:

This project makes two clinical claims:

1. Patients who are managed by this model of care, involving delivery of services by a pharmacist integrated within Aboriginal Community Controlled Health Services (ACCHS), experience either equivalent or superior quality of care outcomes for Aboriginal and/or Torres Strait Islander adult patients with chronic disease compared to baseline data representing pre-intervention.
2. Appropriate funding for services provided by pharmacists within ACCHSs is likely to lead to superior health care service utilisation (towards equity) of patients with chronic disease compared to utilisation at baseline (pre-intervention).

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Expected Project Outcomes:

- Improved chronic disease outcomes;
- Improved prescribing by doctors;
- Improvements in health service activity related to medicines use;
- Cost-effectiveness analysis.

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Project outcome measures:

- **Primary outcomes:**
  - improvements in *quality of care outcomes* (biomedical measures such as BP, HbA1c, lipids, CV risk assessment (levels and risk) in patients with chronic disease.
- **Secondary outcomes:**
  - improvements in *other quality of care outcomes*:
    - **Prescribing indices** (Medication Appropriateness Index, measures of overuse, and assessment of underutilization of medicines)
    - **Home medication reviews (HMR)** (MBS 900 claims), and **other medication reviews ('non-HMR' and 'follow-up to a non-HMR')**
    - **Health service utilisation indices** (MBS items 721, 723, etc) ▪ **Patient survey scores** for adherence and 'reasons for non-adherence'
    - **Patient and stakeholder perceptions** (ie ACCHS staff, IPAC pharmacists, community pharmacy)

- cost-effectiveness analysis.

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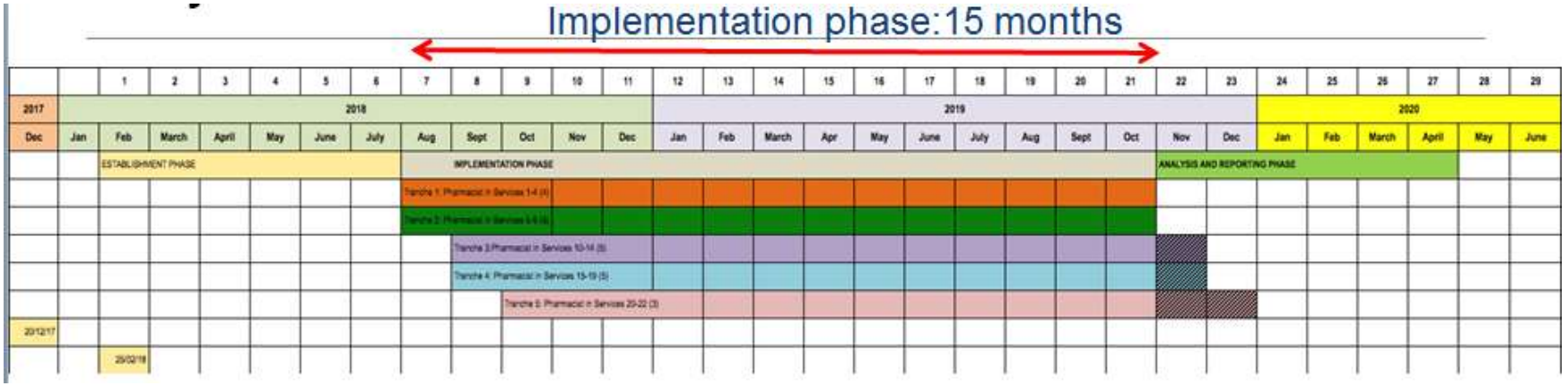
Project Timelines



- Head Agreement signed: 20/12/17 • Partner contracts signed 25/2/18
- **Implementation Phase** started in August 2018
- Timelines for several sites encroaching into Analysis Phase. • Final report due: April 2020

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Ethics approval

- St Vincent's Hospital Human Research Ethics Committee (HREC), Melbourne, Victoria (for Qld and Vic sites)
  - HREC/17/SVHM/280
- JCU HREC (mutual recognition of StVH HREC and approval)
  - HREC/H7348
- Menzies School of Health Research HREC (NT)
  - HREC/2018-3072
- Central Australian HREC (NT)
  - HREC/CA-18-3085.

