ATTACHMENT A

SCHEDULE OF DOCUMENTS – FOI 3397

Document No.	Date	Pages	Description	Decision on access[1]	Exemption/s applied
1	28.04.20	203	Pharmacy Diabetes Screening Trial (PDST) Final Report – Applicant Developed Assessment Report (ADAR)	RE	section 47 – part
2	11.05.20	182	PDST Final Report Appendices (part 1 of 3) - ADAR	RE	section 47 – part
3	11.05.20	16	PDST Final Report Appendices (part 2 of 3) – ADAR	RE	section 47 - part
4	11.05.20	98	PDST Final Report Appendices (part 3 of 3) – ADAR	RE	section 47 – part
5	18.06.21	30	Appendix 12: Supplementary Economic Analysis (Economic evaluations presented in the PDST) – ADAR	E	section 47 - full
6	18.06.21	9	Final PDST Data Set – Trial based Cost-Effective Analysis (CEA) & Sensitivity Analysis (Economic evaluations presented in the PDST) – ADAR	E	section 47 - full
7	18.06.21	9	Pharmacy Diabetes Screening Service Assessment Report, Section E – Financial implications (Estimated extent of use and financial implications) - ADAR	E	section 47 – full
8	18.06.21	5	Budget Impact Analysis – Pharmacy Diabetes Screening Service Final for Submission – (Estimated extent of use	E	section 47 – full

[1] R = Release in full, E = Exempt in full, RE = Release with exemptions applied.

			and financial implications) – ADAR		
9	18.06.21	1	Your Guild, Your Business Support – Member Profiling Data (Estimated extent of use and financial implications) – ADAR	E	section 47 – full
10	18.06.21	25	Burden of diabetes in Australia: It's time for more action – Preliminary Report (Estimated extent of use and financial implications) – ADAR	R	N/A
11	18.06.21	9	Australian Bureau of Statistics September 2020 Data table for national population by age and sex (Estimated extent of use and financial implications) – ADAR	R	N/A
12	16.09.21	89	PDST Final Commentary	RE	section 22 – part section 47 – part
13	16.09.21	6	ESC Policy Paper	RE	section 22 – part section 47 – part section 47C – part
14	24.09.21	7	Pre-ESC Response	E	section 47 – full
15	15.09.21	3	National Pathology Accreditation Advisory Council (NPAAC) advice for applications	RE	section 22 – part section 47F - part
16	28.09.21	1	NPAAC Advice to MSAC	R	N/A
17	05.11.21	3	Summary of Consultation Feedback/Consumer issues received post ESC	R	N/A
18	07.10.21	6	Australian Diabetes Society (ADS) redacted Consultation Feedback	R	N/A
19	08.10.21	6	Australian Medical Association (AMA) redacted Consultation Feedback	R	N/A

20	08.10.21	7	Individual redacted Consultation Feedback	RE	section 47F – part
21	11.10.21	7	Pharmaceutical Society of Australia (PSA) redacted Consultation Feedback	R	N/A
22	15.10.21	2	The Royal Australian College of General Practitioners (RACGP) redacted Consultation Feedback	R	N/A
23	08.10.21	6	Diabetes South Australia redacted Consultation Feedback	RE	section 47F – part
24	04.11.21	29	Final ESC Report	RE	section 47 – part
25	04.11.21	14	MSAC policy paper	RE	section 22 – part section 47 – part section 47C – part
26	17.11.21	6	Pre-MSAC Response	RE	section 47 – part

Pharmacy Diabetes Screening Trial

FINAL REPORT

The Pharmacy Guild of Australia

THE UNIVERSITY OF SYDNEY

DEAKIN UNIVERSITY

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

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Executive Summary

Background

An estimated 500,000 adults in Australia have undiagnosed type 2 diabetes mellitus (T2DM). The risk of diabetes complications can be reduced through early detection and intervention. International evidence suggests that community pharmacy is a feasible setting to provide screening services for diabetes.

Trial Objectives

The objectives of the Pharmacy Diabetes Screening Trial (PDST) were to compare the effectiveness and cost-effectiveness of three different pharmacy-based screening models:

1. The paper based AUSDRISK assessment of diabetes risk, alone (Group A)
2. AUSDRISK followed by a point-of-care (POC) HbA1c test (Group B)
3. AUSDRISK followed by a POC scBGT (Group C)

The primary clinical hypothesis was that the addition of either an HbA1c POC test (Group B) or a scBGT POC test (Group C) to the AUSDRISK™ assessment would be associated with a statistically significant increase in the proportions of newly diagnosed T2DM cases compared with AUSDRISK™ alone (Group A). The core hypothesis for the economic analysis was that addition of either POC test after AUSDRISK™ screening, followed by a referral to GP, if appropriate, was 'cost-effective' in comparison to AUSDRISK™ screening alone, from a health funder perspective.

Methods

The PDST used a clustered randomised controlled design where pharmacies in geographically defined and non-contiguous areas (clusters) across Australia were the unit of randomisation and screening participants the unit of analysis. Adults who were aged between 35-74 years, and who did not have a history of diabetes or prediabetes or recent screening, were invited to participate.

All screening participants were then asked to complete the AUSDRISK questionnaire. In Group A, those with an elevated AUSDRISK score (≥12) were referred to their GP for further testing. In Groups B and C, participants with elevated AUSDRISK scores were given the appropriate POC test and

referred if their HbA1c concentration was ≥39 mmol/mol (5.7%) (Group B) or if a capillary fasting blood glucose (FBG) concentration was ≥ 5.5 mmol/l or a random blood glucose (RBG) concentration was ≥ 7.0 mmol/l (Group C). Referred patients were provided with a GP referral letter, and pharmacists made direct contact with doctors for consenting referred patients.

The primary clinical outcome being considered was diagnosis of T2DM following screening.

Economic analysis addressed the technical efficiency question of how best to undertake screening for T2DM in the pharmacy setting. It involved a trial-based cost-effectiveness analysis conducted from a health service funder perspective; a trial-based sensitivity analysis to explore parameters for which there was potential uncertainty regarding the most appropriate statistic/value for analysis; and a modelled economic evaluation with an extended time horizon (e.g. the expected lifetime of participants) to determine long-term benefits of early diagnosis of T2DM and the associated prevention/delay of T2DM complications. Various versions of the model were developed, using a range of assumptions, including feedback from the Expert Panel (refer to the results section for details of key models).

Results

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The program and clinical results

- A total of 14,093 people were screened in 339 pharmacies (including 55 people who were subsequently excluded from the outcome analysis due to pre-existing T2DM diagnosis)
- 136 referred participants were diagnosed with T2DM – 33 in Group A, 72 in Group B, and 31 in Group C
- 338 participants were diagnosed with prediabetes - 139 participants in Group A, 158 participants in Group B, and 41 in Group C
- A further 4 individuals in Group B and 5 individuals in Group C, who were not referred, were also diagnosed with diabetes (i.e. false negatives [FNs])
- The diagnosis of T2DM as a proportion of the total screened population was higher in Group Bs47 than in Group As47 and Group Cs47
- Using referred participants as the denominator, the rates of diagnosis of T2DM were; Group As47 ; Group Bs47 and Group Cs47

- Rates of qualifying for referral were lower in Groups B s47 and C s47 compared with Group A s47
- Rates of referral uptake were higher in Groups B s47 and C s47) compared with Group A s47
- The most common risk factors in participants diagnosed with T2DM were having a family history of diabetes s47 , being on blood pressure medication s47), having low levels of exercise s47 or vegetable intake s47 , and smoking s47
- The approval rating for the screening service being delivered in community pharmacy was high from pharmacy, pharmacist and screening participants. There was evidence that use of AUSDRISK alone was not as highly rated by pharmacists or patients when compared with the addition of a POC test

The economic results

Overview:

- Both trial-based and modelled cost-effectiveness ratios are reported. These are based on comparisons within each arm (average cost-effectiveness ratios – i.e. total costs divided by total outcomes within each arm), and across the three arms of the trial (incremental cost-effectiveness ratios – ICERs)
- The average cost-effectiveness ratios are helpful for understanding the relationship between resource use (reflecting screening and treatment activities) and associated outcomes (cases detected; QALYs) within each arm. The incremental cost-effectiveness ratios are helpful for understanding relative performance – that is, the extra resources required to achieve the extra outcomes
- Both the trial-based and modelled evaluations are suitable for answering 'technical efficiency' (i.e. which pharmacy-based screening option to adopt), but only the modelled evaluation is designed to assist with assessing allocative efficiency (i.e. value-for-money) as it has a common metric that measures mortality and morbidity impacts (QALYs) and a threshold decision value to help with the assessment of worth (<$50,000 per QALY)
- Taken together, the trial-based and modelled economic evaluations provide a strong case for supporting Option B (AUSDRISK +POC HbA1c) as the most cost-effective option for T2DM screening in community pharmacies, if community pharmacy T2DM screening is to be undertaken

- In terms of financial cost impacts for the health system, the modelled evaluation indicates a strong potential for cost savings using the Group B intervention, compared to Group A. For Group B, Model 3 and Model 4 (all versions) predict savings ranging from s47 per person screened to s47 per person screened, with only Model 1 predicting a net cost. For Group C the results are less promising, with Model 4.2 and Model 4.3 suggesting savings s47 per person screened), while Models 1, 3 and 4.1 all predict a net cost

- The four economic hypotheses and key results are summarised in Executive Summary Table 1

Executive Summary Table 1: The four economic hypotheses and key results

Hypotheses in Economic Evaluation	Results
Hypothesis 1: Addition of either HbA1c POC (Group B) or the scBGT POC (Group C) to AUSDRISK screening alone (Group A) would be cost-effective.	**AUSDRISK +HbA1c (Group B): Yes*** **AUSDRISK + scBGT (Group C): No, dominated by Group A** *s47 per new case of T2DM diagnosed and s47 per new case of T2DM/prediabetes diagnosed considered cost-effective in terms of technical efficiency (i.e. how best to screen)
Hypothesis 2: Addition of either HbA1c POC or scBGT POC to AUSDRISK screening would 'dominate' AUSDRISK screening alone, having regard to longer term health and patient outcomes.	**Varies by Model (preferred models reported – refer Table Notes)** **AUSDRISK + HbA1c (Group B): Dominates Group A** Under Model 3 and Model 4 (including 4.1-4.3) Group B is dominant over AUSDRISK alone (Group A). **AUSDRISK + scBGT (Group C): Mixed results, but mostly dominated** Under Model 3 and 4.1, Group C is dominated by Group A. Under Model 4.2, Group C is dominant over AUSDRISK alone (Group A) and AUSDRISK + HbA1c (Group B). Under Model 4.3 Group C is dominant over AUSDRISK alone (Group A), but dominated by Group B.
Hypothesis 3: Additional financial cost of adding POC testing to AUSDRISK screening would be offset by reduction in GP-based costs in the trial-based analysis due to the fall in FNs.	**AUSDRISK + HbA1c: No@** s47 **AUSDRISK + scBGT: No@** s47 **@** These results are complicated by participants with screening negative results still seeing their GPs for further T2DM testing
Hypothesis 4: Additional financial cost of adding POC testing to AUSDRISK screening would be offset by reduction in GP-based costs having regard to longer term health and patient outcomes.	**Results are variable by model, with Group B having stronger credentials than Group C** **AUSDRISK + HbA1c (Group B)** # No, additional cost of s47 per person screened under Model 1 # Yes, saving of s47 per person screened under Model 3 # Yes, saving of s47 per person screened under Model 4.1

	# Yes, saving of s47 per person under Model 4.2 and 4.3 **AUSDRISK + scBGT (Group C)** # No, additional cost of s47 per person screened (Model 1) # No, additional cost of s47 and s47 under Model 3 and Model 4.1, respectively # Yes, saving of s47 per person screened (Model 4.2) # Yes, saving of s47 per person screened (Model 4.3)

Table Notes:

[1]**Model 4** was developed in response to a request from the Expert Panel to provide additional analysis of false negatives (FNs) and test cut-off/referral rates. There are three versions of Model 4, with Model 4.3 being our preferred version in terms of realism and relevance for policy decisions. **Model 4.1** was based on Model 3, but incorporates a 5% effect decay rate in behavioural interventions for treatment of prediabetes and latest available data for lifetime costs and outcomes weighted by age distribution of PDST participants. **Model 4.2:** was based on 4.1 with 'undiagnosed T2DM' amended in all referred groups to s47 (from s47 in Group A; s4 in Group B; and s47 in Group C); with FN in non-referrals of Group A moving from s47 to s47 [based on AusDiab], Group B left unchanged at s4, and Group C moving from s47 to s47 [based on AusDiab]. **Model 4.3:** was based on 4.2 with the Group C referral rate increased to s47 and FN decreased to s47

[2]**Model 3:** Includes lifetime costs and effectiveness for T2DM, prediabetes and non-diabetics, with different undiagnosed diabetes prevalence in the three screening non-referrals.

The detailed results from the trial-based evaluation:

- The 'average cost per new confirmed case of T2DM' in each arm of the trial was s47 for Group A (AUSRISK alone); s47 for Group B (AUSDRISK +POC HbA1c); and s47 for Group C (AUSDRISK + POC scBGT)

- 'Average cost' reports the total cost of providing the health screening and care activities expressed as a ratio of outcomes achieved - in this case, the 'total new confirmed cases' found in each arm or the 'total number of participants' in the trial. Where cost offsets are available, these would be deducted from total costs to report 'total net cost' and 'average net cost' - no cost offsets were identified within the trial arms

- The next step is to compare costs between arms of the trial to identify 'incremental costs' – these cost differences between arms are then compared with the different outcomes achieved to report cost-effectiveness ratios (ICERs)

- The trial-based incremental cost effectiveness ratio (ICER) was s47 per additional new case of T2DM detected in Group B compared with Group A; or s47 with prediabetes included

- The Group C vs Group A trial-based ICER, however, is unstable - Group C was dominated by Group A (i.e. more costly, less effective) if T2DM detection was expressed as ratio of all referred participants as the denominator, but when using T2DM detection expressed as a ratio of the all screened population as the denominator, Group C becomes more effective at an additional cost of s47 , compared to Group A. This all-screened population ICER, however, is confounded by false negatives (FNs) subsequently found to have T2DM. The Group C performance characteristics therefore were examined extensively in sensitivity analysis

- For the Group B vs Group C comparison, Group B is more effective than Group C, detecting an extra 41 cases of T2DM, but does so at extra cost of s47 per new confirmed case of T2DM; or s47 with prediabetes included

- The most sensitive parameters affecting the trial-based ICERs were the outcome variables, particularly: i) the HbA1c and AUSDRISK risk score cut-off values; ii) the inclusion of prediabetes cases detected; and iii) the overall new cases of T2DM detected in the 'all screened participants' vs 'all referred participants' (where undiagnosed diabetes and false negatives impact)

- For the Group B/Group A ICERs, the most influential variables were the HbA1c and the AUSDRISK risk cut-off values, as well as inclusion of prediabetes cases; while for the Group C/Group A comparison, it was use of the 'all screened participants' as the denominator vs 'all referred participants' for cases of DM diagnosed

The detailed results from the modelled economic evaluation:

- The detailed results vary according to the model used, which were developed to provide a logical sequence in the underlying assumptions, viz:
    - Model 1 was based on detection of T2DM only (the primary outcome in the Trial) with the same undiagnosed diabetes prevalence adopted across groups. The Group C/Group A ICER was s47 per QALY, while the Group B/Group A ICER was s47 per QALY
    - Model 2 was based on detection of both T2DM and prediabetes, still with the same undiagnosed diabetes prevalence across groups. These results are confounded and are not reported here
    - Model 3 was based on detection of both T2DM and prediabetes, but with differential prevalence rates for undiagnosed diabetes. Under Model 3 assumptions, Group B

dominated Group A, while Group C was dominated by Group A, consistent with the trial-based results

- Model 4 was developed in response to feedback from the Expert Panel, together with inclusion of latest available data and an effect decay rate for the behavioural change modelling. Three versions of Model 4 were developed as set out in Executive Summary Table 2 below. Group B was dominant over Groups A and C in 4.1 and 4.3

- In terms of financial cost impacts for the health system, the modelled evaluation indicates a strong potential for cost savings compared to Group A. For Group B, Models 3 and 4 (all versions) predict savings ranging from s47 per person screened tos47 per person screened, with only Model 1 predicting a net cost. For Group C the results are less promising, with Model 4.2 and Model 4.3 suggesting savings s47 per person screened), while Models 1, 3 and 4.1 all predict a net cost

Executive Summary Table 2: Summary of economic modelling from preferred models

Strategy	Cost (per person)	Incremental Cost (per person)	Effectiveness QALYs (per person)	Incremental Effectiveness QALYs (per person)	ICERs '$ per QALY'
Decision Analytical Model 3: (based on T2DM + prediabetes + non-diabetes; different undiagnosed diabetes prev.)					
Group A: AUSDRISK	s47				
Group B: AUSDRISK + HbA1C POC					
Group C: AUSDRISK + BG POC					
Decision Analytical Model 4.1 (based on Model 3 + using weighted lifetime costs and outcomes)					
Group A: AUSDRISK	s47				
Group B: AUSDRISK + HbA1C POC					
Group C: AUSDRISK + BG POC					
Decision Analytical Model 4.2 (based on Model 4.1 + using AusDiab data to update FN in Group A and C)					
Group A: AUSDRISK	s47				
Group B: AUSDRISK + HbA1C POC					
Group C: AUSDRISK + BG POC					
Decision Analytical Model 4.3 (based on Model 4.2 + changing referral rate in Group C)					
Group A: AUSDRISK	s47				
Group B: AUSDRISK + HbA1C POC					
Group C: AUSDRISK + BG POC					

Table Notes: ^Reference case,*Dominant: more effective and less costly, #Dominated: less effective and more costly,
Decision Analytical Model 3: lifetime costs and effectiveness for new cases of T2DM and new cases of prediabetes, with different undiagnosed diabetes prevalence in three screening 'non-referred' groups. We assumed the T2DM diagnosis rate in the referred participants who were not tested by their GP was the same as those who were diabetic but not referred (false negatives). Screening result of non-diabetic also included.

Decision Analytical Model 4 was developed from Model 3 in response to a request from the Expert Panel to provide additional analysis of false negatives (FNs) and test cut-off/referral rates in Group C (revised FN/referrals).
Model 4.1: Original parameters for FNs and undiagnosed T2DM + 5% decay rate in behavioural + updates for lifetime costs and outcomes. Uses weighted average lifetime costs and outcomes.

Model 4.2: Revised undiagnosed T2DM in all referred groups to s47 (from s47 in Group A; s47 Group B; and s47 in Group C); with FN in non-referrals of Group A moving from s47 [AusDiab], Group B unchanged at 1%, and Group C moving from s47 to s47 [based on AusDiab]. Uses weighted average lifetime costs and outcomes.
Model 4.3: Version 4.2, but with Group C referral rate increased to s47 and FN decreased to s47 . Uses weighted average lifetime costs and outcomes.

- Under Model 4 additional analyses were undertaken at the request of the Expert Panel. Model 4.1 was developed as preliminary step to include an effect decay rate for the behavioural interventions, together with updates using latest available data in the lifetime costs and outcome, weighted by age distribution of the trial participants to reflect an opportunistic screening program
- Under Model 4.1 there was no change in the conclusions. Group B remained dominant over Group A and Group C
- Under Model 4.2 false negative rates (FNs) were estimated from AusDiab study. The FNs resulting from the AusDiab data were 1.62% for Group A and 1.94% for Group C. In addition to the false negatives estimates, the AusDiab data provided useful information in estimating undiagnosed T2DM in the referrals. Of the 3,663 AusDiab participants without diabetes and with an AUSDRISK™ score ≥12, 350 participants, 9.6% had undiagnosed diabetes defined as FPG ≥7.0 mmol/L and/or 2hPG ≥11.1 mmol/L. This undiagnosed T2DM prevalence was used for T2DM in the unknown status for the referrals in Groups A, B and C
- Thus in **Model 4.2** the revised undiagnosed T2DM in all referred groups was set at 9.6% (from s47 in Group A; s47 Group B; and s47 in Group C); with FNs in non-referrals of Group A moving from s47 AusDiab], Group B unchanged s47 [1], and Group C moving from s47 to s47 [AusDiab]. Under these assumptions, Groups A and B are both dominated by Group C, with Group B maintaining its dominance over Group A. The problem with Model 4.2, however, is that the referral rate was confounded by a higher test cut-off (i.e. less referrals) than would apply in a realistic scenario relevant for policy consideration. Thus Model 4.2 is not providing an adequate alternative scenario for Group C with improved FN and referral rates
- This takes us to **Model 4.3** where a Group C referral rate of 19.3% and false negative rate of 1.5% was modelled based on the AusDiab data[2] and detailed sensitivity analysis (refer *Appendix 12*).

[1] Due to small numbers in HbA1c measures in the AusDiab study, there is no reliable data for the PDST to estimate the false negatives for Group B.

[2] Referral rates were estimated based on alternate false negative rates and blood glucose cut-off levels for Group C.
Estimates of false negatives (FN) and referral rates for Group C at different cut-off levels, using the AusDiab data

Group C Cut-off levels	Referral rate	False negative rate

With this referral rate for Group C, Group B becomes the clearly preferred strategy with both the highest QALYs and lowest cost among the three screening strategies. Group A is also dominated by Group C

- **The shift in results between Model 4.2 and Model 4.3 demonstrates the importance of the screening referral rate.** The danger in modelling exercises is that that lower referral rates distribute a higher proportion of the screened population to the 'non-diabetes' category and consequently assign greater QALY weights. As our modelling work has demonstrated, compromised referral rates and/or unrealistic referral assumptions make this variable a potential confounder that distorts cost-effectiveness outcomes and associated conclusions**. It is important therefore that screening test, cut-off scores, undiagnosed/FN values and referral rates are carefully assessed and considered together**

- To gain a better appreciation of the impact of referral rates, we ran univariate and bivariate sensitivity analyses with the referral rate and FNs in Model 4.2 focussed on Group C, which are reported in *Appendix 12, Table A10.* When the Group C referral cut-off was lowered to RBG ≥6.0 mmol/L or FBG ≥ 5.5 mmol/L (where the referral rate increased to 19.3%), Group C was no longer a dominant strategy (as in Model 4.2). With the Group C referral rate higher than 19.3%, the effectiveness (i.e. QALYs) in Group B was higher than that of Group C. When the referral rate in Group C was greater than 25%, Group C was less effective compared to Group A. The conclusions of the bivariate sensitivity analysis, involving variations in both referral rates and false negatives, were in line with the univariate analysis *(Appendix 12, Table A14)*

- In summary, Model 3 and Model 4 (when run with realistic assumptions) both favour Group B as the preferred screening modality

- The main clinical uncertainty in the ICER calculations across the various models utilised, arose from the undetected diabetes in the non-referrals and those not tested by their GPs to verify their diabetes status from screening. Models 4.1-4.3 were developed, with the associated sensitivity analyses, to provide further guidance on this issue. Our conclusion on the balance of evidence

RBG Cut off ≥7.0 mmol/L or FBG cut off≥ 5.5 mmol/L	s47
RBG cut offs ≥6.5 mmol/L or FBG cut off≥ 5.5 mmol/L	
RBG Cut off ≥6.0 mmol/L or FBG cut off≥ 5.5 mmol/L	
RBG Cut off ≥5.5 mmol/L or FBG cut off≥ 5.5 mmol/L	

Table Note: *Assumption due to no data available.

from the various modelling analyses undertaken, was that Group B was clearly the preferred screening modality, which reinforces the trial result.

Discussion

The PDST was the first robustly designed pharmacy-based cluster randomised controlled screening trial based on a nationally representative sample of community pharmacies. During the PDST, there were 145 confirmed cases of newly diagnosed T2DM and 338 cases of newly diagnosed prediabetes. Consistent with one of the study hypotheses, of the three approaches to screening, the risk assessment using the AUSDRISK tool followed by a POC HbA1c test for those with AUSDRISK scores of ≥12 showed the highest overall rate of detection of T2DM s47 of the total screened population) compared to Groups A s47 and C s47 . Rates of detection are comparable with the literature.

The economic findings indicated that screening for T2DM with AUSDRISK followed by an appropriate POC test for those at risk is more cost-effective than using the AUSDRISK risk screening tool alone. At s47 per additional confirmed case of T2DM detected in Group B (vs Group A), and s47 per additional case when prediabetes included, strong cost-effectiveness credentials are likely for Group B. It is important to note that, depending on the model and associated assumptions, the modelled cost-effectiveness results can be different from the trial-based results, particularly in relation to Group C. The assumption in Models 1 and 2, for example, that the same level of undiagnosed T2DM prevalence applies to all unknown cases of T2DM across the three arms has potentially biased these results as it impacts on the significance of non-referral rates; particularly in Group C, where non-referral was a higher proportion of all screened participants (92.1%) than in Group A (55%). With non-referrals attributed higher QALYs (lower T2DM risk), total QALYs in Group C are greater than Group A, contrary to the trial-based outcome comparison that focussed on case detection.

Model 3 therefore assumes differential undiagnosed diabetes prevalence rates across the three approaches to screening in community pharmacies. With these more realistic assumptions, Group C is again dominated by Group A, consistent with the trial-based results, while the Group B is dominant over both Group A and Group C.

In discussion with the Expert Panel, further modelling was requested to provide additional analysis of the impact of false negatives (FNs) and the screening cut-off/referral rates. In our preferred version of Model 4 (Model 4.3), a Group C referral rate of 19.3% (together with FN of 1.5%) was

modelled based on the AusDiab data[3]. With this referral rate for Group C, Group B becomes the clearly preferred strategy with both the highest QALYs and lowest cost among the three screening strategies.

This Model 4 analysis reinforced the importance of the screening referral rate. A danger in economic modelling exercises is that that 'poor' referral rates distribute a higher proportion of the screened population to the 'non-diabetes' category and consequently assign greater QALY weights. As our modelling work has demonstrated, compromised referral rates and/or unrealistic referral assumptions make this variable a potential confounder that distorts cost-effectiveness outcomes and associated conclusions**. It is important therefore that screening test cut-off scores and values assigned to undiagnosed diabetes, FNs and referral rates are assessed carefully and in a connected way.**

Finally, while the trial-based and preferred economic evaluation models favoured Group B as the most cost-effective screening modality, it is important to consider these results against broader policy considerations. Accordingly, the three screening modalities were also ranked by considerations of affordability, effectiveness and efficiency in Executive Summary Table 3 below.

Executive Summary Table 3: Ranking of screening options by cost, cases detected and ICER

(1) Least cost alternative in Trial	(2) Rank	(3) Most T2DM Cases Detected (PPV)	(4) Rank	(5) Most T2DM + Prediabetes Detected (Definition 1) (PPV)	(6) Rank	(7) Lowest av. C/E ratio in trial ($ per case of T2DM or Prediabetes)	(8) Rank	(9) Lowest ICER Model 3 and Model 4.3 ($ per QALY)	(10) Rank

[3] Referral rates were estimated based on alternate false negative rates and blood glucose cut-off levels for Group C.

Estimates of false negatives (FN) and referral rates for Group C at different cut-off levels, using the AusDiab data

Group C Cut-off levels	Referral rate	False negative rate
RBG Cut off ≥7.0 mmol/L or FBG cut off≥ 5.5 mmol/L	s47	
RBG cut offs ≥6.5 mmol/L or FBG cut off≥ 5.5 mmol/L		
RBG Cut off ≥6.0 mmol/L or FBG cut off≥ 5.5 mmol/L		
RBG Cut off ≥5.5 mmol/L or FBG cut off≥ 5.5 mmol/L		

*Assumption due to no data available.

Group A s47	1st	**Group B** s47 s47	1st	**Group B** s47	1st	Group A s47	1st	Comparator	n/a in ICER
Group C s47	2nd	Group A s47 s47	2nd	Group A s47	2nd	**Group B** s47	2nd	**Group B** s47 Models 3, 4.1. 4.3	1st
Group B s47	3rd	Group C s47 s47	3rd	Group C s47	Poor 3rd	Group C s47	3rd	Group C s47	2nd

Group B clearly detects the most cases of T2DM and prediabetes, achieved with the best PPVs, but at greater trial-based cost than Groups A or C. On 'cost per case detected' – that is, the average cost-effectiveness ratios for each arm, Group B is 2nd just behind Group A (Column 7). **The financial cost on the health system from the modelled evaluation, however, indicate a strong potential for cost savings.** For Group B compared to Group A, Model 3 and Model 4 (all versions) predict savings ranging from s47 per person screened to s47 per person screened, with only Model 1 predicting a net cost (s47 per person screened). For Group C versus Group A the results are less promising, with Model 4.2 and Model 4.3 suggesting savings s47 per person screened), while Models 1, 3 and 4.1 all predict a net cost s47 per person screened).

On the key incremental cost-effective ratio, however, the additional clinical outcomes and QALYs are achieved efficiently, with Group B achieving dominance over both other screening options in Models 3, 4.1 and 4.3. Our conclusion on the balance of evidence from the various modelling analyses undertaken, was that Group B was the preferred screening modality, which reinforces the trial result.

The modelled ICERs are also supportive of 'value-for-money' in implementing community pharmacy-based T2DM screening, but the absence of a clear control arm (i.e. 'no T2DM screening') or a fully specified 'current practice' comparator '(weighted average of current pharmacy-based T2DM screening activities'), needs to be taken into account. Redirecting any current community pharmacy

based T2DM screening activity into a well organised national program is likely to improve ICERs, as the additional outcomes achieved should outweigh any additional cost involved. Similarly, compared to a 'do nothing' scenario, the average cost-effectiveness results within each arm suggest health improvement could be achieved at reasonable cost or even long-term cost savings. On balance we judge the economic credentials for introducing community pharmacy based T2DM screening to be strong.

In addition to the strong economic case in favour of the Group B intervention, pharmacist and participant preferences for a model involving POC testing suggest such an approach may prove more successful in terms of adoption and dissemination if implemented nationally as an ongoing service.

Recommendations

1. Overall the trial-based and modelled economic evaluations provide a strong case for supporting Option B AUSDRISK +POC HbA1c as the preferred option for T2DM screening in pharmacies.[4]

2. A community pharmacy-based screening program for undiagnosed T2DM and risk of T2DM should adopt a two-step approach, with initial risk assessment using the AUSDRISK screening tool followed by a POC test with HbA1c if the AUSDRISK score is indicative of elevated risk (AUSDRISK cut off should conform with current Australian guidelines), followed by referral to a general practitioner if HbA1c ≥ 5.7% or 39 mmol/mol).

3. A formal training and assessment process be implemented to ensure that pharmacists undertaking a remunerated screening service can demonstrate the requisite competencies to deliver the service at an appropriate standard.

4. Quality assurance processes be required for participating pharmacies to ensure effective uptake and consistent service delivery. Centralised performance monitoring, structured implementation planning, detailed protocols and effective decision support software all

[4] However, it is important therefore that screening test cut-off scores and values assigned to undiagnosed diabetes, FNs and referral rates that have been assessed carefully and in a connected way by sensitivity analyses presented in Appendix 12.

supported effective implementation during the trial.

5. To be eligible to deliver screening services a pharmacy must demonstrate that it has the following:

    a. A separate counselling room or private counselling area
    b. Two or more pharmacists on duty at the same time when delivering screening services
    c. A minimum of one pharmacist with requisite training and competency to conduct screening
    d. Appropriate documentation, software and suitable, regularly calibrated POC equipment and consumables

6. To receive remuneration for the screening service the pharmacy must take reasonable steps to ensure that when conducting a screening assessment, the individual:
    a. Does not already have a diagnosis of T2DM
    b. Has not been tested for T2DM with a valid screening test in the previous 12 months (this is important to avoid unnecessary duplication and costs to the health care system)
    c. Does not have any known contraindication to the use of HbA1c as a POC test (e.g. anaemias)
    d. Must adhere to an approved screening protocol that includes a 6 week follow-up by the pharmacist with any screened individual who has been referred to their GP (this is critical to achieving continuity of care)

7. Given the positive responses of screened individuals to the lifestyle modification advice delivered as part of the screening and referral service protocol, consideration could be given to further investigation of the impact of the screening and referral with the addition of a monitoring component on the reduction of risk factors.

8. Diabetes screening in community pharmacies should be tailored to local conditions and take account of local needs. Depending on local need and demand, they may be offered:
    a. To coincide with targeted campaigns e.g. Diabetes week, local health promotion weeks etc.

b. Opportunistically on a continuing basis in the pharmacy

c. As targeted outreach screenings for community groups

Pages 20 - 203 redacted per s 47

Pharmacy Diabetes Screening Trial

FINAL REPORT

APPENDICES

The Pharmacy Guild of Australia

THE UNIVERSITY OF SYDNEY

DEAKIN UNIVERSITY

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

s47 - pages 2-36 exempt

APPENDIX 1: ELIGIBILITY CARD

Pharmacy Diabetes Screening Trial

This is an Australia-wide trial, involving over 360 pharmacies and 30,000 screening participants. The trial involves a screening assessment in the pharmacy, and possibly a couple of follow-up phone calls and surveys.

To be eligible to participate, you need to be able to answer:

YES to the following:

- Do you have a valid Medicare Card or Veterans' Affairs Card?
- Are you between 35 and 74 years old?

and

NO to all the following:

- Are you pregnant?
- Have you been previously diagnosed with diabetes or pre-diabetes? *(Females with history of gestational diabetes are eligible)*
- In the last 12 months have you done any screening tests for diabetes?
- Are you enrolled in LIFE! (VIC), GET HEALTHY (NSW) or COACH (TAS)?
- Have you been diagnosed with a terminal illness?

Note: Pharmacies have an allocated number of places in the trial for specific age groups and genders.

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APPENDIX 2: AUSDRISK

The Australian Type 2 Diabetes Risk Assessment Tool (AUSDRISK)

1. Your age group

Under 35 years	☐	0 points
35 – 44 years	☐	2 points
45 – 54 years	☐	4 points
55 – 64 years	☐	6 points
65 years or over	☐	8 points

2. Your gender

Female	☐	0 points
Male	☐	3 points

3. Your ethnicity/country of birth:

3a. Are you of Aboriginal, Torres Strait Islander, Pacific Islander or Maori descent?

No	☐	0 points
Yes	☐	2 points

3b. Where were you born?

Australia	☐	0 points
Asia (including the Indian sub-continent), Middle East, North Africa, Southern Europe	☐	2 points
Other	☐	0 points

4. Have either of your parents, or any of your brothers or sisters been diagnosed with diabetes (type 1 or type 2)?

No	☐	0 points
Yes	☐	3 points

5. Have you ever been found to have high blood glucose (sugar) (for example, in a health examination, during an illness, during pregnancy)?

No	☐	0 points
Yes	☐	6 points

6. Are you currently taking medication for high blood pressure?

No	☐	0 points
Yes	☐	2 points

7. Do you currently smoke cigarettes or any other tobacco products on a daily basis?

No	☐	0 points
Yes	☐	2 points

If you scored 6-11 points in the AUSDRISK you may be at increased risk of type 2 diabetes. Discuss your score and your individual risk with your doctor. Improving your lifestyle may help reduce your risk of developing type 2 diabetes.

8. How often do you eat vegetables or fruit?

Every day	☐	0 points
Not every day	☐	1 point

9. On average, would you say you do at least 2.5 hours of physical activity per week (for example, 30 minutes a day on 5 or more days a week)?

Yes	☐	0 points
No	☐	2 points

10. Your waist measurement taken below the ribs (usually at the level of the navel, and while standing)

Waist measurement (cm) ☐

For those of Asian or Aboriginal or Torres Strait Islander descent:

Men	Women	
Less than 90 cm	Less than 80 cm	☐ 0 points
90 – 100 cm	80 – 90 cm	☐ 4 points
More than 100 cm	More than 90 cm	☐ 7 points

For all others:

Men	Women	
Less than 102 cm	Less than 88 cm	☐ 0 points
102 – 110 cm	88 – 100 cm	☐ 4 points
More than 110 cm	More than 100 cm	☐ 7 points

Add up your points ☐

Your risk of developing type 2 diabetes within 5 years*:

☐ *5 or less: Low risk*
Approximately one person in every 100 will develop diabetes.

☐ *6-11: Intermediate risk*
For scores of 6-8, approximately one person in every 50 will develop diabetes. For scores of 9-11, approximately one person in every 30 will develop diabetes.

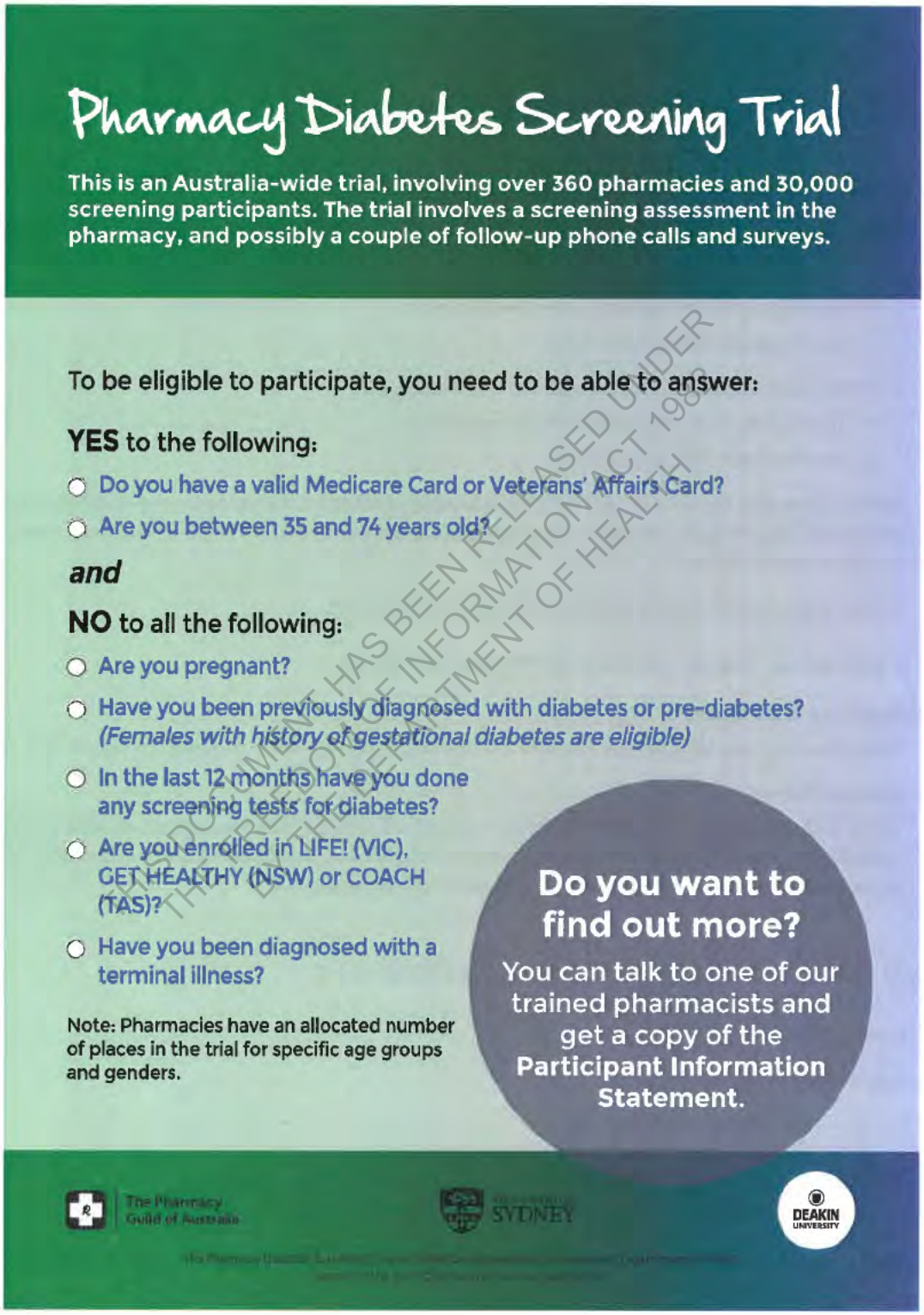
☐ *12 or more: High risk*
For scores of 12-15, approximately one person in every 14 will develop diabetes. For scores of 16-19, approximately one person in every 7 will develop diabetes. For scores of 20 and above, approximately one person in every 3 will develop diabetes.

**The overall score may overestimate the risk of diabetes in those aged less than 25 years.*

If you scored 12 points or more in the AUSDRISK you may have undiagnosed type 2 diabetes or be at high risk of developing the disease. See your doctor about having a fasting blood glucose test. Act now to prevent type 2 diabetes.

s47 - pages 39-77 exempt

APPENDIX 1: ELIGIBILITY CARD



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3. Your ethnicity/country of birth:

3a. **Are you of Aboriginal, Torres Strait Islander, Pacific Islander or Maori descent?**

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3b. **Where were you born?**

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Asia (including the Indian sub-continent), Middle East, North Africa, Southern Europe	☐	2 points
Other	☐	0 points

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Not every day	☐	1 point

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Waist measurement (cm) ☐

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s47 - pages 80-119 exempt

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3b. **Where were you born?**

Australia	☐ 0 points
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s47 - pages 121-129 exempt

Medicare Data

You will be asked to fill out a consent form authorising the study access to your complete Medicare data. Medicare collects information on your medical visits and procedures, and the associated costs. The consent form is sent securely to the Department of Human Services who holds this information confidentially.

By signing the Medicare consent form, your complete Medicare claimed data for the consent period will be released by the Department of Human Services, including the following Medicare information with definitions in brackets:

- Date of service *(the date that the service was rendered by the provider, to the patient)*
- Medicare Item number *(the item number that identifies the service rendered by the provider as per the Medicare Benefits Schedule)*
- Medicare Item description *(describes the service rendered by the provider as per the Medicare Benefits Schedule)*
- Provider charge *(the dollar amount the provider charged for the service)*
- Schedule fee *(the fee listed in the Medicare Benefits Schedule i.e., the Government's recommended fee for that service)*
- Benefit paid *(this is the benefit paid to the patient)*
- Patient out of pocket *(the dollar amount the patient is out of pocket, i.e., provider charge minus benefit paid)*
- Bill type *(the method by which the Medicare benefit was claimed i.e., cash, bulk bill, cheque to patient/provider, direct bill, PCE (easyclaim patient claim), simplified bill and EFT, etc.)*
- Date of referral *(this is the date of referral or request for a service written by the servicing provider)*
- Rendering provider postcode *(the postcode of servicing provider's practice location)*
- Ordering provider postcode *(the postcode of referring provider's practice location)*
- Hospital Indicator *(an indicator on whether or not the service was provided in a hospital)*
- Item category *(groups similar professional services together from within the Medicare Benefits Schedule hierarchical structure of Categories, Groups, Subgroups and Items)*

Confidentiality and security of the data and results

All individual information collected will be kept strictly confidential and will not be published or communicated in a way that makes individuals identifiable. All hardcopy consent forms and screening participant information collected for the screening appointments will be kept in locked filing cabinets at each individual pharmacy and will be forwarded to the University of Sydney by registered post. All electronic and hardcopy data will be retained for a minimum of 20 years after which time it will be permanently destroyed in compliance with the University of Sydney and Deakin University Research Data Management Guidelines. A signed statutory declaration from the University of Sydney and/or Deakin University advising that all the Medicare data has been destroyed will be provided to the Department of Human Services.

Hardcopy data will be stored in a locked file in the archive room N252 in the Faculty of Pharmacy, the University of Sydney. Only members of the small study team will have access to the data. The overall results for this study will be available on the website of the Australian Government Department of Health.

What if you have a complaint or any concerns about the study?

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the University of Sydney [Protocol number 2016/637]. As part of this process, we have agreed to carry out the study according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect people who agree to take part in research studies. If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number.

The Manager, Ethics Administration, University of Sydney:
Telephone: +61 2 8627 8176
Email: ro.humanethics@sydney.edu.au
Fax: +61 2 8627 8177

This information sheet is for you to keep.

If you would like further information regarding any aspect of this trial, you are encouraged to contact your pharmacist or the researcher via the phone number or email address listed above.

Pharmacy Diabetes Screening Trial

Screening Participant Information Statement

The Pharmacy Guild of Australia | The University of Sydney | Deakin University

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

This Participant Information Statement tells you about the research study. Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.

Participation in this research study is voluntary. By giving your consent to take part in this study you are telling us that you understand what you have read; agree to take part in the research study as outlined below; and agree to the use of your personal information as described.

What is this study about?

Type two diabetes affects an estimated 1.7 million Australian adults. This condition increases the risk of serious health problems including heart attacks, kidney disease, strokes and amputation. But the adverse consequences of diabetes can be avoided or reduced if diabetes is diagnosed early and treated. Unfortunately a large proportion of people with diabetes remain undiagnosed.

The aim of this study is to compare three different community pharmacy approaches for screening and identifying people who might be at risk of developing diabetes. The approach taken can affect who is referred, and how many people are referred, to their GP for further assessment. We wish to understand the effect of each approach on the number of new cases of diabetes found.

Why were you chosen for this research?

