



Australian Government
Department of Health



Community
Pharmacy
Agreement



The Pharmacy
Guild of Australia

THE INAUGURAL
**COMMUNITY PHARMACY
STAKEHOLDER FORUM**

15 November 2016



Pharmacy Diabetes Screening Trial



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Project team

- Ms Fiona Mitchell
- Ms Erica Vowles
- Ms Rebecca Segrott

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- Professor Ines Krass
- Dr Bernadette Mitchell
- Ms Francis Wilson

The University
of Sydney



- Dr Kevin Mc Namara
- Professor Rob Carter
- Dr Sophy TF Shih
- Dr Vincent Versace
- Ms Peta Trinder
- Dr Mohammadreza Mohebbi

Deakin
University





EXPERT PANEL

The Expert Panel provides advice and direction on the implementation of the trial. The project team will work closely with the Expert Panel throughout the trial.

The functions of the Expert Panel include providing guidance on:

- practicalities of the proposed trial design
- communication strategies over the life of the trial
- how best to engage with trial participants
- how to support engagement, recruitment, retention of participants, general practitioners, community pharmacies and other relevant health professionals



Expert panel: chair and representatives

Chair

Professor Stephen Colagiuri,
Professor of Metabolic Health and Co-Director of The Boden Institute at University of Sydney.

Members

Associate Professor Sof Andrikopoulos, Australian Diabetes Society.
Kirrily Chambers, Australian Diabetes Educators Association.
Dr Gary Deed, Royal Australian College of General Practitioners.
Teresa Di Franco, Pharmaceutical Society of Australia.
Amanda Galbraith, Community Pharmacist.
Adjunct Professor Greg Johnson, Diabetes Australia.
Professor Ines Krass, Representative of the Project Partners.

Observers

Katrina Howe, Department of Health (observer).
Julianne Quaine, Department of Health (observer).
Emeritus Professor Lloyd Sansom AO, Trials Advisory Group (observer).



Objective

To assess the comparative clinical effectiveness and cost-effectiveness of three different pharmacy-delivered models of opportunistic assessment for diabetes in an asymptomatic, previously undiagnosed population.



Hypothesis

The addition of either a HbA1c Point of Care (POC) test or scBGT POC test to the AUSDRISK assessment is associated with a statistically significant increase in the proportion of new cases of diagnosed type 2 diabetes mellitus (T2DM) and will be more cost effective than the AUSDRISK assessment alone.

Outcomes

- Primary
 - The difference in proportions of newly diagnosed T2DM cases between the two intervention arms and the comparator arm (to be identified by the subsequent GP assessment and blood test results)
- Secondary
 - Proportion of newly diagnosed cases of impaired fasting glucose (IFG) or impaired glucose tolerance (IGT)
 - Proportion of people referred to the GP
 - Proportion who take up the referral to the GP