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ACCHS (site) inclusion criteria:

- Must be an ACCHS in Vic/Qld/NT, accredited to RACGP standards;
- At least 1 FTE prescribing GP;
- No existing non-dispensing practice pharmacist (*doing the same work as the project protocol*);
- Communicare or Best Practice clinical information systems (CIS);
- Has participated in CQI and reporting on the national Key Performance Indicators for at least 24 months;
- GRHANITE site installation checklist approved;
- Physical on-site space for pharmacist (private consulting room), with access to the CIS;
- Nominate a ‘go to’ person to assist with informed patient consent;
- Capacity for CTG scripts/S100 scheme (remote area access);
- *If* conducting ‘point of care’ testing - participates in the QAAMS *(Quality Assurance for Aboriginal and Torres Strait Islander Medical Services)* program.

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Pharmacist inclusion criteria

- Tertiary qualification in pharmacy with current registration as a pharmacist with the Australian Health Practitioner Regulation Agency (AHPRA);
- More than two years post-registration experience in pharmacy (hospital, community or primary care);
- Preferably hold or be working toward accreditation for the delivery of Medication Management Reviews;
- Post-graduate clinical qualifications or demonstrated clinical experience (e.g. hospital or HMRs);
- Excellent communication skills.

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Patient inclusion criteria

Aged 18 years of age and over with:

- Cardiovascular disease (coronary heart disease, stroke, hypertension, dyslipidaemia and any other CV disease),
- Type 2 diabetes mellitus, •

Chronic kidney disease,

- Other chronic conditions at high risk of developing medication- related problems (e.g. polypharmacy).

Patient consent is required

All patient data is deidentified.