Your pharmacy is located in one of the areas selected for the trial and you are invited to participate, subject to your meeting the eligibility criteria. To be eligible you must:

- be aged between 35-74 years
- not have existing diabetes or prediabetes
- not have been screened for diabetes by your GP in the last 12 months
- not have a terminal illness or certain blood disorders
- be able to make independent decisions about your health

We require your pharmacy to recruit a certain number of males and females from different age groups. We may not be able to recruit you if your pharmacist has already recruited enough people with your age group and gender.

What will the study involve for you?

You will be asked to sign two different consent forms:

(1) a participant consent form for the study, and

(2) a Medicare consent form to access your complete Medicare data.

If you consent to participate in the project, your pharmacist will conduct a diabetes screening assessment. This will be done in a private area with a pharmacist. You will be asked some questions, have your waist circumference measured, and a score will be calculated (using a form called the AUSDRISK™).

If your score shows that you are at risk of developing type 2 diabetes, the pharmacist will provide you with a referral to your GP for further investigation. If you do not have a regular GP, the pharmacist can help organise an appointment for you with a local GP.

We will ask you for permission to contact your GP to find out the results of any tests they might perform and for your consent to access your Pathology, National Diabetes Services Scheme (NDSS) and Medicare data for study analysis purposes for a period of 12 months following your screening appointment.

Follow-up by pharmacist and researchers

The pharmacist may phone you six weeks after this screening appointment. The researchers may ask you to complete an online survey via SMS or email at 3 months after your screening appointment and may contact you again up to 12 months after this screening appointment to conduct a follow-up survey.

Potential Risks to you

There are no perceived risks to participating in this project. Your pharmacy and participating pharmacists will be trained in the screening process which adheres to national guidelines and integrates with the current screening activities of general practice.

Withdrawing from this project

Your participation in the study is completely voluntary and you can withdraw from the project at any time. Your decision whether to participate will not affect the care you receive from your pharmacist or GP. If you decide to take part in the study, and then change your mind later, you are free to withdraw at any time. You can do this by contacting your pharmacist or a member of the research team. If you decide to withdraw from the study, and inform the research team, we will not collect any more information about you and all data collected up to the point of withdrawal will be kept by researchers as specified and included unless expressly asked not to do so by you.

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- not have a terminal illness or certain blood disorders
- be able to make independent decisions about your health

We require your pharmacy to recruit a certain number of males and females from different age groups. We may not be able to recruit you if your pharmacist has already recruited enough people with your age group and gender.

What will the study involve for you?

You will be asked to sign two different consent forms:

(1) a participant consent form for the study, and

(2) a Medicare consent form to access your complete Medicare data.

If you consent to participate in the project, your pharmacist will conduct a diabetes screening assessment. This will be done in a private area with a pharmacist. You will be asked some questions, have your waist circumference measured, and a score will be calculated (using a form called the AUSDRISK™).

If your score shows that you are at risk of developing type 2 diabetes, the pharmacist will perform a fingerprick blood test and, depending on the results of this test, may provide you with a referral to your GP for further investigation. If you do not have a regular GP, the pharmacist can help organise an appointment for you with a local GP.

We will ask you for permission to contact your GP to find out the results of any tests they might perform and for your consent to access your Pathology, National Diabetes Service Scheme (NDSS) and Medicare data for study analysis purposes for a period of 12 months following your screening appointment.

Follow-up by pharmacist and researchers

The pharmacist may phone you six weeks after this screening appointment. The researchers may ask you to complete an online survey via SMS or email at 3 months after your screening appointment and may contact you again up to 12 months after this screening appointment to conduct a follow-up survey.

Potential risks to you

Your pharmacy and participating pharmacists will be trained in the screening process which adheres to national guidelines and integrates with the current screening activities of general practice. Any potential risk of cross contamination from fingertip blood testing will be minimised by the use of disposable single use safety lancets with spring-loaded needles that are only exposed when the skin is punctured, and then retract automatically. In addition, the pharmacist is trained in the use of aseptic techniques and sterilization of the area between appointments.

Withdrawing from this project

Your participation in the study is completely voluntary and you can withdraw from the project at any time. Your decision whether to participate will not affect the care you receive from your pharmacist or GP. If you decide to take part in the study, and then change your mind later, you are free to withdraw at any time. You can do this by contacting your pharmacist or a member of the research team. If you decide to withdraw from the study, and inform the research team, we will not collect any more information about you and all data collected up to the point of withdrawal will be kept by researchers as specified and included unless expressly asked not to do so by you.

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Appendix 6: Pharmacy Resources

PDST GP Information Letter – Group A

PDST GP Information Letter – Group B

PDST GP Information Letter – Group C post modification

PDST GP Information Letter – Group C pre modification

PDST Pharmacy Resource – Advertorial

PDST Pharmacy Resource – Eligibility Card

PDST Pharmacy Resource – Flyer

PDST Pharmacy Resource – Poster 1

PDST Pharmacy Resource – Poster 2

PDST Pharmacy Resource – Poster 3

PDST Pharmacy Resource – Poster 4

PDST Participant Consent Form – Medicare

PDST Participant Consent Form

Pharmacy Diabetes Screening Trial

Email: diabetes.ptp@6cpa.com.au
Ph: 1300 555 262

CHIEF INVESTIGATOR: Professor Ines Krass
s47 University of Sydney, NSW 2006, Australia
Ph: (02) 9351 3507 Fax: (02) 9351 4391
Email: ines.krass@sydney.edu.au

GP INFORMATION LETTER

PHARMACY DIABETES SCREENING TRIAL FOR TYPE 2 DIABETES

Local pharmacies are implementing the Pharmacy Diabetes Screening Trial for Type 2 Diabetes Mellitus (T2DM), funded by the Australian Department of Health, as part of the Sixth Community Pharmacy Agreement (6CPA) Pharmacy Trial Program. The purpose of this research study is to evaluate the clinical and cost effectiveness of a model of opportunistic diabetes screening in a previously undiagnosed population.

The aim of the study is to understand how local pharmacies can assist in identifying people at elevated risk of developing T2DM by offering a comprehensive screening appointment and referring people at risk to their GP. This research also aims to develop an approach to pharmacy screening that is integrated with and supports general practice in order to ensure the best possible outcomes for patients.

The outcomes of pharmacist's referral to GPs will be determined using a stepwise approach involving triangulation of the following data sources: patient self-report, information from GPs and pathology laboratories, and Medicare and NDSS data.

The Pharmacy Diabetes Screening Trial will run from September 2016 to September 2017.

Why are you getting this letter?

Your practice is located in one of the areas selected for the trial. Pharmacies in your area will be offering the Pharmacy Diabetes Screening Trial to their customers and will refer people at elevated risk of developing Type 2 diabetes to their GP.

In your area, the protocol for the Pharmacy Diabetes Screening Trial consists of an appointment between the pharmacist and the patient as follows:

1. AUSDRISK™ assessment tool is completed by the patient
2. Referral to GP if AUSDRISK™ score ≥ 12
3. Referred patient makes appointment with their GP for further investigation

If one of your patients receives a referral to go to their GP from a pharmacy in the trial, the research team will contact the practice to determine the outcome of this referral (with consent from the patient).

Thank you for your involvement in the trial. We appreciate your feedback on the referral process and, if you wish to do so, please contact one of the project coordinators, Bernadette Mitchel s47 or Fran Wilson s47

The Pharmacy Guild of Australia | THE UNIVERSITY OF SYDNEY | DEAKIN UNIVERSITY

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In your area, the protocol for the Pharmacy Diabetes Screening Trial consists of an appointment between the pharmacist and the patient as follows:

1. AUSDRISK™ assessment tool is completed by the patient
2. HbA1c point-of-care (POC) test if AUSDRISK™ score ≥ 12
3. Referral to GP is given to patient if HbA1c ≥ 5.7% (39 mmol/mol)*
4. Referred patient makes appointment with their GP for further investigation

*any patient with HbA1C ≥ 9% (75mmol/mol) will have an appointment made for immediate referral.

If one of your patients receives a referral to go to their GP from a pharmacy in the trial, the research team will contact the practice to determine the outcome of this referral (with consent from the patient).

Thank you for your involvement in the trial. We appreciate your feedback on the referral process and, if you wish to do so, please contact one of the project coordinators, Bernadette Mitchell s47 or Fran Wilson s47

The Pharmacy Guild of Australia | THE UNIVERSITY OF SYDNEY | DEAKIN UNIVERSITY

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Why are you getting this letter?

Your practice is located in one of the areas selected for the trial. Pharmacies in your area will be offering the Pharmacy Diabetes Screening Trial to their customers and will refer people at elevated risk of developing Type 2 diabetes to their GP.

In your area, the protocol for the Pharmacy Diabetes Screening Trial consists of an appointment between the pharmacist and the patient as follows:

1. AUSDRISK™ assessment tool is completed by the patient
2. scBGT (small capillary blood glucose test) point-of-care (POC) test if AUSDRISK™ score ≥ 12
3. Referral to GP is given to patient if scBGT ≥ 5.5% mmol/L (fasting) or ≥ 7 mmol/L (random)
4. Referred patient makes appointment with their GP for further investigation

*any patient with BG ≥ 15 mmol/l (fasting or non-fasting) will have an appointment made for immediate referral.

If one of your patients receives a referral to go to their GP from a pharmacy in the trial, the research team will contact the practice to determine the outcome of this referral (with consent from the patient).

Thank you for your involvement in the trial. We appreciate your feedback on the referral process and, if you wish to do so, please contact one of the project coordinators, Bernadette Mitchell s47 or Fran Wilson s47

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3. Referral to GP is given to patient if scBGT ≥ 5.5% mmol/L (fasting) or ≥ 7.8 mmol/L (random)
4. Referred patient makes appointment with their GP for further investigation

*any patient with BG ≥ 15 mmol/l (fasting or non-fasting) will have an appointment made for immediate referral.

If one of your patients receives a referral to go to their GP from a pharmacy in the trial, the research team will contact the practice to determine the outcome of this referral (with consent from the patient).

Thank you for your involvement in the trial. We appreciate your feedback on the referral process and, if you wish to do so, please contact one of the project coordinators, Bernadette Mitchel s47 or Fran Wilson s47

The Pharmacy Guild of Australia | THE UNIVERSITY OF SYDNEY | DEAKIN UNIVERSITY

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

The text in this press release is Ethics Approved text, for this reason please only enter text where highlighted.

LOCAL PHARMACY TO TAKE PART IN NATIONAL DIABETES SCREENING TRIAL

[ABC] Pharmacy is involved in a new trial program to screen asymptomatic, previously undiagnosed individuals for type 2 diabetes.

In Australia, the prevalence of type 2 diabetes is in excess of 1.1 million people, and growing. It is estimated that for every five diagnosed cases there are approximately two undiagnosed cases of type 2 diabetes. This means that many people are unaware that they have type 2 diabetes or that they are at significant risk of developing diabetes. In this so called pre- diabetic state, where people have either impaired glucose tolerance (IGT) or impaired fasting glucose (IFG), damage to blood vessels and nerves may already be underway. Earlier diagnosis of type 2 diabetes or pre-diabetes is the **KEY** to early management of risk factors and prevention or delay of common adverse outcomes such as kidney disease, cardiovascular disease, glaucoma, and amputation.

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 glycaemia/impaired glucose tolerance. 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.

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

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

For more information contact [XYZ] at [ABC] Pharmacy.

Pharmacy Diabetes Screening Trial

This is an Australia-wide trial, involving over 360 pharmacies and 30,000 screening participants. The trial involves a screening assessment in the pharmacy, and possibly a couple of follow-up phone calls and surveys.

To be eligible to participate, you need to be able to answer:

YES to the following:

- ○ Do you have a valid Medicare Card or Veterans' Affairs Card?
- ○ Are you between 35 and 74 years old?

and

NO to all the following:

- ○ Are you pregnant?
- ○ Have you been previously diagnosed with diabetes or pre-diabetes? *(Females with history of gestational diabetes are eligible)*
- ○ In the last 12 months have you done any screening tests for diabetes?
- ○ Are you enrolled in LIFE! (VIC), GET HEALTHY (NSW) or COACH (TAS)?
- ○ Have you been diagnosed with a terminal illness?

Note: Pharmacies have an allocated number of places in the trial for specific age groups and genders.

Do you want to find out more?

You can talk to one of our trained pharmacists and get a copy of the **Participant Information Statement.**

The Pharmacy Guild of Australia

The University of Sydney

Deakin University

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

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.

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.

Pharmacy Diabetes Screening Trial

Half a million Australians have undiagnosed

DIABETES.

Are You at Risk?

Ask Your Pharmacist about the FREE diabetes screening trial.

The Pharmacy Guild of Australia

The University of Sydney

Deakin University

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

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 Guild of Australia

THE UNIVERSITY OF SYDNEY

DEAKIN UNIVERSITY

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

Half a million Australians have undiagnosed

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Appendix 7: GP Faxback Forms

GP Faxback Form Group A

GP Faxback Form Group B

GP Faxback Form Group C

Pharmacy Diabetes Screening Trial: FAXBACK FORM (Group A)

GP Name	
GP Fax Number	
Pharmacy Name	
Participant Name	
Participant ID	
Date of Screening	

Why are you getting this Referral Form?

…….. has recently consented to be part of the Pharmacy Diabetes Screening Trial at their pharmacy and has nominated you as their GP.

The service this pharmacy is investigating is:
Group A: screening based on AUSDRISK™ assessment tool alone with referral to a GP if AUSDRISK™ ≥ 12

The results from the pharmacy screening tests are as follows:

AUSDRISK Score	
AUSDRISK Category	

What should you do with this Referral Form?

We would appreciate it if you could:

- Complete the table below after you have seen the patient (and received the results of any tests you may have ordered).
- **FAX it back to us on: 02 6270 1844 or SCAN and email it back to: diabetes.ptp@6cpa.com.au**

OUTCOME OF REFERRAL			
The patient came to see me after the pharmacy screening appointment:	O Yes O No		
I ordered tests after the pharmacy screening appointment:	O Yes O No		
If you ordered tests, please indicate the type of test, the result and the date of the test.			
Fasting Blood Glucose	O Yes O No	_____mmol/l	Date of test:
HBA1c	O Yes O No	_____% _____mmol/mol	Date of test:
OGTT	O Yes O No	_____mmol/l (FBG) _____mmol/l (2h BG)	Date of test:
Diagnosis	O Diabetes Unlikely	O Prediabetes	O Diabetes
GP Name: _____	Signature: _____		Date: _____

We appreciate your feedback on the screening trial and, if you wish to do so, or would like further information about the trial, please contact the research team by email at diabetes.ptp@6cpa.com.au

This project is funded by the Australian Government Department of Health as part of the Sixth Community Pharmacy Agreement

Pharmacy Diabetes Screening Trial: FAXBACK FORM (Group B)

Pharmacy Name	
Participant Name	
Participant ID	
Date of Screening	
GP Name	
GP Fax Number	

Why are you getting this Referral Form?

…….. has recently consented to be part of the Pharmacy Diabetes Screening Trial at their pharmacy and has nominated you as their GP.

The service this pharmacy is investigating is:
Group B: AUSDRISK™ assessment tool + HbA1c point-of-care (POC) test in patients with AUSDRISK™ ≥ 12 followed by the referral to a GP if HbA1c ≥ 5.7% (39 mmol/mol) is detected

The results from the pharmacy screening tests are as follows:

AUSDRISK Score	
AUSDRISK Category	
POC HbA1c (%)	

What should you do with this Referral Form?

We would appreciate it if you could:

- Complete the table below after you have seen the patient (and received the results of any tests you may have ordered).
- **FAX it back to us on: 02 6270 1844 or SCAN and email it back to: diabetes.ptp@6cpa.com.au**

OUTCOME OF REFERRAL			
The patient came to see me after the pharmacy screening appointment:	O Yes O No		
I ordered tests after the pharmacy screening appointment:	O Yes O No		
If you ordered tests, please indicate the type of test, the result and the date of the test.			
Fasting Blood Glucose	O Yes O No	_____mmol/l	Date of test:
HBA1c	O Yes O No	_____% _____mmol/mol	Date of test:
OGTT	O Yes O No	_____mmol/l (FBG) _____mmol/l (2h BG)	Date of test:
Diagnosis	O Diabetes Unlikely	O Prediabetes	O Diabetes
GP Name: _____	Signature: _____		Date: _____

We appreciate your feedback on the screening trial and, if you wish to do so, or would like further information about the trial, please contact the research team by email at diabetes.ptp@6cpa.com.au

This project is funded by the Australian Government Department of Health as part of the Sixth Community Pharmacy Agreement

Pharmacy Diabetes Screening Trial: FAXBACK FORM (Group C)

GP Name	
GP Fax Number	
Pharmacy Name	
Participant Name	
Participant ID	
Date of Screening	

Why are you getting this Referral Form?

…….. has recently consented to be part of the Pharmacy Diabetes Screening Trial at their pharmacy and has nominated you as their GP.

The service this pharmacy is investigating is: (Group C) AUSDRISK™ assessment tool + small capillary blood glucose test (scBGT) in patients with AUSDRISK™ ≥ 12 followed by the referral to a GP if fasting blood glucose (FBG) ≥ 5.5 mmol/L or random blood glucose (RBG) ≥ 7.0 mmol/L is detected.

The results from the pharmacy screening tests are as follows:

AUSDRISK Score	
AUSDRISK Category	
POC Blood Glucose (mmol/l) Fasting / Non-fasting	

What should you do with this Referral Form?

We would appreciate it if you could:

- Complete the table below after you have seen the patient (and received the results of any tests you may have ordered).
- **FAX it back to us on: 02 6270 1844 or SCAN and email it back to: diabetes.ptp@6cpa.com.au**

OUTCOME OF REFERRAL			
The patient came to see me after the pharmacy screening appointment:	O Yes O No		
I ordered tests after the pharmacy screening appointment:	O Yes O No		
If you ordered tests, please indicate the type of test, the result and the date of the test.			
Fasting Blood Glucose	O Yes O No	_____mmol/l	Date of test:
HBA1c	O Yes O No	_____% _____mmol/mol	Date of test:
OGTT	O Yes O No	_____mmol/l (FBG) _____mmol/l (2h BG)	Date of test:
Diagnosis	O Diabetes Unlikely	O Prediabetes	O Diabetes
GP Name: _____	Signature: _____		Date: _____

We appreciate your feedback on the screening trial and, if you wish to do so, or would like further information about the trial, please contact the research team by email at diabetes.ptp@6cpa.com.au

This project is funded by the Australian Government Department of Health as part of the Sixth Community Pharmacy Agreement

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Appendix 11: Approvals

Organisation	Approval /Details
Australian New Zealand Clinical Trials Registry (ANZCTR)	ACTRN: ACTRN12616001240437
University of Sydney Human Research Ethics Committee	s47
Deakin University Human Research Ethics Committee	s47
s47	

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BURDEN OF DIABETES IN AUSTRALIA: IT'S TIME FOR MORE ACTION

Preliminary Report

July 2018

Authors

Emma Sainsbury Research Officer, The Boden Institute, Faculty of Medicine & Health, University of Sydney

Yumeng Shi Research Officer, The Boden Institute, Faculty of Medicine & Health, University of Sydney

Jeff Flack Conjoint Associate Professor, UNSW; Conjoint Professor, Western Sydney University

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Acknowledgement:

Sonia Lee, Sydney School of Pharmacy, Faculty of Medicine & Health, University of Sydney - assisted with the literature search strategy and extraction.

This report was made possible through an unrestricted grant from Novo Nordisk.

Contents

The report, appendix and the complete reference list can be found at:
www.sydney.edu.au/medicine/research/units/boden/recently-published.php

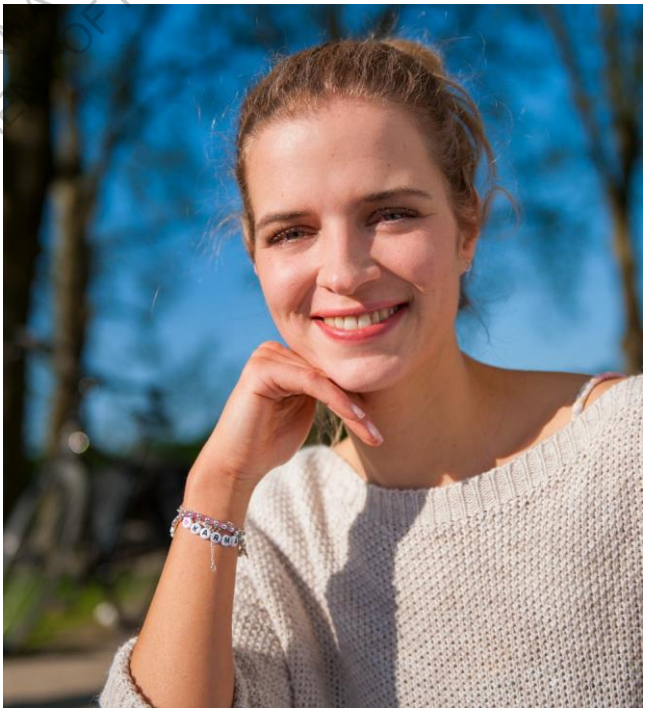
1. Background

Diabetes is a serious, chronic and progressive disease, characterised by elevated blood glucose levels. It is difficult to estimate the exact number of people with diabetes in Australia. The best estimate based on the National Diabetes Services Scheme (NDSS),[1] the Australian Health Survey (National Health Survey, 2014–15),[2] and the AusDiab study (1999–2000)[3] is that there are more than 1.2 million Australians with known diabetes. This accords with the International Diabetes Federation (IDF) estimate that in 2017 there were 1.1 million people aged between 20 and 79 years with diabetes in Australia.[4] Prevalence of diabetes in Australia has more than tripled over the past 25 years and there is no sign that this is slowing.[5] It is also estimated that over 2 million people are at high risk of developing diabetes.[3]

1.2 million
Australians with known diabetes.

Over
2 million
people are at high risk of developing diabetes.

Diabetes is associated with significant premature mortality and morbidity, which impacts not only the individual with diabetes but also their family and the whole of society. Diabetes contributes to 10% of all deaths in Australia.[5] Age-adjusted death rates for people with diabetes were almost double those for the general Australian population and highest in people aged under 45 years (4.5 times higher in people with type 1 diabetes and 5.8 times higher in people with type 2 diabetes). Between 2009 and 2014, the mortality gap increased by 10% for people with type 2 diabetes, against a backdrop of death rates declining in the general population.[5] Compared with adults without diabetes, end-stage renal disease is up to 10 times higher and rates of amputation are typically 10 to 20 times higher.



YASMIN FIEDLER Yasmin has type 1 diabetes

Retinopathy affects an estimated 35% of people with diabetes and may result in severe visual loss and blindness. Adults with diabetes have two to three-fold increased rates of cardiovascular disease.[6] Rates of complications are even higher in Australia's Indigenous population. The total economic cost of diabetes has been estimated at $14 billion, including direct health care costs and indirect costs such as reduced productivity, absence from work, early retirement and premature death. Annual costs are more than twice as high for people with diabetes complications as for people without complications.[7]

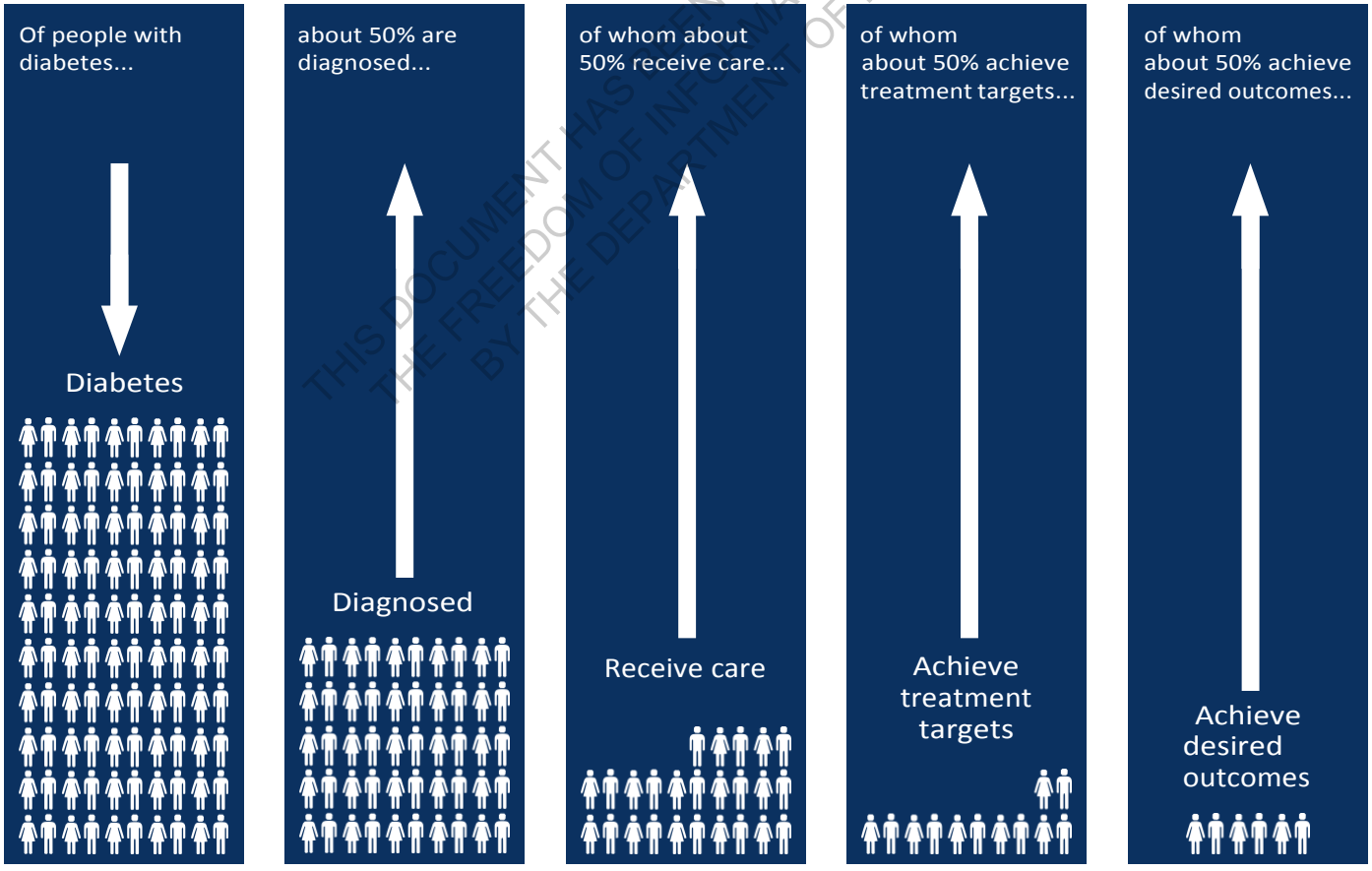
There is strong evidence that diabetes, especially when detected early, can be successfully managed, and complications prevented, but there is an appreciable evidence-practice gap in implementing proven clinical care programs. Multifactorial intervention including control of blood glucose, blood pressure and lipids can reduce the broad range of diabetes-related microvascular and macrovascular complications and premature mortality.[8] The beneficial effects of relatively short term improved glycaemic control on reducing microvascular complications was clearly demonstrated in the UKPDS in newly diagnosed people with type 2 diabetes [UK Prospective Diabetes Study (UKPDS) Group]. Intensive blood-glucose control with sulfonylureas or insulin significantly reduced the risk of microvascular complications compared with conventional treatment in patients with type 2 diabetes[9] whereas the beneficial effect on macrovascular complications takes longer.[10]

The Rule of Halves

The Rule of Halves is a theoretical framework that has been applied to chronic diseases which states that roughly half of all people with diabetes are not diagnosed; half of those diagnosed do not receive care; half of those who receive care do not achieve their treatment targets; and half of those who reach their targets do not achieve the desired outcomes.[11]

The Rule of Halves framework

The Rule of Halves framework illustrates the diabetes burden and indicates where the largest unmet clinical needs are:



This review examined the applicability of the Rule of Halves concept to diabetes in Australia as a first step to identifying gaps and developing strategies for earlier diagnosis, better access to diabetes care, and improving outcomes for people living with diabetes as outlined within the key action areas of the Australian National Diabetes Strategy 2016-2020.[12]

2. Methodology

The analysis was conducted based on existing quantitative data from published peer-reviewed literature, population health surveys and government reports on diabetes in Australia. Electronic databases including Medline, Embase, Cumulative Index to Nursing and Allied Health (CINAHL), PubMed and Cochrane Central Register of Controlled Trials (CENTRAL) were searched in April 2018 for articles relating to four research questions:

1) What is the prevalence of diagnosed and undiagnosed diabetes in Australia?
2) What is the proportion of people with diabetes in Australia receiving standard care?
3) What is the proportion of people with diabetes in Australia meeting management targets?
4) What is the proportion of people with diabetes-related complications in Australia?

A total of 6,111 records were retrieved from the database search (after removal of duplicates) and titles and abstracts were reviewed. Full-text articles of potentially eligible studies were then reviewed by two independent researchers. Studies of gestational diabetes or other diabetes were excluded, as were studies published before the year 2000 and with sample size < 150 (< 100 for studies conducted in the Indigenous population).

Data were extracted in the following areas from included studies:

1) Study Information (first author, country of origin, study name, year);
2) Number of participants;
3) Type of diabetes;
4) Region of Australia;
5) Number (%) of people with diagnosed and undiagnosed diabetes;
6) Criteria for diagnosing diabetes;
7) Number (%) of people receiving standard diabetes care;
8) Number (%) of people meeting treatment/management targets;
9) Number (%) of people with diabetes complications;
10) Methods of data collection/data sources.

For studies of randomised controlled trials (RCT), only the baseline data were included.
Mean proportions were calculated for each question, and separate results presented for people with type 1 diabetes and Indigenous people where there were sufficient data.

MARIA LUISA DE ARAUJA
Maria has type 2 diabetes

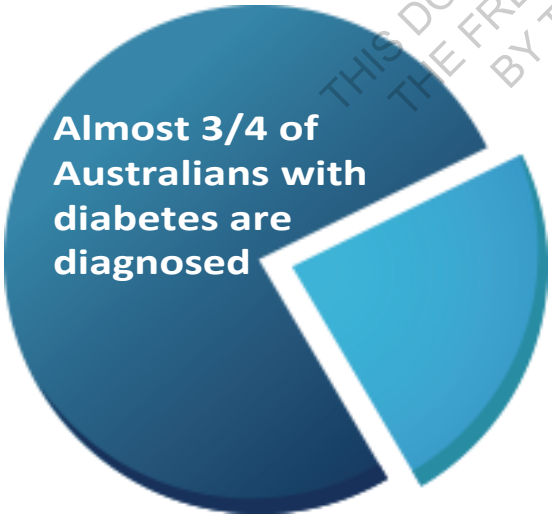
3. Findings

Question 1.
What is the prevalence of diagnosed and undiagnosed diabetes in Australia?

The proportion of people with diagnosed diabetes in Australia

	Proportion of people with diagnosed diabetes in Australia (%)	Sample size (n)
Total population	71	40,494
Indigenous population	81	5,570

Ten sources of data were included of which five reported diagnosed diabetes in the Aboriginal and Torres Strait Islander community (Appendix; Tables 1-2). All were population-based studies in adults (>18 years) of national or community samples. The majority reported total diabetes prevalence while two studies included individuals with a diagnosis of type 2 diabetes only.[13,14] The methods used to establish a diagnosis of diabetes varied between studies and included: people on diabetes treatment (insulin and/or blood glucose lowering medication) at the time of the study, having ever been told by a doctor or nurse that they had diabetes, blood testing including fasting blood glucose alone, oral glucose tolerance test with measurement of fasting blood glucose and two-hour post load blood glucose, or measurement of HbA1c. People with previously undiagnosed diabetes were determined as those who were not on diabetes treatment, had not previously been told by a doctor or nurse that they had diabetes and had a fasting blood glucose and/or two-hour post load blood glucose values and/or HbA1c above the diabetes threshold. The mean prevalence of diagnosed diabetes was 71% (range 50 – 80%) across included studies. Within the Indigenous population, 81% (range 71 - 86%) of people with diabetes were diagnosed.

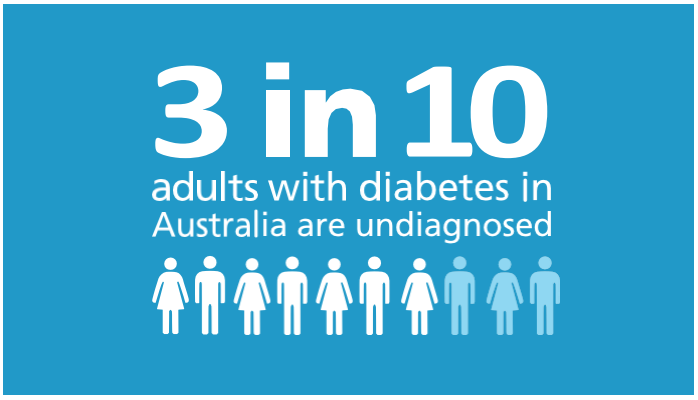


Interpretation of the data

Overall, the data indicate that only 7 of 10 people in Australia with diabetes are diagnosed, with slightly higher rates of diagnosis in the Indigenous population. The results of this analysis are dependent on the representativeness of the population, the accuracy of self-reported diabetes and especially on the diagnostic procedure used to diagnose diabetes. The proportion of people who were found to have previously undiagnosed diabetes was highest when an oral glucose tolerance test was used. The AusDiab study showed that 40% of newly diagnosed diabetes was only detected by the 2hPG following an oral glucose tolerance test. The available studies had several limitations. Most were not nationally representative and focused on particular geographic areas and age groups; others had a low recruitment rate of the eligible population and in others a high proportion of participants had been recently screened for undiagnosed diabetes.

Implications

At least three in ten adults with diabetes in Australia are undiagnosed. As a significant proportion of people have established complications at the time of diagnosis of diabetes, systematic efforts to screen for undiagnosed diabetes have the potential to reduce the burden of diabetes.



Question 2.

What is the proportion of people with diabetes in Australia receiving standard care?

The diabetes annual cycle of care (ACC) is a checklist for use by general practitioners (GPs) to review the diabetes management and general health of people with diagnosed diabetes. It is considered the minimum level of care that a person with diabetes should receive in Australia. The ACC includes ongoing provision of education about diabetes at every visit; medication review, annual measurement of HbA1c, cholesterol and microalbuminuria; biannual assessment of BMI and blood pressure; and a biennial foot and eye examination. A Medicare claim for completion of an ACC may be made by the GP. Four studies assessed the proportion of people completing an ACC based on Medicare claims data or medical records (Appendix; Table 3a). The ACC completion rates ranged from 0.9% in an Indigenous population to 37% over a 12 to 18-month period in non-Indigenous people.[15-18]

The proportion of people with diabetes in Australia receiving standard care

	Population	Proportion of people with diagnosed diabetes completing health checks (%)	Sample size (n)
HbA1c check in the past 6 – 12 months	Total population	51	781,424
	Indigenous population	64	3,856
BP check in the past 6 – 12 months	Total population	71	6,000
	Indigenous population	79	3,856
Lipids check in the past 12 months	Total population	49	269,518
	Indigenous population	69	3,856
Kidney health check *(urinary test)* in the past 12 months	Total population	27	765,194
	Indigenous population	62	3,856
Eye examination in the past 12 – 24 months	Total population	71	53,053
	Indigenous population	45	4,643
Foot assessment in the past 6 – 12 months	Total population	42	50,061
	Indigenous population	46	3,991
Weight check in the past 6 – 12 months	Total population	59	5,245
	Indigenous population	63	3,856

Twenty-four studies investigated the proportion of people with diagnosed diabetes meeting annual care requirements for specific health checks, spanning a time-period of 1992 to 2016 (Appendix; Tables 3b – 3h). Studies which focused on people attending specialised diabetes services for regular care were excluded. Based on review of Medicare claims data and medical records, 51% of people with diabetes received an HbA1c check in the past 6-12 months (range 32 – 71%).

Two studies which assessed results over multiple time-points reported an increase in the proportion of people completing HbA1c checks over time.[13,14] Studies conducted in the Indigenous population reported 64% (range 61 - 68%) had an annual HbA1c check.[11,14-16] The mean proportion of people with diabetes receiving a lipid check in the past 12 months was similar to that for HbA1c (49% for the total population, 69% for the Indigenous population), while the mean proportion of people having a BP check in the past 6-12 months was higher at 71% (79% for the Indigenous population).

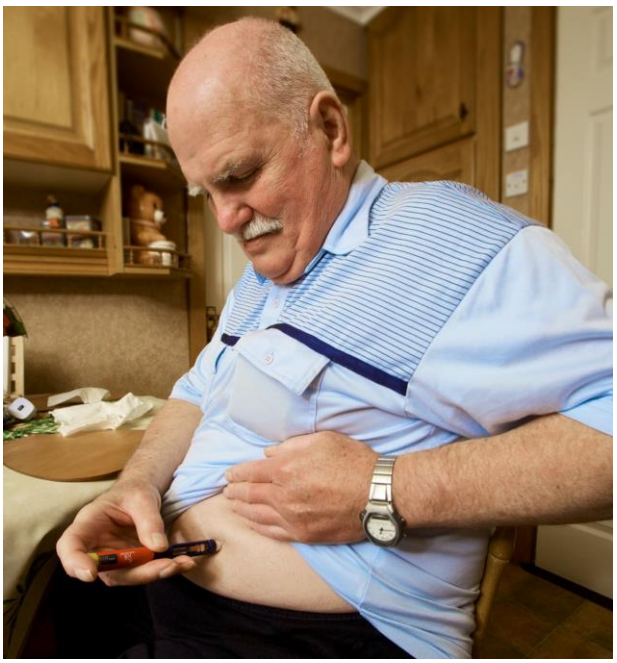
The proportion of people having an eye examination in the past 12-24 months varied significantly across the 16 included studies (range 11% - 96%). Studies where the results were based on participant self-report had significantly higher proportions of eye checks compared with studies that reviewed Medicare claims data and medical records. There was also wide variability in the proportion of people reported to be receiving eye examinations depending on the health professional conducting the check. While some studies assessed eye screenings conducted by an optometrist, others reported the proportion of people receiving eye examinations by other health professionals such as an ophthalmologist or a GP.

Implications

The review highlighted significant deficiencies in important routine checks for many people with diabetes. Better systems would contribute to ensuring that routine health checks are performed and recorded. The process would be assisted by specific education of people with diabetes on the routine checks required as an integral component of expected diabetes care.

Although approximately 50% of individuals had an assessment of HbA1c, lipids, weight and feet, less than a third had the minimum required kidney health examinations (27%; range 10 - 67%). Studies that reported results for the time period 1990 – 2000 reported lower proportions of people receiving checks than studies conducted after the year 2000. Further, three studies where results were based on a large, random sample of community-based people rather than general practice attenders reported fewer people receiving kidney health checks; these results may be more generalisable to the population.[13,14,17]

The results for this question indicate that ethnicity may contribute to disparities in health care. Tran et al. analysed Medicare Benefits Scheme and Pharmaceutical Benefits Scheme claims data for 13,284 people living in New South Wales to determine the proportion of people with diabetes using primary care service over a 15-month period.[15] The study reported that 12.3% of Vietnamese and 25.5% of Chinese-born participants had a claim for allied health services compared with 49.7% of Australian-born participants, while those born in the Philippines had fewer claims for specialist services and Italian-born participants had fewer claims for completing an ACC checklist. Keel et al. reported that only 53% of Indigenous Australians received scheduled eye examinations compared with 78% of non-Indigenous Australians.[18]



THOMAS MCKEON Thomas has type 2 diabetes

Interpretation of the data

Overall the data indicate that many people with diagnosed diabetes in Australia are not receiving expected standards of diabetes care, in particular with monitoring of HbA1c and lipids and kidney and foot checks. The majority of studies utilised Medicare claims data, however 'episode coning' for diagnostic testing may have underestimated biological testing. There were also ethnic disparities in access to diabetes care, with people not born in Australia demonstrating lower rates of received services compared with Anglo-Celts in studies that directly compared the two groups. Although the overall mean results suggest a higher proportion of Indigenous Australians receive diabetes health checks compared with the non-Indigenous population, these studies recruited people from Aboriginal and Torres Strait Islander health centres and may not be generalizable to the broader Indigenous community.

Question 3.
What is the proportion of people with diabetes in Australia meeting management targets?

Thirty-five studies investigated the proportion of people with diabetes meeting management targets, spanning a time-period of 1993 to 2015 (Appendix; Tables 4a-4d). The analysis was not restricted to studies of people who had received only standard care and included some studies which provided more intensive care.

The proportion of people with diabetes in Australia meeting management targets

	Population	Proportion of people with diabetes meeting target (%)	Sample size (n)
HbA1c ≤ 7.0%	Total population	53	1,786,983
	Indigenous population	24	5,295
	Type 1 diabetes	25	2,215
BP ≤ 130/80mmHg	Total population	38	18,826
	Indigenous population	38	1,993
	Type 1 diabetes	67	1,565
Total cholesterol ≤ 4.0mmol/L	Total population	17	10,138
LDL cholesterol < 2.5 mmol/L	Total population	38	20,125
HDL cholesterol ≥ 1.0 mmol/L	Total population	79	14,485
Triglycerides < 2.0 mmol/L	Total population	65	15,677
BMI ≤ 25kg/m^2	Total population	21	14,021

Thirty-one studies investigated the proportion of people meeting the HbA1c target of ≤ 7.0 %, with an overall mean of 53% (range 13-79 %). In the majority of studies, the HbA1c result was obtained either from blood tests or review of medical records. Two studies obtained HbA1c results from participant self-report.[19,20] Five studies reported results for people with type 1 diabetes specifically, indicating 28% achieved an HbA1c ≤ 7.0 %.[19,21-24] Three of these studies directly compared results for people with type 1 and type 2 diabetes, however the results must be interpreted with caution as the groups were not matched for diabetes duration.[19,22,23] Chittleborough et al. compared people with incident (newly diagnosed) diabetes to people with long-term diagnosed diabetes and found better glycaemic control for the newly diagnosed (74% vs. 45.8% achieving HbA1c ≤7%).[25] Eight studies reported results for the Indigenous population, with a mean of 24% of people achieving the HbA1c target of ≤ 7.0%.[17,26-32]

Interpretation of the data

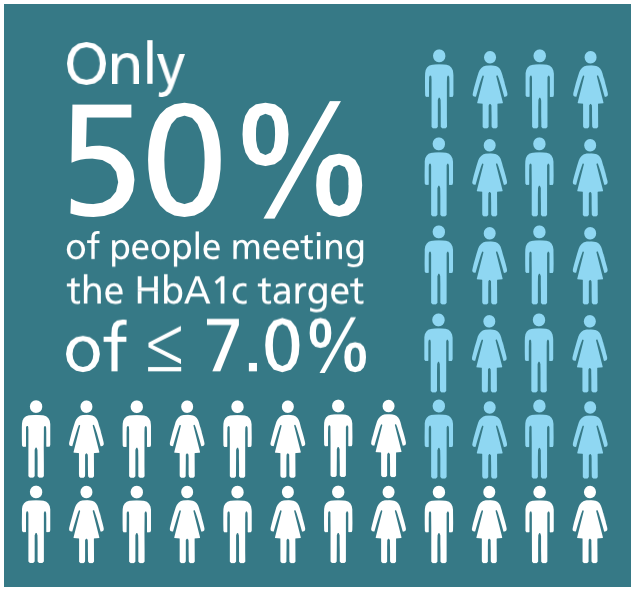
Overall the data indicate that management of diabetes in Australia is suboptimal, with only 50% of people meeting the HbA1c target of ≤ 7.0% and less than 50% meeting management targets for blood pressure, lipids and body weight. The results are dependent on the method of data collection, with studies based on participant self-report indicating significantly higher proportions of people meeting targets compared with data sourced from medical records. Indigenous Australians, people with type 1 diabetes and those with longer diabetes duration are less likely to achieve HbA1c targets.

Nineteen studies investigated the proportion of people meeting the blood pressure target of ≤ 130/80, with an overall mean of 38% (range 15 - 73%). All results were based on measured blood pressure. Four studies reported results for people with type 1 diabetes, indicating 67% met the blood pressure target.[21-23,33] The higher proportion of people with type 1 diabetes meeting the target may be due to this population group being younger in age. Six studies conducted within an Indigenous population reported 38% of participants achieved blood pressure ≤ 130/80,[28-32] a similar result to the total cohort of non-Indigenous and Indigenous combined. Comparing the achievement of targets between those with newly diagnosed and long-term diabetes also revealed similar results between the groups (23.7% vs. 26.8%).[25]

Implications

There is a well established relationship between better glycaemic control and a reduced risk of microvascular complications. Multifactorial intervention that improves glycaemic, blood pressure and lipid control significantly reduces the risk of premature mortality and cardiovascular disease. Improvement in the proportion of people with diabetes meeting targets would translate into improved outcomes.