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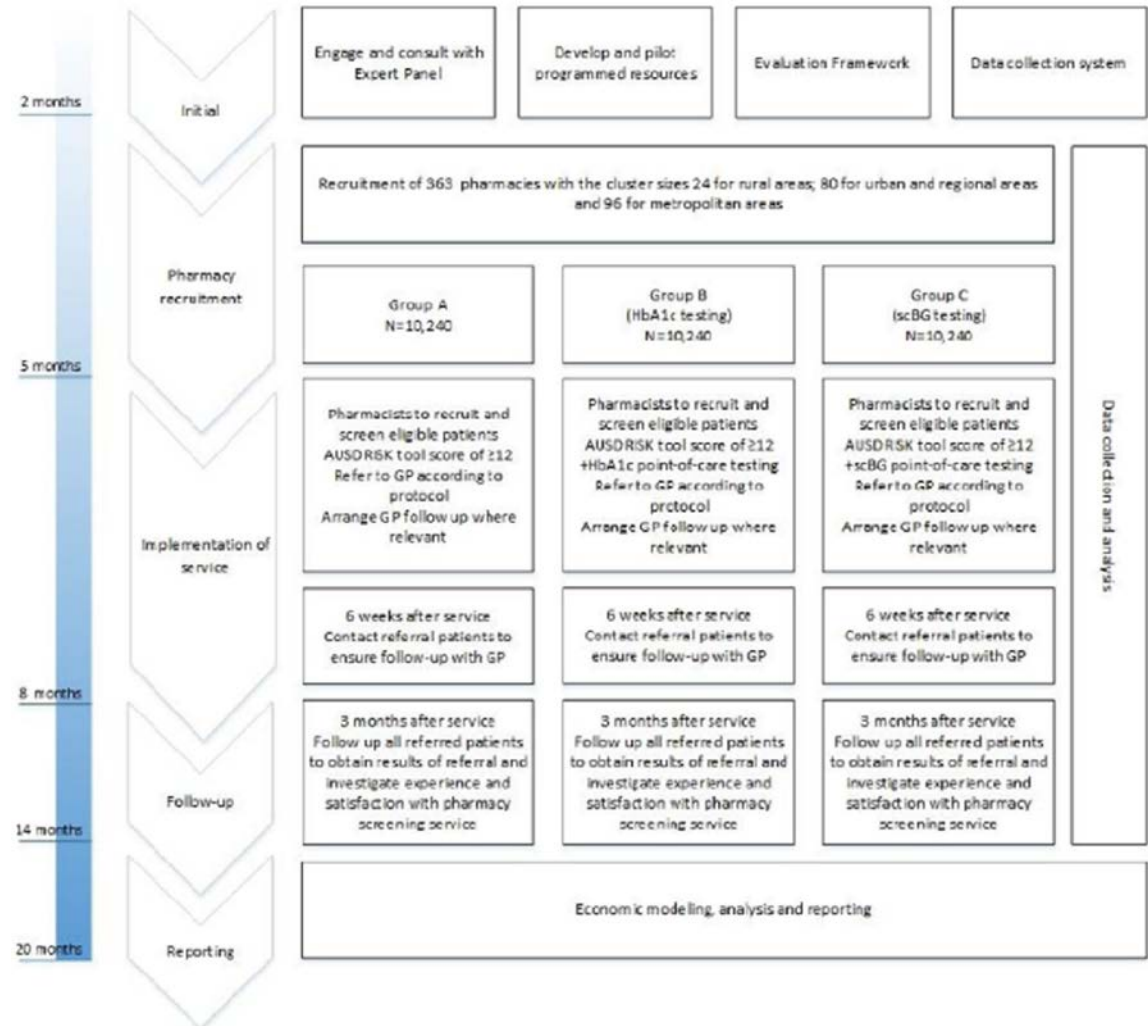


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Overview: Trial design is a Clustered RCT



Trial Groups

****if:**

- **HbA1c \geq 9% (75mmol/mol)**
- or
- **BG \geq 15 mmol/l**

Pharmacist will phone GP and
make an appointment for
IMMEDIATE referral

GROUP A:

- **AUSDRISK** assessment tool alone
- **Referral** to a GP if AUSDRISK \geq 12

GROUP B:

- **AUSDRISK** assessment tool +
- **HbA1c** point-of-care (POC) test in patients with AUSDRISK \geq 12



- **Referral** to a GP if HbA1c $\geq 5.7\%$ (39 mmol/mol) is detected**

GROUP C:

- **AUSDRISK** assessment tool +
- **small capillary blood glucose test (scBGT)** in patients with AUSDRISK ≥ 12
- **Referral** to a GP if
 - fasting blood glucose (FBG) $\geq 5.5\text{mmol/l}^{**}$ or
 - random blood glucose (RBG) $\geq 7.8\text{mmol/l}^{**}$

Trial design

Geographical areas are the unit of randomisation

- Randomised to Group A, B or C
- Stratified by metro/regional/remote residential areas
- Pharmacies in the selected areas will be invited to participate

Patients are the unit of analysis and recruited as follows:

- According to the distribution of the Australian population
- By age groups (35-44, 45-54, 55-64, & 65-74)
- By gender