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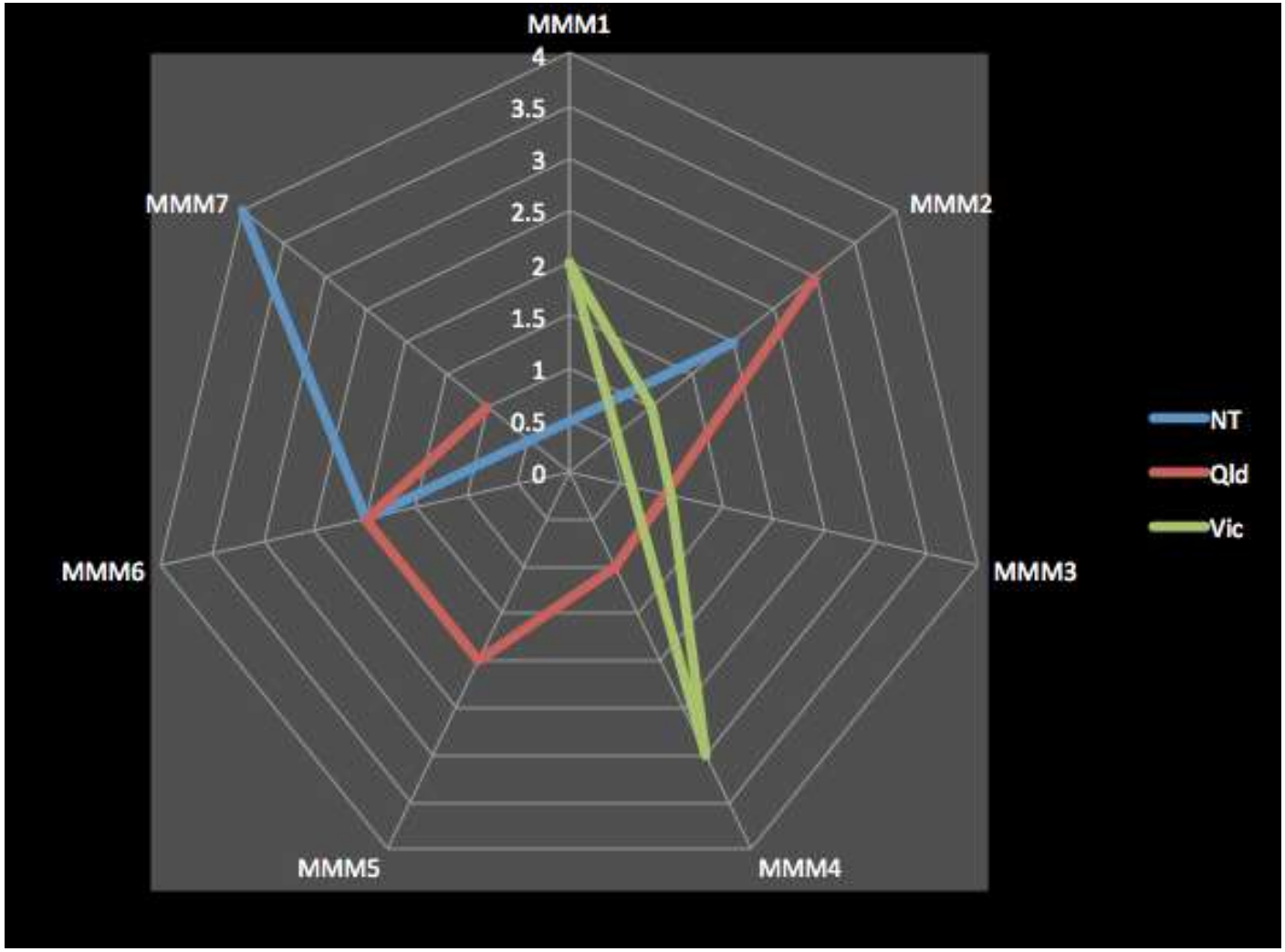
Recruited sites- distribution

ASGS Remoteness Areas (2016)						
	RA1	RA2	RA3	RA4	RA5	Total
NT			2	1	5	8
Qld		3	3	2	1	9
Vic	2	1	4			7
Total	2	4	9	3	6	24

	MMM1	MMM2	MMM3	MMM4	MMM5	MMM6	MMM7	Total
NT		2				2	4	8
Qld		3		1	2	2	1	9
Vic	2	1	1	3				7
Total	2	6	1	4	2	4	5	24


MMM1
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MMM7
NT
Qld
Vic

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Patient recruitment targets

Based on FTE pharmacists and size of the practice:

- 0.2FTE pharmacist base allocation and a proportional allocation related to the total number of patients/site
- Total of 12.54 FTE pharmacists (all sites) for 15 months *(for an average of 0.57 FTE per site)*
- Target of 4 patients/day/1.0 FTE first 4-5 months (phase 1) of implementation phase, with follow-up conducted in the remaining 10 months (phase 2).
- Estimate ~5000 patients.

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Pharmacists 10 core roles

Patient- related activity

1. Medication Management Reviews
2. Team-based collaboration
3. Medication adherence assessment & support
4. Medication appropriateness audit, and Assessment of Underutilisation
5. Preventative health care

Practice- *(health professionals and systems)* related activity

6. Drug Utilisation Review
7. Education and training
8. Medicines information service
9. Medicines stakeholder liaison
10. Transitional care

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Data sources

- Health systems assessment (site assessment by interview)
- Pharmacists logbook (Commonline Pty Ltd)
- GRHANITE: clinical information systems data extraction (UniMelb)
- Qualitative (focus group, stakeholder surveys- to commence in 2019)

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Health Systems Assessment

Site survey to explore site characteristics pre and post intervention.