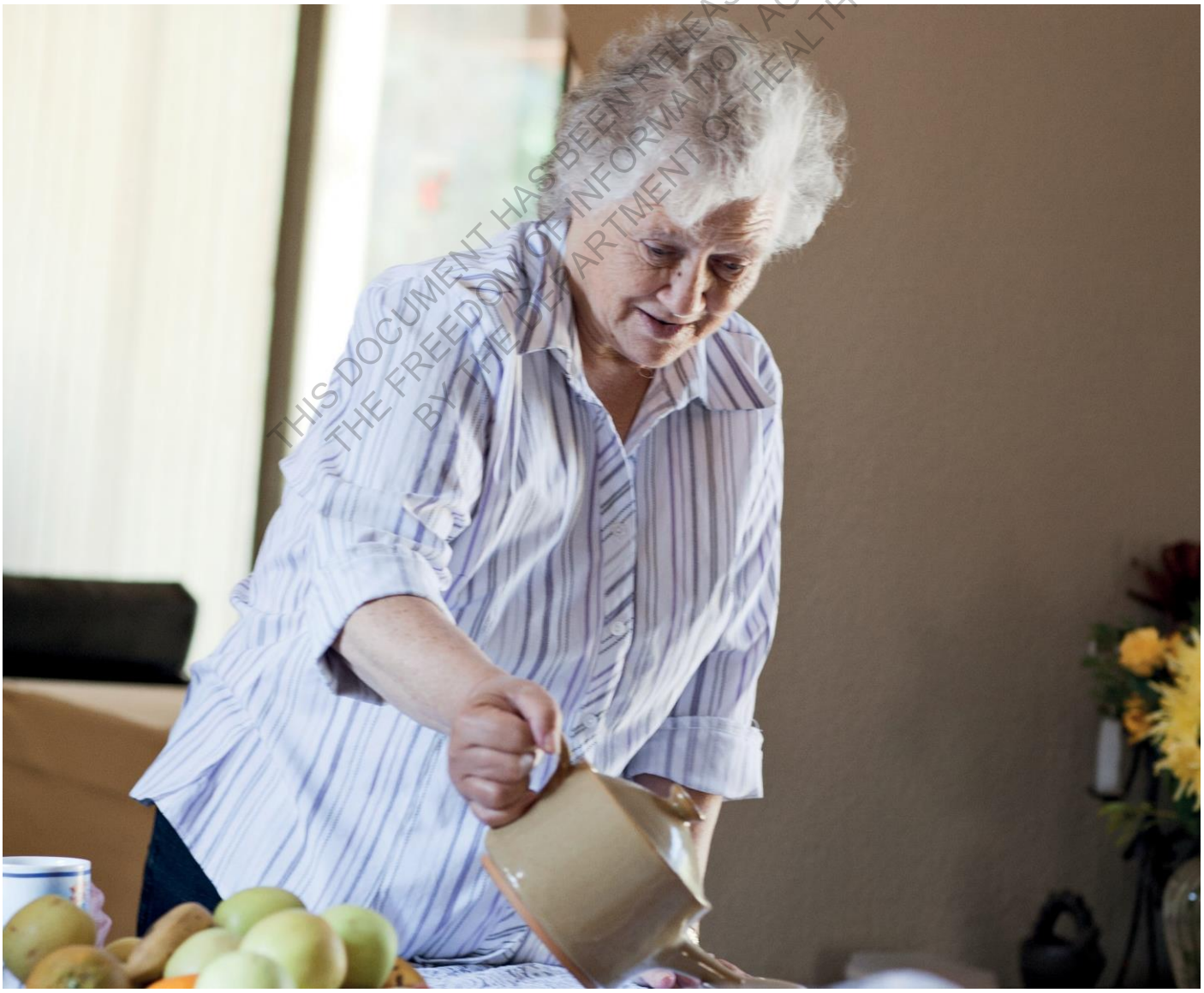
Nine studies reported the proportion of people meeting a total cholesterol target of ≤ 4.0 mmol/L, with an overall result of 17% (range 12 - 40%) for the total cohort of Indigenous and non-Indigenous participants. An additional five studies examined the proportion of people meeting a cholesterol target of 5.5mmol/L with target achievement ranging from 52 - 80%. Two studies in children and adolescents reported > 60% achieved cholesterol targets.[33,34] Although Australian national guidelines recommend an LDL cholesterol target< 2.0mmol/L, all studies included in this review reported on the achievement of LDL cholesterol < 2.5mmol/L.



Thirty-eight percent of people with diabetes met the LDL cholesterol target, 79% of people with diabetes met the HDL cholesterol target of ≥ 1.0 mmol/L and 65% the triglycerides target of < 2.0mmol/L. The proportion of people meeting the LDL cholesterol target was higher among those with long-term diabetes compared with newly diagnosed (45.6% vs. 26.3%).[25]

Four studies conducted within an Indigenous population reported similar results to those for the non-Indigenous population.[28-30,32] Mean proportions were not calculated for the Indigenous population and for people with type 1 diabetes due to limited data for each individual target.

Seven studies investigated the proportion of people with BMI ≤ 25kg/m2, with a mean of 21% (range 17 - 59%). One study of type 1 diabetes patients (mean age 23 years) was included which reported over 50% of participants were within the target BMI range.[21]



MARIA BIRD Maria has type 2 diabetes

DANIELLA BESWICK

Daniella has type 1 diabetes

Question 4.
What is the proportion of people with diabetes-related complications in Australia?

Forty-two studies investigated the prevalence of complications among people with diabetes in Australia, spanning a 26-year time-period (1990-2016) (Appendix; Tables 5a-5f). The main complications assessed were microvascular complications (eye disease, neuropathy, nephropathy and foot disease, amputation) and macrovascular disease (coronary artery disease, peripheral vascular disease, myocardial infarction, stroke). This analysis was unable to look at the prevalence of complications specifically for people within treatment targets due to limited data.

The proportion of people with diabetes-related complications in Australia

	Population	Proportion of people with diabetes-related complications (%)	Sample size (n)
Diabetic retinopathy	Total population	19	36,311
	Indigenous population	27	5,367
	Type 1 diabetes	24	6,162
Foot ulcer	Total population	5	45,274
Peripheral sensory neuropathy	Total population	25	51,031
	Type 1 diabetes	11	1,822
Kidney disease (microalbuminuria or worse)	Total population	33	947,767
	Indigenous population	55	46,460
	Type 1 diabetes	12	6,960
Stroke	Total population	4	40,916
Ischaemic heart disease	Total population	13	46,835
Peripheral arterial disease	Total population	13	49,062

Diabetic eye disease was the most commonly investigated diabetes complication with 36 studies reporting on the prevalence of some form of eye disease including diabetic retinopathy (proliferative and non-proliferative), diabetic macular edema and blindness. Overall, there was a mean prevalence of diabetic retinopathy of 19% (range 7 - 61%) for the total population and 27% (range 16 - 33%) for Indigenous people with diabetes. In three studies where the prevalence of diabetic retinopathy was reported separately for people with type 1 and type 2 diabetes, there was a higher proportion of diagnosed diabetic retinopathy within the type 1 diabetes population; however, the type 1 diabetes group had a significantly longer diabetes duration.[23,34,45] The prevalence of diabetic retinopathy was higher for studies where the diagnosis was based on ocular examination or retinal photography (both diagnostic tests produced similar results) compared with self-report.

Nine studies reported on the prevalence (current or previous history) of foot complications including foot lesions, ulcers, and lower limb amputations. One study that extracted data on 2,731 adults with type 2 diabetes from national GP registers between 2000-2002 reported that 13.8-16.5% of people with diabetes had a foot complication.[36] Within the studies that reported on specific foot complications, 5% (1 - 11%) of participants reported a history of foot ulcers and another 19.6% were at risk for foot ulcers.[37]

Three studies reported on the prevalence of amputations in people with diabetes. ANDIAB data from 1998-2011 indicated a slight increase in the national prevalence of amputations from 1.1% to 1.9%.[38] The average annual rate of extremity amputations in Western Australia from 2000-2010 was reported to be 724 and 564 per 100,000 person-years in type 1 and type 2 diabetes respectively.[39] Only one study investigated the prevalence of foot complications among Indigenous people with diabetes and reported 2% of those with previously diagnosed diabetes and 0% of those with newly diagnosed diabetes had a toe amputation.[32]

KEENAN HENDRICK Keenan has type 1 diabetes

Fourteen studies reported on peripheral sensory neuropathy which was detected in a mean of 25% of participants (range 12 - 63%). Three studies reported results of the Fremantle Diabetes Study, a longitudinal study conducted over two time periods; 1993-1996 and 2008-2011. These studies examined ethnic differences in the rate of complications, indicating both people of Asian background and Aboriginal Australians had higher rates of peripheral sensory neuropathy compared with Anglo-Celts across both time periods.[28,40,41] Two studies of children and adolescents (predominantly with type 1 diabetes) reported that the prevalence of peripheral sensory neuropathy was slightly lower than in the adult population (11%; range 7 - 27%).

Eighteen studies reported on the prevalence of kidney disease (microalbuminuria or worse). Overall there was a mean prevalence of 33% (range 3 - 62%) in the total population, and 55% (range 36 - 62%) in the Indigenous population. The majority of studies reported kidney disease as the presence of albuminuria (micro or macro) detected through a urinary albumin test. The prevalence of kidney disease was lower (12%) for people with type 1 diabetes (predominantly children and adolescents). Only one study audited the prevalence of end-stage kidney disease, reporting a national prevalence of 1.0 - 2.7% from 1998-2011.[38]

Five studies reported the overall prevalence of cardiovascular disease (CVD) among people with diabetes to be 25-50%, with similar rates of CVD between the Indigenous and non-Indigenous population.[25,42-44] Chittleborough et al. reported a higher prevalence of CVD for people with HbA1c ≥ 7.0% (30.5% vs.19.9%).[45] Across the studies that reported on specific diseases 4% reported a diagnosis of stroke and 13% ischaemic heart disease (history of myocardial infarction, angina, coronary artery bypass grafting or angioplasty). Henze et al. also reported 12% prevalence of heart failure among 315 men in Western Australia.[46]

One study that investigated the difference in rates of complications between people with type 1 and type 2 diabetes reported a significantly higher prevalence of stroke and ischaemic heart disease among people with type 2 diabetes;[35] however, the study did not match the groups for diabetes duration and those with type 2 diabetes had a significantly longer duration of diabetes (14.7 years vs. 11.6 years, p=0.001). No studies investigated the differences in CVD prevalence between Indigenous and non-Indigenous populations.

The mean prevalence of peripheral arterial disease (PAD) was 13%. The majority of included studies based the diagnosis on an ankle brachial index ≤ 0.90, but one study was based on self-reported surgery for PAD.[47] Davis et al. compared disease prevalence between Aboriginal and Anglo-Celts and reported higher rates of PAD in the Anglo-Celt community between 1993-1996 (15.8% vs. 29.7%), but higher PAD in the Aboriginal community between 2008-2011 (30.7% vs. 21.5%).[28]

Interpretation of the data

Overall the data indicate a significant burden from diabetes complications in people with diabetes. Indigenous people are more likely to experience adverse complications of diabetes, in particular kidney disease. The inclusion of people both within and outside treatment targets, together with the inclusion of data based on participant self-report may have influenced the results.

DAVID CREER David has type 2 diabetes

Implications

The gaps in standards of care and the high proportion of people with diabetes not achieving targets is translating into significant morbidity. In addition to improving care of diabetes and associated risk factors for complications, surveillance, early detection and specific intervention programs are required to reduce the development and impact of diabetes complications.

4. Conclusion

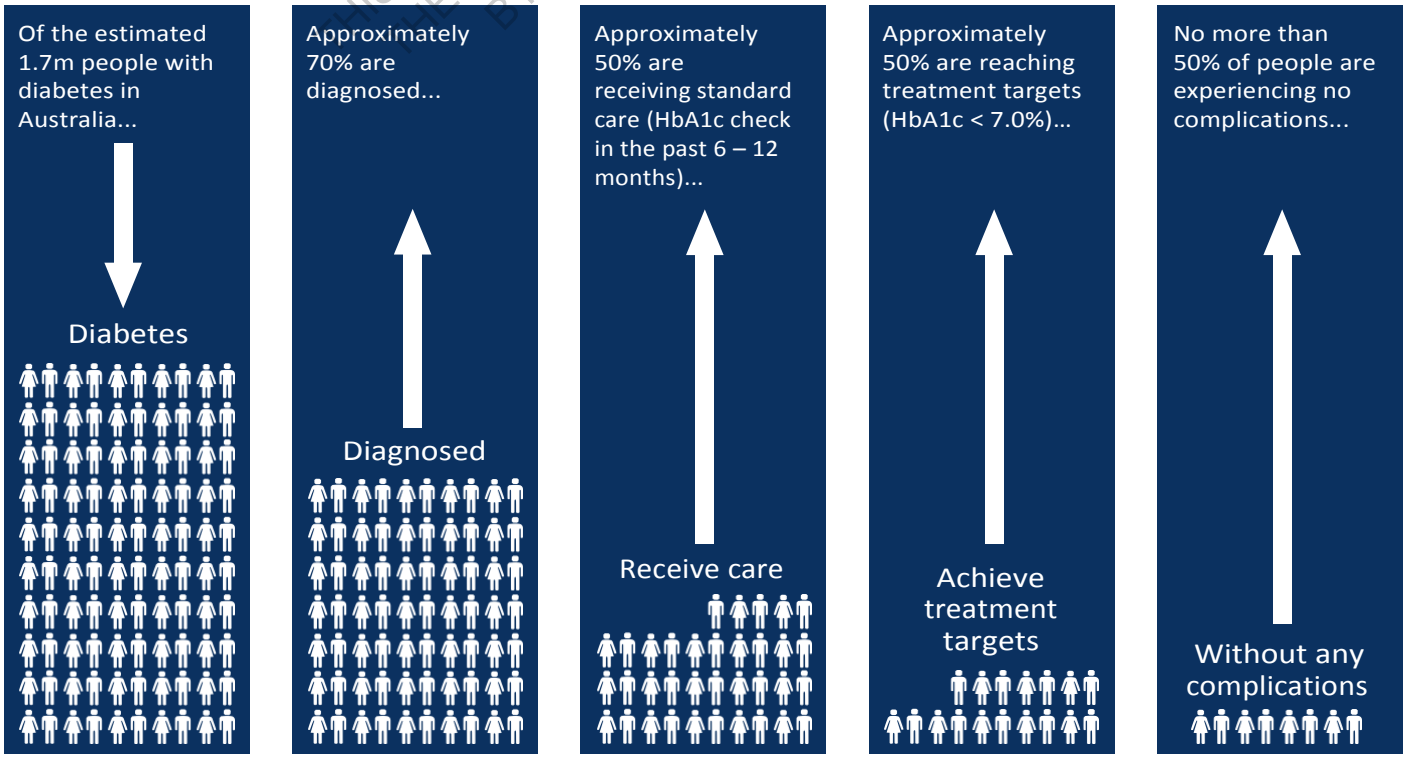
This review highlights the gaps in care, management and outcomes in people with diabetes in Australia. Based on an estimated 1.1 million people with diagnosed type 2 diabetes, another 350,000 have undiagnosed diabetes, which could be detected by fasting glucose or HbA1c, and a further 200,000 have undiagnosed diabetes which could be detected by the 2hPG following an oral glucose tolerance test. Efforts to find these people with undiagnosed diabetes could avert the development of diabetes related complications. In addition, the next national biomedical survey should be used to generate up-to-date accurate data on undiagnosed diabetes by including a sub-sample which has all three tests used to diagnose diabetes.

The review also highlights that a significant proportion of people with known diabetes are not receiving standard care in terms of not being monitored at regular intervals for glycaemic, blood pressure and lipid control or for early signs of the development of diabetes complications. In addition, over half are not achieving treatment targets, predisposing them to developing complications. Consequently, too many people with known diabetes have established micro and macrovascular complications resulting in a significant and potentially avoidable personal, costly and societal burden. Given the strong evidence that the development and progression of complications can be prevented, improved care and management of people with diabetes could substantially reduce this burden.

The results of the Rule of Halves analyses are summarised in the figure below. As can be seen from the figure, the 'Halves' rule does generally apply for Australia apart from diagnosis rates which average approximately 70%, indicating that there is still much that needs to be done to reduce the diabetes burden.

Australia has the basic infrastructure to deliver evidence-based diabetes best practice to address the significant evidence-practice gaps identified in this review. The challenge is to implement the actions identified in the Australian National Diabetes Strategy 2016-2020[12] to achieve earlier diagnosis, better access to diabetes care, and better outcomes for people with diabetes.

Australia's Diabetes Burden



The report, appendix and the complete reference list can be found at:
www.sydney.edu.au/medicine/research/units/boden/recently-published.php

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ALEX SILVERBERG
Alex has type 1 diabetes

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Table 1 Change in estimated resident population, by age group and sex, Australia, selected p

	Males				Females	
Age group (years)	2001–2006	2006–2011	2011–2016	2019–2020	2001–2006	2006–2011
0–4	11,403	84,071	59,366	-5,456	9,450	79,505
5–9	-10,197	33,304	92,014	5,540	-8,018	30,022
10–14	21,989	1,158	23,905	19,898	17,527	3,166
15–19	30,462	31,983	8,976	-3,279	22,234	28,794
20–24	81,874	87,052	41,504	-19,100	76,432	76,176
25–29	1,913	144,873	66,651	3,082	-14,133	131,709
30–34	11,467	35,293	122,850	14,992	5,076	26,724
35–39	13,075	32,252	19,664	23,394	12,721	32,830
40–44	23,043	33,783	20,892	11,417	23,236	37,017
45–49	60,685	32,555	21,521	229	66,802	31,550
50–54	22,032	69,465	23,161	12,360	33,818	76,763
55–59	119,474	33,175	61,669	1,902	136,539	44,826
60–64	79,724	120,291	26,388	20,009	82,643	126,874
65–69	48,714	92,218	114,857	12,327	46,509	88,921
70–74	-1,158	56,953	79,545	21,513	-8,773	46,586
75–79	24,174	8,416	49,744	19,735	6,659	3,244
80–84	37,025	26,164	11,930	11,919	36,594	16,430
85 and over	21,899	35,804	40,168	7,146	33,351	49,111
All ages	597,598	958,810	884,805	157,628	578,667	930,248

eriods to 30 June

Persons					
2011–2016	2019–2020	2001–2006	2006–2011	2011–2016	2019–2020
56,146	-6,038	20,853	163,576	115,512	-11,494
87,633	4,471	-18,215	63,326	179,647	10,011
19,920	20,077	39,516	4,324	43,825	39,975
12,719	-3,820	52,696	60,777	21,695	-7,099
40,907	-18,377	158,306	163,228	82,411	-37,477
89,475	-3,438	-12,220	276,582	156,126	-356
135,074	15,737	16,543	62,017	257,924	30,729
13,888	29,231	25,796	65,082	33,552	52,625
18,640	12,576	46,279	70,800	39,532	23,993
41,572	-3,270	127,487	64,105	63,093	-3,041
31,252	16,369	55,850	146,228	54,413	28,729
78,253	5,599	256,013	78,001	139,922	7,501
52,503	24,696	162,367	247,165	78,891	44,705
123,956	18,346	95,223	181,139	238,813	30,673
82,980	25,286	-9,931	103,539	162,525	46,799
43,115	19,643	30,833	11,660	92,859	39,378
-859	11,423	73,619	42,594	11,071	23,342
38,904	5,414	55,250	84,915	79,072	12,560
966,078	173,925	1,176,265	1,889,058	1,850,883	331,553

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Table 2 Average annual population growth rate, by age group and sex, Australia, selected pe

	Males				Females	
Age group (years)	2001–2006	2006–2011	2011–2016	2019–2020	2001–2006	2006–2011
0–4	0.35	2.41	1.54	-0.68	0.30	2.41
5–9	-0.30	0.96	2.46	0.67	-0.25	0.91
10–14	0.63	0.03	0.66	2.49	0.53	0.09
15–19	0.88	0.88	0.24	-0.43	0.67	0.84
20–24	2.39	2.26	0.99	-2.12	2.30	2.05
25–29	0.06	3.85	1.54	0.32	-0.41	3.58
30–34	0.32	0.94	3.01	1.61	0.14	0.71
35–39	0.35	0.85	0.50	2.64	0.34	0.85
40–44	0.62	0.88	0.53	1.44	0.62	0.95
45–49	1.75	0.87	0.56	0.03	1.89	0.83
50–54	0.67	1.99	0.62	1.65	1.03	2.17
55–59	4.30	1.03	1.80	0.25	5.02	1.39
60–64	3.61	4.48	0.85	2.95	3.78	4.73
65–69	2.77	4.42	4.43	2.07	2.56	4.18
70–74	-0.08	3.53	4.10	4.15	-0.53	2.72
75–79	2.05	0.66	3.58	5.62	0.46	0.22
80–84	5.24	3.00	1.22	5.23	3.41	1.35
85 and over	4.88	6.13	5.21	3.63	3.42	4.19
All ages	1.22	1.82	1.54	1.25	1.16	1.75

riods to 30 June

Persons					
2011–2016	2019–2020	2001–2006	2006–2011	2011–2016	2019–2020
1.53	-0.79	0.33	2.41	1.54	-0.73
2.47	0.57	-0.27	0.94	2.46	0.62
0.58	2.65	0.58	0.06	0.62	2.57
0.36	-0.52	0.77	0.86	0.30	-0.47
1.02	-2.16	2.34	2.16	1.00	-2.14
2.10	-0.36	-0.18	3.72	1.82	-0.02
3.30	1.64	0.23	0.83	3.15	1.62
0.35	3.26	0.35	0.85	0.42	2.95
0.46	1.57	0.62	0.92	0.49	1.50
1.05	-0.38	1.82	0.85	0.81	-0.18
0.82	2.09	0.85	2.08	0.72	1.87
2.22	0.71	4.66	1.21	2.01	0.48
1.65	3.46	3.69	4.61	1.26	3.21
4.70	2.91	2.66	4.30	4.57	2.50
4.13	4.69	-0.32	3.12	4.11	4.42
2.72	5.13	1.17	0.42	3.12	5.36
-0.07	4.12	4.14	2.04	0.49	4.62
2.78	1.70	3.88	4.84	3.64	2.44
1.67	1.36	1.19	1.78	1.60	1.31

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Table 3 Median age, by sex–at 30 June

	New South Wales	Victoria	Queensland	South Australia	Western Australia	Tasmania
				MALES		
2001	35.23	35.07	34.45	36.57	34.28	36.49
2002	35.42	35.23	34.69	36.84	34.62	36.87
2003	35.56	35.39	34.92	37.09	34.93	37.18
2004	35.72	35.57	35.14	37.30	35.22	37.46
2005	35.88	35.78	35.31	37.51	35.46	37.72
2006	36.00	35.94	35.48	37.70	35.65	37.99
2007	36.17	36.02	35.58	37.85	35.74	38.35
2008	36.26	36.02	35.61	37.97	35.69	38.62
2009	36.32	35.94	35.57	38.06	35.53	38.85
2010	36.53	36.05	35.70	38.19	35.56	39.19
2011	36.78	36.24	35.89	38.41	35.53	39.58
2012	36.83	36.25	35.90	38.48	35.31	39.95
2013	36.84	36.21	35.92	38.54	35.18	40.23
2014	36.82	36.15	35.99	38.61	35.31	40.53
2015	36.76	36.08	36.12	38.68	35.45	40.78
2016	36.67	35.96	36.26	38.75	35.65	40.94
2017	36.62	35.89	36.37	38.86	35.97	41.03
2018	36.63	35.84	36.53	38.95	36.31	41.02
2019	36.69	35.86	36.71	39.00	36.61	41.02
2020	37.03	36.18	37.02	39.21	36.98	41.05
				FEMALES		
2001	36.67	36.63	35.60	38.62	35.52	37.91
2002	36.89	36.84	35.90	38.95	35.90	38.39
2003	37.07	37.04	36.13	39.25	36.22	38.84
2004	37.27	37.24	36.34	39.55	36.52	39.19
2005	37.45	37.44	36.52	39.78	36.78	39.49
2006	37.59	37.60	36.67	39.95	36.94	39.77
2007	37.74	37.73	36.76	40.02	36.95	40.03
2008	37.85	37.80	36.82	40.09	36.93	40.24
2009	37.98	37.86	36.87	40.13	36.88	40.45
2010	38.20	38.00	37.03	40.22	36.96	40.73
2011	38.48	38.17	37.22	40.44	36.96	41.13
2012	38.60	38.20	37.28	40.61	36.77	41.60
2013	38.65	38.18	37.37	40.79	36.60	42.03
2014	38.65	38.11	37.51	40.87	36.62	42.44
2015	38.59	38.00	37.66	40.90	36.74	42.86
2016	38.49	37.82	37.78	40.95	36.92	43.16
2017	38.39	37.68	37.88	41.05	37.20	43.31
2018	38.38	37.62	37.99	41.15	37.50	43.40
2019	38.46	37.66	38.17	41.20	37.78	43.42
2020	38.82	38.02	38.48	41.41	38.15	43.48
				PERSONS		
2001	35.95	35.86	35.03	37.61	34.90	37.23
2002	36.16	36.05	35.30	37.91	35.26	37.67
2003	36.32	36.22	35.53	38.19	35.57	38.06

2004	36.49	36.40	35.74	38.44	35.86	38.36
2005	36.67	36.61	35.92	38.65	36.11	38.63
2006	36.80	36.78	36.06	38.81	36.28	38.90
2007	36.94	36.87	36.18	38.92	36.34	39.18
2008	37.06	36.94	36.23	39.02	36.30	39.43
2009	37.17	36.93	36.23	39.08	36.21	39.66
2010	37.38	37.05	36.37	39.22	36.26	39.96
2011	37.64	37.22	36.56	39.45	36.24	40.38
2012	37.73	37.24	36.6	39.58	36.03	40.81
2013	37.75	37.2	36.65	39.69	35.87	41.18
2014	37.74	37.13	36.76	39.74	35.95	41.54
2015	37.68	37.03	36.9	39.79	36.08	41.87
2016	37.58	36.88	37.02	39.85	36.27	42.1
2017	37.49	36.77	37.12	39.97	36.57	42.22
2018	37.49	36.72	37.27	40.04	36.89	42.26
2019	37.57	36.75	37.45	40.09	37.18	42.25
2020	37.92	37.1	37.76	40.3	37.56	42.3

Northern Territory	Australian Capital Territory	Australia
29.84	32.57	34.96
30.24	32.78	35.18
30.60	32.97	35.37
30.87	33.16	35.57
31.08	33.39	35.76
31.30	33.62	35.91
31.31	33.61	36.04
31.19	33.64	36.08
31.10	33.56	36.06
31.07	33.52	36.19
31.30	33.56	36.37
31.49	33.64	36.38
31.59	33.82	36.36
31.90	33.93	36.38
32.07	34.11	36.39
32.42	34.21	36.39
32.61	34.39	36.42
32.86	34.53	36.49
33.09	34.86	36.59
33.52	35.31	36.92
29.32	34.03	36.39
29.71	34.26	36.66
29.99	34.48	36.88
30.24	34.78	37.09
30.42	35.00	37.29
30.66	35.19	37.44
30.72	35.24	37.55
30.79	35.33	37.62
30.89	35.38	37.69
31.06	35.34	37.87
31.35	35.32	38.06
31.46	35.24	38.11
31.53	35.26	38.12
31.81	35.40	38.15
32.11	35.47	38.15
32.33	35.57	38.12
32.53	35.66	38.10
32.86	35.76	38.14
33.19	36.01	38.26
33.60	36.52	38.60
29.58	33.31	35.69
29.98	33.53	35.93
30.30	33.73	36.13

30.56	33.96	36.33
30.76	34.20	36.52
30.98	34.42	36.67
31.03	34.45	36.78
31.00	34.50	36.86
30.99	34.47	36.9
31.07	34.41	37.05
31.33	34.42	37.23
31.47	34.42	37.25
31.56	34.53	37.25
31.85	34.66	37.26
32.09	34.78	37.27
32.38	34.89	37.25
32.57	35.02	37.25
32.86	35.13	37.31
33.14	35.44	37.42
33.56	35.93	37.75

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Table 4 Mean age, by sex–at 30 June

	New South Wales	Victoria	Queensland	South Australia	Western Australia	Tasmania
				MALE		
2001	36.14	36.16	35.49	37.23	35.20	36.66
2002	36.33	36.33	35.71	37.43	35.49	36.95
2003	36.51	36.49	35.92	37.63	35.75	37.22
2004	36.68	36.65	36.10	37.83	35.98	37.47
2005	36.85	36.82	36.25	38.02	36.19	37.71
2006	36.98	36.96	36.38	38.18	36.33	37.92
2007	37.11	37.04	36.44	38.31	36.40	38.17
2008	37.21	37.10	36.47	38.42	36.41	38.37
2009	37.32	37.15	36.50	38.51	36.42	38.56
2010	37.51	37.29	36.64	38.63	36.54	38.81
2011	37.73	37.48	36.84	38.83	36.65	39.11
2012	37.84	37.56	36.93	38.95	36.65	39.40
2013	37.94	37.63	37.05	39.07	36.68	39.65
2014	38.03	37.69	37.21	39.21	36.83	39.92
2015	38.11	37.74	37.40	39.34	36.98	40.17
2016	38.17	37.75	37.58	39.49	37.15	40.35
2017	38.24	37.78	37.75	39.67	37.38	40.58
2018	38.33	37.83	37.93	39.84	37.62	40.77
2019	38.45	37.92	38.12	40.00	37.84	40.97
2020	38.71	38.18	38.37	40.22	38.14	41.19
				FEMALE		
2001	37.90	37.99	36.79	39.38	36.58	38.44
2002	38.07	38.15	37.01	39.58	36.87	38.75
2003	38.24	38.31	37.20	39.78	37.12	39.03
2004	38.41	38.47	37.37	39.98	37.37	39.28
2005	38.58	38.63	37.52	40.16	37.58	39.53
2006	38.70	38.76	37.64	40.30	37.70	39.74
2007	38.84	38.86	37.70	40.39	37.74	39.93
2008	38.94	38.91	37.72	40.47	37.72	40.09
2009	39.03	38.95	37.76	40.53	37.72	40.23
2010	39.18	39.06	37.89	40.63	37.83	40.44
2011	39.37	39.21	38.06	40.77	37.92	40.72
2012	39.47	39.27	38.15	40.86	37.90	41.02
2013	39.56	39.31	38.28	40.98	37.92	41.27
2014	39.64	39.35	38.46	41.08	38.03	41.54
2015	39.70	39.39	38.64	41.17	38.19	41.83
2016	39.74	39.38	38.82	41.28	38.38	42.07
2017	39.80	39.41	39.00	41.46	38.61	42.26
2018	39.91	39.48	39.18	41.63	38.86	42.44
2019	40.05	39.59	39.38	41.80	39.11	42.61
2020	40.32	39.87	39.65	42.04	39.41	42.82
				PERSONS		
2001	37.03	37.09	36.15	38.32	35.89	37.56
2002	37.21	37.26	36.36	38.52	36.18	37.87
2003	37.38	37.41	36.56	38.72	36.43	38.14

2004	37.55	37.57	36.74	38.92	36.67	38.39
2005	37.72	37.74	36.88	39.10	36.88	38.63
2006	37.85	37.87	37.01	39.25	37.01	38.85
2007	37.98	37.96	37.07	39.36	37.06	39.06
2008	38.08	38.01	37.10	39.46	37.06	39.24
2009	38.18	38.06	37.13	39.53	37.06	39.40
2010	38.35	38.19	37.27	39.64	37.18	39.63
2011	38.56	38.35	37.45	39.81	37.28	39.92
2012	38.66	38.42	37.55	39.92	37.27	40.21
2013	38.75	38.48	37.67	40.04	37.29	40.46
2014	38.85	38.53	37.83	40.15	37.42	40.73
2015	38.91	38.57	38.03	40.27	37.58	41.01
2016	38.96	38.57	38.21	40.40	37.76	41.22
2017	39.03	38.61	38.38	40.57	37.99	41.43
2018	39.13	38.67	38.56	40.75	38.24	41.61
2019	39.25	38.77	38.76	40.91	38.48	41.80
2020	39.52	39.03	39.02	41.14	38.78	42.01

Northern Territory	Australian Capital Territory	Australia
30.61	34.00	35.93
30.94	34.23	36.14
31.20	34.48	36.33
31.47	34.67	36.51
31.71	34.92	36.68
32.00	35.14	36.82
32.15	35.21	36.92
32.24	35.31	36.99
32.39	35.36	37.05
32.58	35.43	37.20
32.84	35.55	37.39
33.05	35.63	37.48
33.19	35.76	37.58
33.44	35.88	37.69
33.57	35.99	37.80
33.77	36.04	37.89
33.93	36.14	38.00
34.18	36.23	38.13
34.42	36.44	38.27
34.77	36.74	38.53
30.00	35.32	37.60
30.33	35.58	37.79
30.60	35.84	37.97
30.88	36.15	38.15
31.15	36.40	38.32
31.49	36.58	38.45
31.67	36.67	38.55
31.85	36.80	38.61
32.03	36.91	38.66
32.28	37.00	38.79
32.57	37.11	38.95
32.77	37.15	39.02
32.91	37.27	39.10
33.17	37.42	39.21
33.43	37.51	39.30
33.60	37.61	39.39
33.79	37.67	39.49
34.11	37.76	39.63
34.44	37.95	39.79
34.83	38.25	40.06
30.32	34.67	36.77
30.65	34.91	36.97
30.91	35.17	37.16

31.19	35.42	37.34
31.45	35.67	37.51
31.76	35.87	37.64
31.92	35.94	37.74
32.06	36.06	37.80
32.22	36.14	37.86
32.44	36.22	38.00
32.71	36.34	38.18
32.92	36.40	38.26
33.05	36.52	38.34
33.31	36.65	38.45
33.50	36.76	38.56
33.69	36.83	38.65
33.87	36.91	38.75
34.14	37.01	38.88
34.43	37.20	39.03
34.80	37.51	39.30

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Table 5 Sex ratio–at 30 June

	New South Wales	Victoria	Queensland	South Australia	Western Australia	Tasmania
2001	98.6	97.0	99.1	97.7	100.2	97.1
2002	98.5	97.2	99.4	97.7	100.4	97.1
2003	98.4	97.3	99.3	97.6	100.7	97.3
2004	98.3	97.5	99.4	97.6	101.1	97.2
2005	98.2	97.6	99.5	97.6	101.4	97.2
2006	98.1	97.8	99.6	97.5	101.8	97.2
2007	98.3	98.0	99.7	97.5	101.7	97.6
2008	98.5	98.2	99.8	97.6	101.7	98.1
2009	98.7	98.3	99.8	97.8	101.7	98.5
2010	98.7	98.2	99.7	98	101.5	98.9
2011	98.7	98	99.6	98.1	101.4	99.3
2012	98.6	98	99.5	98.1	101.8	99.2
2013	98.5	97.9	99.4	98.2	101.8	98.9
2014	98.4	97.8	99.1	98	101.3	98.6
2015	98.4	97.8	98.8	97.9	101	98.3
2016	98.3	97.7	98.4	97.8	100.6	98.1
2017	98.3	97.8	98.3	97.7	100.3	98
2018	98.5	98	98	97.6	99.9	98
2019	98.5	98.1	97.8	97.6	99.7	97.8
2020	98.5	98.1	97.6	97.5	99.4	97.9

Northern Territory	Australian Capital Territory	Australia
109.7	97.4	98.4
110.1	97.4	98.5
109.3	97.5	98.5
108.6	97.6	98.6
108.0	97.8	98.6
107.9	97.9	98.7
108.2	98.1	98.9
109.2	98.3	99.0
109.9	98.8	99.2
110.3	98.9	99.1
110.6	98.9	99.1
109.9	98.8	99.1
110.4	98.7	99
109.7	98.5	98.8
109.5	98.3	98.7
108.2	98.3	98.5
108.1	98.1	98.4
107.5	97.9	98.4
106.6	97.8	98.4
105.4	97.5	98.3

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Table 6 Age distribution, by sex, preliminary–30 June 2020

Age group (years)	New South Wales %	Victoria %	Queensland %	South Australia %	Western Australia %
				MALES	
0-4	6.3	6.2	6.3	5.8	6.7
5-9	6.5	6.5	6.8	6.2	6.7
10-14	6.3	6.1	6.9	6.2	6.6
15-19	6.0	5.8	6.4	6.0	6.0
20-24	6.9	7.4	6.7	6.8	6.4
25-29	7.6	8.2	7.2	6.8	7.0
30-34	7.5	7.9	6.9	6.7	7.6
35-39	7.2	7.4	6.8	6.6	7.5
40-44	6.3	6.4	6.2	6.0	6.6
45-49	6.4	6.4	6.7	6.4	6.7
50-54	5.8	5.9	6.1	6.3	6.3
55-59	6.0	5.7	6.1	6.4	6.1
60-64	5.5	5.3	5.5	6.0	5.4
65-69	4.8	4.5	4.8	5.4	4.7
70-74	4.3	4.0	4.4	4.9	4.0
75-79	3.0	2.8	3.0	3.4	2.7
80-84	2.0	1.9	1.8	2.2	1.7
85 and over	1.7	1.6	1.4	2.0	1.4
All ages	**100.0**	**100.0**	**100.0**	**100.0**	**100.0**
				FEMALES	
0-4	5.8	5.8	5.8	5.3	6.2
5-9	6.1	6.0	6.3	5.8	6.4
10-14	5.9	5.7	6.4	5.8	6.2
15-19	5.5	5.4	5.9	5.5	5.7
20-24	6.3	6.7	6.4	6.2	6.1
25-29	7.3	7.8	7.1	6.5	6.9
30-34	7.5	8.0	7.1	6.7	7.7
35-39	7.1	7.4	6.9	6.5	7.4
40-44	6.3	6.3	6.4	5.9	6.5
45-49	6.5	6.5	6.8	6.3	6.7
50-54	6.0	6.1	6.3	6.4	6.3
55-59	6.2	5.9	6.2	6.5	6.1
60-64	5.8	5.5	5.6	6.3	5.6
65-69	5.1	4.8	5.0	5.7	4.9
70-74	4.4	4.2	4.4	5.1	4.1
75-79	3.2	3.0	3.1	3.7	2.8
80-84	2.3	2.2	2.1	2.7	2.1
85 and over	2.7	2.5	2.2	3.2	2.2
All ages	**100.0**	**100.0**	**100.0**	**100.0**	**100.0**
				PERSONS	
0-4	6.1	6.0	6.1	5.6	6.4
5-9	6.3	6.2	6.6	6.0	6.6
10-14	6.1	5.9	6.7	6.0	6.4
15-19	5.7	5.6	6.2	5.8	5.8

20-24	6.6	7.0	6.5	6.5	6.3
25-29	7.4	8.0	7.2	6.7	6.9
30-34	7.5	8.0	7.0	6.7	7.7
35-39	7.1	7.4	6.8	6.6	7.4
40-44	6.3	6.4	6.3	5.9	6.5
45-49	6.5	6.4	6.7	6.3	6.7
50-54	5.9	6.0	6.2	6.3	6.3
55-59	6.1	5.8	6.1	6.5	6.1
60-64	5.6	5.4	5.6	6.2	5.5
65-69	4.9	4.7	4.9	5.6	4.8
70-74	4.3	4.1	4.4	5.0	4.1
75-79	3.1	2.9	3.0	3.5	2.8
80-84	2.1	2.0	1.9	2.4	1.9
85 and over	2.2	2.1	1.8	2.6	1.8
All ages	**100.0**	**100.0**	**100.0**	**100.0**	**100.0**

Tasmania	Northern Territory	Australian Capital Territory	Australia
%	%	%	%
5.6	7.3	6.7	6.3
6.1	7.2	7.0	6.6
6.4	6.9	6.4	6.4
6.0	6.3	5.8	6.0
6.2	6.6	7.6	6.9
6.5	8.8	7.8	7.5
6.2	9.5	8.2	7.4
5.8	8.2	8.2	7.1
5.5	6.9	7.1	6.3
6.2	6.8	6.8	6.5
6.2	6.2	5.9	6.0
6.8	5.8	5.4	6.0
6.8	4.7	4.6	5.5
6.1	3.5	3.9	4.8
5.5	2.6	3.6	4.2
3.7	1.5	2.2	2.9
2.4	0.7	1.5	1.9
1.9	0.4	1.2	1.6
100.0	**100.0**	**100.0**	**100.0**
5.2	7.1	6.2	5.8
5.6	7.2	6.4	6.1
5.9	6.9	5.7	6.0
5.5	6.0	5.3	5.6
5.5	6.4	7.5	6.4
6.2	9.1	7.9	7.3
6.1	9.9	8.4	7.5
6.0	8.5	8.2	7.1
5.6	7.1	6.9	6.3
6.5	6.6	6.7	6.6
6.5	6.4	5.9	6.2
7.1	5.7	5.6	6.1
6.9	4.7	5.0	5.7
6.3	3.5	4.3	5.0
5.6	2.2	3.8	4.4
3.9	1.3	2.6	3.1
2.7	0.7	1.8	2.2
2.8	0.6	1.8	2.5
100.0	**100.0**	**100.0**	**100.0**
5.4	7.2	6.5	6.1
5.9	7.2	6.7	6.3
6.2	6.9	6.0	6.2
5.7	6.1	5.5	5.8

5.9	6.5	7.6	6.7
6.3	9.0	7.9	7.4
6.2	9.7	8.3	7.5
5.9	8.3	8.2	7.1
5.6	7.0	7.0	6.3
6.3	6.7	6.7	6.5
6.4	6.3	5.9	6.1
7.0	5.8	5.5	6.1
6.9	4.7	4.8	5.6
6.2	3.5	4.1	4.9
5.6	2.4	3.7	4.3
3.8	1.4	2.4	3.0
2.5	0.7	1.6	2.1
2.3	0.5	1.5	2.1
100.0	**100.0**	**100.0**	**100.0**

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Table 7 Estimated resident population, by age and sex–at 30 June 2019

Age (years)	New South Wales	Victoria	Queensland	South Australia	Western Australia	Tasmania
				MALES		
0	50,992	39,852	31,499	9,671	17,107	2,839
1	49,943	40,626	31,644	9,875	17,416	2,825
2	50,371	41,257	32,415	10,198	18,017	2,935
3	53,080	44,091	33,299	10,827	18,560	3,297
4	51,951	43,005	33,460	10,591	17,971	3,184
0-4	*256,337*	*208,831*	*162,317*	*51,162*	*89,071*	*15,080*
5	51,896	42,619	34,145	10,753	17,571	3,161
6	53,090	43,255	34,514	10,894	17,925	3,243
7	52,730	42,181	34,569	10,996	17,465	3,184
8	52,390	41,631	34,676	10,772	17,799	3,418
9	52,351	41,659	35,163	11,021	17,665	3,382
5-9	*262,457*	*211,345*	*173,067*	*54,436*	*88,425*	*16,388*
10	51,614	40,924	35,404	10,759	17,526	3,463
11	51,582	40,813	35,403	10,728	17,482	3,497
12	51,163	40,343	35,294	10,665	17,426	3,443
13	49,246	38,911	33,991	10,436	16,623	3,378
14	47,817	37,411	32,741	10,137	16,029	3,271
10-14	*251,422*	*198,402*	*172,833*	*52,725*	*85,086*	*17,052*
15	47,052	37,458	32,171	10,160	15,851	3,143
16	46,866	36,933	31,570	10,114	15,252	3,055
17	46,690	37,086	32,041	10,282	15,397	3,272
18	50,145	40,356	33,094	10,634	16,044	3,323
19	53,687	43,791	33,482	11,459	16,311	3,380
15-19	*244,440*	*195,624*	*162,358*	*52,649*	*78,855*	*16,173*
20	54,802	45,287	33,246	11,550	16,818	3,360
21	54,774	46,763	33,180	11,602	16,634	3,261
22	56,120	49,748	33,713	11,732	16,829	3,267
23	58,760	53,266	35,733	12,368	17,567	3,324
24	61,576	56,547	36,683	12,525	18,201	3,539
20-24	*286,032*	*251,611*	*172,555*	*59,777*	*86,049*	*16,751*
25	61,607	55,398	36,970	11,841	18,100	3,471
26	61,246	53,318	36,906	11,756	18,195	3,303
27	61,540	52,599	36,317	11,485	18,697	3,366
28	61,893	52,885	36,575	11,698	19,193	3,282
29	62,312	53,387	36,438	11,731	19,895	3,440
25-29	*308,598*	*267,587*	*183,206*	*58,511*	*94,080*	*16,862*
30	60,965	51,896	35,097	11,657	19,835	3,197
31	59,866	52,218	34,967	11,483	20,145	3,202
32	59,171	51,224	34,532	11,467	20,324	3,128