Pharmacy inclusion/exclusion criteria

- Approved Section 90 pharmacy
- Appropriate private area in the pharmacy
- Appropriate storage and disposal of reagents and consumables
- Accredited by an approved Pharmacy Accreditation Program
- Agree to adhere to standards, terms and conditions, guidelines and protocols
- Endeavour to include the Pharmacy Diabetes Screening Trial CPD training in annual training plans as appropriate
- Agree to obtain written patient consent and to provide data required for evaluation of the trial

Pharmacy Recruitment Targets

State/Territory	Major Cities	Regional	Remote	Total
New South Wales	80	25	3	108
Victoria	59	24	2	85
Queensland	38	31	5	74
South Australia	14	9	7	30
Western Australia	22	6	6	34
Tasmania	0	10	3	13
Northern Territory	0	7	4	11
Australian Capital Territory	8	0	0	8
Total	221	112	30	363



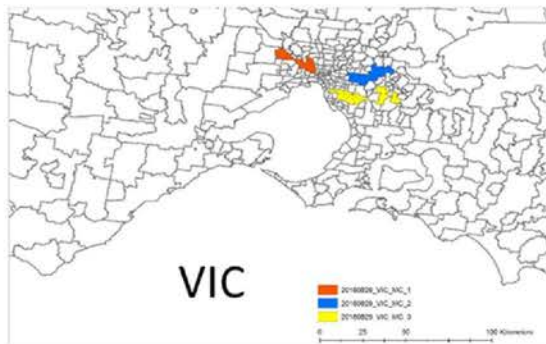
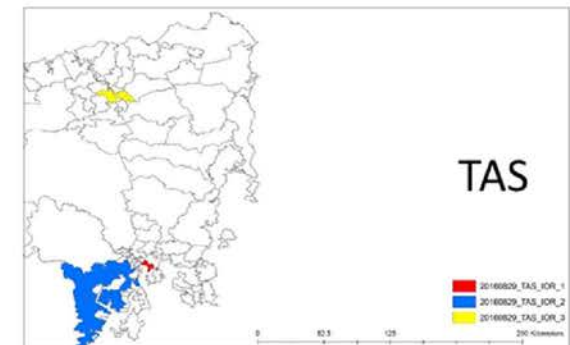
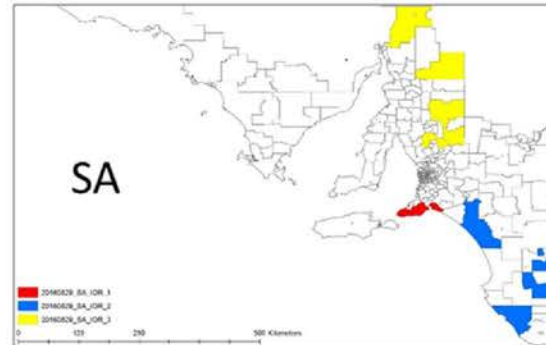
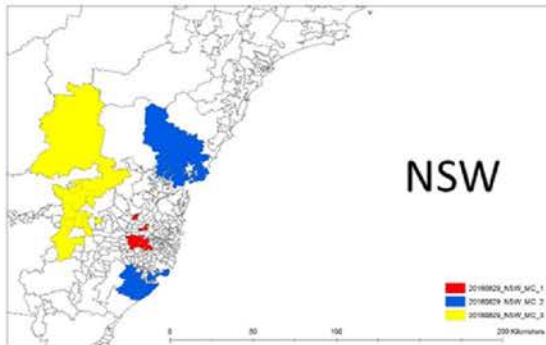
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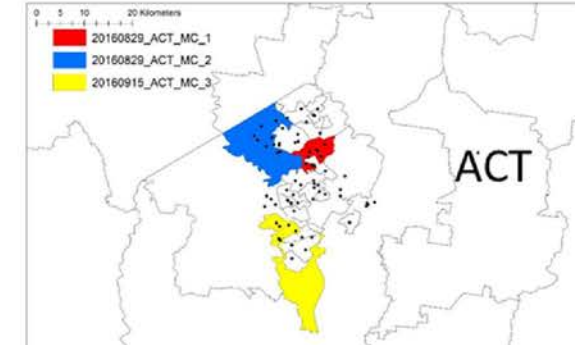
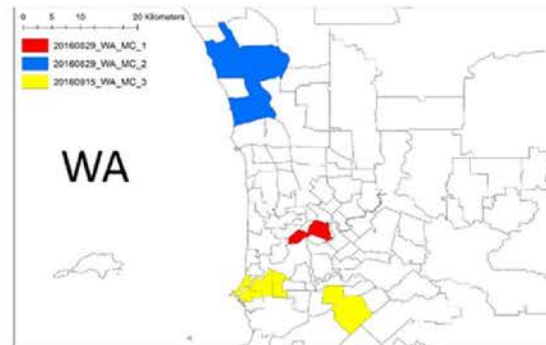
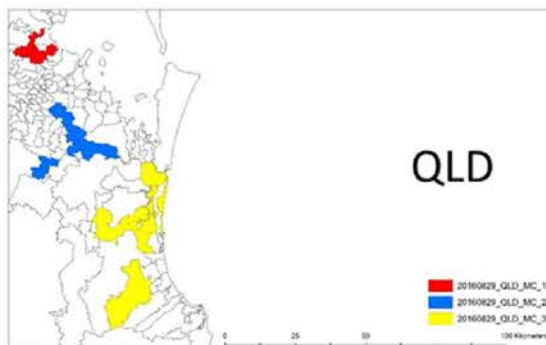
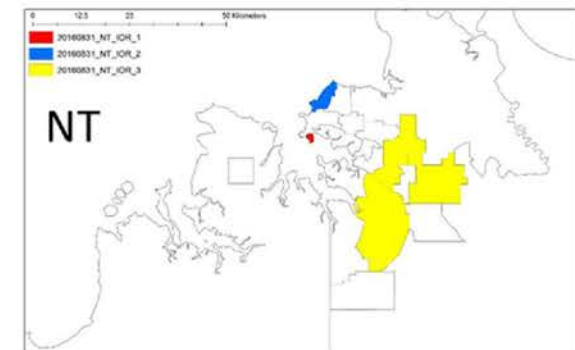
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Sampling Maps