Section	Characteristic
A	General characteristics of IPAC sites (eg size, location, etc)
B	FTE Staff employed (doctors, nurses, AHWs, etc)
C	FTE Allied health employed and type
D	Access to allied health in the local community (eg average drive-time)
E	Access to specialists in the local community (eg average drive-time)
F	Community engagement (pharmacy, hospitals, other partnerships?)
G	Other engagement (research, Healthcare Homes, CQI partners)
H	Quality of communication with hospital system, specialists, PHNs
I	Quality of communication with community pharmacy
J	Care planning
K	Systems for clinical management and chronic disease care
L	Resources used routinely
M	Economic characteristics of the service

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Pharmacists Logbook

- Unique domain name! www.ipac.net.au
- Custom built data entry and real time data management system developed for JCU *(Copyright: Commonline Pty Ltd*)
- Data source for JCU evaluation. • Pharmacists enter data.
- Assists IPAC Pharmacists to manage their activity.
- PSA can audit and track pharmacists activity.
- Simple to use.

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GRHANITE ™

- Pharmacists have full access to clinical information systems (CIS).
- JCU subcontracted the Research Information Technology Unit, Faculty of Medicine, Dentistry & Health Sciences, Melbourne Medical School, at the University of Melbourne to use the GRHANITE data extraction tool from two CISs *(Best Practice and Communicare)*.
- *Assoc Prof Douglas Boyle* (developer) is a member of the JCU evaluation team.
- Minimally intrusive, pre-programmed, automatic, weekly extraction in Microsoft SQL format.
- Data is extracted ONLY from consented participants

(opt-in). • Only ethics approved data is extracted.

- Data is de-identified.

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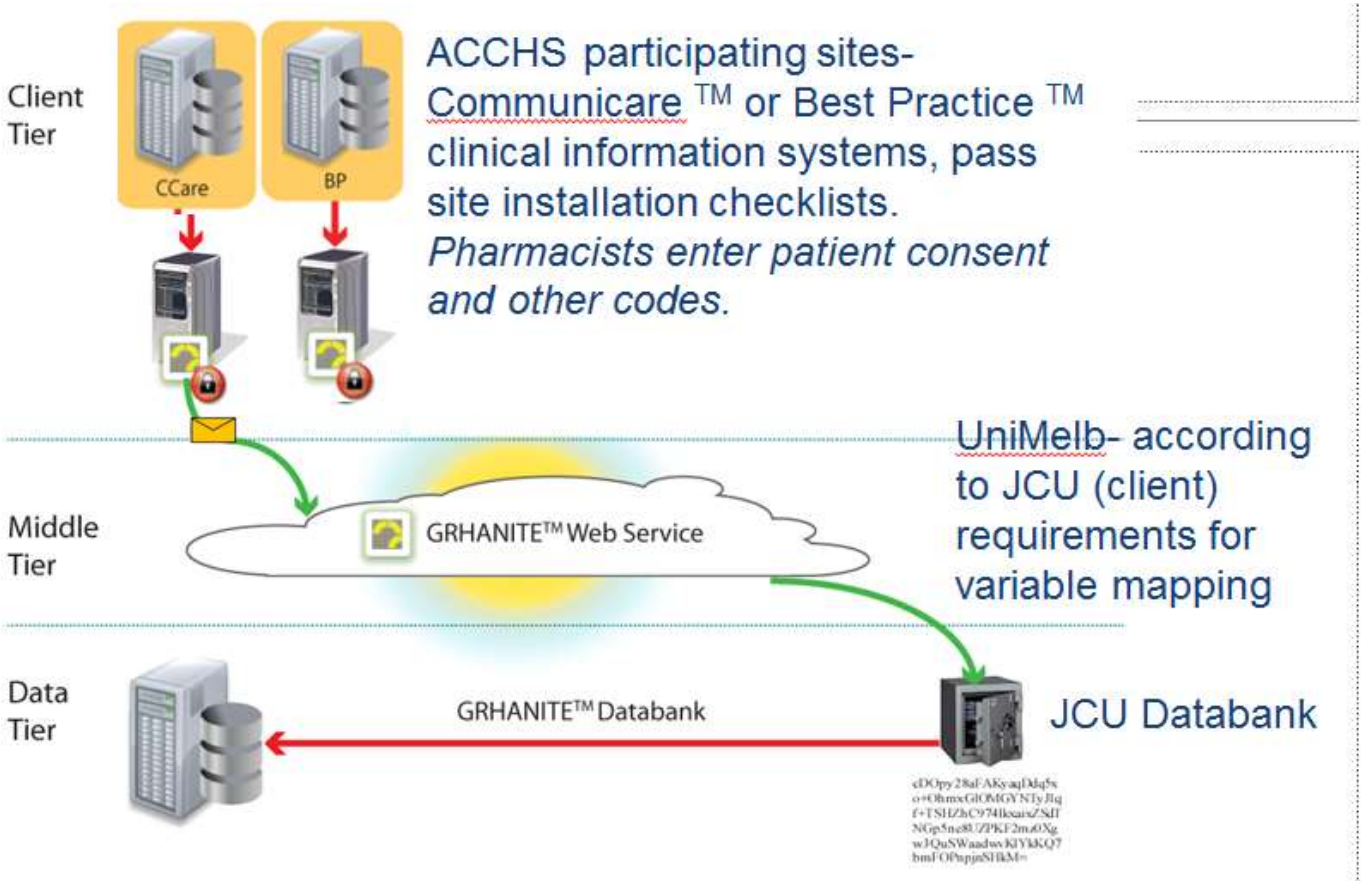