33	59,469	51,337	34,703	11,788	20,567	3,193
34	58,882	50,419	34,505	11,725	20,051	3,102
30-34	*298,353*	*257,094*	*173,804*	*58,120*	*100,922*	*15,822*
35	58,936	49,918	34,418	11,764	20,143	3,132
36	58,426	49,338	34,826	11,490	20,103	3,143
37	57,302	47,731	34,005	11,105	19,544	2,987
38	55,631	46,330	33,320	11,014	18,868	2,890
39	53,385	44,298	32,170	10,585	18,143	2,918
35-39	*283,680*	*237,615*	*168,739*	*55,958*	*96,801*	*15,070*
40	51,340	42,814	31,294	10,382	17,520	2,925
41	50,528	41,792	30,811	10,237	17,299	2,846
42	49,869	41,095	31,224	10,369	17,004	2,828
43	50,143	41,230	31,886	10,436	17,133	2,991
44	50,290	40,863	32,086	10,571	17,019	3,053
40-44	*252,170*	*207,794*	*157,301*	*51,995*	*85,975*	*14,643*
45	51,654	41,830	33,474	10,759	17,305	3,137
46	51,938	41,802	34,107	10,983	17,826	3,206
47	53,411	42,916	34,695	11,543	18,468	3,462
48	53,072	42,938	34,955	11,766	18,457	3,570
49	49,298	40,899	32,740	11,331	17,438	3,491
45-49	*259,373*	*210,385*	*169,971*	*56,382*	*89,494*	*16,866*
50	48,065	40,174	31,776	11,157	17,315	3,448
51	46,505	39,131	30,817	11,030	16,526	3,298
52	45,801	37,337	30,339	10,594	16,204	3,181
53	46,645	37,568	29,758	10,790	16,185	3,163
54	46,399	37,136	30,057	10,884	16,021	3,316
50-54	*233,415*	*191,346*	*152,747*	*54,455*	*82,251*	*16,406*
55	48,621	38,134	31,202	11,260	16,334	3,639
56	49,414	38,477	31,197	11,417	16,298	3,671
57	49,333	37,932	30,995	11,174	15,971	3,786
58	48,672	37,401	30,765	11,427	15,693	3,810
59	46,527	36,243	29,613	11,026	15,181	3,694
55-59	*242,567*	*188,187*	*153,772*	*56,304*	*79,477*	*18,600*
60	45,362	35,628	28,705	10,759	14,760	3,700
61	44,803	34,537	27,946	10,633	14,326	3,705
62	43,800	33,563	27,180	10,273	13,877	3,523
63	42,760	33,459	26,645	10,091	13,889	3,613
64	41,132	31,528	25,565	9,893	12,824	3,382
60-64	*217,857*	*168,715*	*136,041*	*51,649*	*69,676*	*17,923*
65	39,783	30,455	24,902	9,537	12,569	3,237
66	39,436	29,993	24,902	9,551	12,276	3,343
67	37,813	29,387	24,503	9,255	12,110	3,308
68	37,756	28,831	24,240	9,141	11,971	3,250
69	36,936	28,059	23,487	9,140	11,314	3,141
65-69	*191,724*	*146,725*	*122,034*	*46,624*	*60,240*	*16,279*
70	35,444	27,075	23,207	8,840	11,021	3,031
71	36,190	27,174	22,926	8,753	11,182	3,054
72	36,452	27,816	23,477	9,067	11,106	3,252
73	30,927	23,435	19,595	7,497	8,890	2,498
74	28,978	21,438	18,583	6,993	8,281	2,355

70-74	*167,991*	*126,938*	*107,788*	*41,150*	*50,480*	*14,190*
75	27,355	20,130	17,027	6,481	8,008	2,332
76	23,853	18,015	14,895	5,934	6,954	2,023
77	23,129	17,815	14,530	5,584	6,980	1,873
78	21,176	16,288	12,942	5,026	5,986	1,739
79	19,671	15,053	11,986	4,697	5,695	1,592
75-79	*115,184*	*87,301*	*71,380*	*27,722*	*33,623*	*9,559*
80	17,929	13,969	10,714	4,450	5,238	1,467
81	16,436	12,791	9,685	4,087	4,775	1,340
82	15,390	11,869	8,807	3,823	4,298	1,200
83	13,839	10,721	7,846	3,322	3,804	1,043
84	11,927	9,325	6,694	2,973	3,491	914
80-84	*75,521*	*58,675*	*43,746*	*18,655*	*21,606*	*5,964*
85-89	*43,870*	*33,979*	*23,423*	*11,127*	*11,654*	*3,210*
90-94	*18,417*	*14,568*	*9,384*	*4,852*	*4,761*	*1,212*
95-99	*4,207*	*3,503*	*2,126*	*1,102*	*1,018*	*295*
100 and over	*447*	*367*	*256*	*164*	*115*	*35*
All ages	**4,014,062**	**3,266,592**	**2,518,848**	**865,519**	**1,309,659**	**264,380**
				FEMALES		
0	47,444	37,808	29,522	9,216	16,080	2,709
1	47,225	38,248	29,953	9,174	16,497	2,672
2	48,154	38,928	30,473	9,430	16,812	2,875
3	49,938	41,498	31,902	10,378	17,338	2,973
4	49,176	40,780	31,936	10,063	16,967	2,974
0-4	*241,937*	*197,262*	*153,786*	*48,261*	*83,694*	*14,203*
5	49,516	40,159	32,294	10,172	17,024	3,030
6	49,936	41,050	32,866	10,364	17,028	3,050
7	49,789	39,998	32,880	10,383	16,833	3,095
8	49,727	39,214	33,324	10,216	17,097	3,116
9	49,917	39,619	33,808	10,327	16,820	3,110
5-9	*248,885*	*200,040*	*165,172*	*51,462*	*84,802*	*15,401*
10	49,054	38,636	33,421	10,383	16,429	3,296
11	49,238	38,521	33,438	10,438	16,874	3,249
12	48,468	38,253	33,015	10,346	16,578	3,235
13	46,387	36,874	32,330	9,815	16,037	3,124
14	44,879	35,371	30,952	9,699	15,110	3,044
10-14	*238,026*	*187,655*	*163,156*	*50,681*	*81,028*	*15,948*
15	44,006	35,234	30,645	9,631	14,860	2,933
16	44,306	35,166	30,212	9,689	14,876	2,972
17	44,305	35,536	30,232	9,764	14,789	3,035
18	46,637	38,175	31,412	10,323	15,196	3,043
19	49,725	41,472	31,887	10,636	15,677	3,021
15-19	*228,979*	*185,583*	*154,388*	*50,043*	*75,398*	*15,004*
20	50,340	42,296	31,936	10,901	15,903	3,042
21	51,274	43,700	32,727	11,076	15,737	2,918
22	53,029	46,380	33,847	11,217	16,076	3,029
23	55,828	49,501	35,222	11,407	16,389	3,134
24	58,426	51,576	36,820	11,680	17,008	3,218

20-24	*268,897*	*233,453*	*170,552*	*56,281*	*81,113*	*15,341*
25	59,141	51,740	36,481	11,547	17,435	3,224
26	59,204	51,540	36,731	11,535	18,132	3,259
27	60,441	52,105	37,039	11,597	18,383	3,291
28	62,068	53,415	37,322	11,563	19,231	3,396
29	62,897	54,590	37,492	11,859	20,017	3,324
25-29	*303,751*	*263,390*	*185,065*	*58,101*	*93,198*	*16,494*
30	61,956	53,865	36,570	11,731	20,104	3,289
31	61,454	53,599	36,314	11,889	20,450	3,266
32	60,496	52,428	36,037	11,854	20,635	3,196
33	60,644	52,899	36,502	11,970	20,828	3,273
34	59,877	52,161	36,393	11,882	20,449	3,337
30-34	*304,427*	*264,952*	*181,816*	*59,326*	*102,466*	*16,361*
35	59,678	50,937	36,274	11,937	20,227	3,249
36	59,292	49,942	36,581	11,624	19,859	3,136
37	57,221	48,313	34,866	11,438	19,165	3,253
38	55,683	46,584	34,407	11,146	18,575	3,251
39	53,101	44,563	33,481	10,799	17,944	3,056
35-39	*284,975*	*240,339*	*175,609*	*56,944*	*95,770*	*15,945*
40	51,885	42,992	32,549	10,468	17,552	3,076
41	50,940	41,877	32,595	10,326	16,828	3,114
42	50,232	41,168	32,643	10,441	16,795	2,948
43	50,487	41,302	33,012	10,388	16,944	3,037
44	50,424	41,800	33,114	10,461	17,009	3,236
40-44	*253,968*	*209,139*	*163,913*	*52,084*	*85,128*	*15,411*
45	52,048	42,915	34,280	10,725	17,156	3,294
46	53,411	43,355	35,396	11,213	17,530	3,499
47	55,118	45,291	36,326	11,787	18,355	3,688
48	55,738	46,335	36,930	12,111	18,672	3,807
49	51,517	43,344	34,646	11,731	17,506	3,561
45-49	*267,832*	*221,240*	*177,578*	*57,567*	*89,219*	*17,849*
50	50,946	42,847	33,635	11,561	17,471	3,636
51	49,580	41,122	32,475	11,366	16,683	3,523
52	47,874	39,531	31,988	10,983	16,346	3,474
53	48,144	39,650	31,319	11,155	16,243	3,423
54	48,291	39,129	31,305	11,245	16,189	3,551
50-54	*244,835*	*202,279*	*160,722*	*56,310*	*82,932*	*17,607*
55	50,602	40,329	32,637	11,568	16,426	3,855
56	51,318	40,164	32,871	11,721	16,527	3,818
57	50,853	39,621	32,656	11,694	16,164	3,903
58	50,619	39,751	32,044	11,837	16,127	4,080
59	49,293	38,632	30,789	11,623	15,685	3,953
55-59	*252,685*	*198,497*	*160,997*	*58,443*	*80,929*	*19,609*
60	47,773	37,352	30,017	11,469	15,111	3,904
61	47,900	36,936	29,572	11,040	14,737	3,689
62	46,223	35,823	28,351	10,976	14,399	3,733
63	44,963	35,361	27,934	10,740	14,393	3,619
64	43,840	34,017	26,986	10,393	13,831	3,471
60-64	*230,699*	*179,489*	*142,860*	*54,618*	*72,471*	*18,416*

65	42,640	33,116	26,492	10,348	13,317	3,540
66	41,732	32,453	25,991	10,240	13,024	3,518
67	40,196	31,238	25,188	9,925	12,518	3,391
68	39,415	31,103	24,955	10,001	12,155	3,354
69	38,418	30,181	24,553	9,617	11,827	3,297
65-69	*202,401*	*158,091*	*127,179*	*50,131*	*62,841*	*17,100*
70	36,897	28,851	23,436	9,345	11,413	3,143
71	36,997	29,151	23,156	9,221	11,176	3,116
72	37,708	29,362	23,702	9,675	11,318	3,256
73	32,145	24,638	19,806	8,120	9,071	2,659
74	30,383	23,102	19,158	7,701	8,556	2,541
70-74	*174,130*	*135,104*	*109,258*	*44,062*	*51,534*	*14,715*
75	28,875	22,205	17,645	7,141	8,307	2,362
76	25,934	19,795	15,748	6,610	7,413	2,053
77	25,156	19,553	15,222	6,264	7,311	2,069
78	23,584	18,134	13,835	5,852	6,799	1,916
79	22,290	17,504	12,989	5,600	6,449	1,744
75-79	*125,839*	*97,191*	*75,439*	*31,467*	*36,279*	*10,144*
80	21,086	16,409	12,046	5,388	6,089	1,637
81	19,750	15,662	10,922	4,983	5,679	1,558
82	18,743	14,452	10,331	4,593	5,221	1,426
83	17,476	13,637	9,330	4,264	4,854	1,294
84	15,723	12,174	8,521	3,908	4,400	1,124
80-84	*92,778*	*72,334*	*51,150*	*23,136*	*26,243*	*7,039*
85-89	*62,558*	*49,076*	*32,770*	*15,985*	*16,933*	*4,612*
90-94	*33,907*	*26,086*	*17,633*	*9,054*	*8,656*	*2,244*
95-99	*10,672*	*8,053*	*5,319*	*2,843*	*2,681*	*704*
100 and over	*1,136*	*1,035*	*674*	*363*	*285*	*48*
All ages	**4,073,317**	**3,330,288**	**2,575,036**	**887,162**	**1,313,600**	**270,195**
				PERSONS		
0	98,436	77,660	61,021	18,887	33,187	5,548
1	97,168	78,874	61,597	19,049	33,913	5,497
2	98,525	80,185	62,888	19,628	34,829	5,810
3	103,018	85,589	65,201	21,205	35,898	6,270
4	101,127	83,785	65,396	20,654	34,938	6,158
0-4	*498,274*	*406,093*	*316,103*	*99,423*	*172,765*	*29,283*
5	101,412	82,778	66,439	20,925	34,595	6,191
6	103,026	84,305	67,380	21,258	34,953	6,293
7	102,519	82,179	67,449	21,379	34,298	6,279
8	102,117	80,845	68,000	20,988	34,896	6,534
9	102,268	81,278	68,971	21,348	34,485	6,492
5-9	*511,342*	*411,385*	*338,239*	*105,898*	*173,227*	*31,789*
10	100,668	79,560	68,825	21,142	33,955	6,759
11	100,820	79,334	68,841	21,166	34,356	6,746
12	99,631	78,596	68,309	21,011	34,004	6,678
13	95,633	75,785	66,321	20,251	32,660	6,502
14	92,696	72,782	63,693	19,836	31,139	6,315
10-14	*489,448*	*386,057*	*335,989*	*103,406*	*166,114*	*33,000*

15	91,058	72,692	62,816	19,791	30,711	6,076
16	91,172	72,099	61,782	19,803	30,128	6,027
17	90,995	72,622	62,273	20,046	30,186	6,307
18	96,782	78,531	64,506	20,957	31,240	6,366
19	103,412	85,263	65,369	22,095	31,988	6,401
15-19	*473,419*	*381,207*	*316,746*	*102,692*	*154,253*	*31,177*
20	105,142	87,583	65,182	22,451	32,721	6,402
21	106,048	90,463	65,907	22,678	32,371	6,179
22	109,149	96,128	67,560	22,949	32,905	6,296
23	114,588	102,767	70,955	23,775	33,956	6,458
24	120,002	108,123	73,503	24,205	35,209	6,757
20-24	*554,929*	*485,064*	*343,107*	*116,058*	*167,162*	*32,092*
25	120,748	107,138	73,451	23,388	35,535	6,695
26	120,450	104,858	73,637	23,291	36,327	6,562
27	121,981	104,704	73,356	23,082	37,080	6,657
28	123,961	106,300	73,897	23,261	38,424	6,678
29	125,209	107,977	73,930	23,590	39,912	6,764
25-29	*612,349*	*530,977*	*368,271*	*116,612*	*187,278*	*33,356*
30	122,921	105,761	71,667	23,388	39,939	6,486
31	121,320	105,817	71,281	23,372	40,595	6,468
32	119,667	103,652	70,569	23,321	40,959	6,324
33	120,113	104,236	71,205	23,758	41,395	6,466
34	118,759	102,580	70,898	23,607	40,500	6,439
30-34	*602,780*	*522,046*	*355,620*	*117,446*	*203,388*	*32,183*
35	118,614	100,855	70,692	23,701	40,370	6,381
36	117,718	99,280	71,407	23,114	39,962	6,279
37	114,523	96,044	68,871	22,543	38,709	6,240
38	111,314	92,914	67,727	22,160	37,443	6,141
39	106,486	88,861	65,651	21,384	36,087	5,974
35-39	*568,655*	*477,954*	*344,348*	*112,902*	*192,571*	*31,015*
40	103,225	85,806	63,843	20,850	35,072	6,001
41	101,468	83,669	63,406	20,563	34,127	5,960
42	100,101	82,263	63,867	20,810	33,799	5,776
43	100,630	82,532	64,898	20,824	34,077	6,028
44	100,714	82,663	65,200	21,032	34,028	6,289
40-44	*506,138*	*416,933*	*321,214*	*104,079*	*171,103*	*30,054*
45	103,702	84,745	67,754	21,484	34,461	6,431
46	105,349	85,157	69,503	22,196	35,356	6,705
47	108,529	88,207	71,021	23,330	36,823	7,150
48	108,810	89,273	71,885	23,877	37,129	7,377
49	100,815	84,243	67,386	23,062	34,944	7,052
45-49	*527,205*	*431,625*	*347,549*	*113,949*	*178,713*	*34,715*
50	99,011	83,021	65,411	22,718	34,786	7,084
51	96,085	80,253	63,292	22,396	33,209	6,821
52	93,675	76,868	62,327	21,577	32,550	6,655
53	94,789	77,218	61,077	21,945	32,428	6,586
54	94,690	76,265	61,362	22,129	32,210	6,867
50-54	*478,250*	*393,625*	*313,469*	*110,765*	*165,183*	*34,013*
55	99,223	78,463	63,839	22,828	32,760	7,494
56	100,732	78,641	64,068	23,138	32,825	7,489

57	100,186	77,553	63,651	22,868	32,135	7,689
58	99,291	77,152	62,809	23,264	31,820	7,890
59	95,820	74,875	60,402	22,649	30,866	7,647
55-59	495,252	386,684	314,769	114,747	160,406	38,209
60	93,135	72,980	58,722	22,228	29,871	7,604
61	92,703	71,473	57,518	21,673	29,063	7,394
62	90,023	69,386	55,531	21,249	28,276	7,256
63	87,723	68,820	54,579	20,831	28,282	7,232
64	84,972	65,545	52,551	20,286	26,655	6,853
60-64	*448,556*	*348,204*	*278,901*	*106,267*	*142,147*	*36,339*
65	82,423	63,571	51,394	19,885	25,886	6,777
66	81,168	62,446	50,893	19,791	25,300	6,861
67	78,009	60,625	49,691	19,180	24,628	6,699
68	77,171	59,934	49,195	19,142	24,126	6,604
69	75,354	58,240	48,040	18,757	23,141	6,438
65-69	*394,125*	*304,816*	*249,213*	*96,755*	*123,081*	*33,379*
70	72,341	55,926	46,643	18,185	22,434	6,174
71	73,187	56,325	46,082	17,974	22,358	6,170
72	74,160	57,178	47,179	18,742	22,424	6,508
73	63,072	48,073	39,401	15,617	17,961	5,157
74	59,361	44,540	37,741	14,694	16,837	4,896
70-74	*342,121*	*262,042*	*217,046*	*85,212*	*102,014*	*28,905*
75	56,230	42,335	34,672	13,622	16,315	4,694
76	49,787	37,810	30,643	12,544	14,367	4,076
77	48,285	37,368	29,752	11,848	14,291	3,942
78	44,760	34,422	26,777	10,878	12,785	3,655
79	41,961	32,557	24,975	10,297	12,144	3,336
75-79	*241,023*	*184,492*	*146,819*	*59,189*	*69,902*	*19,703*
80	39,015	30,378	22,760	9,838	11,327	3,104
81	36,186	28,453	20,607	9,070	10,454	2,898
82	34,133	26,321	19,138	8,416	9,519	2,626
83	31,315	24,358	17,176	7,586	8,658	2,337
84	27,650	21,499	15,215	6,881	7,891	2,038
80-84	*168,299*	*131,009*	*94,896*	*41,791*	*47,849*	*13,003*
85-89	*106,428*	*83,055*	*56,193*	*27,112*	*28,587*	*7,822*
90-94	*52,324*	*40,654*	*27,017*	*13,906*	*13,417*	*3,456*
95-99	*14,879*	*11,556*	*7,445*	*3,945*	*3,699*	*999*
100 and over	*1,583*	*1,402*	*930*	*527*	*400*	*83*
All ages	**8,087,379**	**6,596,880**	**5,093,884**	**1,752,681**	**2,623,259**	**534,575**

Northern Territory	Australian Capital Territory	Australia
1,882	2,719	156,573
1,855	2,727	156,924
1,898	2,914	160,022
1,889	2,977	168,037
1,837	3,046	165,069
9,361	*14,383*	*806,625*
1,830	2,949	164,961
1,799	3,005	167,759
1,902	2,960	166,023
1,898	2,885	165,501
1,869	2,889	166,031
9,298	*14,688*	*830,275*
1,764	2,757	164,240
1,774	2,688	163,997
1,717	2,603	162,687
1,723	2,540	156,881
1,600	2,332	151,359
8,578	*12,920*	*799,164*
1,584	2,337	149,774
1,631	2,348	147,794
1,540	2,292	148,628
1,606	2,600	157,817
1,562	2,939	166,632
7,923	*12,516*	*770,645*
1,616	3,214	169,917
1,751	3,394	171,385
1,786	3,476	176,690
1,748	3,572	186,360
2,099	3,512	194,708
9,000	*17,168*	*899,060*
2,134	3,401	192,961
2,234	3,407	190,397
2,334	3,297	189,671
2,490	3,440	191,483
2,561	3,440	193,234
11,753	*16,985*	*957,746*
2,400	3,431	188,509
2,510	3,380	187,812
2,478	3,396	185,763

2,355	3,577	187,028
2,307	3,449	184,475
12,050	*17,233*	*933,587*
2,167	3,637	184,140
2,244	3,569	183,177
2,023	3,428	178,158
1,991	3,397	173,480
1,812	3,148	166,494
10,237	*17,179*	*885,449*
1,847	3,192	161,356
1,720	2,959	158,222
1,780	2,893	157,095
1,763	2,846	158,456
1,709	2,873	158,494
8,819	*14,763*	*793,623*
1,761	2,862	162,820
1,652	2,787	164,333
1,716	2,903	169,160
1,900	2,970	169,669
1,682	2,788	159,704
8,711	*14,310*	*825,686*
1,627	2,551	156,139
1,561	2,516	151,412
1,590	2,370	147,453
1,551	2,427	148,126
1,526	2,274	147,652
7,855	*12,138*	*750,782*
1,512	2,325	153,062
1,536	2,337	154,386
1,519	2,362	153,123
1,426	2,277	151,509
1,355	2,177	145,861
7,348	*11,478*	*757,941*
1,245	2,017	142,208
1,137	2,014	139,142
1,166	1,912	135,330
1,142	1,861	133,496
1,088	1,713	127,156
5,778	*9,517*	*677,332*
971	1,766	123,253
951	1,708	122,193
848	1,626	118,881
781	1,585	117,596
793	1,622	114,535
4,344	*8,307*	*596,458*
742	1,572	110,959
672	1,568	111,541
644	1,608	113,452
519	1,337	94,715
460	1,154	88,260

3,037	*7,239*	*518,927*
396	1,057	82,805
376	951	73,022
366	940	71,228
321	781	64,276
282	770	59,758
1,741	*4,499*	*351,089*
181	730	54,692
188	646	49,955
140	581	46,114
134	533	41,251
86	499	35,914
729	*2,989*	*227,926*
312	*1,617*	*129,208*
116	*659*	*53,978*
23	*194*	*12,470*
4	*16*	*1,406*
127,017	**210,798**	**12,579,377**
1,711	2,613	147,120
1,692	2,598	148,081
1,715	2,712	151,110
1,847	2,857	158,766
1,737	2,845	156,503
8,702	*13,625*	*761,580*
1,695	2,746	156,664
1,820	2,832	158,966
1,840	2,701	157,544
1,712	2,663	157,095
1,724	2,682	158,038
8,791	*13,624*	*788,307*
1,686	2,524	155,455
1,745	2,443	155,976
1,597	2,376	153,892
1,607	2,369	148,573
1,456	2,243	142,780
8,091	*11,955*	*756,676*
1,431	2,150	140,916
1,449	2,148	140,843
1,495	2,245	141,428
1,403	2,437	148,649
1,414	2,766	156,620
7,192	*11,746*	*728,456*
1,371	3,094	158,905
1,430	3,402	162,281
1,533	3,504	168,637
1,652	3,591	176,732
1,799	3,623	184,166

7,785	*17,214*	*850,721*
1,975	3,623	185,178
2,138	3,400	185,961
2,301	3,467	188,638
2,438	3,614	193,062
2,457	3,657	196,307
11,309	*17,761*	*949,146*
2,401	3,627	193,569
2,486	3,571	193,056
2,392	3,620	190,680
2,223	3,652	192,015
2,292	3,635	190,055
11,794	*18,105*	*959,375*
2,105	3,662	188,108
2,098	3,434	185,998
1,984	3,557	179,817
1,874	3,384	174,934
1,839	3,283	168,089
9,900	*17,320*	*896,946*
1,784	3,041	163,379
1,711	2,874	160,288
1,621	2,888	158,762
1,704	2,783	159,685
1,536	2,872	160,477
8,356	*14,458*	*802,591*
1,631	2,883	164,963
1,524	2,960	168,933
1,673	2,984	175,255
1,690	2,919	178,237
1,602	2,739	166,683
8,120	*14,485*	*854,071*
1,602	2,740	164,480
1,552	2,484	158,812
1,489	2,412	154,125
1,518	2,570	154,060
1,361	2,437	153,540
7,522	*12,643*	*785,017*
1,375	2,475	159,299
1,437	2,391	160,276
1,386	2,502	158,818
1,344	2,387	158,226
1,278	2,288	153,578
6,820	*12,043*	*790,197*
1,197	2,268	149,128
1,098	2,151	147,158
1,095	2,101	142,738
1,025	2,066	140,138
963	1,924	135,455
5,378	*10,510*	*714,617*

899	1,870	132,256
859	1,894	129,740
797	1,886	125,167
734	1,832	123,576
661	1,717	120,306
3,950	*9,199*	*631,045*
585	1,745	115,443
546	1,714	115,091
501	1,750	117,290
433	1,424	98,317
362	1,304	93,124
2,427	*7,937*	*539,265*
356	1,258	88,163
331	1,081	78,983
314	1,081	76,982
291	982	71,403
258	902	67,744
1,550	*5,304*	*383,275*
176	830	63,676
173	787	59,524
167	770	55,708
140	668	51,673
126	615	46,594
782	*3,670*	*277,175*
422	*2,266*	*184,648*
183	*1,246*	*99,014*
48	*337*	*30,660*
4	*39*	*3,586*
119,126	**215,487**	**12,786,368**
3,593	5,332	303,693
3,547	5,325	305,005
3,613	5,626	311,132
3,736	5,834	326,803
3,574	5,891	321,572
18,063	*28,008*	*1,568,205*
3,525	5,695	321,625
3,619	5,837	326,725
3,742	5,661	323,567
3,610	5,548	322,596
3,593	5,571	324,069
18,089	*28,312*	*1,618,582*
3,450	5,281	319,695
3,519	5,131	319,973
3,314	4,979	316,579
3,330	4,909	305,454
3,056	4,575	294,139
16,669	*24,875*	*1,555,840*

3,015	4,487	290,690
3,080	4,496	288,637
3,035	4,537	290,056
3,009	5,037	306,466
2,976	5,705	323,252
15,115	*24,262*	*1,499,101*
2,987	6,308	328,822
3,181	6,796	333,666
3,319	6,980	345,327
3,400	7,163	363,092
3,898	7,135	378,874
16,785	*34,382*	*1,749,781*
4,109	7,024	378,139
4,372	6,807	376,358
4,635	6,764	378,309
4,928	7,054	384,545
5,018	7,097	389,541
23,062	*34,746*	*1,906,892*
4,801	7,058	382,078
4,996	6,951	380,868
4,870	7,016	376,443
4,578	7,229	379,043
4,599	7,084	374,530
23,844	*35,338*	*1,892,962*
4,272	7,299	372,248
4,342	7,003	369,175
4,007	6,985	357,975
3,865	6,781	348,414
3,651	6,431	334,583
20,137	*34,499*	*1,782,395*
3,631	6,233	324,735
3,431	5,833	318,510
3,401	5,781	315,857
3,467	5,629	318,141
3,245	5,745	318,971
17,175	*29,221*	*1,596,214*
3,392	5,745	327,783
3,176	5,747	333,266
3,389	5,887	344,415
3,590	5,889	347,906
3,284	5,527	326,387
16,831	*28,795*	*1,679,757*
3,229	5,291	320,619
3,113	5,000	310,224
3,079	4,782	301,578
3,069	4,997	302,186
2,887	4,711	301,192
15,377	*24,781*	*1,535,799*
2,887	4,800	312,361
2,973	4,728	314,662

2,905	4,864	311,941
2,770	4,664	309,735
2,633	4,465	299,439
14,168	23,521	1,548,138
2,442	4,285	291,336
2,235	4,165	286,300
2,261	4,013	278,068
2,167	3,927	273,634
2,051	3,637	262,611
11,156	*20,027*	*1,391,949*
1,870	3,636	255,509
1,810	3,602	251,933
1,645	3,512	244,048
1,515	3,417	241,172
1,454	3,339	234,841
8,294	*17,506*	*1,227,503*
1,327	3,317	226,402
1,218	3,282	226,632
1,145	3,358	230,742
952	2,761	193,032
822	2,458	181,384
5,464	*15,176*	*1,058,192*
752	2,315	170,968
707	2,032	152,005
680	2,021	148,210
612	1,763	135,679
540	1,672	127,502
3,291	*9,803*	*734,364*
357	1,560	118,368
361	1,433	109,479
307	1,351	101,822
274	1,201	92,924
212	1,114	82,508
1,511	*6,659*	*505,101*
734	*3,883*	*313,856*
299	*1,905*	*152,992*
71	*531*	*43,130*
8	*55*	*4,992*
246,143	**426,285**	**25,365,745**

31010do002_202009 National, state and territory population, Sep 2020

Released at 11:30 am (Canberra time) Thu 18 Mar 2021

Table 8 Estimated resident population, by age and sex–at 30 June 2020

Age (years)	New South Wales	Victoria	Queensland	South Australia	Western Australia	Tasmania
				MALES		
0	50,013	40,129	31,384	9,801	16,850	3,019
1	50,897	39,906	31,759	9,741	17,171	2,870
2	50,067	40,880	31,978	9,947	17,533	2,861
3	50,585	41,530	32,754	10,290	18,135	2,963
4	53,385	44,360	33,781	10,945	18,708	3,317
0-4	*254,947*	*206,805*	*161,656*	*50,724*	*88,397*	*15,030*
5	52,345	43,374	34,009	10,674	18,144	3,223
6	52,215	42,935	34,639	10,866	17,722	3,193
7	53,336	43,485	34,991	10,961	18,081	3,261
8	52,958	42,458	34,988	11,086	17,584	3,195
9	52,575	41,877	35,134	10,847	17,965	3,423
5-9	*263,429*	*214,129*	*173,761*	*54,434*	*89,496*	*16,295*
10	52,529	41,934	35,602	11,080	17,788	3,394
11	51,837	41,203	35,825	10,849	17,668	3,474
12	51,816	41,018	35,819	10,800	17,567	3,509
13	51,306	40,625	35,663	10,723	17,509	3,460
14	49,497	39,151	34,373	10,480	16,714	3,394
10-14	*256,985*	*203,931*	*177,282*	*53,932*	*87,246*	*17,231*
15	48,035	37,674	33,090	10,233	16,123	3,265
16	47,300	37,778	32,503	10,289	15,971	3,137
17	47,089	37,327	31,831	10,204	15,307	3,064
18	47,726	38,427	32,400	10,500	15,558	3,265
19	51,835	42,710	33,759	10,993	16,345	3,326
15-19	*241,985*	*193,916*	*163,583*	*52,219*	*79,304*	*16,057*
20	53,948	44,978	33,681	11,578	16,551	3,365
21	54,330	45,792	33,192	11,526	17,054	3,326
22	55,100	47,900	33,386	11,699	16,843	3,276
23	56,957	51,554	34,180	11,829	17,154	3,269
24	58,820	54,373	36,031	12,360	17,846	3,307
20-24	*279,155*	*244,597*	*170,470*	*58,992*	*85,448*	*16,543*
25	61,173	56,691	36,739	12,462	18,450	3,579
26	61,230	55,442	36,981	11,755	18,247	3,512
27	61,184	53,446	37,062	11,740	18,334	3,412
28	61,455	53,000	36,626	11,499	18,802	3,419
29	61,938	53,306	36,851	11,810	19,318	3,376
25-29	*306,980*	*271,885*	*184,259*	*59,266*	*93,151*	*17,298*
30	62,373	53,871	36,746	11,803	20,008	3,550
31	61,089	52,487	35,420	11,736	19,827	3,284
32	59,972	52,919	35,159	11,574	20,160	3,297

33	59,367	51,829	34,811	11,599	20,333	3,188
34	59,797	51,898	35,085	11,921	20,644	3,264
30-34	*302,598*	*263,004*	*177,221*	*58,633*	*100,972*	*16,583*
35	59,071	50,846	34,852	11,838	20,129	3,183
36	59,139	50,353	34,823	11,810	20,208	3,216
37	58,470	49,736	35,281	11,603	20,224	3,188
38	57,545	48,003	34,424	11,127	19,671	3,054
39	55,772	46,620	33,686	11,087	18,899	2,937
35-39	*289,997*	*245,558*	*173,066*	*57,465*	*99,131*	*15,578*
40	53,492	44,520	32,570	10,615	18,234	2,957
41	51,501	43,146	31,620	10,427	17,622	2,957
42	50,537	41,990	31,141	10,252	17,367	2,859
43	49,932	41,256	31,470	10,385	17,068	2,885
44	50,150	41,361	32,091	10,464	17,176	3,003
40-44	*255,612*	*212,273*	*158,892*	*52,143*	*87,467*	*14,661*
45	50,309	41,021	32,331	10,579	17,048	3,081
46	51,634	41,918	33,670	10,799	17,275	3,178
47	51,887	41,922	34,308	11,002	17,815	3,214
48	53,273	43,026	34,981	11,556	18,459	3,472
49	53,005	42,967	35,194	11,752	18,480	3,589
45-49	*260,108*	*210,854*	*170,484*	*55,688*	*89,077*	*16,534*
50	49,229	40,943	32,919	11,326	17,406	3,516
51	48,043	40,232	31,904	11,135	17,300	3,471
52	46,462	39,197	30,845	11,030	16,544	3,306
53	45,742	37,386	30,418	10,590	16,259	3,173
54	46,597	37,615	29,844	10,748	16,181	3,155
50-54	*236,073*	*195,373*	*155,930*	*54,829*	*83,690*	*16,621*
55	46,249	37,116	30,180	10,894	16,003	3,338
56	48,596	38,199	31,287	11,253	16,359	3,652
57	49,365	38,573	31,305	11,388	16,310	3,685
58	49,209	37,965	31,108	11,145	16,024	3,797
59	48,556	37,392	30,891	11,415	15,693	3,832
55-59	*241,975*	*189,245*	*154,771*	*56,095*	*80,389*	*18,304*
60	46,551	36,320	29,717	11,015	15,178	3,695
61	45,361	35,815	28,777	10,747	14,807	3,702
62	44,885	34,697	28,001	10,614	14,358	3,722
63	43,824	33,713	27,316	10,296	13,910	3,514
64	42,774	33,649	26,733	10,104	13,925	3,622
60-64	*223,395*	*174,194*	*140,544*	*52,776*	*72,178*	*18,255*
65	41,151	31,815	25,644	9,901	12,861	3,382
66	39,740	30,605	24,890	9,539	12,586	3,218
67	39,352	30,091	24,885	9,533	12,278	3,314
68	37,695	29,386	24,448	9,244	12,132	3,303
69	37,575	28,806	24,113	9,112	11,987	3,210
65-69	*195,513*	*150,703*	*123,980*	*47,329*	*61,844*	*16,427*
70	36,694	27,989	23,375	9,093	11,314	3,103
71	35,130	26,864	23,003	8,763	10,973	2,994
72	35,863	26,960	22,743	8,650	11,170	3,018
73	36,024	27,543	23,277	8,986	11,064	3,213
74	30,414	23,173	19,327	7,384	8,826	2,452

70-74	*174,125*	*132,529*	*111,725*	*42,876*	*53,347*	*14,780*
75	28,447	21,120	18,312	6,867	8,181	2,292
76	26,777	19,744	16,714	6,354	7,862	2,269
77	23,244	17,592	14,537	5,812	6,806	1,970
78	22,501	17,336	14,151	5,438	6,844	1,803
79	20,443	15,823	12,554	4,843	5,804	1,676
75-79	*121,412*	*91,615*	*76,268*	*29,314*	*35,497*	*10,010*
80	18,904	14,541	11,562	4,521	5,506	1,535
81	17,135	13,423	10,275	4,272	5,053	1,402
82	15,612	12,147	9,213	3,881	4,570	1,270
83	14,525	11,179	8,326	3,612	4,096	1,119
84	12,970	10,066	7,407	3,097	3,587	972
80-84	*79,146*	*61,356*	*46,783*	*19,383*	*22,812*	*6,298*
85-89	*44,205*	*34,280*	*23,955*	*11,128*	*12,145*	*3,294*
90-94	*19,678*	*15,341*	*10,051*	*5,113*	*5,163*	*1,290*
95-99	*4,670*	*3,888*	*2,250*	*1,189*	*1,143*	*327*
100 and over	*613*	*519*	*375*	*228*	*190*	*43*
All ages	**4,052,601**	**3,315,995**	**2,557,306**	**873,756**	**1,328,087**	**267,459**
				FEMALE		
0	47,212	37,814	29,666	9,101	15,853	2,862
1	47,356	37,920	29,744	9,252	16,200	2,736
2	47,209	38,495	30,329	9,250	16,627	2,706
3	48,223	39,155	30,869	9,576	16,956	2,917
4	50,144	41,797	32,338	10,509	17,527	3,016
0-4	*240,144*	*195,181*	*152,946*	*47,688*	*83,163*	*14,237*
5	49,490	41,148	32,381	10,166	17,130	3,017
6	49,779	40,464	32,737	10,243	17,204	3,066
7	50,121	41,273	33,306	10,448	17,157	3,078
8	50,033	40,230	33,310	10,464	16,969	3,120
9	49,926	39,416	33,752	10,296	17,220	3,141
5-9	*249,349*	*202,531*	*165,486*	*51,617*	*85,680*	*15,422*
10	50,144	39,876	34,217	10,386	16,950	3,124
11	49,172	38,826	33,840	10,450	16,572	3,324
12	49,402	38,723	33,847	10,496	16,978	3,265
13	48,595	38,549	33,329	10,368	16,665	3,242
14	46,583	37,169	32,690	9,874	16,126	3,132
10-14	*243,896*	*193,143*	*167,923*	*51,574*	*83,291*	*16,087*
15	45,096	35,702	31,335	9,773	15,187	3,041
16	44,239	35,655	31,002	9,751	14,962	2,927
17	44,538	35,603	30,419	9,781	14,986	2,973
18	45,039	36,663	30,593	9,902	14,930	3,016
19	47,653	39,795	32,082	10,548	15,514	3,005
15-19	*226,565*	*183,418*	*155,431*	*49,755*	*75,579*	*14,962*
20	49,690	42,238	32,352	10,728	16,022	2,971
21	49,933	42,615	32,507	10,886	16,148	2,993
22	51,525	44,329	33,164	11,116	16,025	2,896
23	54,027	47,653	34,626	11,284	16,396	3,023
24	55,903	50,118	35,705	11,419	16,670	3,215

20-24	*261,078*	*226,953*	*168,354*	*55,433*	*81,261*	*15,098*
25	58,374	51,555	36,983	11,689	17,371	3,327
26	59,430	52,163	36,830	11,655	17,787	3,298
27	59,452	52,312	37,166	11,660	18,430	3,295
28	61,011	52,980	37,464	11,742	18,625	3,354
29	62,644	54,298	37,766	11,733	19,499	3,543
25-29	*300,911*	*263,308*	*186,209*	*58,479*	*91,712*	*16,817*
30	63,338	55,466	37,948	11,980	20,213	3,412
31	62,295	54,630	37,034	11,886	20,339	3,353
32	61,739	54,163	36,659	12,049	20,633	3,342
33	60,687	52,980	36,608	11,989	20,836	3,286
34	60,933	53,430	37,071	12,124	21,022	3,350
30-34	*308,992*	*270,669*	*185,320*	*60,028*	*103,043*	*16,743*
35	60,141	52,632	36,866	12,052	20,680	3,388
36	59,894	51,319	36,875	12,023	20,406	3,290
37	59,585	50,348	37,135	11,751	19,989	3,184
38	57,395	48,653	35,376	11,494	19,352	3,318
39	55,812	46,911	34,901	11,243	18,711	3,326
35-39	*292,827*	*249,863*	*181,153*	*58,563*	*99,138*	*16,506*
40	53,268	44,787	33,971	10,878	18,135	3,106
41	51,980	43,288	33,010	10,531	17,703	3,106
42	51,063	42,167	33,023	10,435	16,914	3,142
43	50,364	41,366	33,029	10,522	16,850	2,973
44	50,516	41,437	33,283	10,462	17,072	3,075
40-44	*257,191*	*213,045*	*166,316*	*52,828*	*86,674*	*15,402*
45	50,492	41,961	33,434	10,518	17,091	3,259
46	52,069	43,025	34,602	10,768	17,239	3,328
47	53,487	43,551	35,634	11,262	17,579	3,535
48	55,164	45,449	36,586	11,809	18,380	3,705
49	55,778	46,410	37,263	12,173	18,672	3,833
45-49	*266,990*	*220,396*	*177,519*	*56,530*	*88,961*	*17,660*
50	51,616	43,449	34,901	11,769	17,595	3,583
51	51,069	43,004	33,912	11,567	17,521	3,664
52	49,656	41,323	32,678	11,406	16,746	3,539
53	47,997	39,722	32,185	11,017	16,438	3,500
54	48,297	39,888	31,562	11,229	16,300	3,447
50-54	*248,635*	*207,386*	*165,238*	*56,988*	*84,600*	*17,733*
55	48,469	39,467	31,590	11,314	16,215	3,593
56	50,899	40,724	32,890	11,667	16,520	3,882
57	51,687	40,636	33,127	11,772	16,667	3,857
58	51,094	39,981	32,858	11,789	16,285	3,912
59	50,992	40,174	32,253	11,929	16,221	4,111
55-59	*253,141*	*200,982*	*162,718*	*58,471*	*81,908*	*19,355*
60	49,745	39,163	30,980	11,713	15,805	3,960
61	48,078	37,766	30,285	11,582	15,293	3,916
62	48,329	37,422	29,765	11,092	14,873	3,706
63	46,511	36,324	28,568	11,093	14,571	3,746
64	45,271	35,858	28,175	10,842	14,533	3,641
60-64	*237,934*	*186,533*	*147,773*	*56,322*	*75,075*	*18,969*

65	44,079	34,459	27,234	10,452	13,951	3,474
66	42,876	33,456	26,599	10,399	13,500	3,543
67	41,900	32,722	26,068	10,264	13,114	3,500
68	40,258	31,427	25,258	9,934	12,624	3,365
69	39,408	31,212	24,975	10,011	12,216	3,335
65-69	*208,521*	*163,276*	*130,134*	*51,060*	*65,405*	*17,217*
70	38,370	30,269	24,554	9,597	11,877	3,285
71	36,721	28,834	23,384	9,314	11,427	3,119
72	36,781	29,094	23,101	9,177	11,194	3,110
73	37,459	29,259	23,617	9,629	11,343	3,237
74	31,824	24,479	19,652	8,079	9,041	2,625
70-74	*181,155*	*141,935*	*114,308*	*45,796*	*54,882*	*15,376*
75	30,061	22,911	18,987	7,626	8,502	2,509
76	28,460	21,973	17,441	7,069	8,245	2,324
77	25,515	19,519	15,542	6,513	7,342	2,011
78	24,710	19,229	14,969	6,162	7,210	2,023
79	23,083	17,818	13,569	5,717	6,689	1,860
75-79	*131,829*	*101,450*	*80,508*	*33,087*	*37,988*	*10,727*
80	21,697	17,136	12,695	5,471	6,317	1,692
81	20,444	15,952	11,738	5,239	5,947	1,580
82	19,000	15,170	10,578	4,814	5,502	1,501
83	17,994	13,916	9,992	4,425	5,070	1,349
84	16,709	13,038	8,906	4,041	4,669	1,227
80-84	*95,844*	*75,212*	*53,909*	*23,990*	*27,505*	*7,349*
85-89	*62,494*	*48,845*	*33,118*	*15,881*	*17,419*	*4,607*
90-94	*34,463*	*26,825*	*18,083*	*8,970*	*8,937*	*2,263*
95-99	*11,423*	*8,522*	*5,681*	*3,134*	*2,872*	*728*
100 and over	*1,549*	*1,202*	*753*	*425*	*381*	*63*
All ages	**4,114,931**	**3,380,675**	**2,618,880**	**896,619**	**1,335,474**	**273,321**
				PERSONS		
0	97,225	77,943	61,050	18,902	32,703	5,881
1	98,253	77,826	61,503	18,993	33,371	5,606
2	97,276	79,375	62,307	19,197	34,160	5,567
3	98,808	80,685	63,623	19,866	35,091	5,880
4	103,529	86,157	66,119	21,454	36,235	6,333
0-4	*495,091*	*401,986*	*314,602*	*98,412*	*171,560*	*29,267*
5	101,835	84,522	66,390	20,840	35,274	6,240
6	101,994	83,399	67,376	21,109	34,926	6,259
7	103,457	84,758	68,297	21,409	35,238	6,339
8	102,991	82,688	68,298	21,550	34,553	6,315
9	102,501	81,293	68,886	21,143	35,185	6,564
5-9	*512,778*	*416,660*	*339,247*	*106,051*	*175,176*	*31,717*
10	102,673	81,810	69,819	21,466	34,738	6,518
11	101,009	80,029	69,665	21,299	34,240	6,798
12	101,218	79,741	69,666	21,296	34,545	6,774
13	99,901	79,174	68,992	21,091	34,174	6,702
14	96,080	76,320	67,063	20,354	32,840	6,526
10-14	*500,881*	*397,074*	*345,205*	*105,506*	*170,537*	*33,318*