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Inclusion/Exclusion Criteria – Screening Participants

Inclusion Criteria

- Adults aged between 35 and 74 years
- Living in the community (i.e., not a permanent resident of residential aged care facility or correction facility)
- Is the holder of a valid Medicare card or the holder of a valid Department of Veterans' Affairs Repatriation card (Gold, White or Orange)

Exclusion Criteria

- Unable to give informed consent
- Women who are pregnant
- Has an established diagnosis of T2DM, IGT, or IFG (based on participant self-report)
- Has been screened in previous 12 months for diabetes/pre-diabetes
- Has a terminal illness
- Has had a blood glucose test or oral glucose tolerance test for any reason associated with abnormal glucose homeostasis
- Subjects with severe hematologic diseases (e.g., thrombocytopenia, leukaemia)
- Has a blood condition not suitable for POC HbA1c testing (Group B only)

Trial Sample – Screening Participants

24 participants for rural/remote areas, 80 participants for urban/regional areas and 96 participants for metro areas

Algorithm for selecting RCT participants in rural, regional and metro areas respectively

Age groups	Gender		Total
	Male	Female	
35-44	3, 10, 12	3, 10, 12	6, 20, 24
45-54,	3, 10, 12	3, 10, 12	6, 20, 24
55-64	3, 10, 12	3, 10, 12	6, 20, 24
65-74	3, 10, 12	3, 10, 12	6, 20, 24
Total	12, 40, 48	12, 40, 48	24, 80, 96