Modified from source: https://www.grhanite.com/technologies/

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GRHANITE measures

- Data is extracted for the 15-month duration of the project, and 12-month pre-intervention period (for each participant).

Measure	Example
Patient characteristics	Age, Indigenous status, condition, etc
Encounters	Clinic visits, job role (staff)
Biometric indices	BP, HbA1c, lipids, absolute CV risk, etc
Prescribing indices	All medications, date script generated, etc
Dispensing indices	*For Communicare only (S100 sites)*
Medicare	MBS item claimed: HMR, Care plan, etc

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Qualitative measures

- To be conducted June- October 2019

Qualitative measure	Source
General data sources	HSA, Logbook
Site-visit fieldwork • *3 sites, case studies in urban, rural and remote locations. Interviews with Practice Pharmacist, patient and clinic staff focus-group discussion*	Site visit
Remote data collection • *interview with all IPAC pharmacists; online survey involving GPs within IPAC sites; online survey community pharmacists*	Online tools

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Economic measures

Economic measure	Source
Cost of implementing the intervention: eg. *Pharmacist salary, on-costs and overheads, training costs, time of other professionals with the pharmacist, plus any other costs*	PSA, Logbook
Value of non-HMRs	Logbook
MBS utilisation	GHRANITE

Training of pharmacists

Three parts:

1. Cultural sensitivity
2. 10 Core roles
3. Data capture

Training Workshops:

- Late July/Aug 2018: 16 pharmacists trained.
- Assoc Prof Lindy Swain/Emma Walke: *"Becoming a culturally aware pharmacist – Pharmacists working with Aboriginal people*"
- Megan Tremlett (PSA) developed '10 Core roles' materials
- Hands-on *Pharmacist Logbook* and CIS training (BP and CC).