15	93,131	73,376	64,425	20,006	31,310	6,306
16	91,539	73,433	63,505	20,040	30,933	6,064
17	91,627	72,930	62,250	19,985	30,293	6,037
18	92,765	75,090	62,993	20,402	30,488	6,281
19	99,488	82,505	65,841	21,541	31,859	6,331
15-19	*468,550*	*377,334*	*319,014*	*101,974*	*154,883*	*31,019*
20	103,638	87,216	66,033	22,306	32,573	6,336
21	104,263	88,407	65,699	22,412	33,202	6,319
22	106,625	92,229	66,550	22,815	32,868	6,172
23	110,984	99,207	68,806	23,113	33,550	6,292
24	114,723	104,491	71,736	23,779	34,516	6,522
20-24	*540,233*	*471,550*	*338,824*	*114,425*	*166,709*	*31,641*
25	119,547	108,246	73,722	24,151	35,821	6,906
26	120,660	107,605	73,811	23,410	36,034	6,810
27	120,636	105,758	74,228	23,400	36,764	6,707
28	122,466	105,980	74,090	23,241	37,427	6,773
29	124,582	107,604	74,617	23,543	38,817	6,919
25-29	*607,891*	*535,193*	*370,468*	*117,745*	*184,863*	*34,115*
30	125,711	109,337	74,694	23,783	40,221	6,962
31	123,384	107,117	72,454	23,622	40,166	6,637
32	121,711	107,082	71,818	23,623	40,793	6,639
33	120,054	104,809	71,419	23,588	41,169	6,474
34	120,730	105,328	72,156	24,045	41,666	6,614
30-34	*611,590*	*533,673*	*362,541*	*118,661*	*204,015*	*33,326*
35	119,212	103,478	71,718	23,890	40,809	6,571
36	119,033	101,672	71,698	23,833	40,614	6,506
37	118,055	100,084	72,416	23,354	40,213	6,372
38	114,940	96,656	69,800	22,621	39,023	6,372
39	111,584	93,531	68,587	22,330	37,610	6,263
35-39	*582,824*	*495,421*	*354,219*	*116,028*	*198,269*	*32,084*
40	106,760	89,307	66,541	21,493	36,369	6,063
41	103,481	86,434	64,630	20,958	35,325	6,063
42	101,600	84,157	64,164	20,687	34,281	6,001
43	100,296	82,622	64,499	20,907	33,918	5,858
44	100,666	82,798	65,374	20,926	34,248	6,078
40-44	*512,803*	*425,318*	*325,208*	*104,971*	*174,141*	*30,063*
45	100,801	82,982	65,765	21,097	34,139	6,340
46	103,703	84,943	68,272	21,567	34,514	6,506
47	105,374	85,473	69,942	22,264	35,394	6,749
48	108,437	88,475	71,567	23,365	36,839	7,177
49	108,783	89,377	72,457	23,925	37,152	7,422
45-49	*527,098*	*431,250*	*348,003*	*112,218*	*178,038*	*34,194*
50	100,845	84,392	67,820	23,095	35,001	7,099
51	99,112	83,236	65,816	22,702	34,821	7,135
52	96,118	80,520	63,523	22,436	33,290	6,845
53	93,739	77,108	62,603	21,607	32,697	6,673
54	94,894	77,503	61,406	21,977	32,481	6,602
50-54	*484,708*	*402,759*	*321,168*	*111,817*	*168,290*	*34,354*
55	94,718	76,583	61,770	22,208	32,218	6,931
56	99,495	78,923	64,177	22,920	32,879	7,534

57	101,052	79,209	64,432	23,160	32,977	7,542
58	100,303	77,946	63,966	22,934	32,309	7,709
59	99,548	77,566	63,144	23,344	31,914	7,943
55-59	*495,116*	*390,227*	*317,489*	*114,566*	*162,297*	*37,659*
60	96,296	75,483	60,697	22,728	30,983	7,655
61	93,439	73,581	59,062	22,329	30,100	7,618
62	93,214	72,119	57,766	21,706	29,231	7,428
63	90,335	70,037	55,884	21,389	28,481	7,260
64	88,045	69,507	54,908	20,946	28,458	7,263
60-64	*461,329*	*360,727*	*288,317*	*109,098*	*147,253*	*37,224*
65	85,230	66,274	52,878	20,353	26,812	6,856
66	82,616	64,061	51,489	19,938	26,086	6,761
67	81,252	62,813	50,953	19,797	25,392	6,814
68	77,953	60,813	49,706	19,178	24,756	6,668
69	76,983	60,018	49,088	19,123	24,203	6,545
65-69	*404,034*	*313,979*	*254,114*	*98,389*	*127,249*	*33,644*
70	75,064	58,258	47,929	18,690	23,191	6,388
71	71,851	55,698	46,387	18,077	22,400	6,113
72	72,644	56,054	45,844	17,827	22,364	6,128
73	73,483	56,802	46,894	18,615	22,407	6,450
74	62,238	47,652	38,979	15,463	17,867	5,077
70-74	*355,280*	*274,464*	*226,033*	*88,672*	*108,229*	*30,156*
75	58,508	44,031	37,299	14,493	16,683	4,801
76	55,237	41,717	34,155	13,423	16,107	4,593
77	48,759	37,111	30,079	12,325	14,148	3,981
78	47,211	36,565	29,120	11,600	14,054	3,826
79	43,526	33,641	26,123	10,560	12,493	3,536
75-79	*253,241*	*193,065*	*156,776*	*62,401*	*73,485*	*20,737*
80	40,601	31,677	24,257	9,992	11,823	3,227
81	37,579	29,375	22,013	9,511	11,000	2,982
82	34,612	27,317	19,791	8,695	10,072	2,771
83	32,519	25,095	18,318	8,037	9,166	2,468
84	29,679	23,104	16,313	7,138	8,256	2,199
80-84	*174,990*	*136,568*	*100,692*	*43,373*	*50,317*	*13,647*
85-89	*106,699*	*83,125*	*57,073*	*27,009*	*29,564*	*7,901*
90-94	*54,141*	*42,166*	*28,134*	*14,083*	*14,100*	*3,553*
95-99	*16,093*	*12,410*	*7,931*	*4,323*	*4,015*	*1,055*
100 and over	*2,162*	*1,721*	*1,128*	*653*	*571*	*106*
All ages	**8,167,532**	**6,696,670**	**5,176,186**	**1,770,375**	**2,663,561**	**540,780**

Northern Territory	Australian Capital Territory	Australia
1,858	2,862	155,929
1,820	2,736	156,912
1,821	2,748	157,848
1,864	2,953	161,091
1,876	2,998	169,389
9,239	*14,297*	*801,169*
1,808	3,068	166,669
1,816	2,975	166,400
1,775	3,027	168,951
1,888	2,981	167,174
1,863	2,905	166,621
9,150	*14,956*	*835,815*
1,867	2,913	167,139
1,731	2,761	165,376
1,744	2,697	164,999
1,701	2,622	163,642
1,709	2,555	157,906
8,752	*13,548*	*819,062*
1,592	2,337	152,370
1,578	2,351	150,925
1,614	2,412	148,873
1,539	2,420	151,863
1,603	2,749	163,335
7,926	*12,269*	*767,366*
1,553	2,984	168,659
1,555	3,155	169,955
1,664	3,325	173,220
1,794	3,373	180,130
1,809	3,428	187,996
8,375	*16,265*	*879,960*
2,088	3,294	194,502
2,131	3,301	192,638
2,175	3,347	190,732
2,291	3,289	190,417
2,468	3,445	192,539
11,153	*16,676*	*960,828*
2,540	3,449	194,370
2,331	3,411	189,616
2,434	3,451	189,007

2,422	3,419	187,011
2,291	3,635	188,575
12,018	*17,365*	*948,579*
2,208	3,508	185,670
2,114	3,636	185,324
2,182	3,551	184,273
1,958	3,431	179,247
1,902	3,388	174,329
10,364	*17,514*	*908,843*
1,738	3,151	167,313
1,792	3,200	162,307
1,687	3,009	158,872
1,750	2,911	157,689
1,737	2,849	158,859
8,704	*15,120*	*805,040*
1,643	2,877	158,919
1,722	2,871	163,105
1,635	2,811	164,626
1,680	2,921	169,415
1,852	2,969	169,850
8,532	*14,449*	*825,915*
1,641	2,791	159,806
1,597	2,555	156,263
1,516	2,524	151,452
1,561	2,356	147,521
1,514	2,407	148,100
7,829	*12,633*	*763,142*
1,495	2,256	147,570
1,480	2,309	153,171
1,502	2,314	154,481
1,495	2,340	153,134
1,403	2,267	151,487
7,375	*11,486*	*759,843*
1,331	2,139	145,991
1,217	2,011	142,469
1,128	1,981	139,428
1,158	1,886	135,653
1,117	1,840	133,800
5,951	*9,857*	*697,341*
1,059	1,701	127,545
932	1,761	123,303
916	1,686	122,086
822	1,621	118,682
755	1,568	117,169
4,484	*8,337*	*608,785*
771	1,607	113,990
722	1,546	110,022
650	1,550	110,625
631	1,606	112,374
506	1,330	93,429

3,280	*7,639*	*540,440*
445	1,136	86,818
389	1,031	81,160
356	929	71,268
350	914	69,349
310	757	62,229
1,850	*4,767*	*370,824*
272	743	57,597
169	707	52,451
176	625	47,501
133	558	43,554
126	508	38,742
876	*3,141*	*239,845*
304	*1,695*	*131,023*
126	*687*	*57,459*
30	*230*	*13,730*
7	*19*	*1,996*
126,325	**212,950**	**12,737,005**
1,690	2,697	146,907
1,690	2,617	147,532
1,642	2,644	148,923
1,668	2,733	152,108
1,833	2,873	160,072
8,523	*13,564*	*755,542*
1,693	2,883	157,933
1,662	2,786	157,969
1,800	2,835	160,038
1,819	2,729	158,699
1,680	2,682	158,139
8,654	*13,915*	*792,778*
1,685	2,698	159,111
1,663	2,546	156,419
1,731	2,466	156,938
1,583	2,375	154,730
1,568	2,382	149,555
8,230	*12,467*	*776,753*
1,432	2,259	143,850
1,418	2,171	142,151
1,437	2,203	141,965
1,487	2,386	144,044
1,427	2,579	152,626
7,201	*11,598*	*724,636*
1,450	2,849	158,320
1,437	3,102	159,643
1,491	3,435	163,998
1,620	3,490	172,139
1,721	3,485	178,244

7,719	*16,361*	*832,344*
1,888	3,374	184,576
2,011	3,499	186,685
2,187	3,410	187,934
2,328	3,450	190,968
2,464	3,583	195,545
10,878	*17,316*	*945,708*
2,491	3,718	198,580
2,395	3,683	195,641
2,426	3,625	194,662
2,335	3,662	192,404
2,190	3,681	193,825
11,837	*18,369*	*975,112*
2,233	3,701	191,721
2,069	3,707	189,620
2,058	3,432	187,513
1,938	3,604	181,151
1,842	3,396	176,172
10,140	*17,840*	*926,177*
1,775	3,319	169,262
1,763	3,082	164,495
1,690	2,914	161,370
1,611	2,935	159,676
1,706	2,785	160,364
8,545	*15,035*	*815,167*
1,521	2,874	161,175
1,618	2,880	165,560
1,482	2,966	169,540
1,641	3,009	175,777
1,661	2,925	178,749
7,923	*14,654*	*850,801*
1,570	2,721	167,241
1,592	2,747	165,118
1,554	2,503	159,432
1,472	2,399	154,758
1,486	2,588	154,837
7,674	*12,958*	*801,386*
1,349	2,432	154,461
1,366	2,493	160,473
1,439	2,399	161,613
1,373	2,509	159,837
1,328	2,366	159,412
6,855	*12,199*	*795,796*
1,261	2,273	154,934
1,172	2,275	150,405
1,089	2,154	148,465
1,075	2,134	144,059
1,005	2,088	141,450
5,602	*10,924*	*739,313*

941	1,946	136,565
879	1,885	133,172
834	1,906	130,337
782	1,882	125,559
731	1,843	123,758
4,167	*9,462*	*649,391*
647	1,696	120,327
572	1,738	115,135
534	1,709	114,713
501	1,746	116,809
428	1,417	97,567
2,682	*8,306*	*564,551*
352	1,308	92,275
341	1,240	87,109
313	1,073	77,846
308	1,070	75,693
283	965	69,995
1,597	*5,656*	*402,918*
256	890	66,162
175	816	61,906
167	765	57,508
158	743	53,652
129	641	49,370
885	*3,855*	*288,598*
449	*2,338*	*185,170*
197	*1,225*	*100,966*
54	*350*	*32,767*
6	*38*	*4,419*
119,818	**218,430**	**12,960,293**
3,548	5,559	302,836
3,510	5,353	304,444
3,463	5,392	306,771
3,532	5,686	313,199
3,709	5,871	329,461
17,762	*27,861*	*1,556,711*
3,501	5,951	324,602
3,478	5,761	324,369
3,575	5,862	328,989
3,707	5,710	325,873
3,543	5,587	324,760
17,804	*28,871*	*1,628,593*
3,552	5,611	326,250
3,394	5,307	321,795
3,475	5,163	321,937
3,284	4,997	318,372
3,277	4,937	307,461
16,982	*26,015*	*1,595,815*

3,024	4,596	296,220
2,996	4,522	293,076
3,051	4,615	290,838
3,026	4,806	295,907
3,030	5,328	315,961
15,127	*23,867*	*1,492,002*
3,003	5,833	326,979
2,992	6,257	329,598
3,155	6,760	337,218
3,414	6,863	352,269
3,530	6,913	366,240
16,094	*32,626*	*1,712,304*
3,976	6,668	379,078
4,142	6,800	379,323
4,362	6,757	378,666
4,619	6,739	381,385
4,932	7,028	388,084
22,031	*33,992*	*1,906,536*
5,031	7,167	392,950
4,726	7,094	385,257
4,860	7,076	383,669
4,757	7,081	379,415
4,481	7,316	382,400
23,855	*35,734*	*1,923,691*
4,441	7,209	377,391
4,183	7,343	374,944
4,240	6,983	371,786
3,896	7,035	360,398
3,744	6,784	350,501
20,504	*35,354*	*1,835,020*
3,513	6,470	336,575
3,555	6,282	326,802
3,377	5,923	320,242
3,361	5,846	317,365
3,443	5,634	319,223
17,249	*30,155*	*1,620,207*
3,164	5,751	320,094
3,340	5,751	328,665
3,117	5,777	334,166
3,321	5,930	345,192
3,513	5,894	348,599
16,455	*29,103*	*1,676,716*
3,211	5,512	327,047
3,189	5,302	321,381
3,070	5,027	310,884
3,033	4,755	302,279
3,000	4,995	302,937
15,503	*25,591*	*1,564,528*
2,844	4,688	302,031
2,846	4,802	313,644

2,941	4,713	316,094
2,868	4,849	312,971
2,731	4,633	310,899
14,230	*23,685*	*1,555,639*
2,592	4,412	300,925
2,389	4,286	292,874
2,217	4,135	287,893
2,233	4,020	279,712
2,122	3,928	275,250
11,553	*20,781*	*1,436,654*
2,000	3,647	264,110
1,811	3,646	256,475
1,750	3,592	252,423
1,604	3,503	244,241
1,486	3,411	240,927
8,651	*17,799*	*1,258,176*
1,418	3,303	234,317
1,294	3,284	225,157
1,184	3,259	225,338
1,132	3,352	229,183
934	2,747	190,996
5,962	*15,945*	*1,104,991*
797	2,444	179,093
730	2,271	168,269
669	2,002	149,114
658	1,984	145,042
593	1,722	132,224
3,447	*10,423*	*773,742*
528	1,633	123,759
344	1,523	114,357
343	1,390	105,009
291	1,301	97,206
255	1,149	88,112
1,761	*6,996*	*528,443*
753	*4,033*	*316,193*
323	*1,912*	*158,425*
84	*580*	*46,497*
13	*57*	*6,415*
246,143	**431,380**	**25,697,298**

Pharmacy Diabetes Screening Trial

September 2021

MSAC application no. 1677

Commentary

ISBN (Online) TBA

ISSN (Online) 1443-7139

Internet site www.msac.gov.au

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The technical information in this document is used by the Medical Services Advisory Committee (MSAC) to inform its deliberations. MSAC is an independent committee established to provide advice to the Minister for Health on the strength of evidence available on new and existing medical technologies and procedures in terms of their safety, effectiveness, and cost-effectiveness. This advice will help to inform government decisions about which medical services should attract funding through the Medicare Benefits Schedule (MBS) or alternative funding programs/arrangements.

MSAC's advice does not necessarily reflect the views of all individuals who participated in the MSAC evaluation.

This report was prepared by s47

The report was commissioned by the Australian Government Department of Health.

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Commentary Executive Summary

Main issues for MSAC consideration

Clinical issues:

- *The ADAR did not present a comparison with usual care. For most patients usual care is likely to be opportunistic screening of type 2 diabetes mellitus (T2DM) by GPs using AUSDRISK™ only every 3 years for patients not at high risk of T2DM according to The Royal Australian College of General Practitioners guidelines.[1] The pharmacy diabetes screening trial (PDST) was not designed to determine whether any of the community pharmacy screening options was effective compared with usual care.*
- s47

Economic issues:

- *The ADAR did not present an economic evaluation comparing pharmacy-based screening with usual care. The modelled evaluation compared the three pharmacy-based screening interventions.*
- *The ADAR's modelled economic evaluation assumed an inconsistent underlying prevalence of T2DM and Pre-DM (diagnosed and undiagnosed) across the three pharmacy-based intervention groups and the modelled incremental cost-effectiveness results are driven by these differences.*
- *The ADAR's modelled economic evaluation assumed T2DM screening only occurs once in a patient's lifetime. Thus, without community pharmacy screening leading to a diagnosis of T2DM, patients remain undiagnosed (and untreated) for the rest of their life, rather than allowing for delayed diagnosis (and treatment) by GPs (potentially after a future referral from a community pharmacy screening program).*
- *The economic model had several other limitations. Notably, it included costs generally not considered when assessing funding for the MBS (such as trial recruitment and capital costs).*
- *A revised based case was developed during the evaluation that compared against usual care, adopted a consistent underlying prevalence of T2DM and Pre-DM across the groups, and allowed for delayed diagnosis by GPs. According to the revised base case, none of the community pharmacy screening options are likely to be cost effective when compared against the appropriate usual care comparator of opportunistic screening by GPs.*

Financial issues:

- The ADAR estimates that the financial impact of implementing Group B (AUSDRISK™ + PoC HbA1c) is approximately s47 over 5 years, which included capital costs for pharmacies.
- *After removing capital costs to pharmacies, the estimated cost to government was* s47 *over 5 years. The financial estimates were uncertain and sensitive to the*

proportion of the eligible population who use community pharmacy screening which was based on expert opinion.

1. Purpose of application

An application requesting public funding of community pharmacy-based opportunistic screening of Type 2 Diabetes Mellitus (T2DM) using the AUSDRISK™ questionnaire and point-of-care testing (PoC/T) of glycated haemoglobin was received from the Pharmacy Guild of Australia by the Department of Health.

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The ADAR is summarised in normal font, *with evaluation comments in italics.*

2. Background

The Sixth Community Pharmacy Agreement (6CPA) provided $50 million over the term to fund the Pharmacy Trial Program (PTP) to trial new and expanded community pharmacy programs, which sought to improve clinical outcomes for consumers and/or extend the role of pharmacists in the delivery of primary health care services.

Once finalised, consistent with the 6CPA, the outcomes of each PTP trial are to be evaluated by an independent health technology assessment body to determine the effectiveness and cost-effectiveness of the trial intervention and inform decisions about any broader rollout. A decision to fund any future programs would be a matter for Government.

The MSAC Executive considered the Pharmacy Diabetes Screening Trial (PDST) at its January 2021 meeting. A summary of the key matters raised by the MSAC Executive *and related issues* are presented in *Table 1*.

Table 1: Summary of key matters of concern

Component	Matter of concern	How the current assessment report addresses it
Comparison with usual care	*The PDST and economic evaluation do not compare community pharmacy screening with current services or alternative screening options. The MSAC Executive noted that this information is pertinent to MSAC's decision making.*	*Not addressed - no comparison with usual care presented.* *The commentary includes a revised base case comparing community pharmacy screening against usual care.*
Duplication with pathology services	*Double up in services as a diagnosis confirmation would be required through a pathology test. MSAC Executive also previously considered it reasonable to assume that between 60 – 90% of laboratory HbA1c tests would be coned out (p3, 1431 PSD)*	*Not addressed.*
Fee arrangement was not proposed	*The PDST did not explicitly propose a fee arrangement*	*The ADAR financial impact analysis proposes a screening fee per service of* s47 *. Which is a weighted average of* s47 *for administering AUSDRISK™ and* s47 *for administering both AUSDRISK™ and HbA1c PoC testing.*

Component	Matter of concern	How the current assessment report addresses it
HbA1c as a screening tool	*MSAC did not support HbA1c PoC testing for diagnosis of T2DM in the context of medical practitioners (p1, 1431 PSD). Based on that precedent, HbA1c PoC testing may not be appropriate as a screening tool.*	*Not addressed.*
Negative mean bias of HbA1c PoC testing	*In their consideration of HbA1c PoC testing for T2DM, MSAC was particularly concerned that there may be evidence of a negative assay bias suggesting that the PoC test result is more likely to be less than the laboratory result, which would underdiagnose diabetes (p2 1431 PSD)*	*Not addressed.*
HbA1c threshold	*Full HTA should include base case economic analysis and its sensitivity to the threshold of HbA1c used*	*Somewhat addressed. The ADAR within-trial economic evaluation contains a univariate sensitivity analysis exploring the impact of adopting a HbA1c cut-off ≥6.0%. No corresponding sensitivity analysis was presented for the modelled economic evaluation.*
Financial estimates	*Total cost to Government was not presented*	*Partially addressed.* *Additional costs of treatment related to newly diagnosed cases not considered. Unlike the modelled economic evaluation, the financial impact analysis assumes costs savings of fewer diabetes related complications will occur more than 5 years in the future.*

Abbreviations: MSAC - Medical Services Advisory Committee; PoC – point of care; PDST-Pharmacy Diabetes Screening Trial; PSD - Public Summary Document; T2DM – type 2 diabetes mellitus

3. Prerequisites to implementation of any funding advice

The ADAR states that a formal training and assessment process would need to be implemented to ensure that pharmacists undertaking a remunerated screening service can demonstrate the requisite competencies to deliver the service at an appropriate standard. Similarly, the ADAR recognises that quality assurance processes be required for participating pharmacies to ensure effective uptake and consistent service delivery.

The exact nature of the quality assurance system is not documented in the ADAR.

Pathology accreditation standards are applicable for pathology laboratories seeking accreditation in order to be able to provide MBS pathology services. Community pharmacies that perform point of care (PoC) testing fall outside the scope of the proposed NPAAC Requirements for Point of Care Testing (First Edition 2015). However, the Requirements would provide guidance on good practice for the performance of PoC testing in other health care settings.

MBS item 3893 for HbA1c testing for diagnosis of diabetes requires that the practitioner or the organisation for which the practitioner works is participating in the Quality Assurance in Aboriginal Medical Services (QAAMS) Program. Further information related to the November MBS listing of HbA1c PoC testing is presented in the Committee in confidence section.

4. Proposal for public funding

The ADAR did not present an explicit fee proposal. In the financial implications section, the ADAR proposed a screening fee per service of s47 . This was calculated based on a weighted average of a screening service fee of s47 for a short consultation involving an AUSDRISK™ assessment (for patients not requiring PoC testing) and s47 for a standard consultation involving AUSDRISK™ assessment AND HbA1c PoC testing, counselling, and referral, with weights based on the proportion requiring PoC testing in the PDST. *The applicant is requested to confirm the proposed fees in its pre-ESC response.*

The modelled economic evaluation did not use the same cost of community pharmacy screening as the financial impact analysis.

Table 2 presents the MBS fees for potentially comparable pathology and consultation items. MSAC may wish to advise on the appropriate reimbursed fee for the proposed intervention.

Table 2: MBS fees for relevant pathology and consultation items

MBS item	Descriptor (abridged)	Fee and benefit [a]
Pathology testing items		
66841	*Quantitation of HbA1c (glycated haemoglobin) performed for the diagnosis of diabetes in asymptomatic patients at high risk.*	*$16.80* *Benefit: 85% = $14.30*
73839	*Quantitation of HbA1c (glycated haemoglobin) performed for the diagnosis of diabetes in asymptomatic patients at high risk - not more than once in a 12 month period. (QAAMS item)*	
TBC	*TBC: Quantitation of glycated haemoglobin (HbA1c) via point of care testing for the management of established diabetes*	s47
66500	*Quantitation in serum, plasma, urine or other body fluid (except amniotic fluid), by any method except reagent tablet or reagent strip of glucose [or other specified substances]- 1 test*	*$9.70* *Benefit: 85% = $8.25*
66542	*Oral glucose tolerance test for the diagnosis of diabetes mellitus that includes: (a) administration of glucose; and (b) at least 2 measurements of blood glucose.*	*$18.95* *Benefit: 85% = $16.15*
Consultation items (general practitioners)		
3	*Professional attendance by a general practitioner for an obvious problem characterised by the straightforward nature of the task that requires a short patient history and, if required, limited examination and management-each attendance*	*$17.90*
23	*Professional attendance by a general practitioner lasting less than 20 minutes including any of the following that are clinically relevant:* *(a) taking a patient history;* *(b) performing a clinical examination;* *(c) arranging any necessary investigation;* *(d) implementing a management plan;* *(e) providing appropriate preventive health care;* *for one or more health-related issues, with appropriate documentation-each attendance*	*$39.10*
Consultation items (nurse practitioners)		
82200	*Professional attendance by a participating nurse practitioner for an obvious problem characterised by the straightforward nature of the task that requires a short patient history and, if required, limited examination and management.*	*$10.00* *Benefit: 85% = $8.50*
82205	*Professional attendance by a participating nurse practitioner lasting less than 20 minutes and including any of the following:*	*$21.80* *Benefit: 85% = $18.55*

	a) taking a history; *b) undertaking clinical examination;* *c) arranging any necessary investigation;* *d) implementing a management plan;* *e) providing appropriate preventive health care,* *for 1 or more health related issues, with appropriate documentation.*	
Consultation items (other medical practitioners)		
53	*Professional attendance at consulting rooms of more than 5 minutes in duration but not more than 25 minutes (other than a service to which any other item applies)-each attendance, by:* *(a) a medical practitioner (who is not a general practitioner); or* *(b) a Group A1 disqualified general practitioner, as defined in the dictionary of the General Medical Services Table (GMST).*	*$21.00*

Source: MBS Schedule July 2021

[a] *85% benefit presented as the proposed service is not expected to be rendered to a patient as part of an episode of hospital treatment or hospital-substitute treatment*

5. Population

The ADAR did not explicitly nominate a population for the proposed service.

The population considered in the PDST were adults aged between 35-74 years, who do not have a history of diabetes or prediabetes and have not recently been screened for diabetes. The ADAR financial impact analysis suggests 'recent' to be within 12 months.

The RACGP Guidelines recommend individuals not at high risk should be screened for diabetes every 3 years from 40 years of age using the AUSDRISK™ only.

The Australian Health Survey: Biomedical Results for Chronic Diseases, 2011–12 estimated the prevalence of diabetes (including those diagnosed and undiagnosed) using HbA1c testing (Table 3).

Table 3: Diabetes prevalence based on diagnosis status using HbA1c

	Age Group						
Diabetes status	***18–34***	***35–44***	***45–54***	***55–64***	***65–74***	***≥ 75***	***All (≥ 18)***
Known diabetes	*0.4%**	*2.2%*	*4.0%*	*6.4%*	*12.7%*	*10.5%*	*4.2%*
Newly diagnosed diabetes (previously undiagnosed)	*0.1%***	***0.5%****	***1.3%****	***2.4%***	***2.8%***	*2.3%**	*1.2%*
Total with diabetes	*0.5%**	*2.7%*	*5.3%*	*8.8%*	*15.5%*	*12.8%*	*5.4%*

Source: Table 12.3, Australian Health Survey: Biomedical Results for Chronic Diseases, 2011–12 Australian Bureau of Statistics[2]

** Estimate has a relative standard error of 25% to 50% and should be used with caution*

*** Estimate has a relative standard error greater than 50% and is considered too unreliable for general use*

Bold represents the target population of the proposed service

The Pharmacy Trial Program Evaluation noted that it was intended that the Community Pharmacy Programmes, including the Pharmacy Trials Program, would have a focus on benefits for Aboriginal and Torres Strait Islander people. Although not specifically considered in ADAR, MSAC may wish to consider whether a younger population of Aboriginal and Torres Strait Islander people should be considered eligible for the proposed intervention. The 2018-19 National Aboriginal and Torres Strait Islander Health Survey[3] estimated that 2.5% of the

Aboriginal and Torres Strait Islander people aged 25-34 years had diabetes, which is similar to the estimated prevalence of 2.7% in the broader Australian population aged 35-44 years. The RACGP Guidelines recommend that Aboriginal and Torres Strait Islander peoples should have their risk of diabetes assessed every three years from 18 years of age.

6. Comparator

The comparator in the clinical trial and economic evaluations presented in the ADAR was community pharmacy screening using the AUSRISK™ questionnaire only (Group A).

As community pharmacy screening is intended to complement and not replace any existing screening service the comparator should be usual care. This would be consistent with the 2017 MSAC Guidelines (p19) which states that the primary comparison is likely to be either another investigative medical service in terms of alternate diagnostic method or modality or in some instances 'no testing'/'usual care'.

In this setting usual care for most patients is likely to be opportunistic screening by GPs. The Royal Australian College of General Practitioners guidelines for management of T2DM recommend individuals aged 40 and over not at risk of T2DM should be screened every 3 years using the AUSDRISK™ questionnaire (i.e., Group A). Individuals at a high risk of developing diabetes should be screened with either fasting blood glucose or HbA1c every 3 years, and individuals with impaired glucose tolerance (i.e., Pre-diabetes) should undergo testing every year.

A 2014-15 survey by the Australian Bureau of Statistics found 83% of respondents had seen a GP in the previous year; therefore, the population inaccessible to GP screening for T2DM is unlikely to be large but some people may experience a longer time to a diagnosis in usual care.[4] The applicant's response to the Preliminary Evaluation contended that although patients may visit a GP, this is often for an acute condition and it is known that preventive services are not routinely delivered in general practice. Additionally, even if people have been tested, they may be unaware of their status especially those with prediabetes as observed among a group of screened participants in the trial. The applicant's response to the Preliminary Evaluation stated that it could be argued that Group A received a more intensive screening approach than usual care (no pharmacy screening), presumably creating a strong argument that if another intervention is deemed more effective than group A, as occurred in the PDST, that it would also be more effective than usual care (Applicant Response to Preliminary Evaluation, p7).

The commentary's revised base case includes a comparison against usual care, understood to most likely be opportunistic screening by GPs but there is limited evidence available to inform this comparison.

7. Summary of public consultation input

No public consultation input was received at the time of preparing the commentary.

8. Characteristics of the evidence base

The PDST was a clustered randomised controlled trial that compared the effectiveness of three different pharmacy-based screening models:

1. The paper based AUSDRISK™ assessment of diabetes risk, alone (Group A)

2. AUSDRISK™ followed by a point-of-care (PoC) HbA1c test for those at risk (Group B)

3. AUSDRISK™ followed by a PoC small capillary blood glucose testing (scBGT) for those at risk (Group C)

The focus of the ADAR is a proposal to fund the services provided in Group B.

Table 4: Key features of the included evidence

Criterion	Type of evidence supplied	Extent of evidence supplied	Overall risk of bias in evidence base [a]
Change in patient management	The PDST provides evidence to show that community pharmacy screening of T2DM identifies previously unidentified T2DM and Pre-DM	k=1 n= 14,093	*Significant due to recruiting an inequitable population across the groups*

Abbreviations: k=number of studies, n=number of patients, T2DM – type 2 diabetes mellitus
[a] *Based on the preliminary evaluation*

In the development of AUSDRISK™ a score of ≥ 12 corresponded to the point on the receiver operating characteristic (ROC) curve at which sensitivity (74.0%) plus specificity (67.7%) were maximised for predicting incident T2DM over 5 years.[5]

9. Comparative safety

In its previous consideration of HbA1c PoC for diagnosis of T2DM, MSAC considered that there are no significant acute differences in the safety of the HbA1c PoC testing technique over standard laboratory testing (p2 MSAC 1431 PSD).

10. Comparative effectiveness

The clinical results of the PDST are presented in Table 5.

Table 5: Pharmacy screening diabetes trial results

	Group A (AUSDRISK™ only)	Group B (AUSDRISK™ + PoC HbA1c)	Group C (AUSDRISK™ + PoC scBGT)
Recruited	3,957	5,165	4,971
Know T2DM	s47		
AUSDRISK™ ≥ 12	s47		
Referred to GP	s47		
Visited GP (Self-reported)	s47		
Tested (Self-reported)	s47		
Tested (Medicare data)	s47		
Diagnosed T2DM	s47		
Diagnosed Pre-DM[1]	s47		

Source: PDST Final Report, Figure 11, p76 and Figure 18, p97

[1] Pre-DM defined as HbA1c 5.7%-6.4% or FGB 6.1-6.9 mmol/L

Abbreviations: AUSDRISK™ - Australian type 2 diabetes risk assessment tool; GP – general practitioner; PoC – point of care; Pre-DM - pre-diabetes mellitus; scBGT - small capillary blood glucose testing; T2DM – type 2 diabetes mellitus

Overall, a small number of additional cases of diabetes were detected: s47 of T2DM and s47 Pre-DM across the 14,093 participants screened (s47 and s47 respectively).

This is low, given the expected prevalence of undiagnosed T2DM used in the sample size calculation (s47). The Preliminary Evaluation, however, noted that that the observed rate of new diagnoses of less than 1% is unsurprising because other population-based screening programs returned a similar percentage of new cases. This was also acknowledged in the PDST Final Report (p173 of the PDST Final Report). *The new T2DM diagnoses also corresponded closely with the ABS National Health Survey estimates of undiagnosed diabetes (1.2% in the total adult population).*

Fewer cases were diagnosed in regional areas and very few cases were detected in remote areas. The relative shortage of GPs in regional and remote areas is suggested as a reason for this finding (p172 of the PDST Final Report), on the grounds that it may have been more difficult for regional and remote participants referred by pharmacists to have a diagnosis of T2DM or Pre-DM confirmed.

The Preliminary Evaluation noted that no data was presented to confirm a lower GP attendance rate in referred participants in regional and remote areas (though it could have been extracted from the data set). In any case, it is in communities with a relative shortage of GPs that effective screening by non-GP providers is most desirable, and where the rate of undiagnosed T2DM is generally found to be highest, so the low yield of pharmacy-based screening in regional and remote areas was considered troubling.

The ADAR did not address the issue of a negative assay bias suggesting that the PoC test result is more likely to be less than the laboratory result (p2, Application 1431 PSD). The ADAR did not provide evidence for improved assay precision or whether the assay imprecision associated with HbA1c PoC testing would be less critical in the context of screening asymptomatic individuals.

Clinical claim

The ADAR's clinical claim is that Group B (AUSDRISK™ + PoC HbA1c) is the most effective community pharmacy screening option, leading to the most T2DM diagnoses per person screened. *This appears to be true for T2DM diagnoses, but not for Pre-DM, where Group A (AUSDRISK™ only) lead to the most Pre-DM diagnoses per person screened.*

The ADAR did not make a clinical claim with respect to usual care. The ADAR did not provide any clinical evidence demonstrating that pharmacy-based diabetes screening using AUSDRISK™ + HbA1c PoC testing is superior to usual care for diagnosing T2DM and Pre-DM.

There is some suggestive evidence that AUSDRISK™ + HbA1c PoC would result in more 'earlier' diagnoses of T2DM; however, there is also suggestive evidence that AUSDRISK™ only would result in more 'earlier' diagnoses of Pre-DM. Therefore, the preferred option for community pharmacy-based opportunistic screening remains unclear. In addition, no evidence is provided on the how much 'earlier' these diagnoses would occur.

11. Economic evaluation

The ADAR economic evaluation comprises both a within-trial evaluation estimating the cost per additional T2DM (and Pre-DM) diagnosis and a modelled cost-utility extrapolation.

The ADAR included several alternative cost-utility models. The ADAR (PDST Final Report) stated that Model 4.3 was the preferred model. *This model is the focus of the commentary.*

The modelled economic evaluation did not compare pharmacy-based screening with usual care.

The cost-utility analysis uses a short-term decision tree model covering the one-off community pharmacy screening phase followed by a long-term Markov cohort model extrapolating the impact of diagnosed T2DM, undiagnosed T2DM, diagnosed Pre-DM, and No DM detected, on lifetime costs and QALYs.

Table 6: Summary of the economic evaluation

Component	Description
Perspective	Health care system perspective
Population	Adult (35-75) population of Australia without a prior T2DM diagnosis
Underlying prevalence (T2DM / Pre-DM)	Group A (AUSDRISK™ only) – s47 Group B (AUSDRISK™ + PoC HbA1c) – s47 Group C (AUSDRISK™ + PoC scBGT) – s47
Prior testing	No prior diagnosis of T2DM – opportunistic community pharmacy screening programme
Comparator	Relative cost-effectiveness of **one-off screening** using: Group A (AUSDRISK™ only) Group B (AUSDRISK™ + PoC HbA1c) Group C (AUSDRISK™ + PoC scBGT)
Type(s) of analysis	1. Within-trial cost-effectiveness analysis 2. Modelled cost-utility extrapolation
Outcomes	1. Cost per T2DM diagnosis / cost per Pre-DM diagnosis 2. Cost per QALY gained
Time horizon	1. N/A 2. Lifetime (Cohort all dead 60 years post screening)
Computational method	1. N/A 2. Short-term decision tree & long-term Markov cohort models
Generation of the base case	1. Trial-based 2. Modelled • Total cost & QALYs for diagnoses - T2DM (+/-Intensive Tx), Pre-DM (+/- Lifestyle Tx), No DM calculated in long-term Markov cohort models • Total cost & QALYs applied to short-term decision tree to determine cost effectiveness of alternative screening options
Health states	Short-term decision tree **terminal nodes**: • Diagnosed T2DM (+/-Intensive Tx) • Undiagnosed T2DM • Diagnosed Pre-DM (+/- Lifestyle Tx) • No DM detected Long-term Markov cohort model **health states**: • No complication • Post CVD • End stage renal disease (ESRD) • Blindness • Amputation • Death
Cycle length	1 year (with half-cycle correction)
Discount rate	s47 for both costs and outcomes

Component	Description
Software	Microsoft Excel (Trial-based economic evaluation) TreeAge Pro (Short-term decision tree & Long-term Markov cohort models)

Source: Compiled based on the PDST Final Report and Appendices

Abbreviations: AUSDRISK™ - Australian type 2 diabetes risk assessment tool; DM – diabetes mellitus; PoC – point of care; Pre-DM – pre-diabetes mellitus; scBGT - small capillary blood glucose testing; Tx – treatment; T2DM – type 2 diabetes mellitus

Within-trial economic evaluation

The costs, which are applied to each cohort, included in the ADAR within-trial evaluation are:

1. Cost of community pharmacy screening
2. Cost of GP follow-up

The ADAR includes two alternative costing methods for the cost of community pharmacy screening – one in the within-trial economic evaluation, which is also used in the modelled economic evaluation, and one in the financial impact analysis which applied a fee for pharmacy screening. The ADAR economic evaluation costs of community pharmacy screening significantly exceed that in the ADAR financial impact analysis.

The ADAR's approach to costing GP follow-up excludes participants who visited the GP but did not receive pathology testing according to Medicare. Therefore, the ADAR's approach may have underestimated the total cost of GP follow-up.

In calculating these costs, the ADAR's within-trial economic evaluation takes a wider perspective, including the following costs that are not usually considered by MSAC for MBS reimbursement purposes:

- *PDST establishment and recruitment costs*
- *PDST bonus paid to pharmacies for screening*
- *PoC device capital costs.*

The commentary includes a revised within-trial evaluation, removing these clinical trial and capital costs. This resulted in a revised cost of s47 *per screened patient in Group B (AUSDRISK™ +HbA1c) including consumables. This was higher than the weighted average screening service cost of* s47 *in the financial estimates which excluded consumables.*

The ADAR does not address pathology coning of HbA1c tests. Previously, the MSAC executive considered it would be reasonable to assume between 60 – 90% of laboratory HBA1c tests will be coned out (p3, PSD Application 1431.1). Across all groups, s47 *participants received diagnostic testing during GP follow-up according to Medicare data, whereas* s47 *participants self-reported receiving diagnostic testing. Perhaps this difference was due to coning, but the ADAR does not present any data to support this theory. Significant uncertainty regarding the costs remain.*

Within-trial totals costs are compared to the number of T2DM diagnoses to generate the incremental cost-effectiveness results, presented for the ADAR and revised evaluations (removing costs trial and capital costs) in Table 7.

Table 7: Results of ADAR and revised within-trial evaluation – T2DM diagnoses (Incremental vs. Group A)

	Cost	Inc. Cost	T2DM Diagnoses	Inc. T2DM Diagnoses	ICER ($ per T2DM Diagnosis)
ADAR					
Group A (AUSDRISK™ only)	s47				
Group B (AUSDRISK™ + PoC HbA1c)	s47				
Group C (AUSDRISK™ + PoC scBGT)	s47				
Revised [a]					
Group A (AUSDRISK™ only)	s47				
Group B (AUSDRISK™ + PoC HbA1c)	s47				
Group C (AUSDRISK™ + PoC scBGT)	s47				

Source: ADAR – PDST Final Report, Table 42, p151; Revised – MSAC 1677 Revised Within-trial.xlsx

Abbreviations: AUSDRISK™ - Australian type 2 diabetes risk assessment tool; ICER – incremental cost-effectiveness ratio; Inc. – incremental; PoC – point of care; scBGT – small capillary blood glucose testing; T2DM – type 2 diabetes mellitus

[a] *Revised screening cost per participant was* s47 *for Group A,* s47 *for Group B, and* s47 *for Group C.*

In the ADAR within-trial evaluation, Group C is dominated by Group A. Group B is associated with an ICER of s47 per additional T2DM diagnosis compared to Group A.

The removal of costs not normally considered in the revised within-trial evaluation does not significantly impact the within-trial cost per T2DM diagnosis. The revised cost of community pharmacy screening per participant screened is closer to that used in the ADAR's financial impact analysis.

The ADAR includes a series of univariate sensitivity analysis revealing the key drivers of the results of the within-trial economic evaluation (Figure 8). The within-trial economic evaluation is most sensitive to the HbA1c cut-off for referral, HbA1c PoC test strips unit price, HbA1c diagnostic threshold, AUSDRISK™ cut-off for referral and the definitions of DM and Pre-DM.

Modelled economic evaluation

The modelled evaluation included a short-term decision tree that mirrors the design of the PDST, with the eligible population screened at community pharmacy, referred to GP, diagnostic tested and then diagnosed. Long term outcomes were modelled using Markov cohort model has a similar structure to common reference models in T2DM, chiefly the United Kingdom Prospective Diabetes Study (UKPDS) model.[6]

There is research suggesting the first UKPDS overestimates risk of T2DM-related health events in the Australian T2DM population.[7]

The short-term decision tree does not define a consistent underlying prevalence of undiagnosed T2DM and Pre-DM at the start of the model for each group, the underlying prevalence is 'revealed' through the proportions that achieve a T2DM or Pre-DM diagnosis or remain undiagnosed at the end of the model. Undiagnosed Pre-DM is not considered and thus implicitly set to zero in the model.

Given this decision tree structure, estimates for two parameters were not available from the PDST:

1. The proportion of those not referred with T2DM (false negatives among non-referred)
2. The undiagnosed prevalence among those referred.

In the ADAR's modelled evaluation these are informed by AusDiab on recommendation from the PDST Expert Panel, presented in Table 8.

Table 8: Short-term decision tree parameters informed by AusDiab data

Parameter	Group A (AUSDRISK™ only)	Group B (AUSDRISK™ + PoC HbA1c)	Group C (AUSDRISK™ + POC scBGT)
False negative among non-referred	s47		
Undiagnosed prevalence among referred	s47		

Source: PDST Final Report, Appendix 12

Abbreviations: AUSDRISK™ - Australian type 2 diabetes risk assessment tool; PoC – point of care; scBGT - small capillary blood glucose testing

It is inconsistent for each screening option to be associated with the same undiagnosed prevalence among referred participants (who then did not attend their GP). Given the screening options are not expected to have the same sensitivity, the prevalence of T2DM among those referred would not be the same.

Given these parameters, the assumed underlying prevalence of T2DM and Pre-DM is presented in Table 9 for the ADAR base case.