Evaluation – Baseline, Formative and Process

Type of evaluation	Description/measure	Data source
Baseline data	Survey of current screening services provision of participating pharmacies	Web based self-completion questionnaire
Formative	To identify (a) overall experience, with service implementation, any difficulties with compliance, and options for overcoming these; and (b) perceptions of sustainability of the screening model, and requirements for sustainability	Qualitative interviews with a 10% sample of participating pharmacists/pharmacy staff
Process	Median number of trial screening services/pharmacy/week	Pharmacy records
	Total number of trial screening services per pharmacy	Pharmacy records
	% with elevated risk who received appropriate further screening and who were referred to the GP for further	Pharmacy records
	% who were screened who were referred to evidence based lifestyle modification programs in pharmacy or	Pharmacy records
	Patient satisfaction with the pharmacy screening service	Follow up survey of a 10% sample of all screening participants

Evaluation – Clinical Outcomes and Economic Analysis

Type of Evaluation	Description/Measure	Data Source
Clinical Outcomes	% at elevated risk (AUSDRISK score of ≥ 12)	Pharmacy records - GuildCare
	% referred to the GP	Pharmacy records - GuildCare
	% who acted on GP referral	Follow up participant survey, GP records.
	% who were diagnosed with prediabetes	GP records, Pathology results, MBS and Medicare data.
	% who were diagnosed with type 2 diabetes	GP records, Pathology results, NDSS, MBS and Medicare data.
Economic Analyses	Trial based economic evaluation	Pharmacy baseline survey, Medicare and MBS data, Pharmacy/ GuildCare records.
	Modelled economic evaluation to extend time horizon beyond the trial period	Medicare and MBS data
	Financial evaluation	Medicare and MBS data



Incentive Payments

Group	No. participant	Component of service	\$	Total \$ per
Group A	10240	Initial screen only	10.00	10.00
		Referral	11.00	21.00
Group B	10240	Initial screen only	10.00	10.00
		POC testing	10.50	20.50
		Referral	11.00	31.50
Group C	10240	Initial screen only	10.00	10.00
		POC testing	10.50	20.50
		Referral	11.00	31.50

A bonus of \$750.00 will also be provided to the pharmacies as an incentive to maintain the quality of the collected data e.g., payable upon the completeness of the data collected according to the protocol



Human Ethics Approval

- Application has been approved
- Participant Information Statement (PIS) for pharmacies/pharmacists
- Pharmacy/pharmacist consent form
- PIS for screening participants
- Screening participant consent form
- GP information/engagement letter
- GP Referral
- Pharmacy baseline survey
- Patient 3 month follow up survey



Dept of Human Resources Approval

Application to use participant Medicare Data has been approved:

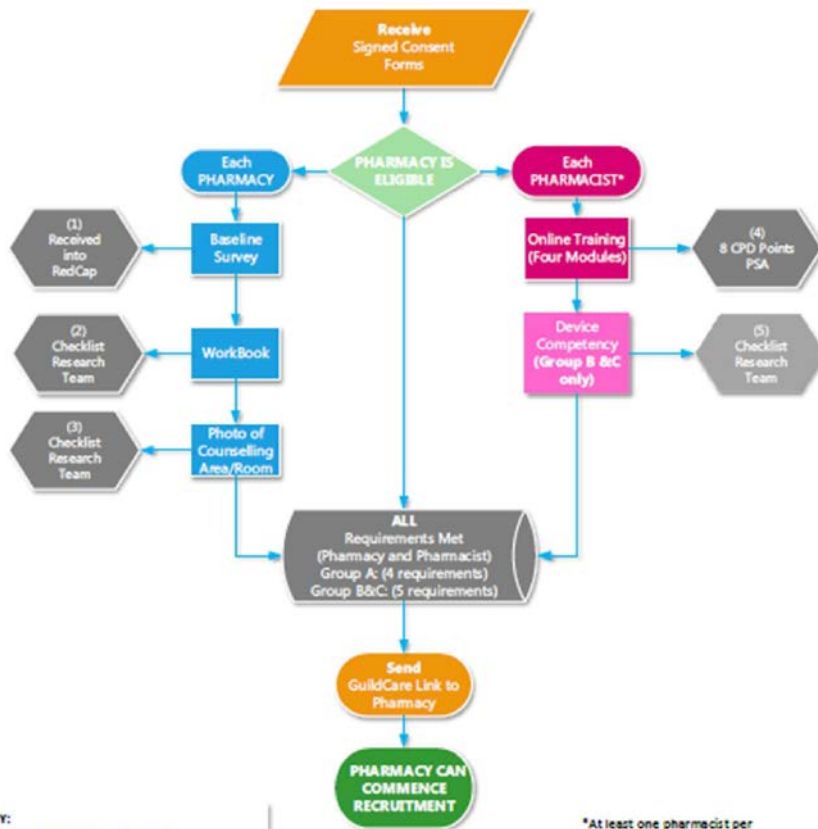
- Medicare Consent Form

Medicare Data will be used to:

- Verify clinical outcomes
- Conduct economic analyses

Training Requirements

Pharmacy Diabetes Screening Trial TRAINING REQUIREMENTS



*At least one pharmacist per pharmacy needs to complete training in order to commence recruitment.



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Pharmacy Diabetes Screening Trial

Welcome to the
Pharmacy Diabetes Screening Trial





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Module Four: Clinical Procedures

This module has four different case scenarios to demonstrate the screening and follow-up procedures in the Pharmacy Diabetes Screening Trial.





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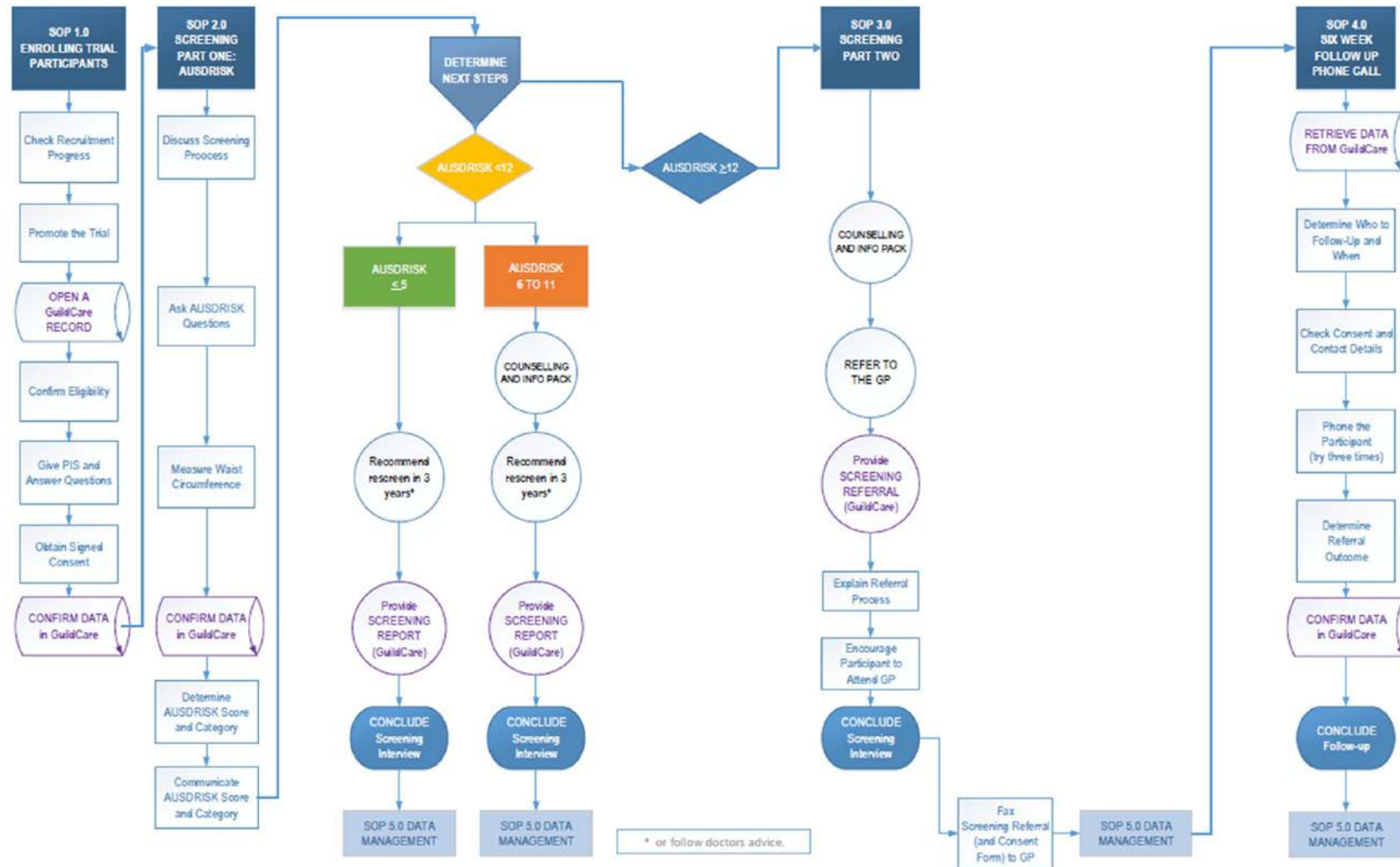