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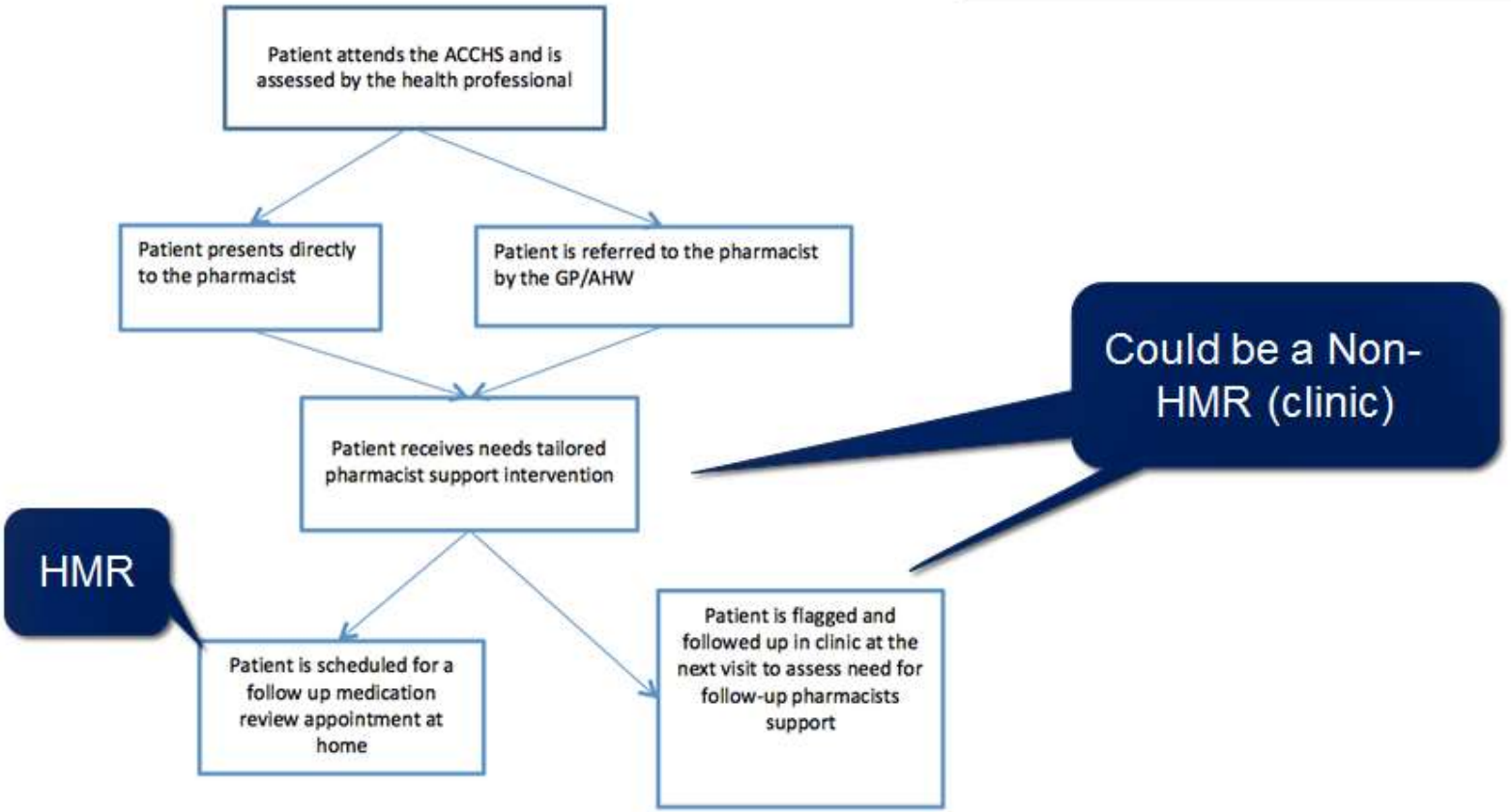
Patient journey