Table 9: Short-term decision tree outcomes

Outcome	Group A (AUSDRISK™ only)	Group B (AUSDRISK™ + PoC HbA1c)	Group C (AUSDRISK™ + PoC scBGT)
T2DM	s47		
Undiagnosed	s47		
Diagnosed	s47		
Intensive Tx [a]	s47		
No Intensive Tx [a]	s47		
Pre-DM	s47		
Undiagnosed	s47		
Diagnosed	s47		
Lifestyle Tx	s47		
No Lifestyle Tx	s47		
No DM	s47		

Source: Compiled from PDST_CEA_Model4.3.trex

[a] As in the UKPDS, Intensive Treatment comprised either sulfonylurea or insulin or, in overweight patients, metformin for glucose control. No Intensive Treatment was the conventional therapy, i.e., diet modification.

Abbreviations: AUSDRISK™ - Australian type 2 diabetes risk assessment tool; DM – diabetes mellitus; Pre-DM – pre-diabetes mellitus; PoC – point of care; scBGT - small capillary blood glucose testing; T2DM – type 2 diabetes mellitus; Tx – treatment

In the ADAR base case, Group A has a higher prevalence of underlying T2DM and Pre-DM than both Group B and Group C.

This inconsistent underlying prevalence of T2DM and Pre-DM is the major driver of incremental costs and QALYs.

The probability of participation in Intensive Treatment for T2DM patients (80%) was an assumption, *with no justification or threshold sensitivity analysis provided in the ADAR.*

The ADAR economic evaluation assumes that screening for T2DM only occurs once in a patient's lifetime, at the community pharmacy, and if they remain undiagnosed at this point, they will remain undiagnosed for the rest of their life. This is unlikely and will overestimate incremental QALYs for community pharmacy screening vs. usual care. Instead, it is probable that patients with undiagnosed T2DM would have been diagnosed by their GP at some later date if they had not been referred through community pharmacy screening. Therefore, implementing community pharmacy screening for T2DM may not diagnose many more patients, but simply diagnose T2DM earlier than under the usual care of opportunistic screening by GPs.

There are also a number of other limitations that impact the model's incremental results:

- *The model does not explicitly capture undiagnosed Pre-DM.*
- *A coding error applying Intensive Treatment costs to the No Intensive Treatment arm.*
- *The use of costs from 2003 without inflation or consideration of the current price level.*
- *The unjustified use of a discount rate (s47) not recommended by MSAC guidelines.*
- *Costs not normally considered allocated to community pharmacy screening.*
- *An inconsistency in the cost of GP follow-up.*
- *The misinterpretation of all-cause mortality data from the literature.*

Based on the available evidence, a revised base case has been developed to address these limitations in the ADAR's modelled economic evaluation.

Results

The results of the Markov cohort models are applied to the screening outcomes of the short-term decision tree to generate the ADAR base case results, presented in Table 9.

Table 10: Results of ADAR base case (Incremental vs. Group A)

	Cost	Inc. Cost	QALYs	Inc. QALYs	ICER ($/QALY)
ADAR base case					
Group A (AUSDRISK™ only)	s47				
Group B (AUSDRISK™ + PoC HbA1c)	s47				
Group C (AUSDRISK™ + PoC scBGT)	s47				

Source: Compiled from PDST_CEA_Model4.3.trex and MSAC 1677 - Revised DTree (Incon Prev).trex

Abbreviations: AUSDRISK™ - Australian type 2 diabetes risk assessment tool; ICER – incremental cost-effectiveness ratio; Inc. - incremental; POC – point of care; scBGT - small capillary blood glucose testing

These incremental results are driven by the inconsistent underlying prevalence of T2DM and Pre-DM across the groups.

Revised Base Case - Methods

A revised base-case was developed, based on the available evidence, to provide the Committee with relevant information to inform the funding question. The key revisions include:

- *A consistent underlying prevalence of T2DM and Pre-DM using the prevalence figures for Group A (AUSDRISK™ only) from the base case analysis (T2DM –* s47 *, Pre-DM* s47 *.*

This revision is presented for Group B in Figure 1, with revision for Group C performed in an identical manner. The model is not sensitive to the overall underlying prevalence of T2DM and Pre-DM, only to the proportion that receive a diagnosis through screening.

- s47 *of undiagnosed T2DM patients received a delayed diagnosis three years later. Three-yearly screening is consistent with the RACGP guidelines.[1] Consistent with the ADAR decision tree, 80% of those diagnosed with T2DM would receive Intensive Treatment. Based on this assumption,* s47 *remained undiagnosed for life.*
- *Incorporating a usual care group (Group D) into the short-term decision tree, presented in Figure 2. In this arm, patients do not receive community pharmacy screening and are allocated to Undiagnosed T2DM, Undiagnosed Pre-DM, and No DM, based on the underlying prevalence in the population. In this arm, the same proportion of T2DM patients (*s47*) received a 'delayed diagnosis' after three years.*
- *Inflated the cost of T2DM-related health events to 2020 price levels*
- *Applied a 5% discount rate (*s47 *in the ADAR).*

Additional revisions are presented in Table 49 of the main body.

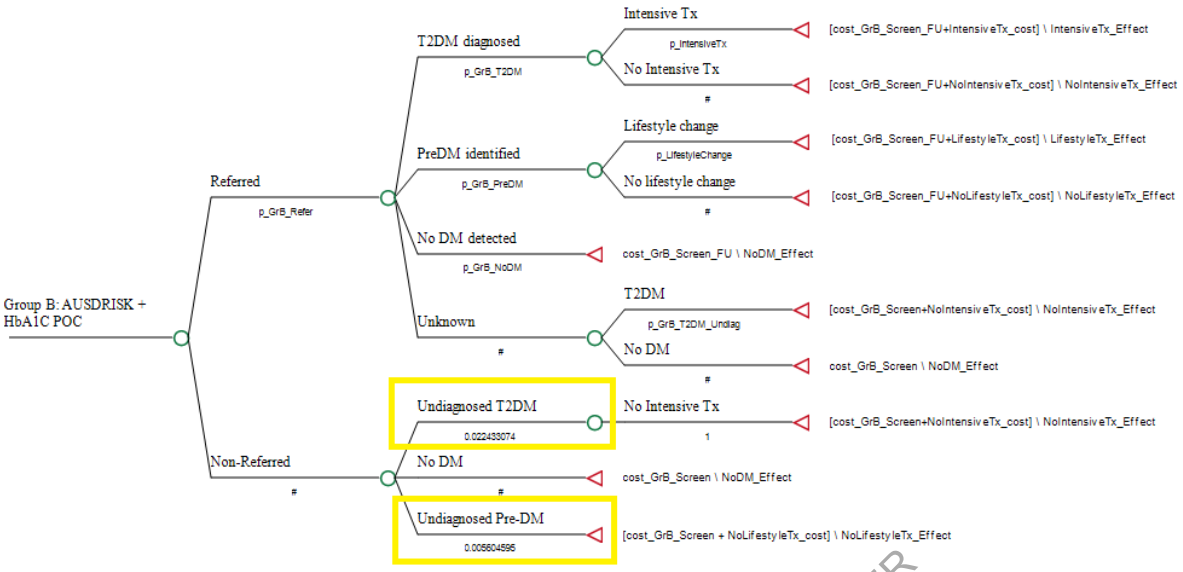

Figure 1: Revised base case – Undiagnosed Pre-DM

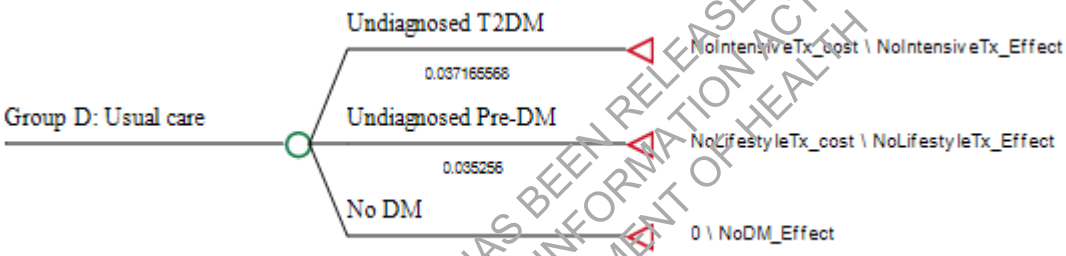

Figure 2: Revised base case - Usual care

Results

Table 11 presents the result of the analysis relevant to the funding question – a comparison against Group D (Usual care) with a consistent underlying prevalence of T2DM and Pre-DM applied across the groups.

Table 11: Results of revised base case (Incremental vs. Group D)

	Cost	Inc. Cost	QALYs	Inc. QALYs	ICER ($/QALY)
Group D (Usual care)	s47				
Group A (AUSDRISK™ only)	s47				
Group B (AUSDRISK™ + PoC HbA1c)	s47				
Group C (AUSDRISK™ + PoC scBGT)	s47				

Source: MSAC 1677 - Revised DTree (Con Prev).trex

Abbreviations: AUSDRISK™ - Australian type 2 diabetes risk assessment tool; ICER – incremental cost-effectiveness ratio; Inc. - incremental; POC – point of care; scBGT - small capillary blood glucose testing

In this analysis, incremental QALYs are very low for all community pharmacy screening options versus usual care, leading to ICERs over s47 */QALY.*

No sensitivity analysis was performed on the ADAR's modelled economic evaluation.

The ADAR and revised base case analyses contains a number of limitations worth noting:

- *The long-term Markov models remains populated with cost data from 2003 for the intensive treatment of T2DM and benefit data from 1998 or 2008 for the treatment of T2DM and Pre-DM, which are the key drivers of incremental costs and QALYs. The costs of some diabetes treatments will have changed since then and newly funded treatments for diabetes have since been added to the PBS.*
- *In the revised base case, patients who progress from Pre-DM to T2DM are not modelled in the same way as T2DM patients diagnosed at community pharmacy screening (i.e., not exposed to T2DM-related health events).*
- *The concept of delayed diagnosis by GPs after a time lag of three years is not informed by trial data. In addition, there is evidence of a 'legacy' effect such that early intensive treatment for T2DM may translate into future benefits even after the delayed diagnosis. There remains significant uncertainty around the size of the benefits of earlier diagnosis.*
- *The participation rate for Intensive Treatment for T2DM remains an assumption.*

These limitations notwithstanding, the revised base case provides valuable, relevant information to inform MSAC's consideration of whether public funding of community pharmacy-based screening would be cost effective compared to usual care.

Conclusions

Inconsistencies in the ADAR model are the key drivers of its incremental cost-effectiveness results. After adjusting, and comparing with the appropriate comparator, usual care, none of the community pharmacy screening options appear to be cost effective, noting that considerable uncertainties remain regarding the evidence.

A higher cost per QALY may be acceptable if wider screening in community pharmacies would lead to more equitable access to Intensive Treatment for T2DM, but no evidence on this has been presented.

12. Financial/budgetary impacts

The ADAR uses an epidemiological approach to estimating financial impact using the proportion of the population who would be eligible for community pharmacy screening for T2DM. The ADAR uses Group B (AUSDRISK™ + PoC HbA1c) as the funded programme in the financial impact analysis.

The ADAR assumes the population eligible for community pharmacy screening for T2DM is people aged 35-74 who have not been diagnosed or screened for diabetes in the last 12 months. *This implies that individuals could be screened yearly - at a higher frequency of screening than that suggested by the RACGP, who recommend every 3 years in their guidelines for the management of T2DM.*[1]

Table 12 presents the population parameters used in the financial impact analysis. The uptake of the eligible population is the key parameter that influences the overall financial impact. *This is estimated by expert opinion in the ADAR analysis. The uptake is also likely to be heavily influenced by the financial reimbursement offered to pharmacies to undertake T2DM screening.* The ADAR estimated that s47 of the total aged 35-74 Australian population would be eligible for community pharmacy screening. *The assumed eligible population relies on criteria for how often individuals should be screened.*

Based on the epidemiological estimates, 1.7% of the eligible population has undiagnosed T2DM. This is below all of the estimates provided in the ADAR's economic base case and scenarios (s47 to s47).

The ADAR's financial impact analysis assumes that community pharmacy screening is not associated with cost offsets of reduced GP screening for T2DM.

Table 12: Population data sources applied in financial estimates

Data	Source and value	Justification
Population of Australia aged 35-74	ABS – 12,051,931	-
Prevalence of T2DM diabetes, aged 35-74	AIHW - 5.7%	-
Prevalence of Pre-DM, aged 35-74	AIHW - 13.0%	-
Percentage of T2DM already diagnosed	The Boden Institute – 71.0%	-
Percentage of Pre-DM already diagnosed	Estimate (PDST) – s47	-
Percentage of people already screened in the last 12 months	Estimate (Expert) – s47	-
Undiagnosed T2DM	s47	*See text below*
Undiagnosed Pre-DM	s47	*See text below*

Source: Budget Impact Analysis - Pharmacy Diabetes Screening Service Final for Submission

[1] The population of interest can be calculated as s47 The subsequent estimate of undiagnosed T2DM is s47

[2] The population of interest can be calculated as s47 The subsequent estimate of undiagnosed Pre-DM is s47

Abbreviation: ABS - Australian Bureau of Statistics; AG – assessment group; AIHW – Australian Institute of Health and Welfare; Pre-DM – pre-diabetes mellitus; PDST – pharmacy diabetes screening trial; T2DM – type 2 diabetes mellitus

Table 13 presents the pharmacy data used in the ADAR financial impact analysis.

Table 13: Pharmacy data applied in the financial estimates

Data	Source and value	Justification
Screened and referred	PDST – s47 p.a.	-
Referral uptake	PDST – s47 p.a.	Conditional on screened and referred
Diagnosis testing	PDST – s47 p.a.	Conditional on referral uptake
T2DM diagnosis	PDST – s47 p.a.	Conditional on diagnosis testing
Pre-DM diagnosis	PDST – s47 p.a.	Conditional on diagnosis testing
Expected number of eligible pharmacies	Pharmacy Guild - s47	Reflects the proportion of pharmacies expected to meet eligibility criteria.
Measuring tape unit cost	PDST - s47	-
PoC test device	PDST - s47	-
PoC & measurement device cost per pharmacy per annum	s47	**Used in the final financial impact calculation**
PoC consumables cost per participant screened	s47	**Used in the final financial impact calculation**
PoC test consumables	PDST - s47	Total consumables based on the trial expenses provided by the Pharmacy Guild. *Higher than $10/test in MSAC 1431.1 (p15, 1431 PSD)*
Short consultation - AUSDRISK™ & counselling service cost	PDST - s47	Participants with AUSDRISK™ < 12 who did not receive PoC testing
Standard consultation - AUSDRISK™ + HbA1c PoC testing, counselling & referral	PDST - s47	Participants with AUSDRISK™ ≥ 12 who did receive PoC testing
Cost of community pharmacy screening per participant screened	PDST - s47	Weight average of short and standard consultation **Used in the final financial impact calculation**
GP Consultation	MBS item 23 - $38.75	-
T2DM Pathology testing	MBS - various	-
Cost of GP follow-up per T2DM and Pre-DM diagnosis	Calculation - s47	**Used in the final financial impact calculation**

Source: Budget Impact Analysis - Pharmacy Diabetes Screening Service Final for Submission

Abbreviations: ABS - Australian Bureau of Statistics; AIHW – Australian Institute of Health and Welfare; Cum – cumulative; DM – diabetes mellitus; Inc. - incremental; MBS – Medicare benefits schedule; p.a. – per annum; PEI – patient episode initiation; PDST – pharmacy diabetes screening trial; PoC – point of care; scBGT - small capillary blood glucose testing; T2DM – type 2 diabetes mellitus

The ADAR financial impact analysis includes the same PoC device capital cost as the ADAR within-trial economic evaluation. *A revised financial impact was estimated removing the PoC device capital and consumable costs.*

The number of Group B (AUSDRISK™ + HbA1c PoC) participants who received a short and standard consultation used in the financial impact analysis do not match Figure 11 of the PDST Final Report which shows s47 and (s47 - s47 =) s47 , respectively.

The GP follow-up cost in the ADAR's financial impact analysis is per diabetes (T2DM or Pre-DM) diagnosis, which resulted a significantly higher GP follow-up cost than that in the economic analysis (i.e. s47 *vs* s47 *).*

In the revised financial impact analysis, the cost of GP follow-up was revised to align with how the GP follow up costs calculated for the economic analysis.

Table 14 presents the financial impact calculations.

Table 14: Financial implications of community pharmacy screening for T2DM for the first 5 years

Parameter	Year 1	Year 2	Year 3	Year 4	Year 5
Number of participants					
Eligible	s47				
Screened	s47				
AUSDRISK™ < 12	s47				
AUSDRISK™ ≥ 12 + PoC	s47				
Referred	s47				
Visit GP	s47				
Diagnosis tested	s47				
T2DM diagnosed	s47				
Pre-DM diagnosed	s47				
Financial Impact					
Pharmacy Screening costs	s47				
PoC device & consumables	s47				
Screening service	s47				
GP Follow-up costs	s47				
Total (p.a.)	s47				
Cumulative	s47				
Revised Financial Impact (net cost to government)					
Pharmacy Screening costs	s47				
GP Follow-up costs [a]	s47				*043*
Total (p.a.)	s47				
Cumulative	s47				

Source: ADAR - Budget Impact Analysis - Pharmacy Diabetes Screening Service Final for Submission; Revised – MSAC 1677 – Revised Financial Implications.xlsm

Italics represent revised results estimated by the assessment group.

Abbreviations: GP – general practitioner; p.a. – per annum; PoC – point of care; T2DM – type 2 diabetes mellitus

[a] *For patients who visit their GP*

The ADAR financial impact analysis suggests the 5-year cumulative financial impact of adopting community pharmacy screening for T2DM using the AUSDRISK™ + PoC HbA1c would be approximately s47 . *The revised financial impact analysis suggests this figure is significantly lower, approximately* s47 *over 5 years.*

The financial impact of community pharmacy screening is heavily influenced by the proportion of the eligible population that use the service which was informed by expert opinion.

Doubling the proportion of eligible patients who receive screening (which was based on expert opinion) almost exactly doubles the revised financial impact. Therefore, considerable uncertainty remains as to the true financial impact. The numbers screened per year is likely to depend on whether the financial reimbursement to pharmacies is high or low compared to the work involved.

The ADAR analysis also does not include the additional costs related to the increased use of Intensive Treatment for T2DM or Lifestyle Treatment for Pre-DM, respectively.

13. Committee-in-confidence information

Table 15: Committee-in-confidence information

New	Category 6 – PATHOLOGY SERVICES Group P9 – Simple Basic Pathology Tests
73812	Quantitation of glycated haemoglobin (HbA1c) via Point of Care testing performed using a National Glycohemoglobin Standardization Program (NGSP) certified instrument with a total coefficient of variation (CV) <3.0% at 48 mmol/mol (6.5%) in the management of established diabetes; a maximum of three Point of Care tests in a 12-month period and a maximum of four glycated haemoglobin tests in total (Point of Care and laboratory) in a 12 month period. (Item is subject to rule 25). (Item is subject to RACGP Point of Care Testing Standards accreditation requirements. Item is subject to restrictions in rule PR.9.X of explanatory notes to this category) Fee: $11.80 Benefit: 75% = $8.85; 85% = $10.05 Extended Medicare Safety Net Cap (if applicable): N/A

Rules of Interpretation

Rule 25(##): For any particular patient, item 738XX (HbA1c PoC) and item 66551 (HbA1c laboratory testing) are not applicable more than four times in total in a 12-month period, and item 738XX is not applicable more than three times in a 12-month period.

PR.9.2 Point of Care in General Practice item

Item number 738XX (HbA1c Point of Care testing) can only be performed in the following circumstances:

a) the service is rendered by or on behalf of a medical practitioner; and

b) the practitioner referred to in paragraph (a), or the organisation for which the practitioner works, is accredited to the RACGP Point of Care Testing Standards.

Acronyms and abbreviations

ABS	Australian Bureau of Statistics
AIHW	Australian Institute of Health and Welfare
AUSDRISK™	Australian type 2 diabetes risk assessment tool
CVD	cardiovascular disease
DM	diabetes mellitus
HbA1c	glycated haemoglobin
ICER	incremental cost-effectiveness ratio
MSAC	Medical Services Advisory Committee
OGTT	oral glucose tolerance test
PDST	Pharmacy Diabetes Screening Trial
POC	point of care
Pre-DM	pre-diabetes mellitus
QALY	quality-adjusted life year
scBGT	small capillary blood glucose testing
T2DM	type 2 diabetes mellitus

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exempt

Australian Government
Medical Services Advisory Committee
Evaluation Sub-committee

ESC Meeting
7 October 2021

Application 1677 – Pharmacy Diabetes Screening Trial (PDST)

ACTIONS

That ESC:

1. DISCUSS the following key issues:
   a. appropriateness of the proposed use of opportunistic HbA1c Point of Care (PoC) testing in community pharmacies as a screening tool for patients with an AUSDRISK score of 12 or greater.
   b. eligibility of patients.
   c. frequency of testing.
   d. service fee arrangement for the intervention.
   e. appropriateness of the comparator used for trial.
   f. appropriateness of pharmacy and pharmacist accreditation.

2. NOTE that MSAC has:
   a. supported the MBS listing of new Item # 73812 for the quantitation of glycated haemoglobin via Point of Care testing in the management of established diabetes.
   b. rejected an application for PoC glycated haemoglobin testing as an alternative to HbA1c testing in an accredited laboratory for the diagnosis of diabetes in asymptomatic patients.

BACKGROUND

With the rising prevalence of type 2 diabetes in Australia, screening and earlier diagnosis is needed to provide opportunities to intervene with evidence-based lifestyle and treatment options to reduce the individual, social and economic impact of the disease. It is estimated that there are 500 000 Australians with undiagnosed Type 2 Diabetes Mellitus (T2DM).

Implemented between October 2017 and November 2019, the objectives of the Pharmacy Diabetes Screening Trial (PDST) were to compare the clinical effectiveness and cost-effectiveness of three screening models for T2DM in a previously undiagnosed population. The trial included the following pharmacy-based models:

i. The paper-based Australian Type 2 Diabetes Risk Assessment Tool (AUSDRISK) assessment of diabetes risk, alone (Group A);
ii. AUSDRISK followed by a point-of-care (POC) glycated haemoglobin (HbA1c) test (Group B); and
iii. AUSDRISK followed by a POC small capillary blood glucose test (scBGT) (Group C).

The PDST was not designed to determine whether any of the above options was effective compared with usual care, which for most patients is likely to be opportunistic screening for T2DM by GPs using AUSDRISK every 3 years for patients not at high risk according to *The Royal Australian College of General Practitioners (RACGP)* standards for PoC.

The primary clinical hypothesis was that the addition of either a HbA1c POC test (Group B) or a POC scBGT test (Group C) to the AUSDRISK assessment would be associated with a statistically significant increase in the proportion of newly diagnosed T2DM cases compared

with AUSDRISK assessment alone. Additional clinical hypotheses related to the primary hypothesis were that compared with Group A, Groups B and C would be associated with a lower rate of referral to the GP and higher rates of referral uptake, and subsequent newly diagnosed prediabetes, (i.e., Impaired Fasting Glycaemia (IFG) or Impaired Glucose Tolerance (IGT)) or a composite of diabetes or prediabetes.

In the trial, 339 pharmacies recruited 14,093 participants aged 35-74 years, of whom 136 s47 people were diagnosed with T2DM, and 338 s47 people were found having pre-diabetes. The diagnosis of T2DM as a proportion of the total screened population being higher in Group B s47 than in Group A s47 and Group C s47 Using referred participants as the denominator, the rates of diagnosis of T2DM were higher in Group B s47 compared with Group A s47 and Group C s47 . Rates of qualifying for referral were lower in Groups B s47 and C s47 compared with Group A s47 and rates of referral uptake were higher in Groups B s47 and C s47) compared with Group A s47

The core economic analysis hypothesis was that the addition of either a HbA1c POC test after AUSDRISK screening, followed by a referral to GP, if appropriate, was 'cost-effective' in comparison to AUSDRISK screening alone from a health funder's (i.e. the Department/Government) perspective. The cost-effectiveness of a community pharmacy based AUSDRISK based opportunistic screening program compared to current practice has not been assessed.

The trial-based economic evaluation supported the Group B option (AUSDRISK followed by a POC HbA1c test) as the preferred option for T2DM screening in pharmacies as it dominated AUSDRISK screening alone, having regard to longer term health and patient outcomes.

MSAC has supported the listing of new MBS Item 73812 for the quantitation of glycated haemoglobin via Point of Care testing in the management of established diabetes. This is with a maximum of three PoC tests in a 12 month period (and a maximum of 4 glycated haemoglobin tests in total (PoC plus laboratory testing) in a 12 month period. The fee allocated is $11.80 Benefit (75%=$8.85) which does not include capital costs or the costs of consumables.

The MSAC has rejected an application for PoC glycated haemoglobin testing as an alternative to HbA1c testing in an accredited laboratory for the diagnosis of diabetes in asymptomatic patients.

In addition, MBS Item 701(fee of $61.75) for a GP consultation is used for a health assessment lasting <30 mins in patients aged 40-49 with a high risk of developing T2DM as assessed by the AUSDRISK score.

POLICY AND IMPLEMENTATION ISSUES

While the aim of the PDST is understood to provide a more convenient avenue for diabetes screening in the community, there are several issues that need to be considered:

1. Eligibility for proposed screening

The PDST entry requirements included people aged 35-74 years, who did not have a history of diabetes or pre-diabetes and had not undergone screening for diabetes in the past 12 months. Those with a AUSDRISK score of 12 or greater were either referred to a GP, underwent HbA1c, or, undertook random blood glucose, as this score is accepted as an indication of high risk for developing diabetes.

The screening for diabetes in the entry requirements is not defined. It may include HbA1c, fasting blood glucose or glucose tolerance testing. Furthermore, there is an issue for the pharmacy to identify whether patients had undergone screening for diabetes in the past 12 months or even whether diabetes had been diagnosed. Consideration should be given to pharmacists accessing My Health Record for patients to determine if prior testing or other evidence is available to determine eligibility.

An identified issue is whether the persons undergoing screening in community pharmacies will be people less likely to visit GPs, and whether in this group (not defined) earlier diagnosis of diabetes may be the result with anticipated better health outcomes.

ESC is requested to consider whether the entrance eligibility should be people aged 40 or greater who have an AUSDRISK score of 12 or greater(this aligns with MBS Item 701).

Since the prevalence of T2DM in the Aboriginal and Torres Strait Islander population is much higher including a higher aged-matched prevalence of diabetes, lowering the entry age, eg. 25 years, should also be considered for this population.

Furthermore, ESC is requested to consider whether patient eligibility should be restricted to those:

- who have not been previously diagnosed with diabetes or prediabetes;
- who have not been screened for diabetes in the last 12 months;
- who have not enrolled in any lifestyle change programs for T2DM;
- who do not have a terminal illness or certain blood disorders; (including severe haematological diseases, e.g. thrombocytopaenia, leukaemia; shorter erythrocyte lifespan, e.g. renal anaemia, chronic and haemolytic anaemia, acute blood loss, and recent transfusion; haemoglobinopathy and red cell turnover disorders; and iron deficiency anaemia); and
- who are not pregnant;
- who are not participating in the Coordinated Veterans Care (CVC) program; and
- have the capacity to provide informed consent to undergo the service.

2. Comparator used for the Trial

The comparator used in the trial was referral to a GP for patients with an AUSDRISK score of at least 12. ESC is requested to consider the whether the appropriate comparator should have been usual care, that is, *opportunistic monitoring* by a GP. As mentioned previously, the RACGP recommendation is screening for diabetes in non-high risk patients aged 40 years and over by monitoring AUSDRISK scores every 3 years.

3. Frequency of testing

As mentioned earlier, the RACGP standards for PoC testing recommend that patients 40 years and over who are not at risk of T2DM should be screened every 3 years by AUSDRISK questionnaire. In addition, individuals with risk factors for diabetes should be tested with fasting blood glucose or HbA1c every 3 years.

ESC is requested to consider potential repeat access for patients who had an AUSDRISK of 12 or greater but who had a 'normal" HbA1c level.

4. Accreditation of pharmacies and pharmacists

Since pharmacists who participated in the PDST were required to undertake an education program and satisfy certain criteria and pharmacies were required to satisfy specific requirements including a separate consulting room, consideration needs to be given to pharmacy and pharmacist accreditation requirements, including:

- MSAC position on POC HbA1c testing, and accreditation standards for pharmacists and pharmacies.

- Options for accreditation standards include, but not limited to those currently applied for non-pharmacy PoC testing (eg conducted by external agency such as Flinders University), or through accreditation by the Pharmaceutical Society of Australia and/or the Pharmacy Guild of Australia

Although community pharmacies that perform PoC testing fall outside the scope of the proposed NPAAC Requirements for Point of Care Testing (First Edition 20xx), the requirements would provide guidance on good practice for the performance of PoC testing in other health care settings such as pharmacies

ESC is also requested to consider whether there should be similar requirements to MBS Item 73812 in regard to the use of a certified instrument for testing.

5. Quality assurance of testing devices

ESC is requested to give consideration to performance criteria currently applied to MBS item 73812for GP PoC testing devices and their application to PoC testing for HbA1c in community pharmacies.

6. Auditing requirements

The Department recommends that consideration be given to processes for auditing pharmacies and pharmacists, including adequate record keeping of test results, and consequence and evidence of referrals where appropriate.

FINANCIAL IMPACT

The applicant's financial impact analysis estimated s47 over five years, if the second screening model (AUSDRISK plus PoC HbA1c) was to be publically funded. This amount included capital costs for pharmacies, but did not include the additional costs related to the increased use of Intensive Treatment for T2DM or Lifestyle Treatment for Pre-DM, respectively.

After removing capital costs to pharmacies, the estimated cost to government would be s47 over 5 years.

The financial estimates were uncertain and sensitive to the proportion of the eligible population who would use community pharmacy screening, which was based on expert opinion.

Doubling the proportion of eligible patients who receive screening almost exactly doubles the revised financial impact. Therefore, considerable uncertainty remains as to the true financial impact. The numbers screened per year is likely to depend on whether the financial reimbursement to pharmacies is high or low compared to the work involved.

***Appropriate Service* Fee and Structure**

During the trial, pharmacists were paid $10.00 for the AUSDRISK evaluation, $10.50 for the PoC test, and $11.00 for a referral. Additionally, pharmacies were paid a bonus of $750 upon reaching their specified target screenings provided the data was completed according to the protocol.

In the financial impact analysis, a fee of s47 is proposed being the weighted average of s47 for administering AUSDRISK, and s47 for administering AUSDRISK plus a HbA1c PoC test. Excluding a GP consultation fee (for example, Item 701), this is s47 of the proposed MBS item fee for the use of PoC HbA1c testing in the diagnosis of diabetes, or s47 of an Item 701 plus a PoC test.

In addition, consideration needs to be given to aligning the consistent principles for the fee structure for the conduct of a PoC HbA1c test irrespective of where the test is conducted.

ESC is requested to consider whether, for testing in pharmacies, the cost of administering the AUSDRISK tool should be reimbursed at all, or whether the only fee payable should be equal to the MBS Item 73812 which is for a PoC test for people who have a high risk as evidenced by an elevated AUSDRISK score.

There are also likely to be higher costs when patients are referred to a GP following screening in a community pharmacy because tests are likely to be repeated by the GP. However, it has been predicted by MSAC Executive that 60-90% of laboratory HbA1c tests will be coned out.

There may be a risk of some pharmacies over-servicing eligible patients and duplicating GPs' MBS health assessments. This risk could be mitigated by including measures of patient experience (i.e. when conducting a screening assessment, the pharmacist should be required to ensure the individual does not already have a diagnosis of T2DM and has not been tested for T2DM with a valid screening test in the previous 12 months).

s47C

Applicant:	The Pharmacy Guild of Australia
Clinical experts consulted and their expertise:	Emeritus Professor Lloyd Sansom AO
Co-dependency (if applicable):	Not applicable
Date of PASC consideration:	8 March 2016
Date of ESC consideration:	Not applicable
Date of previous MSAC consideration (if applicable):	Not applicable
Professional bodies/ organisations/consumer groups consulted during targeted consultation:	Australian Diabetes Educators Association Australian Medical Association Australian Diabetes Society Diabetes Australia (including States and Territories) Diabetes support groups Diabetes Strategy Refresh – Expert Advisory Group Members Juvenile Diabetes Research Foundation Royal Australian College of General Practitioners Pharmaceutical Society of Australia Consumer Health Forum

Contact: s22

Cleared by: David Laffan
Assistant Secretary
Pharmacy Branch

From: tony.badrick@rcpaqap.com.au
To: s47F s47F s22
Cc: s47F
Subject: RE: NPAAC ADVICE: Request for consultation on nine MSAC applications [SEC=OFFICIAL]
Date: Wednesday, 15 September 2021 1:44:02 PM
Attachments: image002.png
image004.png
image042133.png

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Hello s47F

See additional column in Table below

Tony Badrick
Chief Executive
s47F

RCPAQAP
The Royal College of Pathologists of Australasia
Quality Assurance Programs

RCPAQAP
Suite 201, 8 Herbert Street
St Leonards NSW 2065

rcpaqap.com.au
1300 78 29 20

From: s47F >
Sent: Tuesday, 14 September 2021 5:11 PM
To: s47F s47F s22

Cc: BANKS, Margaret <Margaret.Banks@safetyandquality.gov.au>
Subject: NPAAC ADVICE: Request for consultation on s22 MSAC applications [SEC=OFFICIAL]

Dear NPAAC Executive,

The Medical Services Advisory Committee are seeking NPAAC's advice on s22 applications

ahead of the Evaluation Sub-Committee (ESC) meeting Thursday 7 October 2021 to Friday 8 October 2021.

Of the s22 MSAC applications:

- s22
-
- one is part of the Australian Government Department of Health's (the Department) Pharmacy Trial Program.

These applications are summarised in **Table 1**.

Table 1: MSAC applications requiring clinical advice from NPAAC

Application number	Title	Reason for application	EQA Available
s22			

s22			
1677	Pharmacy Diabetes Screening Trial	Part of the Department's Pharmacy Trial Program	QAP HbA1c EQA available

Of the s22 applications, s22 and an executive summary about the Pharmacy Diabetes Screening Trial are attached for your convenience. Additional application details, including service descriptions, are also provided at MSAC's website.

The MSAC Secretariat have also provided a template for you to use when developing your advice.

Could you please email your feedback by **5:00pm AEST Friday 24 September 2021**
s47F

If you experience any issues s22 or need more time for a considered response, please let me know.

Kind regard,

s47F
Senior Project Officer, National Standards Program
Australian Commission on Safety and Quality in Health Care
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AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

NSQHS STANDARDS
A better way to care

The Australian Commission on Safety and Quality in Health Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

National Pathology Accreditation Advisory Council Advice to the Medical Services Advisory Committee

Application 1677 – Pharmacy Diabetes Screening Trial

ADVICE

That MSAC consider the following key questions/concerns raised by NPAAC:

1.

BACKGROUND

Brief summary

IMPLEMENTATION ISSUES

Point of care testing is to be used in this trial of screening by pharmacies in partnership with Aboriginal Health Services for diabetes mellitus. It is unclear if the well established Australian Government funded Point of care testing program QAMMS - **Q**uality **A**ssurance for **A**boriginal and **T**orres **S**trait Islander **M**edical **S**ervices - is a part of this program. https://www.flinders.edu.au/international-centre-for-point-of-care-testing/chronic-qaams

QAAMS uses on-site point-of-care pathology testing for haemoglobin A1c (HbA1c) and urine albumin:creatinine ratio (ACR) conducted on the Siemens DCA Vantage under a quality management framework.

If it is not a part of this trial, the elements required to provide reliable point of care testing are outlined in NPAAC Guidelines on point of care testing (2015) or the draft Standard, Requirements for point of care testing (2021).

They include:

- Selection of the test machine based on its analytical performance and robustness in use
- Training of staff in the use and interpretation of results
- Participation in an external Quality assurance program(offered by RCPA QAP P/L)
- Access to advice on troubleshooting
- Secure private recording of results.

DATA

Application 1677: Pharmacy Diabetes Screening Trial (PDST)

Summary of public consultation feedback/consumer issues

Prior to MSAC consideration (and subsequent to the ESC), consultation feedback was received from five health professional organisations, two consumer organisations and one health professional individual (pharmacist). The seven organisations that provided input on the application were:

- Australian Diabetes Educators Association (ADEA)
- Australian Diabetes Society (ADS)
- Australian Medical Association (AMA)
- Australian Pharmaceutical Society of Australia (PSA)
- Diabetes Australia (DA)
- Diabetes South Australia (SA)
- Royal Australian College of General Practitioners (RACGP).

Consultation feedback from five of the seven organisations (ADS, ADEA, DA, Diabetes SA and PSA) and the individual were mostly supportive of the proposed service: community pharmacy-based opportunistic screening for pre-diabetes and T2DM. Collectively, the supportive responses considered the benefits of the proposed service included early identification of individuals at high risk of T2DM (pre-diabetes) and/or with undiagnosed T2D, enabling timely referral to a General Practitioner (GP) and if appropriate referral to a credentialled diabetes educator and accredited practising dietitian (and other allied health professionals) for education regarding the self-management. The responses expect that this would lead to earlier lifestyle intervention which would reduce the risk of developing T2DM and delay or prevent diabetes-related complications such as heart disease, stroke, kidney disease, blindness, anxiety, depression and amputations. The ADS, ADEA and DA also considered the proposed service aligns with the *Australian National Diabetes Strategy*.

Consultation feedback from the AMA and RACGP acknowledged the importance to improve the identification and management of people with diabetes but was not supportive of the application, expressing a number of concerns with the proposed medical service and the evidence from the PDST.

The following considerations were raised in the consultation responses:

- *Proposed service is outside pharmacist scope of practice*
  The AMA recommended MSAC consult the Pharmacy Board to determine their views and if necessary, conduct a consultation on expanding pharmacist scopes of practice into medical services.

- *Proposed service may fragment patient care and reduce the comprehensiveness of care*
  The AMA and RACGP expressed concern that the proposed medical service encourages one-off, opportunistic screening for a single medical condition without the background biopsychosocial information of the individual and without the history of previous screening. The AMA and RACGP highlighted that GPs provide comprehensive patient care whereas the proposed pharmacy service model has the potential to fragment patient care and that poorly coordinated patient care within the

health system and inadequate links between health and social services results in poorer health outcomes and increased health care cost. The AMA considered there were more useful models of care involving pharmacists that should be considered as part of a patient-centred medical home model rather than further fragmenting care.

- *Pharmacists ability to confirm diabetes status and testing history*
  The AMA and RACGP raised concern that it is unclear how pharmacists plan to confirm whether an individual has had a recent diabetes test which was likely initiated by a GP, which is crucial to determine whether costs and services are being duplicated.

- *Alignment with clinical guidelines for managing T2DM*
  The AMA and RACGP noted that the PDST allowed anyone aged 35-74 to be screened, as long as a diabetes screening test has not been conducted in the past 12 months. This differed to the clinical guidelines on the management of T2DM[1] which recommend patients without a high risk of type 2 diabetes to be screened using AUSDRISK every three years from when they reach 40 years of age.

- *Populations at high risk of T2DM*
  Feedback from ADS, ADEA, DA, PSA and Diabetes SA raised that Aboriginal and Torres Strait Islander people have higher rates of undiagnosed diabetes and therefore culturally sensitive screening programs (along with lifestyle information and support) should be supported to enable earlier detection intervention to delay or prevent diabetes-related complications. However, Diabetes SA and the RACGP expressed that the PDST protocol did not target Aboriginal and Torres Strait Islander populations and did not address other populations at higher risk of T2DM or emerging populations who are younger than the 35 year age cut-off in the PDST.

- *Appropriateness of the comparator in the PDST*
  The AMA and RACGP highlighted that the PDST did not have an appropriate control group and did not research the effectiveness or cost-effectiveness in the context of wider public health or other more readily available and evidence-based medical services. Similarly, Diabetes SA and the individual pharmacist considered that the appropriate comparator for the proposed intervention would be diabetes screening in the GP setting.

- *Equitable access for rural and remote communities*
  Consultation feedback from ADS, ADEA and DA considered that access to traditional medical or clinic-led diabetes screening can be limited in rural and remote areas and by enabling pharmacy-led screening, there is potential to reduce this service gap. However, the RACGP noted that pharmacies can only provide the diabetes screening service if they have two trained pharmacists on duty at the same time, and a private room is available.

- *Potential for misdiagnosis*
  The ADS, ADEA and DA collectively expressed concerns that misdiagnosis as a result of either false positive or false negative screening results may be a potential

[1] The Royal Australian College of General Practitioners. Management of type 2 diabetes: A handbook for general practice. East Melbourne, Vic. RACGP; 2020.

issue, as with all screening programs. However, ADS, ADEA and DA considered that these risks may be minimized through appropriate education of pharmacists and quality control of testing apparatus, as well as referral of positive results to GPs. The AMA, Diabetes SA and PSA raised the potential risk of undermanaged 'diagnosis' if referrals are not made and that understanding the GP referral uptake rates (or lack of), particularly those diagnosed with diabetes would be informative.

- *Patient education and support*
  Diabetes SA noted that the report does not provide any detail about what education and support people in the trial received to assist them reduce their lifestyle risk factors. Diabetes SA considered it important to understand what people in the trial perceived to be their benefits and disadvantages of participating in this trial.

Australian Government

Department of Health

Consultation Survey on MSAC Application 1677

Pharmacy Diabetes Screening Trial

Please use this template to prepare your feedback on the Pharmacy Diabetes Screening trial. You are welcome to provide feedback from either a personal or group perspective for consideration when the application is being reviewed.

The data collected will be used to inform the Medical Services Advisory Committee (MSAC) process to ensure that when proposed healthcare interventions are assessed for public funding in Australia, they are patient focused and seek to achieve best value.

You may also wish to supplement your responses with further documentation or diagrams or other information to assist the Department in considering your feedback.

Thank you for taking the time to provide valuable feedback.

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Your submission and contact details will be stored in accordance with the Privacy Act 1988 and the Archives Act 1983. Should you have any concerns about the storage of your submission, or if you wish to gain access to make a correction, please contact commentsMSAC@health.gov.au and cc: pharmacy.trial.program@health.gov.au. A copy of the Department's privacy policy is available on request. If you wish to make a complaint about the handling of your private information, you may contact the Department of Health Privacy Contact Officer and, if unsatisfied with the response, you may submit a complaint to the Office of the Australian Information Commissioner.

Please reply to the HTA Team:

Email: commentsMSAC@health.gov.au and cc: pharmacy.trial.program@health.gov.au

Postal: MDP 959 GPO 9848 ACT 2601

PART 1 – PERSONAL AND ORGANISATIONAL INFORMATION

1. Respondent details

Name: Sof Andrikopoulos

Email: ceo@diabetessociety.com.au

Phone No: [redacted]

2. (a) Is the feedback being provided on an individual basis or by a collective group? (please select)

- [ ] Individual
- [X] Collective Group

(b) If individual, specify the name of the organisation you work for

(c) If collective group, specify the name of the group

Diabetes Australia, Australian Diabetes Society, Australian Diabetes Educators Association

3. How would you best identify yourself?

- [ ] General Practitioner
- [X] Specialist
- [ ] Pharmacist
- [ ] Researcher
- [X] Consumer
- [ ] Care giver
- [ ] Other

(a) If other, please specify

PART 2 – CLINICAL NEED AND PUBLIC HEALTH SIGNIFICANCE

4. Describe your experience with supporting people with the medical condition (disease) and/or with the proposed intervention.

The Australian Diabetes Society and the Australian Diabetes Educators Association are the peak health professional bodies representing endocrinologists, credentialed diabetes educators and research scientists who provide evidence-based care for the person living with diabetes. Diabetes Australia is the peak consumer organization that provides support and education so that the person living with diabetes can live the best possible life they can. Collectively we care for 1.4 million Australians living with diabetes, through education, research and clinical care.

5. What do you see as the benefit(s) of the proposed intervention, in particular for the person involved and/or their family and carers?

Diabetes is diagnosed by elevated glucose levels, which in turn contribute to diabetes-related complications, including heart disease, stroke, kidney disease, blindness, anxiety and depression and amputations. The longer a person lives with diabetes and high blood glucose levels, the more likely they will develop some or all of the above-mentioned complications. Early detection of type 2 diabetes through screening and diagnosis provides opportunities for earlier treatment, improved quality of life and complication prevention. It is estimated that up to 500,000 Australians are living with undiagnosed diabetes.

Screening for undiagnosed type 2 diabetes is a strategy for reducing the burden of diabetes recommended in the **Australian National Diabetes Strategy** and by the Australian Diabetes Society, the Australian Diabetes Educators Association and Diabetes Australia.

The purpose of the Pharmacy Diabetes Screening Trial was to compare the effectiveness of three pharmacy-based screening models in detecting type 2 diabetes, so that diagnosis can be made early and management of blood glucose levels may be started in a clinically timely manner.

The advantages of early screening and detection of diabetes are:

- Delay or prevention of diabetes-related complications
- A reduction in health-care related costs due to a delay/prevention of complications
- Improved quality of life and reduced burden on family/carers
- A reduction in financial costs for the person and their family/carers
- Improved workforce participation
- Improved mortality rates

6. What do you see as the disadvantage(s) of the proposed intervention, in particular for the person involved and/or their family and carers?

There are few disadvantages from a screening program for diabetes for the person at risk of diabetes or their family and carers.