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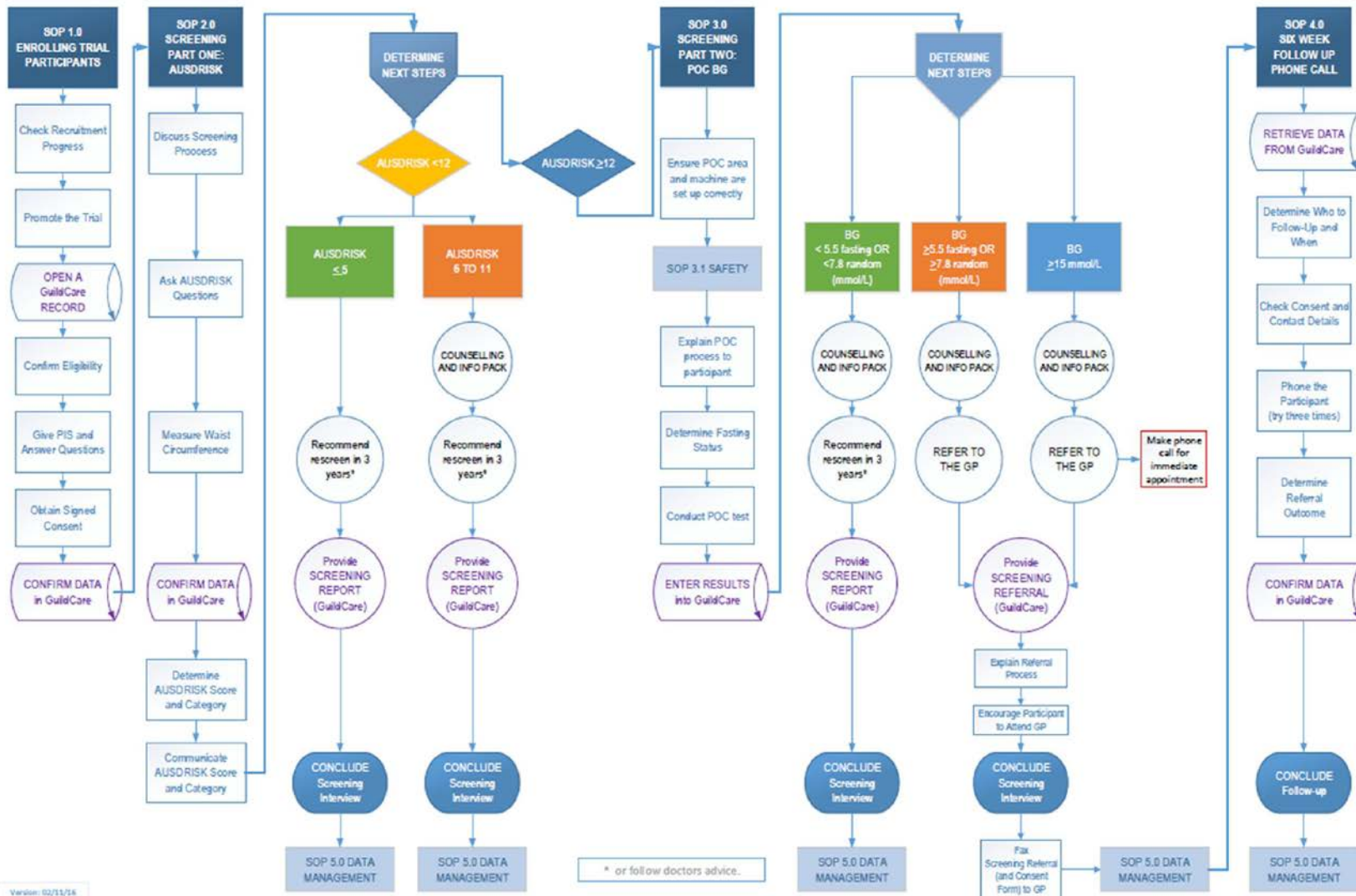
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PHARMACY DIABETES SCREENING TRIAL: GROUP A PROTOCOL FLOWCHART