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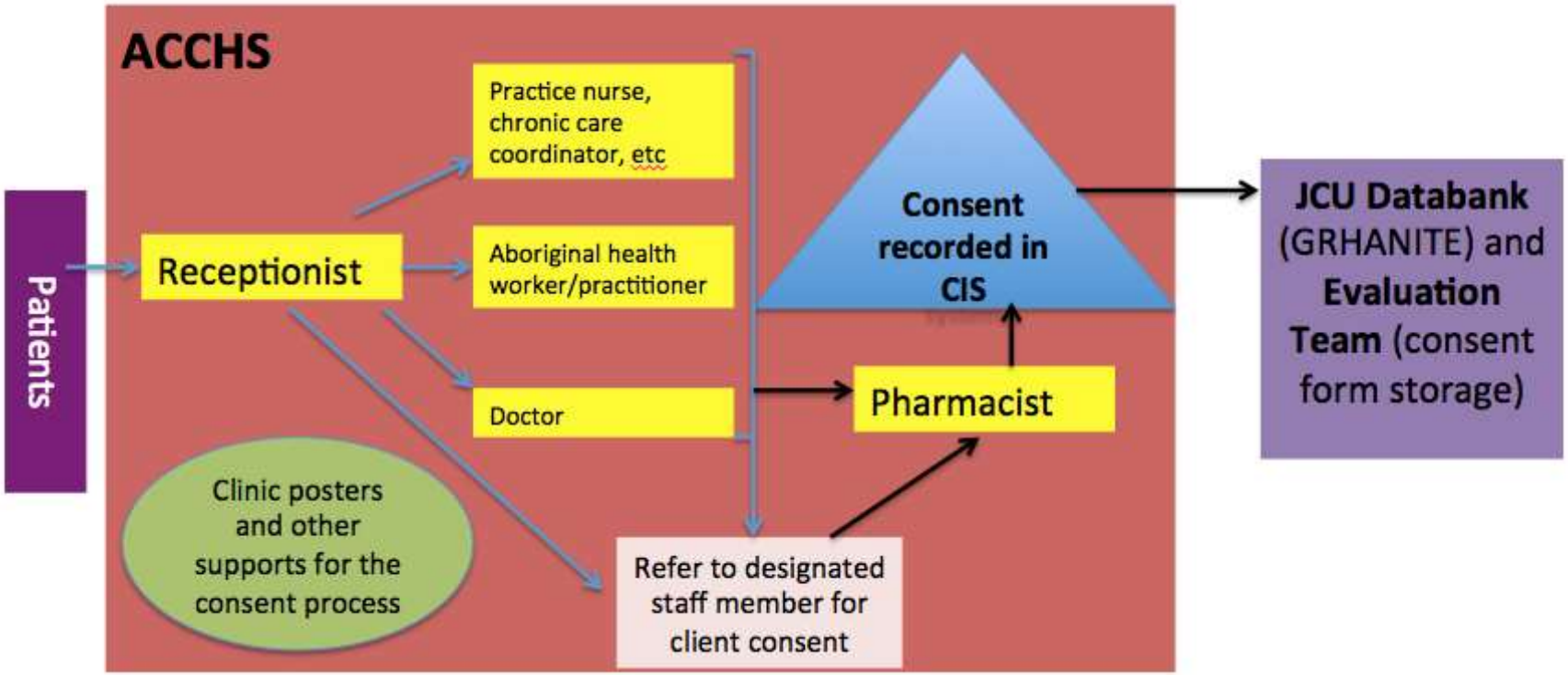
Patient consent process



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Promotional material

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Current status

- 20 ACCHSs contracted to date (24 sites)

19 Pharmacists trained; 4 pending.

- 3 IPAC pharmacists commenced their roles in August 2018
- GHRANITE site acceptance testing completed for BP; Communicare testing underway
- Pharmacist Logbook is fully operational

First patient recruited, 9th August 2018!

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Final acknowledgement:

- **To the pharmacists** who have been contracted to this project:
  - The project partners acknowledge their passion, enthusiasm and commitment to delivering care to the patients of ACCHSs, to undertake training for this project, and to adhere to the project protocol!

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FOR FURTHER INFORMATION ABOUT THE EVALUATION:

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Assoc Prof Sophia Couzos (Evaluation Lead)
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