Misdiagnosis, either false positive or negative, is a potential issue. However, this is a general issue associated with all screening programs, not just diabetes. These risks can be minimized through appropriate education of pharmacists and quality control of testing apparatus. False positive at the pharmacy would be corrected by the subsequent referral to the GP. Diabetes screening studies have shown no significant psychological harm from false positive or negative tests.

Other risks such as cost and potential for duplication are more a system issue than a disadvantage to the person and again not specific to pharmacy testing.

7. What other benefits can you see from having this intervention publicly funded by the Australian Government?

The predominant benefit will be the reduction in the personal, societal and economic burden of diabetes. This screening process will also provide us with a better understanding of the rates of undiagnosed diabetes in the community, which will provide opportunities to raise further awareness of diabetes and continue to support improved screening. Diagnosing diabetes earlier means that clinical management can begin earlier delaying or even preventing diabetes-related complications. This screening will also provide a better understanding of pre-diabetes prevalence and again can be used to provide advice to the person with pre-diabetes on lifestyle interventions that support prevention of progression to diabetes. A healthier society means that there is increased workforce participation and capacity and a reduction in health care costs. Knowing the prevalence of prediabetes can also be used to raise awareness of the risk in the community and health care providers.

PART 3 – INDICATION(S) FOR THE PROPOSED MEDICAL SERVICE AND CLINICAL CLAIM

8. Do you agree or disagree with the proposed population(s) for the proposed intervention as specified in the Executive Summary?

- [X] Strongly Agree
- [ ] Agree
- [ ] Disagree
- [ ] Strongly Disagree

(a) Specify why or why not:
The Executive Summary appropriately describes the adult population that should be screened for diabetes.

This is the globally agreed at risk population in which there is a significant number of individuals with undiagnosed diabetes who would benefit from earlier diagnosis. It also includes a significant proportion with undiagnosed pre-diabetes.

9. What is the appropriate comparator for the proposed intervention?

- [ ] Strongly Agree
- [X] Agree
- [ ] Disagree
- [ ] Strongly Disagree

The main comparator used in this study was the AUSDRISK questionnaire alone which is appropriate. Diabetes screening programs are targeted at higher risk individuals and the AUSDRISK has been specifically developed for an Australian population to determine risk level. It is easily applied in various setting, including in a pharmacy and by personal on-line assessment.

PART 4 – ADDITIONAL QUESTIONS

10. Do you have any comments relating to access to the proposed intervention by people who identify as Aboriginal and/or Torres Strait Islander persons. Do you have any comments relating to access to the proposed intervention by other population groups?

It is important to note and acknowledge that Aboriginal and Torres Strait Islander people have higher rates of undiagnosed diabetes, diabetes and diabetes-related complications and indeed reduced quality of life and early death. Earlier detection through culturally sensitive screening programs should be supported to enable earlier intervention to delay or prevent diabetes-related complications.

Access to traditional medical or clinic led diabetes screening can be limited in rural and remote areas. Complementing these services with pharmacy-led screening has the potential to reduce this service gap. In this respect it is important to support the regional/remote pharmacy to be able to provide this critically important service to their community.

11. Do you have any comments on the proposed intervention from a consumer perspective?

Increasing convenient diabetes screening options for consumers should increase willingness for individuals to be screened for undiagnosed diabetes. Pharmacists are trusted and well respected by community members and are a commonly used and cost-effective health resource. This is being demonstrated by the COVID vaccination roll out.

PART 5 – ADDITIONAL COMMENTS

12. Do you have any additional comments on the proposed intervention and/or medical condition (disease)?

We are strongly supportive of a diabetes screening program and pharmacists have an important role in increasing access to diabetes screening. Diabetes guidelines recommend the screening approach used in this trial, namely formal risk assessment followed by HbA1c testing. An additional benefit is the identification of individuals with pre-diabetes who are suitable for lifestyle interventions to reduce their risk of developing diabetes.

13. Do you have any comments on this feedback survey? Please provide comments or suggestions on how this process could be improved.

Again, thank you for taking the time to provide valuable feedback.

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AMA submission to the Medical Services Advisory Committee – 1677 Pharmacy Diabetes Screening Trial

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Introduction

The AMA welcomes the opportunity to provide feedback on the Pharmacy Diabetes Screening Trial (PDST) and welcomes an independent Health Technology Assessment to determine the effectiveness and cost-effectiveness of the trial. The AMA has previously supported that pharmacy programs should come under the same level of transparency and scrutiny as medical services when they are examined through the Medical Services Advisory Committee (MSAC) process, and also under the recent Medicare Benefits Schedule (MBS) Reviews[1]. The AMA is deeply concerned with the spread of pharmacy health services across Australia that have not been appropriately assessed at the same standard as other medical services. The AMA considers these services as outside the scope of practice for pharmacists and represents a push by pharmacies to increase their profits at the expense of evidence-based, cost-effective health care. Pharmacy programs must be subject to independent evidence-based assessment, reporting and monitoring, and adequate accountability and transparency to ensure they are in the patients' best interest and are the best use of public funds.

The AMA does not believe that the evidence provided in this MSAC application is sufficient to justify continuing Pharmacy Diabetes Screening Programs when there is already an evidence-based diabetes screening process in place in general practice.

Funding pharmacy health services

The AMA agrees there are benefits in future Community Pharmacy Agreements (CPAs) being limited to remuneration for the dispensing of Pharmaceutical Benefits Scheme (PBS) medicines and associated regulation. This would allow pharmacy programs, such as medication adherence and management services currently funded under the CPA, to be funded in ways that are more consistent with how other primary care health services are funded. Given these programs are about providing health services, rather than medicines dispensing per se, it makes sense for them to be assessed, monitored, evaluated and audited in a similar way to medical services under the

[1] Australian Medical Association (2017) *AMA submission – Pharmacy remuneration and regulation review – interim report.*

MBS. $1.26 billion (including $50 million for the Pharmacy Trial Program) was provided to pharmacies under the Sixth CPA[2] without this level of transparency and accountability. This MSAC process is the first time evaluations of pharmacy programs under the CPA have been made (relatively) public. Moving pharmacist health services outside of the CPA would also open the way for more flexible models of funding, for example, support for pharmacists working within a general practice team and other innovative, patient-focused models of care.

Assessing health services

The Review of Pharmacy Remuneration and Regulation[3] provided a set of principles for the programs offered in community pharmacy to uphold. The AMA considers this MSAC process to at least begin providing appropriate scrutiny of pharmacy services, as recommended by the Review. The first principle is that "programs should be based on evidence of clinical and cost-effectiveness and the health benefits they provide to the community".

The Department of Health's *Population Based Screening Framework*[4] highlights specific criteria that must be met when considering a screening program, including that the benefits outweigh the harms and that there is community consensus that the benefits outweigh the financial costs[5]. While the PDST does not fit the definition of a population screening program, the Framework provides appropriate guidance to refer to when determining the appropriateness of the PDST. In particular, the Framework outlines that screening programs require a high level of evidence from high quality randomised controlled trials and systematic reviews.

Any cost-benefit analysis would also need to take into account the indirect costs of delayed or missed diagnoses leading to higher cost care, that are more likely when care is fragmented by patients relying on health care provided by a pharmacist (see section on general practice).

The Pharmacy Diabetes Screening Trial

The AMA does not believe there is a high level of quality evidence for pharmacy diabetes screening programs. A meta-analysis cited[6] by the PDST researchers highlights that most studies were observational, and studies overall had significant variation in outcomes (referral to patient's practitioner and uptake of referral), with high rates of attrition between screening and follow up. High proportions of patients did not attend follow up appointments. Two of the four Australian studies included in the analysis were rated as 'poor quality'[7]. The AMA is concerned that similar poor results could occur if the screening program continues in Australia.

[2] Department of Health (2020) *Pharmacy Trial Program.*
[3] Department of Health (2017) *Review of pharmacy remuneration and regulation – final report.*
[4] Department of Health (2018) *Population Based Screening Framework.*
[5] See also: World Health Organization (2020) *Screening programs: a short guide.*
[6] Krass et al (2017) *Pharmacy diabetes screening trial: protocol for a pragmatic cluster-randomised controlled trial to compare three screening methods for undiagnosed type 2 diabetes in Australian community pharmacy.* BMJ Open
[7] Willis et al (2014) *The effectiveness of screening for diabetes and cardiovascular disease risk factors in a community pharmacy setting.* PLOS one.

Medical services are typically backed by several high quality studies before they even considered through the MSAC process[8] In contrast, the PDST is only one trial that does not research the effectiveness or cost-effectives in the context of wider public health or other more readily available and evidence-based medical services. Rather, it provides an analysis *between* different pharmacy diabetes screening models that is largely based on economic analysis. It is unclear whether this study has been peer-reviewed and it appears that full trial results will not be publicly available until after the HTA assessment[9]. It is unclear how researchers determined GP-based costs and how potential cost offsets were measured. It is also unclear whether the trials had acceptable follow up and referral uptake in comparison to general practice robust recall systems. Without this information, and the fact that many results have been redacted in the MSAC Executive Summary, it is difficult to determine a full view on the PDST.

The PDST itself is sponsored by the Pharmacy Guild of Australia[10], an organisation that aims to represent the interest of their members - community pharmacies (businesses). This represents a direct conflict of interest because Guild members will directly benefit from government funding and an increase in profits by expanding the program. Ideally, research should be independent.

The AMA is also concerned that pharmacies are actively recruiting and marketing unnecessary and expensive pathology tests to their customers under the cover of 'health screening'. For example, the clinical guidelines state that patients without a high risk of type 2 diabetes should only be screened using AUSDRISK every three years from when they reach 40 years of age[11]. In contrast, the PDST allows anyone aged 35-74 to be screened more regularly (the customer can participate if they have not had a recent diabetes test in the past 12 months). It is also unclear how the pharmacist plans to confirm whether the patient has had a recent diabetes test which was likely initiated by a general practitioner and not the specific pharmacy. This will be crucial to determine whether costs and services are being duplicated. The AMA believes this perfectly illustrates the push by pharmacies to increase profits at the expense of evidence-based, cost effective health care.

The AMA would also expect these services to be regularly independently audited to ensure diabetes screening offers to patients were clinically necessary and not over-serviced, and that the program was effective in ensuring patients went to their GP.

General practice

The AMA opposes proposed reforms that fragment care and provide a lower quality service than medical practitioners. It is internationally recognised that GPs are the cornerstone of a successful primary healthcare system, and countries with a strong general practice have better health outcomes[12]. The patient-centred medical home model (PCMHM) is a well-regarded system of

[8] Department of Health (2019) *Medical Services Advisory Committee – Frequently Asked Questions*.
[9] Department of Health (2020) *Pharmacy Trial Program.*
[10] National Health and Medical Research Council (2017) *Australian clinical trials – The Pharmacy Diabetes Screening Trial: a comparison of three community pharmacy based approaches to screening for type 2 diabetes on proportions of newly diagnosed type 2 diabetes cases.*
[11] Royal Australian College of General Practitioners (2020) *Management of type 2 diabetes: A handbook for general practice*
[12] The World Health Organisation (2008) *The World Health Report 2008 - primary health care (now more than ever).*

integrated care that is more efficient, reduces hospital admissions and provides better support for patients[13,14]. Despite a move towards the PCMHM, fragmentation of care, such as the PDST, is becoming more common as health system pressures grow. Poorly coordinated patient care within the health system and inadequate links between health and social services results in poorer health outcomes and increased health care costs[15]. Ill-considered cost reduction strategies, like task substitution of non-medical health professionals for GP-led patient care, are increasingly proposed as a solution to these pressures. Government should be focusing on increasing funding and support for general practice instead of seeking ways to produce lower-quality care solutions that are not necessarily cheaper in the long term. For example, the AMA believes that investment into general practice pharmacists is a more valuable method of providing holistic care while improving engagement between pharmacists and GPs[16].

Pharmacies in the community play an important role in providing medicines information to the public and ensuring that all Australians have access to medicines in a timely and safe manner. However, medical practitioners are the only health professionals trained to fully assess a person, initiate further investigations, make a diagnosis, and understand and recommend the full range of clinically appropriate treatments for a given condition.

There is so much more to patient care than simply completing a screening tool and the AMA is concerned that patients with or at risk of type 2 diabetes will be subjected to a tick box exercise in retail pharmacies. General practitioners are already best placed in advising their patients about prevention, diagnosis, and treatment of type 2 diabetes and can help their patient achieve health goals such as improving their diet, BMI, physical activity, cigarette, and alcohol consumption[17]. Patients with, or at risk of, type 2 diabetes typically have other health conditions and concerns that are best addressed through their usual GP. Almost half of patients with type 2 diabetes have two or more additional health conditions, and more than 80 per cent will have multimorbidity within 16 years of being diagnosed[18]. In most cases, tests and/or several medications are required, and some patients may require specialist referral. Pharmacists cannot initiate or prescribe these requirements.

While the AMA understands that under the PDST pharmacists refer patients to their GP if they identify test results above a certain threshold, it is in the patient's best interest that they receive a more holistic, person-centred approach at their general practice at the beginning of their patient journey so they receive appropriate education around prevention and risk factors, and all the required referrals and tests are ordered and conducted in a more efficient manner at the medical practice and associated pathology centres. The PDST adds an unnecessary step for patients that is out of sync with holistic care.

[13] NSW Government (2021) *Navigating the health care neighbourhood – What is the patient centred medical home model?*
[14] NSW Government (2021) *Navigating the health care neighbourhood – benefits for health professionals.*
[15] Frandsen BR, et al (2015) *Care fragmentation, quality, and costs among chronically ill patients*. Am J Manag Care 2015;21:355–62
[16] Australian Medical Association (2015) *general practice pharmacists – improving patient care.*
[17] Royal Australian College of General Practitioners (2020) *Management of type 2 diabetes: A handbook for general practice.*
[18] Royal Australian College of General Practitioners (2020) *Management of type 2 diabetes: A handbook for general practice*.

Scopes of practice

Current scopes of practice exist to protect patient safety and ensure patients receive best value, high quality care. The AMA considers pharmacists undertaking expanded roles, including non-medicine related tasks such as the PDST, to be expanding their scope of practice.

Under the Health Practitioner Regulation National Law Act, which governs the practice of registered health practitioners, the national boards are responsible for setting the accreditation standards for education and training for the knowledge, skills and professional attributes to practise the profession.

To ensure patient safety and cost-effectiveness for the health care system, any expanded scopes of practice by non-medical health practitioners should be underpinned by a process that ensures:

- there are no new safety risks for patients;
- the change to scope of practice is rationally related to the practice of the profession and to core qualifications and competencies of their profession;
- the change in scope of practice is consistent with the evolution of the healthcare system and the dynamics between health professionals who work in collaborative care models;
- the training opportunities for other health practitioner groups is not diminished; and
- the cost to the health care system will be lower than the current service offering, taking account of supervision costs.

In addition, processes for expanding scopes of practice should also ensure that:

- the required competencies are predetermined, and accredited training and education programs are available to deliver those competencies; and
- there are documented protocols for collaboration with other health practitioners.

The AMA is not aware of the above considerations and processes being undertaken by the Pharmacy Board prior to the Pharmacy Guild determining an expansion in pharmacists' scope of practice. The AMA recommends MSAC consults the Pharmacy Board to determine their views on the above and if necessary, conduct a consultation on expanding pharmacist scopes of practice into medical services.

Conclusion

The AMA welcomes the MSAC assessment for the PDST, so the program's effectiveness and cost-effectiveness is determined by the same process that assesses all other health services. The AMA has several concerns if pharmacy diabetes screening programs are to receive future government funding, due to the lack of high-quality evidence that these programs are in the patients' best interest, in the context of wider public health and existing primary care services. The AMA values pharmacists as experts in medicines and there are more pressing and useful models of care involving pharmacists that should be considered as part of a patient-centred medical home model rather than further fragmenting care.

October 2021

Contact
Hannah Wigley
Senior Policy Adviser
hwigley@ama.com.au

Australian Government

Department of Health

Consultation Survey on MSAC Application 1677

Pharmacy Diabetes Screening Trial

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1. Respondent details

Name: [redacted]

Email: s47F

Phone No: [redacted]

2. (a) Is the feedback being provided on an individual basis or by a collective group? (please select)

☒ Individual
☐ Collective Group

(b) If individual, specify the name of the organisation you work for

Cincotta Discount Chemist Merrylands (2160)

(c) If collective group, specify the name of the group

3. How would you best identify yourself?

☐ General Practitioner
☐ Specialist
☒ Pharmacist
☐ Researcher
☐ Consumer
☐ Care giver
☒ Other

(a) If other, please specify

Credentialled Diabetes Educator + Naturopath (other than Pharmacist of 38 years experience)

s47F

s47F

s47F

s47F

Australian Government

Department of Health

Consultation Survey on MSAC Application 1677

Pharmacy Diabetes Screening Trial

Please use this template to prepare your feedback on the Pharmacy Diabetes Screening trial. You are welcome to provide feedback from either a personal or group perspective for consideration when the application is being reviewed.

The data collected will be used to inform the Medical Services Advisory Committee (MSAC) process to ensure that when proposed healthcare interventions are assessed for public funding in Australia, they are patient focused and seek to achieve best value.

You may also wish to supplement your responses with further documentation or diagrams or other information to assist the Department in considering your feedback.

Thank you for taking the time to provide valuable feedback.

Privacy

Responses may be provided to the MSAC, its subcommittees, a health technology assessment group and the applicant. Should you require de-identification please contact the HTA team (details below).

While stakeholder feedback is used to inform the application process, you should be aware that your feedback may be used more broadly by the applicant. Responsibility for copyright in submissions resides with the author(s), not with the Department of Health.

Your submission and contact details will be stored in accordance with the Privacy Act 1988 and the Archives Act 1983. Should you have any concerns about the storage of your submission, or if you wish to gain access to make a correction, please contact commentsMSAC@health.gov.au and cc: pharmacy.trial.program@health.gov.au. A copy of the Department's privacy policy is available on request. If you wish to make a complaint about the handling of your private information, you may contact the Department of Health Privacy Contact Officer and, if unsatisfied with the response, you may submit a complaint to the Office of the Australian Information Commissioner.

Please reply to the HTA Team:

Email: commentsMSAC@health.gov.au and cc: pharmacy.trial.program@health.gov.au

Postal: MDP 959 GPO 9848 ACT 2601

PART 1 – PERSONAL AND ORGANISATIONAL INFORMATION

1. Respondent details

Name: Mark Kinsela

Email: ceo@psa.org.au

Phone No: 02 6283 4703

2. (a) Is the feedback being provided on an individual basis or by a collective group? (please select)

☐ Individual
☒ Collective Group

(b) If individual, specify the name of the organisation you work for

(c) If collective group, specify the name of the group

Pharmaceutical Society of Australia

3. How would you best identify yourself?

☐ General Practitioner
☐ Specialist
☒ Pharmacist
☐ Researcher
☐ Consumer
☐ Care giver
☒ Other

(a) If other, please specify

Australian Government-appointed health peak and advisory body – pharmacy profession

PART 2 – CLINICAL NEED AND PUBLIC HEALTH SIGNIFICANCE

4. Describe your experience with supporting people with the medical condition (disease) and/or with the proposed intervention.

Pharmacists are one of the most accessible health practitioners in the community with a core role in chronic disease management. Australia's network of community pharmacies provide people with a location where regular health care as well as opportunistic services can be delivered. Pharmacists can tailor services according to their local patient demographics and needs, and also target specific campaigns.

The most common form of diabetes – type 2 diabetes – is largely preventable through appropriate management of lifestyle factors. Pharmacists are well placed to identify and support at-risk individuals, their families and carers and the wider public through health promotion activities and consistent, evidence-based messages. Pharmacists recognise the value in tailoring support according to a person's healthcare needs and receptiveness to support. After diagnosis, empowering individuals is an important part of diabetes care to achieve quality of life and optimal health outcomes.

Pharmacists have a strong public health role in raising public awareness about health conditions, providing information about risk factors, and delivering health promotion and preventive healthcare activities. Being the most accessible healthcare professional in the community, pharmacists have good reach within the community and deliver key health messages consistent with Government policies and programs to a wide range of consumers. Pharmacists also work in partnership with other healthcare practitioners and health service providers to deliver and reinforce health messages to consumers.

Pharmacists also work within general practices, aged care facilities, Aboriginal Community Controlled Health Services as well as providing direct care to patients in their homes.

5. What do you see as the benefit(s) of the proposed intervention, in particular for the person involved and/or their family and carers?

PSA believes that the proposed intervention itself is important, but also suggests there will be flow-on benefits to the individual as well as more broadly.

Thus, the intervention will have short- and long-term benefits including:

- Raising public awareness about the signs and impact of diabetes
- Supporting at-risk individuals and family members
- Encouraging preventive care and activities – for individuals and the community
- Minimising the effects of diabetes through early identification and referral if necessary
- Facilitating holistic care before and after diagnosis
- Coordinating care and connecting individuals with other services according to their healthcare needs
- Decreasing diabetes-related disease burden and longer term healthcare expenditure.

6. What do you see as the disadvantage(s) of the proposed intervention, in particular for the person involved and/or their family and carers?

Potential risk of undermanaged 'diagnosis' if referrals are not made.

7. What other benefits can you see from having this intervention publicly funded by the Australian Government?

According to data published by the Australian Institute of Health and Welfare in 2020, close to 5% of Australians had diabetes in 2017-18. This was based on self-reported data and therefore the actual figure is expected to be higher. It was also reported that 1.2 million hospitalisations in the same period were associated with diabetes. In 2015-16 (AIHW data published in 2019), the estimated total health system expenditure in Australia attributable to diabetes was $2.7 billion.

The 1999-2000 Australian Diabetes Obesity and Lifestyle Study found that, for every known case of diabetes, there was one undiagnosed case. It is also reported that the 2011-12 Australian Bureau of Statistics Australian Health Survey found 20% of participating adults aged 18 and over had undiagnosed diabetes prior to the survey. The Executive Summary to this application states "an estimated 500,000 adults in Australia have undiagnosed type 2 diabetes mellitus". These figures help to put into context the potential costs associated with diabetes in Australia.

As healthcare needs grow and evolve, healthcare services need to be responsive, timely and innovative. With regards to chronic diseases such as diabetes, it is important that there is good information and awareness by the broader public about the condition, and that health consumers have access to opportunities for early identification and intervention, including referral to GPs and local services. Once diagnosed, a person with diabetes (as well as their families and carers) will require access to regular care through a health professional who can support treatment and management of their health condition. Pharmacists are ideally placed to deliver diabetes-related information and care through a wide spectrum of activities **before and after** diagnosis.

The Australian Government is making significant investments in preventive health care. A National Preventive Health Strategy is under development following recent public consultation. Pharmacists have a fundamental role in delivering primary healthcare services that meet and deliver on Government policies and objectives.

PSA strongly supports public funding of the pharmacy diabetes screening intervention. Through appropriate investment, this intervention will enable pharmacists to contribute to early identification and referral of people who may otherwise receive delayed medical attention and experience significant diabetes disease burden over their lifetime. Pharmacists will also help to inform, encourage and empower people to adopt preventive behaviours more generally. For those with a confirmed diagnosis of diabetes, pharmacists will continue to deliver patient care through monitoring, assisting with self-management, and medication management advice.

The intervention is not only consistent with the Australian Government's focus on prevention, but it will also result in greater recognition and acceptance of pharmacists' role in diabetes care, and have a positive impact on the health and wellbeing of all people living with, or at risk of, diabetes. Importantly this should lead to a decrease in diabetes-related disease burden in Australia and have a positive impact on disease-related health system expenditure, including pharmaceuticals and hospitalisations.

PART 3 – INDICATION(S) FOR THE PROPOSED MEDICAL SERVICE AND CLINICAL CLAIM

8. Do you agree or disagree with the proposed population(s) for the proposed intervention as specified in the Executive Summary?

- [x] Strongly Agree
- [ ] Agree
- [ ] Disagree
- [ ] Strongly Disagree

(a) Specify why or why not:

The intervention is screening for undiagnosed type 2 diabetes. The use of the AUSDRISK tool initially to estimate a person's risk of developing type 2 diabetes in the next five years is appropriate. This will avoid unnecessary duplication of resources and costs to the healthcare system.

9. What is the appropriate comparator for the proposed intervention?

- [ ] Strongly Agree
- [ ] Agree
- [ ] Disagree
- [ ] Strongly Disagree

PART 4 – ADDITIONAL QUESTIONS

10. Do you have any comments relating to access to the proposed intervention by people who identify as Aboriginal and/or Torres Strait Islander persons. Do you have any comments relating to access to the proposed intervention by other population groups?

Diabetes is one of the diseases that contributes to the higher rates of hospitalisation and mortality for Indigenous Australians.

It was reported (https://indigenoushpf.gov.au/measures/1-09-diabetes) that, in 2018-19, 13% of Aboriginal and Torres Strait Islander adults self-reported having diabetes or high sugar levels. This rate, adjusted for age, was 2.8 times the rate of non-Indigenous adults.

With respect to death rates due to diabetes, while there was a 17% decrease for Indigenous Australians between 2006 and 2018, the reported rate of 8% in the period of 2014-18 was five times that of non-Indigenous Australians.

These rates are unacceptable. It is vital that people who identify as Aboriginal and/or Torres Strait Islander persons have access to this proposed intervention. It is important that pharmacists can support with early identification of risk and detection of disease.

PSA notes that the screening tool is based on written language and that may be a barrier for some Aboriginal or Torres Strait Islander groups.

PSA is aware that there is a level of stigma associated with a diagnosis of type 2 diabetes for Aboriginal and Torres Strait Islander peoples. Cultural safety training will be essential for pharmacists and PSA would welcome the opportunity to develop and deliver this with appropriate resourcing.

It is reported that the impact of diabetes generally increases with increasing remoteness and socioeconomic disadvantage. In addition, people with other chronic health conditions may be susceptible to developing diabetes, or diabetes can cause or lead to other conditions. It is important that people with, for example, cardiovascular disease, chronic kidney disease, mental health conditions

11. Do you have any comments on the proposed intervention from a consumer perspective?

While PSA does not represent consumers, pharmacists as the most accessible health professional in the primary health setting have good insight into their healthcare needs through regular and frequent interactions. This is particularly the case for people with chronic diseases including diabetes.

Diabetes is a growing chronic condition requiring close monitoring and regular self-care. The role of pharmacists in supporting people with diabetes clearly extend beyond the supply of medicines and devices, and include improving health literacy, working in partnership with the person's regular GP and broader healthcare team, supporting holistic preventive care, and encouraging positive behaviour and achievement of realistic treatment goals.

Research indicates that consumers welcome the accessibility of pharmacists and value the care they receive. This has been re-iterated strongly, for example, during the COVID-19 pandemic.

Australia has a well-regarded network of community pharmacies and pharmacists are healthcare professionals highly trusted by consumers. In some regional, rural and remote locations, a pharmacist may be the only health provider in the community. The data update provided through the AIHW on

the indicators for the *Australian National Diabetes Strategy 2016-2020* (www.aihw.gov.au/reports/diabetes/diabetes-indicators-strategy-2016-2020/data) reported that diabetes death and hospitalisation rates in remote and very remote areas were twice as high as the rate in major cities. Thus, pharmacists can do more to support people in these areas.

PART 5 – ADDITIONAL COMMENTS

12. Do you have any additional comments on the proposed intervention and/or medical condition (disease)?

Training and support for pharmacists to ensure quality referrals will be needed for the intervention to be cost effective. Practice tools to ensure compliance should be clear and easy to access.

13. Do you have any comments on this feedback survey? Please provide comments or suggestions on how this process could be improved.

The availability of this survey document in Word format is appreciated. Many consultations undertaken by government departments and agencies now tend to limit submissions to be made through a cumbersome survey instrument which creates a barrier to organisations such as PSA to consult widely within its membership and provide considered feedback.

Again, thank you for taking the time to provide valuable feedback.

RACGP
Royal Australian College *of* General Practitioners

Healthy Profession.
Healthy Australia.

15 October 2021

Health Technology Assessment Team
Via email. commentsMSAC@health.gov.au
pharmacy.trial.program@health.gov.au

Dear Health Technology Assessment Team,

Re: MSAC 1677 – Pharmacy Diabetes Screening Trial

The Royal Australian College of General Practitioners (RACGP) thanks the Department of Health (DoH) for the opportunity to respond to the MSAC 1677 Pharmacy Diabetes Screening Trial evaluation.

Whilst the RACGP supports efforts to improve the identification and management of people with diabetes, we have some serious concerns with the evidence base underpinning the screening protocol in this trial and the potential for the model to fragment patient care and reduce the comprehensiveness of care. These specific concerns about the trial are outlined below:

General comments regarding the trial

- The proposed screening protocol within the trial[1] using the AUSDRISK differs significantly to the evidence-based recommendation of screening with AUSDRISK every three years as set out in the RACGP Management of type 2 diabetes: A handbook for general practice and Guidelines for preventive activities in general practice, 9th Edition.
- In an evaluative study by Siu, one reported barrier to successful diabetes screening implementation within the Pharmacy Diabetes Screening Trial (PDST) was the limited interaction between pharmacy and the patient's general practice. [2] The PDST encourages one-off, opportunistic screening for a single medical condition without the background biopsychosocial information of the patient and without the history of previous screening. It therefore fragments patient care.
- The trial protocol does not address the needs of people at higher risk of type 2 diabetes such as the Aboriginal and Torres Strait Islander populations, and also emerging populations such as younger persons with type 2 diabetes as the AUSDRISK has a lower age cut-off at 35 years.

Lack of reported data and concern about the study design

- 55% of the AUSDRISK only group were referred, presumably because they were deemed high risk and therefore this two-stage screening process is very inefficient.
- It was not possible to ascertain the false positive, false negative, screening positive, screening negative predictive values as much of the information was redacted.
- The trial did not identify how many people had been effectively screened for diabetes by their GP. The information provided indicated 55 patients already had diabetes diagnosed but were still engaged in the research. Only 136 undiagnosed diabetes patients out of 14,000 participants were identified in the trial. Pharmacists are unlikely to adequately identify which patients have previously been tested for diabetes as part of GP-requested pathology. Asking patients about their medical history will not necessarily provide comprehensive and robust answers.
- The trial had no control group.

The Royal Australian College of General Practitioners Ltd
100 Wellington Parade, East Melbourne VIC 3002
Tel **1800 4RACGP** | 1800 472 247 Fax (03) 8699 0400 Email racgp@racgp.org.au
racgp.org.au ACN 000 223 807 ABN 34 000 223 807

- There was no reference to peer reviewed research, so it is not possible to determine the level of evidence provided by the cluster randomised trial.

Almost 90% of the Australian population visit their GP each year, with an average of 6 visits per year.[3] A more efficient model would be to conduct HbA1c screening in general practice directly rather than introducing the step of opportunistic screening in pharmacy.
GPs provide comprehensive patient care and have available relevant biopsychosocial information for assessing the risk of diabetes for each patient. For example, the patient's family history; previous blood tests; history of gestational diabetes; information about ethnicity; and Aboriginal and Torres Strait Islander status; diagnoses of Polycystic Ovary Syndrome (PCOS); knowledge of antipsychotic medication use.

Pharmacies can only provide this service if they have two trained pharmacists on duty, and a private room. Thus, it provides an inequitable model of care with access barriers depending on pharmacy staffing. This limits the availability of the service and will further fragment patient care.

Thank you again for the opportunity to provide feedback. If you have any queries please contact Mr Stephan Groombridge, National Manager, eHealth and Quality Care on (03) 8669-0544 or at stephan.groombridge@racgp.org.au

Yours sincerely

Dr Karen Price

President

[1] Krass I, Carter R, Mitchell B et al. Pharmacy Diabetes Screening Trial: protocol for a pragmatic cluster-randomised controlled trial to compare three screening methods for undiagnosed type 2 diabetes in Australian community pharmacy. BMJ Open 2017;7:e017725. Doi: 10.1136/bmjopen-2017-01775

[2] Siu A, Krass I, Mitchell B, McNamara K. Implementation of diabetes screening in community pharmacy – factors influencing successful implementation. Research in Social and Administrative Pharmacy 17 2021 1606-1613.

[3] AIHW (Australian Institute of Heath and Welfare) Primary health care snapshot 2020. Https://www.aihw.gov.au/reports/australias-health/primary-health-care

Australian Government

Department of Health

Consultation Survey on MSAC Application 1677

Pharmacy Diabetes Screening Trial

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Email: commentsMSAC@health.gov.au and cc: pharmacy.trial.program@health.gov.au

Postal: MDP 959 GPO 9848 ACT 2601

PART 1 – PERSONAL AND ORGANISATIONAL INFORMATION

1. Respondent details

Name: Fiona Benton, Executive Manager of Health and Research, Diabetes SA

Email: s47F

Phone s47F

2. (a) Is the feedback being provided on an individual basis or by a collective group? (please select)

☐ Individual
☒ Collective Group

(b) If individual, specify the name of the organisation you work for

(c) If collective group, specify the name of the group

Diabetes SA

3. How would you best identify yourself?

☐ General Practitioner
☐ Specialist
☐ Pharmacist
☐ Researcher
☐ Consumer
☐ Care giver
☒ Other

(a) If other, please specify

Executive Manager of Health & Research (Health Professional)

PART 2 – CLINICAL NEED AND PUBLIC HEALTH SIGNIFICANCE

4. Describe your experience with supporting people with the medical condition (disease) and/or with the proposed intervention.

Diabetes SA is a not-for-profit organisation providing support to people with diabetes and those at risk. This includes group education, individual consultations, information, resources, phone and online support (including advocacy). Our approach is across the pillars of **early detection** (including risk awareness and screening), **prevention** and **management** of all types of diabetes. Our health professional staff are comprised of credentialed diabetes educators, accredited practising dietitians, exercise physiologist and registered pharmacist. Our research professionals support development and enhancement of all the health services we offer, ensuring they are underpinned by the latest global evidence while maintaining alignment with best-clinical practice guidelines for Australia. The research team also develop and conduct a range of research trials to pilot new and innovative approaches to detect, prevent and manage diabetes and we have a strong program of work across these pillars currently focussing on type 2 diabetes.

5. What do you see as the benefit(s) of the proposed intervention, in particular for the person involved and/or their family and carers?

The main benefit for people in the trial was the ability to access screening and receiving an appropriate, timely, referral to the GP. Early identification of being at high risk of type 2 diabetes, and for some the early detection of undiagnosed diabetes, enables them to access early intervention to make lifestyle changes to reduce their risk for developing the condition, or to manage their diabetes to prevent complications (or the worsening of complications where a person has been living with undiagnosed diabetes for a period of time). Moreover, if a diagnosis of type 2 diabetes is made as a result of screening, the ability to refer to a credentialled diabetes educator and accredited practising dietitian (and other allied health professionals) for education regarding the self-management of the condition is a key benefit for both the individual and also the healthcare system (and government).

It must be noted however that the report does not provide any detail about what education people in the trial received regarding education and support to assist them reduce their risk which is a lost opportunity in a trial with such large funding.

6. What do you see as the disadvantage(s) of the proposed intervention, in particular for the person involved and/or their family and carers?

Disadvantage is that it is difficult to ascertain from the information accessed the type of information people in the trial were provided to support them reduce their lifestyle risk factors. Given the screening was done in the pharmacy setting, any lifestyle information (if given) would most likely be brief and not wholistic. Evidence indicates that people do not make sustained changes to behaviour based on a brief intervention/information session. Understanding the GP referral uptake rates (or lack of), particularly those diagnosed with diabetes, needs to be included in the report and information made publicly available.

Given this was a publicly funded trial by the Australian Government, a better understanding of what supporting resources were provided, what level of health literacy they were pitched, and who people were referred to for more comprehensive support would be beneficial to provide feedback (the report lacks this information).

It is also important to understand what people in the trial perceived to be their benefits and disadvantages of participating in this trial. I would expect people in Group A felt disadvantaged from not being given the opportunity to have a point of care blood test at the pharmacy, and may have experienced more distress and anxiety about their risk score before they got confirmation from their GP about their diabetes status.

7. What other benefits can you see from having this intervention publicly funded by the Australian Government?

Good to see that there is a focus on early detection of high risk and for undiagnosed, however the evidence suggests that there are groups of people who are at higher risk, and a targeted approach would be more cost effective. Costs have been redacted so it is not possible ~~impossible~~ to determine the cost effectiveness of this general community approach.

From the available documentation regarding the Pharmacy Diabetes Screening Trial there are many gaps in the reports related to how the trial was run and evaluated across different states and pharmacies within states to comment on the effectiveness of the lifestyle advice provide by the pharmacist and the sustained behaviour changes that occur. It is great an economic evaluation on the cost-effectiveness of the screening program was done but really disappointing so much data was redacted so the public cannot see this to draw educated conclusions on the success of this funded trial.

PART 3 – INDICATION(S) FOR THE PROPOSED MEDICAL SERVICE AND CLINICAL CLAIM

8. Do you agree or disagree with the proposed population(s) for the proposed intervention as specified in the Executive Summary?

- ☐ Strongly Agree
- ☐ Agree
- ☒ Disagree
- ☐ Strongly Disagree

(a) Specify why or why not:

Difficult to comment as the proposed population is not clearly identified, in the recommendations of the Executive Summary, we assume it is general community when presenting at a pharmacy (opportunistically).

9. What is the appropriate comparator for the proposed intervention?

- ☐ Strongly Agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly Disagree

Don't understand the question but if it is asking about a comparator that should have been included in the trial then perhaps it could have been the usage rate of the AUSDRISK tool within the GP setting and how that triggers GPs to do further clinical testing to diagnose diabetes, or the number of people accessing online tools (AUSDRISK).

PART 4 – ADDITIONAL QUESTIONS

10. Do you have any comments relating to access to the proposed intervention by people who identify as Aboriginal and/or Torres Strait Islander persons. Do you have any comments relating to access to the proposed intervention by other population groups?

All high-risk groups including those from Aboriginal and/or Torres Strait Islander decent, should be prioritised, this would be more cost effective than delivering the service to general community. Delivering screening and lifestyle information and support needs to be delivered in a culturally safe manner. There is no indication in the Executive Summary that there was any targeting to these groups.

11. Do you have any comments on the proposed intervention from a consumer perspective?

There are many gaps in the reports related to how the trial was run and evaluated across different states and within different pharmacies. To determine the effectiveness of the lifestyle advice provide by the pharmacist and the sustained behaviour changes that occur you need to know exactly what each pharmacy did – i.e. what resources or advice did they give to people; was that the same at every pharmacy; how were pharmacies and their staff trained to deliver consistent quality care etc. It is great if an economic evaluation on the cost-effectiveness of the screening program was done but really disappointing so much data was redacted so the public cannot see this to draw educated conclusions on the success of this funded trial.

PART 5 – ADDITIONAL COMMENTS

12. Do you have any additional comments on the proposed intervention and/or medical condition (disease)?

Executive summary recommendations cite referring to GP if HbA1c greater than or equal to 5.7%. The RACGP guidelines state 6%. This needs to be reviewed in the recommendations put forward. Screening is most cost effective when targeted, and it appears that the population screened was general community. The results indicate that there is less than 3.4% detection rates (type 2 and prediabetes), if targeted high-risk populations were made the focus, the rates may be higher (and therefore more cost effective).

13. Do you have any comments on this feedback survey? Please provide comments or suggestions on how this process could be improved.

Yes, it is difficult to provide feedback when there is a significant amount of information redacted in the document. A request for further information was not successful (we were advised that this was not possible). Q9 is difficult to understand, as the responses to select from do not match the question, and it is very unclear what you are asking.

Again, thank you for taking the time to provide valuable feedback.

Australian Government

Medical Services Advisory Committee

Evaluation Sub-committee

ESC Report

1677 – ADAR - Pharmacy Trial Program (PTP) - Community Pharmacy Screening and Referral Service for Undiagnosed Type 2 Diabetes Mellitus

Applicant: Pharmacy Guild of Australia

Date of ESC consideration: 7 October 2021

Key issues from ESC to MSAC

ESC key issue	ESC advice to MSAC
Intended use population and frequency of testing.	The ADAR did not explicitly define the eligible population for the pharmacy-based opportunistic screening using AUSDRISK and HbA1c point-of-care (PoC) testing. ESC advised that it may be appropriate to align the eligible population with the RACGP guidelines which recommend screening every 3 years from 40 years of age using the AUSDRISK only. The RACGP guidelines recommend that people with an AUSDRISK score ≥ 12 should undergo fasting blood glucose (FBG) or HbA1c every 3 years. Aboriginal and Torres Strait Islander people should have their risk of diabetes assessed every year using blood testing (HbA1c or fasting plasma glucose) from 18 years of age. ESC advised the frequency of testing could be aligned to the RACGP guidelines but queried whether testing should be done more frequently given the negative test bias.
Fee proposal	The fee proposal was s47 for AUSDRISK alone and s47 for AUSDRISK and PoC HbA1c testing. ESC queried whether AUSDRISK assessment alone should be publicly funded as the AUSDRISK score is an eligibility criterion for HbA1c testing. The pre-ESC response also appeared to suggest a higher fee would be requested if capital costs are not reimbursed.
No comparison with usual care	The ADAR did not provide relevant clinical or economic evidence for the intervention plus usual care vs usual care alone. The commentary's economic evaluation which presents a comparison with usual care suggests pharmacy-based screening is not cost-effective.
HbA1c as a screening tool and negative mean bias of HbA1c PoC testing	MSAC did not support HbA1c PoC testing for diagnosing T2DM in general practice. Based on this, HbA1c PoC testing may not be appropriate as a screening tool. There is also possible negative assay bias, which could provide false reassurance.
Potential for over-diagnosis	There is a potential for over-diagnosing pre-diabetes, which will not benefit, but may harm and will add costs to the health system.

ESC key issue	ESC advice to MSAC
Limited potential to address inequity in diabetes diagnosis	The small number of diagnoses in regional and remote areas in the trial suggested that pharmacy-based screening may not address health inequities or access issues.
Very poorly constructed economic model with multiple deficiencies	The economic model has many issues, making it relatively uninformative. The ADAR's economic evaluation has not answered the more fundamental funding question of whether screening for diabetes by community pharmacies is a cost-effective addition to usual care. The different intervention arms had a different prevalence of T2DM (due to the recruitment into the trial) and is a major flaw and a significant driver of the results. The model costs were inappropriate and did not include the proposed fee for the screening intervention. The model developed by the commentary is more appropriate to base decisions on; however, this also has limitations due to the input data. These issues have led to significant uncertainties.
The financial estimates have several inappropriate or inconsistent assumptions	The financial estimates are highly uncertain and highly sensitive to the proportion of the eligible population who use community pharmacy screening, which was based on expert opinion.

ESC discussion

ESC noted that this application, from the Pharmacy Guild of Australia, was for public funding of community pharmacy-based opportunistic screening for pre-diabetes and type 2 diabetes mellitus (T2DM) in undiagnosed patients, including counselling and referral. The service includes risk assessment using the Australian Type 2 Diabetes Risk Assessment Tool (AUSDRISK) and point-of-care (PoC) glycated haemoglobin (HbA1c) testing for people with an AUSDRISK score of 12 or greater. The application proposed referring patients with a HbA1c of 5.7% or greater to a general practitioner (GP) for further T2DM testing.

ESC noted that the application was developed as a full health technology assessment after recommendation at the January 2021 MSAC Executive meeting. The application was based on the Pharmacy Diabetes Screening Trial (PDST) report, which aimed to compare the clinical effectiveness and cost-effectiveness of three screening models for T2DM in a previously undiagnosed population. The MSAC Executive noted that the PDST trial report does not provide information pertinent to MSAC decision making, particularly regarding cost-effectiveness as there was no analysis of the value of a pharmacy-based service in addition to current services or compared to alternative options for screening undiagnosed T2DM. The applicant-developed assessment report (ADAR) did not present a comparison with usual care. ESC considered this to be a major limitation of the ADAR.

The ADAR did not explicitly nominate a population for the proposed service. ESC noted the trial population was adult patients aged 35–74 years that have not been previously diagnosed with pre-diabetes or T2DM. ESC considered the PDST population did not align with the Royal Australian College of General Practitioners (RACGP) guidelines[1] which recommend that individuals who are not at high risk should be screened for diabetes every 3 years from 40 years of age using the AUSDRISK only. The RACGP guidelines recommend that Aboriginal and Torres Strait Islander people should have their risk of diabetes assessed every year with blood testing (HbA1c or fasting plasma glucose) from 18 years of age. ESC noted Aboriginal and Torres Strait Islander people have a higher prevalence of T2DM at younger

[1] The Royal Australian College of General Practitioners. Management of type 2 diabetes: A handbook for general practice. East Melbourne, Vic. RACGP; 2020.

ages. ESC advised that it may not be appropriate to exclude people enrolled in lifestyle change programs for T2DM from pharmacy-based T2DM screening. ESC considered that the requirement to "not have a terminal illness or certain blood disorders" which was a criterion in the PDST maybe be difficult to assess in a pharmacy as mild thrombocytopenia and anaemia are relatively common. ESC considered that this may be more suitable for a GP to assess. ESC considered that it may be appropriate to align the eligible population with the RACGP guidelines.