PHARMACY DIABETES SCREENING TRIAL: GROUP C PROTOCOL FLOWCHART



Resources for Participating Pharmacies

Promotional and Printed Material

- Posters
- Flyers
- PIS
- Consent Forms
- GP Letters
- Eligibility Cards
- Brochure Stands

Equipment and Devices

- Point of Care Devices, Waist Measurement Tape, and Consumables
- Tender process based on an open request for proposals.
- Currently being reviewed by Pharmacy Guild, Research Team and Expert Panel



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Promotional
Material In
Pharmacy

Half a million Australians have undiagnosed

DIABETES

Are You at Risk?

Are you aged
35-74 years,
DON'T have diabetes,
and haven't been
screened for diabetes
in the past year?

If this sounds like you or someone you
care about, ask a pharmacist about our
free diabetes screening service



The Pharmacy in Action Screening Trial is funded by the Australian Government, Department of Health as part of the 6th Community Pharmacy Agreement



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Pharmacy Diabetes Screening Trial

The provision of the pharmacy-based diabetes screening service aims to identify individuals at elevated risk of type 2 diabetes. If a person is identified as having a high-risk for diabetes, they will be referred to their GP for further assessment of undiagnosed diabetes or prediabetes.

To be eligible for the **FREE DIABETES SCREENING** patients need to meet the following criteria:

- Aged between 35-74 years
- Have not been diagnosed with diabetes
- Have not been screened for diabetes by their GP in the last 12 months

Ask your pharmacist for more information about this free service.

Half a million Australians have undiagnosed

DIABETES.

Are you at Risk?

Ask Your Pharmacist about the **FREE** diabetes screening trial.

As this is a trial program, there are a limited number of spaces for people to participate, however, your pharmacy can make other arrangements if necessary for those people who may not be eligible or who may miss out.

The current trial program is being managed by the Pharmacy Guild of Australia, in partnership with the University of Sydney and Deakin University, with support and funding from the Australian Government Department of Health.

The Pharmacy Diabetes Screening Trial is funded by the Australian Government, Department of Health as part of the Sixth Community Pharmacy Agreement.



Summary of progress

Human Ethics final approval received – University of Sydney

Medicare data final approval received – Department of Human Resources

Online training – Available on Guild Academy

Checklists for device competency – Research Team

Accredited CPD points – Pharmaceutical Society of Australia

Online baseline survey developed – Research Team

Standard Operating Procedures (SOPs) and Flowcharts – Research Team

Pharmacy Operations Manual and Workbook – Research Team

Printed resources for pharmacies (PIS, consent forms, flyers, posters, GP letters, etc) - Guild

Random sample of pharmacies generated – Research Team

Invitation and recruitment of pharmacies from random sample – Guild

GuildCare Pharmacy Diabetes Screening Trial software - Guild

Tender for point of care devices and other resources/consumables for pharmacies - Guild