The ADAR did not explicitly nominate a frequency for testing. The PDST recruited participants who had not been screened for diabetes in the last 12 months. ESC noted this was more frequent than the RACGP guidelines for most people, including those with an AUSDRISK score of ≥12. ESC considered this could lead to over-testing. ESC queried whether a pharmacy-based test should be limited to every 3 years (as per RACGP guidelines for laboratory-based tests) or if it should be done more frequently given the negative test bias.

ESC noted that the ADAR did not include a fee proposal. The pre-ESC response clarified that the fee proposal was s47 for AUSDRISK alone and s47 for AUSDRISK and PoC HbA1c testing. However, the pre-ESC response stated that the fee per occasion of service would need to be reconsidered in the event capital expenditure cannot be considered for these devices. This appeared to suggest the applicant is seeking additional reimbursement for capital costs. ESC queried whether AUSDRISK assessment alone should be publicly funded as the AUSDRISK score is an eligibility criterion for HbA1c testing.

ESC noted that the ADAR did not present a clinical management algorithm. ESC expanded on the clinical management algorithm that was presented in the commentary. ESC considered the appropriate comparator to pharmacy-based opportunistic screening is usual care. For most patients this would be opportunistic screening by GPs. ESC noted the pre-ESC response presented several reasons for not including usual care (GP-based opportunistic screening) as the comparator. This included the proposed service complementing, rather than replacing usual care and that community pharmacy will serve a population not receiving GP-based opportunistic screening. ESC considered that people attending GPs and pharmacies were not separate populations, however, some people may prefer T2DM screening through community pharmacy. ESC noted that there is limited data to quantify the population screened for T2DM by GPs. The pre-ESC response suggested that only 15-20% of T2DM is diagnosed by GPs. ESC considered this to be low. ESC considered that GPs will often request fasting blood glucose measurements alongside other blood tests.

ESC noted that no public consultation feedback was available for this application at the time of the ESC meeting. ESC considered that consumer consultation feedback would be important for MSAC's consideration. ESC noted that the Department had contacted consumer groups for feedback and this may be available for MSAC consideration. ESC noted possible equity issues, such as whether people who speak English as a second language and Aboriginal and Torres Strait Islander communities would have equitable access to the proposed service. ESC advised that programs such as this should be designed with input from these communities. ESC noted that the PDST detected few cases in regional areas, and very few cases in remote areas, which the ADAR attributed to possible lower numbers of GPs in these areas available to confirm the diagnosis. However, ESC considered that it is these areas with GP shortages that may benefit the most from a community pharmacy-based screening program, as the rate of undiagnosed T2DM is the highest in these areas. For these reasons, ESC was concerned that the pharmacy-based T2DM screening may worsen health inequities rather than address them.

ESC noted that the PDST included a survey for participant feedback that had a s47 response rate, which ESC considered to be low. ESC noted that participant feedback was generally positive, however, some consumers did not value a service without a blood test. ESC also considered there may be privacy issues with patients discussing their medical history in community pharmacies that may not have a separate room to offer private consultations. ESC considered this may be a more significant concern for people in regional and remote communities. A separate area is a requirement of the Pharmacy Board.

In addition, ESC noted that the National Pathology Accreditation Advisory Council (NPAAC) advised that there is an existing Australian Government–funded PoC testing program called Quality Assurance in Aboriginal and Torres Strait Islander Medical Services (QAAMS) Program, which includes onsite PoC pathology testing for HbA1c and urine albumin:creatinine ratio. It is unclear how the proposed community pharmacy screening program would fit with the QAAMS program.

ESC noted that the PDST included the following pharmacy-based trial groups:

A. The paper-based AUSDRISK assessment of diabetes risk alone and GP referral for persons with an AUSDRISK score of 12 or greater
B. AUSDRISK followed by a PoC HbA1c test for persons with an AUSDRISK score of 12 or greater
C. AUSDRISK followed by a PoC small capillary blood glucose test (scBGT) for persons with an AUSDRISK score of 12 or greater

ESC noted the clinical claim was that Group B (AUSDRISK + PoC HbA1c) is the most effective community pharmacy screening option, leading to the most T2DM diagnoses per person screened s47 people were diagnosed with T2DM and s47 people were diagnosed with pre-diabetes). ESC noted that the numbers diagnosed with T2DM was consistent with estimated rates of undiagnosed T2DM in the adult Australian population (estimated to be 1.2%) in the PDST.

ESC noted that this is not directly relevant to MSAC decision making, which depends on the incremental clinical and cost-effectiveness compared to usual care (opportunistic screening by GPs). ESC noted that the ADAR instead presented clinical evidence for AUSDRSK + HbA1c (Group B) vs AUSDRISK alone (Group A).

ESC noted that the clinical relevance of a diagnosis of pre-diabetes is controversial[2] and raised concerns the label may contribute to overdiagnosis and unnecessary medicalisation which may be harmful. ESC considered that asymptomatic T2DM is a risk factor for developing macrovascular and microvascular complications. Therefore, pre-diabetes is a risk factor for developing T2DM, which itself is a risk factor. ESC highlighted that the 2021 United States Preventative Services Taskforce (USPST) report [3] which recommended screening for prediabetes and type 2 diabetes but found no direct evidence that screening for prediabetes improves clinical outcomes. The evidence for improvement in clinical outcomes for treating newly diagnosed T2DM was from the UK Prospective Diabetes Study (UKPDS) trial[4]. The UKPDS recruited patients before the diagnostic criterion for T2DM changed in

[2] Lam K, Lee SJ. Prediabetes-A Risk Factor Twice Removed. *JAMA Intern Med*. 2021;181(4):520-521.
[3] US Preventive Services Task Force. Screening for Prediabetes and Type 2 Diabetes: US Preventive Services Task Force Recommendation Statement. *JAMA*. 2021;326(8):736-743.
[4] UK Prospective Diabetes Study Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *The lancet*. 1998;352(9131):837-853.

1997. This reduced the diagnostic threshold for fasting glucose concentration from 7.8 mmol/l to 7.0 mmol/l. ESC considered that a diagnosis of T2DM now captured a population with a lower risk of developing macrovascular and microvascular complications than the UKPDS.

ESC noted that the MSAC Executive was concerned about possible doubling of services should community pharmacy screening be publicly funded, as a diagnosis confirmation would be required through a pathology test. Between 60% and 90% of laboratory HbA1c tests (requested in primary care) would be coned out and not incur a cost to government. In its pre-ESC response, the applicant stated that the pharmacy PoC would count as one of the two separate testing occasions that are required for diagnosis. ESC considered that this may be incorrect, as the assays used for diagnosing need to be suitable for diagnostic use and PoC HbA1c may not be suitable for diagnostic purposes.

ESC noted that, in MSAC's previous consideration of HbA1c PoC for diagnosis of T2DM, it considered that there are no significant acute differences in the safety of the HbA1c PoC testing technique over standard laboratory testing (MSAC 1431 Public Summary Document). ESC noted the MSAC Executive's concern that there might be evidence of a negative assay bias (as per the MSAC 1431 Public Summary Document), resulting in possible underdiagnosis. The applicant provided a citation (Sobolesky 2018[5]) in its pre-ESC response outlining the accuracy and precision of the Afinion PoC HbA1c testing method. Sobolesky (2018) did not examine testing in people without a diagnosis of T2DM and it was not clear whether the PoC assessment was blinded to the laboratory or reference method result.

In its pre-ESC response, the applicant stated that this application was different because the PDST trialled the use of PoC testing in screening, which ESC considered to be contradictory to the applicant's response to the issue of doubling-up of services.

ESC noted that the ADAR presented a cost-utility analysis using a short-term decision tree model covering the one-off community pharmacy screening phase. This was followed by a long-term Markov cohort model extrapolating the impact of diagnosed T2DM, undiagnosed T2DM, diagnosed pre-diabetes and no diabetes detected, on lifetime costs and quality-adjusted life years (QALYs).

ESC considered the economic models presented in ADAR were not informative for MSAC as they did not assess whether pharmacy-based opportunistic screening was a cost-effective addition to usual care. For this reason, ESC considered the commentary's revised base case was more informative for decision-making.

ESC noted that, for Group A in the ADAR, the Markov model assumed that T2DM screening only occurs once in a patient's lifetime, and that without community pharmacy screening leading to a diagnosis of T2DM, patients remain undiagnosed (and untreated) for the rest of their life, rather than allowing for delayed diagnosis (and treatment) by GPs (potentially after a future referral from a community pharmacy screening program).

ESC noted that the major limitation of the economic evaluation in the ADAR was that it compared different populations across the groups (e.g. there were more T2DM and pre-

[5] Sobolesky PM, Smith BE, Amy K, et al. Multicenter assessment of a hemoglobin A1c point-of-care device for diagnosis of diabetes mellitus. *Clinical Biochemistry.* 2018; 61:18–22

diabetes patients in Group A than in Groups B or C). ESC considered that there were many poorly justified assumptions in the short-term decision tree including:

- Different underlying prevalence of T2DM across the interventions.
- Although Group B (AUSDRISK + HbA1c) and Group C referred a subset of patients with AUSDRISK ≥ 12:
    - Group A had a higher rate of false negatives; and
    - The prevalence of T2DM in referred participants was the same across all groups.

ESC noted that the differences in costs and QALYs are driven by these differences in the populations entering the model. ESC considered that the decision tree structure should have first defined the underlying prevalence of T2DM and pre-diabetes in the population eligible for screening. This would have avoided needing to make assumptions about false negative rates.

ESC considered the screening decision-tree in the model may be oversimplified because it does not allow for a sensitivity analysis of alternate thresholds for AUSDRISK and PoC test results.

ESC noted the long-term outcomes were modelled based on the UKPDS diabetes model. ESC considered the decision not to use the newer version of the UKPDS model (UKPDS 2) published in 2013 was not justified. ESC noted that the ADAR model included three separate Markov cohort models for each diagnosis (i.e. T2DM, pre-diabetes and no diabetes). The results were then applied to the diagnoses in each group as payoffs to the screening outcomes of the short-term decision tree. ESC considered this approach to be inappropriate, as it does not provide information about the incremental value of the intervention against usual care. ESC noted that there is evidence the UPKDS model may overestimate the risk of T2DM-related health events in the Australian T2DM population.

The ADAR presented several scenario analyses. The model was sensitive to changes in the rates of false negatives, test cut-offs and referral rates, all of which are uncertain.

The ESC noted there were numerous problems with the costs applied in the economic model as outlined in the commentary. The screening intervention cost was not the proposed service fee. The economic evaluation applied costs incurred on a per-patient basis, including trial establishment and recruitment costs. This led to Group C's community pharmacy screening cost being lower than Group A, despite the intervention in Group C comprising Group A plus a PoC blood glucose test. In the PDST, Group A recruited more pharmacies than Group C, resulting in higher set-up costs, but fewer participants, so the cost per participant screened was greater in Group A.

ESC also noted that the MSAC Executive previously concluded that PoC HbA1c testing for GPs is cost-effective for prices up to $11.80, which is significantly below the ADAR's incremental community pharmacy screening cost for Group B compared to Group A.

ESC noted that the model used a s47 discount rate, but the MSAC guidelines recommend using 5%. ESC considered this difference to be significant when assessing models that adopt a lifetime time horizon.

ESC noted that, because the ADAR did not include any comparisons against usual care, the commentary included a revised Markov model using a consistent underlying prevalence of

T2DM for usual care + PDST compared with usual care alone. The commentary also presented cost-effectiveness results for the comparisons in the ADAR as well as each for community pharmacy screening option (Groups A–C) against usual care (Group D). This resulted in incremental cost-effectiveness ratios (ICERs) of s47 per QALY to nearly s47 QALY. In its pre-ESC response, the applicant revised this analysis by removing the adjustment for delayed diagnosis and adjusted for higher treatment costs in the intensive treatment arm of the T2DM Markov model. These revisions gave ICERs of s47 for Groups A–C compared to Group D. The applicant asserted that its pharmacy-based screening program complements, not replaces, usual care, but ESC noted that the model presented in the ADAR is not structured to address this assertion. ESC also noted one of the revised analyses in the pre-ESC response calculated the ICERs incorrectly (i.e. costs for usual were simply added to the incremental costs of pharmacy screening).

ESC noted that the financial analysis in the ADAR used an epidemiological approach and costs were based on implementing AUSDRISK and HbA1c PoC testing. The costs assumed that patients would be screened once per year, which conflicts with the RACGP guidelines. ESC noted that patient uptake is a key parameter that influences the overall impact, which was estimated by expert opinion in the ADAR. The financials also assume no cost offsets of reduced GP screening. In its pre-ESC response, the applicant claimed that GPs only accounted for 15–20% of diabetes diagnoses. ESC noted a recent study in western Sydney that screened patients who presented to hospital, and found that 38.4% (487/1,267) had T2DM and 32.2% (157/487) of these were newly diagnosed with T2DM.[6] This may suggest that hospitals may diagnose a subset of T2DM cases. However, the generalisability is unclear as the study authors described the population as "seemingly enriched with cases of diabetes".

ESC noted the following additional issues with financial analysis presented in the ADAR:

- The financial estimates include PoC device capital costs, which is inappropriate.
- The number of Group B participants who received a short and standard consultation used in the financial impact analysis do not match.
- The GP follow-up cost in the ADAR's financial impact analysis is per T2DM or pre-diabetes diagnosis, which results in a significantly higher GP follow-up cost than that in the economic analysis.
- The ADAR assumed that s47 of the eligible population has undiagnosed T2DM, which is less than the estimates provided in the ADAR's economic base case and scenarios s47

ESC considered that these issues resulted in a very uncertain financial impact, which was calculated at up to s47 per year by year 5. The commentary presented a revised financial impact analysis correcting for the issues identified in the ADAR, which resulted in a financial impact of s47 in year 1 to s47 in year 5.

ESC advised that pharmacists should require formal training and accreditation to be competent to deliver the service at an acceptable standard, and need to participate in quality assurance processes. ESC noted that community pharmacies that perform PoC testing fall outside the scope of the proposed *NPAAC requirements for point of care testing* (first edition 2015). However, the NPAAC requirements would provide guidance on good practice for the performance of PoC testing in other healthcare settings. ESC noted that MBS item 73893 for HbA1c testing for diagnosis of diabetes requires that the practitioner or the organisation for

[6] Hng TM *et al.* Diabetes case finding in the emergency department, using HbA1c: an opportunity to improve diabetes detection, prevention, and care. *BMJ Open Diabetes Res Care*. 2016;4(1):e000191.

which the practitioner works is participating in the QAAMS Program. ESC also noted that participating pharmacies would need to adhere to Departmental requirements, such as adequate record keeping of AUSDRISK and test results, and consequence and evidence of referrals where appropriate.

1. Purpose of application

An application requesting public funding of community pharmacy-based opportunistic screening of T2DM using the AUSDRISK questionnaire and PoCT of HbA1c was received from the Pharmacy Guild of Australia by the Department of Health.

Diabetes mellitus is a chronic disorder that reduces the body's ability to produce and/or use insulin (a hormone produced by the pancreas to regulate blood sugar levels). This results in high blood sugar levels, which lead to serious complications such as stroke; diabetes-related eye disease such as diabetic retinopathy; heart disease; high blood pressure; kidney disease; vascular disease; nerve damage; and foot problems. Many people with T2DM will not have any symptoms.

2. Background

The Sixth Community Pharmacy Agreement (6CPA) provided $50 million over the term to fund the Pharmacy Trial Program (PTP) to trial new and expanded community pharmacy programs, which sought to improve clinical outcomes for consumers and/or extend the role of pharmacists in the delivery of primary health care services.

Once finalised, consistent with the 6CPA, the outcomes of each PTP trial are to be evaluated by an independent health technology assessment body to determine the effectiveness and cost-effectiveness of the trial intervention and inform decisions about any broader rollout. A decision to fund any future programs would be a matter for Government.

The MSAC Executive considered the PDST at its January 2021 meeting. A summary of the key matters raised by the MSAC Executive and related issues are presented in Table 1.

Table 1: Summary of key matters of concern

Component	Matter of concern	How the current assessment report addresses it
Comparison with usual care	The PDST and economic evaluation do not compare community pharmacy screening with current services or alternative screening options. The MSAC Executive noted that this information is pertinent to MSAC's decision making.	Not addressed - no comparison with usual care presented. The commentary includes a revised base case comparing community pharmacy screening against usual care.
Duplication with pathology services	Double up in services as a diagnosis confirmation would be required through a pathology test. MSAC Executive also previously considered it reasonable to assume that between 60 – 90% of laboratory HbA1c tests would be coned out (p3, 1431 PSD)	Not addressed.
Fee arrangement was not proposed	The PDST did not explicitly propose a fee arrangement	The ADAR financial impact analysis proposes a screening fee per service of s47 . Which is a weighted average of s47 for administering AUSDRISK and s47 for administering both AUSDRISK and HbA1c PoC testing.

Component	Matter of concern	How the current assessment report addresses it
HbA1c as a screening tool	MSAC did not support HbA1c PoC testing for diagnosis of T2DM in the context of medical practitioners (p1, 1431 PSD). Based on that precedent, HbA1c PoC testing may not be appropriate as a screening tool.	Not addressed.
Negative mean bias of HbA1c PoC testing	In their consideration of HbA1c PoC testing for T2DM, MSAC was particularly concerned that there may be evidence of a negative assay bias suggesting that the PoC test result is more likely to be less than the laboratory result, which would underdiagnose diabetes (p2 1431 PSD)	Not addressed.
HbA1c threshold	Full HTA should include base case economic analysis and its sensitivity to the threshold of HbA1c used	Somewhat addressed. The ADAR within-trial economic evaluation contains a univariate sensitivity analysis exploring the impact of adopting a HbA1c cut-off ≥6.0%. No corresponding sensitivity analysis was presented for the modelled economic evaluation.
Financial estimates	Total cost to Government was not presented	Partially addressed. Additional costs of treatment related to newly diagnosed cases not considered. Unlike the modelled economic evaluation, the financial impact analysis assumes costs savings of fewer diabetes related complications will occur more than 5 years in the future.

Source: Table 1, p7 of the commentary
Abbreviations: MSAC - Medical Services Advisory Committee; PoC – point of care; PDST-Pharmacy Diabetes Screening Trial; PSD - Public Summary Document; T2DM – type 2 diabetes mellitus

3. Prerequisites to implementation of any funding advice

The ADAR states that a formal training and assessment process would need to be implemented to ensure that pharmacists undertaking a remunerated screening service can demonstrate the requisite competencies to deliver the service at an appropriate standard. Similarly, the ADAR recognises that quality assurance processes be required for participating pharmacies to ensure effective uptake and consistent service delivery.

The exact nature of the quality assurance system is not documented in the ADAR. Pathology accreditation standards are applicable for pathology laboratories seeking accreditation in order to be able to provide MBS pathology services. Community pharmacies that perform PoC testing fall outside the scope of the proposed NPAAC Requirements for Point of Care Testing (First Edition 2015). However, the commentary considered the Requirements would provide guidance on good practice for the performance of PoC testing in other health care settings.

MBS item 73893 for PoC HbA1c testing for diagnosis of diabetes requires that the practitioner or the organisation for which the practitioner works is participating in the Quality Assurance in Aboriginal Medical Services (QAAMS) Program.

The 1 November 2021 MBS listing of PoC HbA1c testing for the monitoring of established diabetes must be performed:

- by or on behalf of a medical practitioner who works in a general practice that is accredited against the point of care testing accreditation module under the National General Practice Accreditation Scheme; and
- using a method and instrument certified by the National Glycohemoglobin Standardization Program (NGSP), if the instrument has a total coefficient variation less than 3.0% at 48 mmol/mol (6.5%).

4. Proposal for public funding

The ADAR did not present an explicit fee proposal. The pre-ESC response clarified that the fee proposal was s47 for AUSDRISK alone and s47 for AUSDRISK and PoC HbA1c testing. However, the pre-ESC response fee per occasion of service would need to be reconsidered in the event capital expenditure cannot be considered for these devices. This was consistent with the screening service fees in the financial estimates. The modelled economic evaluation did not use the same cost of community pharmacy screening as the financial impact analysis.

Table 2 presents the MBS fees for potentially comparable pathology and consultation items. MSAC may wish to advise on the appropriate reimbursed fee for the proposed intervention.

Table 2: MBS fees for relevant pathology and consultation items

MBS item	Descriptor (abridged)	Fee and benefit [a]
Pathology testing items		
66841	Quantitation of HbA1c (glycated haemoglobin) performed for the diagnosis of diabetes in asymptomatic patients at high risk.	$16.80 Benefit: 85% = $14.30
73839	Quantitation of HbA1c (glycated haemoglobin) performed for the diagnosis of diabetes in asymptomatic patients at high risk – not more than once in a 12 month period. (QAAMS item)	
73812	Quantitation of glycated haemoglobin (HbA1c) performed in the management of established diabetes when performed: (a) as a point-of-care test; and (b) by or on behalf of a medical practitioner who works in a general practice that is accredited against the point of care testing accreditation module under the National General Practice Accreditation Scheme; and (c) using a method and instrument certified by the National Glycohemoglobin Standardization Program (NGSP), if the instrument has a total coefficient variation less than 3.0% at 48 mmol/mol (6.5%) Applicable not more than 3 times per 12 months per patient	$11.80
66500	Quantitation in serum, plasma, urine or other body fluid (except amniotic fluid), by any method except reagent tablet or reagent strip of glucose [or other specified substances]- 1 test	$9.70 Benefit: 85% = $8.25
66542	Oral glucose tolerance test for the diagnosis of diabetes mellitus that includes: (a) administration of glucose; and (b) at least 2 measurements of blood glucose.	$18.95 Benefit: 85% = $16.15
Consultation items (general practitioners)		
3	Professional attendance by a general practitioner for an obvious problem characterised by the straightforward nature of the task that requires a short patient history and, if required, limited examination and management-each attendance	$17.90
23	Professional attendance by a general practitioner lasting less than 20 minutes including any of the following that are clinically relevant: (a) taking a patient history; (b) performing a clinical examination; (c) arranging any necessary investigation;	$39.10

MBS item	Descriptor (abridged)	Fee and benefit [a]
	(d) implementing a management plan; (e) providing appropriate preventive health care; for one or more health-related issues, with appropriate documentation-each attendance	
Consultation items (nurse practitioners)		
82200	Professional attendance by a participating nurse practitioner for an obvious problem characterised by the straightforward nature of the task that requires a short patient history and, if required, limited examination and management.	$10.00 Benefit: 85% = $8.50
82205	Professional attendance by a participating nurse practitioner lasting less than 20 minutes and including any of the following: a) taking a history; b) undertaking clinical examination; c) arranging any necessary investigation; d) implementing a management plan; e) providing appropriate preventive health care, for 1 or more health related issues, with appropriate documentation.	$21.80 Benefit: 85% = $18.55
Consultation items (other medical practitioners)		
53	Professional attendance at consulting rooms of more than 5 minutes in duration but not more than 25 minutes (other than a service to which any other item applies)-each attendance, by: (a) a medical practitioner (who is not a general practitioner); or (b) a Group A1 disqualified general practitioner, as defined in the dictionary of the General Medical Services Table (GMST).	$21.00

Source: MBS Schedule July 2021

[a] 85% benefit presented as the proposed service is not expected to be rendered to a patient as part of an episode of hospital treatment or hospital-substitute treatment

5. Summary of public consultation feedback/consumer issues

No consumer feedback/consumer comments were received for this application for ESC to consider.

The PDST surveyed participants three months after their screening date. Surveys were sent to s47 referred participants and s47 responses were received (response rate s47). A further s47 surveys were emailed to all non-referred participants and s47 responses were received (response rate s47). The key findings included:

- more than s47 of respondents rating the service as professional or very professional;
- more than s47 of respondents stating that they would recommend the screening service to a family member or friend;
- more than s47 of respondents were either satisfied or very satisfied with the way the pharmacist explained their screening test results;
- a small number of participants were not satisfied with the amount of information provided and some appeared not to value a service that did not include a blood test; and
- more than s47 of respondents reported making healthy lifestyle changes since attending the pharmacy screening service.

6. Proposed intervention's place in clinical management

The ADAR did not explicitly nominate a population for the proposed service. The population considered in the PDST were adults aged between 35-74 years, who do not have a history of

diabetes or prediabetes and have not recently been screened for diabetes. The ADAR financial impact analysis suggests 'recent' to be within 12 months. The RACGP guidelines recommend individuals not at high risk should be screened for diabetes every 3 years from 40 years of age using the AUSDRISK only.

The Australian Health Survey: Biomedical Results for Chronic Diseases, 2011–12 estimated the prevalence of diabetes (including those diagnosed and undiagnosed) using HbA1c testing (Table 3).

Table 3: Diabetes prevalence based on diagnosis status using HbA1c

Diabetes status	Age Group						
	18–34	**35–44**	**45–54**	**55–64**	**65–74**	**≥ 75**	**All (≥ 18)**
Known diabetes	0.4%*	2.2%	4.0%	6.4%	12.7%	10.5%	4.2%
Newly diagnosed diabetes (previously undiagnosed)	0.1%**	0.5%*	1.3%*	2.4%	2.8%	2.3%*	1.2%
Total with diabetes	0.5%*	2.7%	5.3%	8.8%	15.5%	12.8%	5.4%

Source: Table 12.3, Australian Health Survey: Biomedical Results for Chronic Diseases, 2011-12 Australian Bureau of Statistics [2]

* Estimate has a relative standard error of 25% to 50% and should be used with caution

** Estimate has a relative standard error greater than 50% and is considered too unreliable for general use

Bold represents the target population of the proposed service

The Pharmacy Trial Program Evaluation noted that it was intended that the Community Pharmacy Programmes, including the Pharmacy Trials Program, would have a focus on benefits for Aboriginal and Torres Strait Islander people. Although not specifically considered in ADAR, MSAC may wish to consider whether a younger population of Aboriginal and Torres Strait Islander people should be considered eligible for the proposed intervention. The 2018-19 National Aboriginal and Torres Strait Islander Health Survey[3] estimated that 2.5% of the Aboriginal and Torres Strait Islander people aged 25-34 years had diabetes, which is similar to the estimated prevalence of 2.7% in the broader Australian population aged 35-44 years. The RACGP guidelines recommend that Aboriginal and Torres Strait Islander peoples should have their risk of diabetes assessed every three years from 18 years of age.

The ADAR did not present current and proposed clinical management algorithms. The clinical management algorithms presented in Figure 1 were developed by ESC.

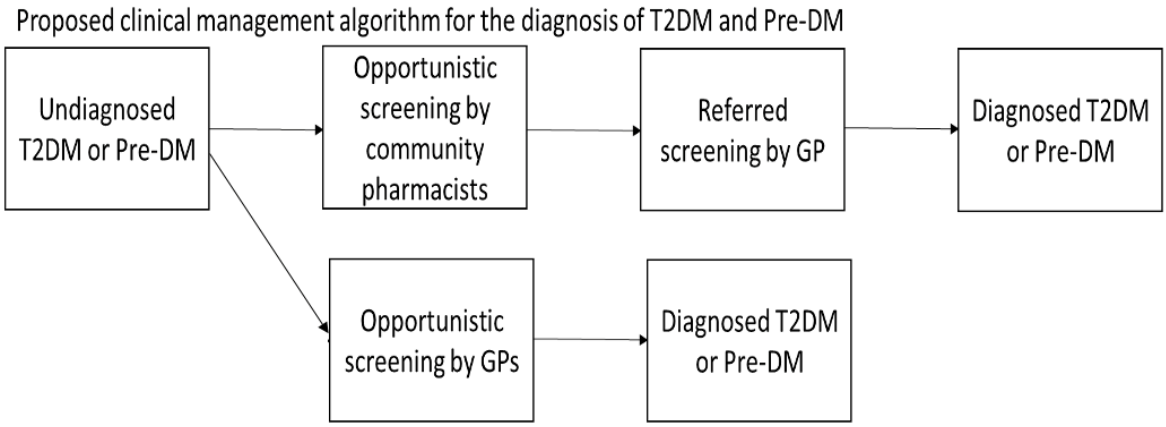

Figure 1: Clinical management algorithms

Source: Developed by ESC using the algorithm presented in the commentary

Abbreviations: GP - general practitioner; Pre-DM – pre-diabetes mellitus; T2DM – type 2 diabetes mellitus

Under the current management algorithm, T2DM and Pre-DM are diagnosed by GPs through opportunistic screening, as indicated by RACGP guidelines. Under the proposed clinical management algorithm, community pharmacists would perform opportunistic screening using the AUSDRISK questionnaire and PoC HbA1c testing before referral to GPs who would confirm the diagnosis with additional pathology testing.

The ADAR suggests that three GP visits would be required to diagnose T2DM in Group A *(*AUSDRISK only) and Group C (AUSDRISK + PoC scBGT), but only two GP visits in Group B (AUSDRISK + PoC HbA1c*)* considering a lab equivalent HbA1c PoC had been conducted by community pharmacists.

In the ADAR's modelled economic evaluation, patients diagnosed with Pre-DM are offered Lifestyle Treatment (diet modification, increased physical activity) while patients diagnosed with T2DM are offered Intensive Treatment (either sulfonylurea or insulin or, in overweight patients, metformin for glucose control) or No Intensive Treatment (diet modification). The commentary considered that this may not be reflective of current medical management of T2DM where metformin is the usual first-line therapy unless contraindicated or not tolerated (RACGP guidelines). The adoption of community pharmacy screening would not change the clinical management algorithm for the treatment of T2DM or Pre-DM.

7. Other options for MSAC consideration

Nil.

8. Comparator to the proposed intervention

The comparator in the clinical trial and economic evaluations presented in the ADAR was community pharmacy screening using the AUSDRISK questionnaire only (Group A). As community pharmacy screening is intended to complement and not replace any existing screening service, the commentary considered the comparator should be usual care. The commentary considered this would be consistent with the 2017 MSAC Guidelines (p19) which states that the primary comparison is likely to be either another investigative medical service in terms of alternate diagnostic method or modality or in some instances 'no testing'/'usual care'.

In this setting, the commentary considered usual care for most patients is likely to be opportunistic screening by GPs. The RACGP guidelines for management of T2DM recommend individuals aged 40 and over not at risk of T2DM should be screened every 3 years using the AUSDRISK questionnaire (i.e., Group A). Individuals at a high risk of developing diabetes should be screened with either fasting blood glucose or HbA1c every 3 years, and individuals with impaired glucose tolerance (i.e., Pre-diabetes) should undergo testing every year.

A 2014-15 survey by the Australian Bureau of Statistics found 83% of respondents had seen a GP in the previous year; therefore, the population inaccessible to GP screening for T2DM is unlikely to be large but some people may experience a longer time to a diagnosis in usual care. The applicant's response to the Preliminary Evaluation contended that although patients may visit a GP, this is often for an acute condition and it is known that preventive services are not routinely delivered in general practice. Additionally, even if people have been tested, they may be unaware of their status especially those with prediabetes as observed among a group of screened participants in the trial. ESC considered that most GPs would request

blood glucose testing when they order blood tests. However, patients may not have fasted when blood is drawn.

The pre-ESC response claimed that GPs detect 15-20% of T2DM cases. This was estimated based on National Diabetes Services Scheme (NDSS) registrations (assuming 85% registration rate) and an estimated annual T2DM incidence of 3% of the adult population aged 25-75 years. The pre-ESC report's estimated incidence for T2DM could not be verified.

The applicant's response to the Preliminary Evaluation stated that it could be argued that Group A received a more intensive screening approach than usual care (no pharmacy screening), presumably creating a strong argument that if another intervention is deemed more effective than group A, as occurred in the PDST, that it would also be more effective than usual care (Applicant Response to Preliminary Evaluation, p7).

The commentary's revised base case includes a comparison against usual care, understood to most likely be opportunistic screening by GPs but there is limited evidence available to inform this comparison.

9. Comparative safety

Characteristics of the evidence base

The PDST was a clustered randomised controlled trial that compared the effectiveness of three different pharmacy-based screening models:

1. The paper based AUSDRISK assessment of diabetes risk, alone (Group A)
2. AUSDRISK followed by a point-of-care (PoC) HbA1c test for those at risk (Group B)
3. AUSDRISK followed by a PoC small capillary blood glucose testing (scBGT) for those at risk (Group C).

The focus of the ADAR is a proposal to fund the services provided in Group B.

Table 4: Key features of the included evidence

Criterion	Type of evidence supplied	Extent of evidence supplied	Overall risk of bias in evidence base [a]
Change in patient management	The PDST provides evidence to show that community pharmacy screening of T2DM identifies previously unidentified T2DM and Pre-DM	k=1 n= 14,093	*Significant due to recruiting an inequitable population across the groups*

Abbreviations: k=number of studies, n=number of patients, T2DM – type 2 diabetes mellitus
[a] *Based on the preliminary evaluation*

In the development of AUSDRISK a score of ≥ 12 corresponded to the point on the receiver operating characteristic (ROC) curve at which sensitivity (74.0%) plus specificity (67.7%) were maximised for predicting incident T2DM over 5 years.[7]

In its previous consideration of HbA1c PoC for diagnosis of T2DM, MSAC considered that there are no significant acute differences in the safety of the HbA1c PoC testing technique over standard laboratory testing (p2 MSAC 1431 PSD).

[7] Chen L, Magliano DJ, Balkau B, et al. Maximizing efficiency and cost-effectiveness of Type 2 diabetes screening: the AusDiab study. *Diabet Med*. 2011;28(4):414-423.

10. Comparative effectiveness

The clinical results of the PDST are presented in Table 5.

Table 5: Pharmacy screening diabetes trial results

	Group A (AUSDRISK only)	Group B (AUSDRISK + PoC HbA1c)	Group C (AUSDRISK + PoC scBGT)
Recruited	3,957	5,165	4,971
Know T2DM	s47	s47	s47
AUSDRISK ≥ 12	s47	s47	s47
Referred to GP	s47	s47	s47
Visited GP (Self-reported)	s47	s47	s47
Tested (Self-reported)	s47	s47	s47
Tested (Medicare data)	s47	s47	s47
Diagnosed T2DM	s47	s47	s47
Diagnosed Pre-DM[1]	s47	s47	s47

Source: PDST Final Report, Figure 11, p76 and Figure 18, p97

[1] Pre-DM defined as HbA1c 5.7%-6.4% or FGB 6.1-6.9 mmol/L

Abbreviations: AUSDRISK - Australian type 2 diabetes risk assessment tool; GP – general practitioner; PoC – point of care; Pre-DM - pre-diabetes mellitus; scBGT - small capillary blood glucose testing; T2DM – type 2 diabetes mellitus

Overall, a small number of additional cases of diabetes were detected: s47 of T2DM and s47 Pre-DM across the 14,093 participants screened (s47 and s47 respectively).

The commentary considered that this is low, given the expected prevalence of undiagnosed T2DM used in the sample size calculation s47). The Preliminary Evaluation, however, noted that that the observed rate of new diagnoses of less than 1% is unsurprising because other population-based screening programs returned a similar percentage of new cases. This was also acknowledged in the PDST Final Report (p173 of the PDST Final Report). The new T2DM diagnoses also corresponded closely with the ABS National Health Survey estimates of undiagnosed diabetes (1.2% in the total adult population).

Fewer cases were diagnosed in regional areas and very few cases were detected in remote areas. The trial report suggested that the relative shortage of GPs in regional and remote areas as a reason for this finding (p172 of the PDST Final Report), on the grounds that it may have been more difficult for regional and remote participants referred by pharmacists to have a diagnosis of T2DM or Pre-DM confirmed.

The Preliminary Evaluation noted that no data was presented to confirm a lower GP attendance rate in referred participants in regional and remote areas (though it could have been extracted from the data set). In any case, it is in communities with a relative shortage of GPs that effective screening by non-GP providers is most desirable, and where the rate of undiagnosed T2DM is generally found to be highest, so the low yield of pharmacy-based screening in regional and remote areas was considered troubling.

The ADAR did not address the issue of a negative assay bias suggesting that the PoC test result is more likely to be less than the laboratory result (p2, Application 1431 PSD). The ADAR did not provide evidence for improved assay precision or whether the assay imprecision associated with HbA1c PoC testing would be less critical in the context of screening asymptomatic individuals.

The pre-ESC response referred to Sobolesky (2018)[8] to address MSAC's previous concerns that there may be evidence of a negative assay bias suggesting that the PoC test result is more likely to be less than the laboratory result, which would underdiagnose diabetes (p2, 1431 PSD). Sobolesky (2018) tested remnant EDTA anti-coagulated whole blood specimens with clinical orders and indications for HbA1c testing. Patient characteristics were not further described. It assessed the Afinion AS100 device used in the PDST and laboratory methods. Sobolesky (2018) reported a relative percentage mean bias of the Afinion device as −0.9% (95% CI: −1.38%, −0.45%) and −0.6% (95% CI: −0.86%, −0.39%) at HbA1c level of 5.0% and 6.5%, respectively. The corresponding relative percentage mean bias was −1.1% (95% CI: −1.61%, −0.65%) and −0.9% (95% CI: −1.18%, −0.58%) at HbA1c level of 5.0% and 6.5%, respectively, was for laboratory testing. Figure 2 presents the difference plots POC and routine laboratory standard-of-care. For HbA1c values less than 7%, there appeared to be a higher proportion of samples where PoC testing reported a lower value than the reference method.

[8] Sobolesky PM *et al*. Multicenter assessment of a hemoglobin A1c point-of-care device for diagnosis of diabetes mellitus. *Clinical Biochemistry.* 2018; 61:18–22

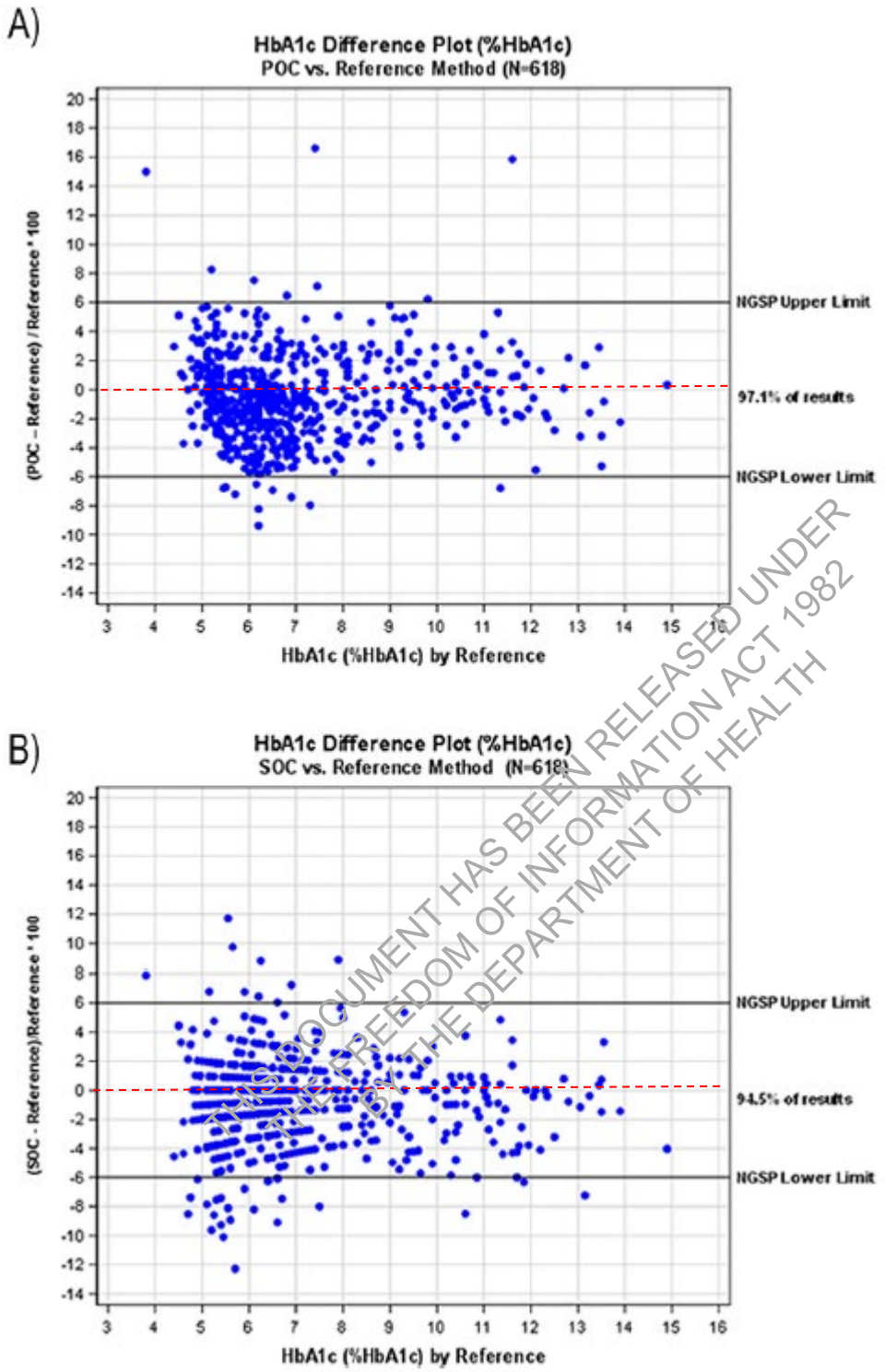

Figure 2 Difference plots comparing point of care and routine laboratory standard-of-care HbA1c results with an NGSP reference method. Limit lines of ±6% are illustrated on the graph. (a) The POC device versus the mean results from the reference method. (b) SOC laboratory result versus the mean reference method result.

Source: Figure 2, p21 of Sobolesky (2018)

Sobolesky (2018) had the following limitations:

- *The publication did not describe the selection of samples/participants for testing. It is unknown what proportion was for testing was requested for people without T2DM;*

- *The laboratory test appeared to have been performed first, with PoC testing performed within 72 hours of collection. The publication did not state whether PoC test results were interpreted without knowledge of the laboratory test result;*
- *Whether PoC testing up to 72 hours after collection would reflect accuracy when tested at the time of collection;*
- *Not all the laboratory methods were cleared by the United States Food and Drug Administration for diagnostic testing and only one method was a NGSP certified reference method; and*
- *The NGSP requirement was based on 40 samples whereas the study reported results for all 618 samples. It was unclear whether 40 samples would meet the requirement.*

Clinical claim

The ADAR's clinical claim is that Group B (AUSDRISK + PoC HbA1c) is the most effective community pharmacy screening option, leading to the most T2DM diagnoses per person screened. The commentary considered that this appears to be true for T2DM diagnoses, but not for Pre-DM, where Group A (AUSDRISK only) lead to the most Pre-DM diagnoses per person screened.

The ADAR did not make a clinical claim with respect to usual care. The ADAR did not provide any clinical evidence demonstrating that pharmacy-based diabetes screening using AUSDRISK + HbA1c PoC testing is superior to usual care for diagnosing T2DM and Pre-DM.

The commentary considered that there is some suggestive evidence that AUSDRISK + HbA1c PoC would result in more 'earlier' diagnoses of T2DM; however, there is also suggestive evidence that AUSDRISK only would result in more 'earlier' diagnoses of pre-DM. Therefore, commentary considered the preferred option for community pharmacy-based opportunistic screening remains unclear. In addition, no evidence is provided on the how much 'earlier' these diagnoses would occur.

11. Economic evaluation

The ADAR economic evaluation comprises both a within-trial evaluation estimating the cost per additional T2DM (and Pre-DM) diagnosis and a modelled cost-utility extrapolation. The ADAR included several alternative cost-utility models. The ADAR (PDST Final Report) stated that Model 4.3 was the preferred model. This model was focussed on in the commentary. The modelled economic evaluation did not compare pharmacy-based screening with usual care.

The cost-utility analysis uses a short-term decision tree model covering the one-off community pharmacy screening phase followed by a long-term Markov cohort model extrapolating the impact of diagnosed T2DM, undiagnosed T2DM, diagnosed Pre-DM, and No DM detected, on lifetime costs and QALYs.

Table 6: Summary of the economic evaluation

Component	Description
Perspective	Health care system perspective
Population	Adult (35-75) population of Australia without a prior T2DM diagnosis
Underlying prevalence (T2DM / Pre-DM)	Group A (AUSDRISK only) – s47 Group B (AUSDRISK + PoC HbA1c) – s47

Component	Description
	Group C (AUSDRISK + PoC scBGT) – s47
Prior testing	No prior diagnosis of T2DM – opportunistic community pharmacy screening programme
Comparator	Relative cost-effectiveness of **one-off screening** using; Group A (AUSDRISK only) Group B (AUSDRISK + PoC HbA1c) Group C (AUSDRISK + PoC scBGT)
Type(s) of analysis	1. Within-trial cost-effectiveness analysis 2. Modelled cost-utility extrapolation
Outcomes	1. Cost per T2DM diagnosis / cost per Pre-DM diagnosis 2. Cost per QALY gained
Time horizon	1. N/A 2. Lifetime (Cohort all dead 60 years post screening)
Computational method	1. N/A 2. Short-term decision tree & long-term Markov cohort models
Generation of the base case	1. Trial-based 2. Modelled • Total cost & QALYs for diagnoses - T2DM (+/-Intensive Tx), Pre-DM (+/- Lifestyle Tx), No DM calculated in long-term Markov cohort models • Total cost & QALYs applied to short-term decision tree to determine cost effectiveness of alternative screening options
Health states	Short-term decision tree **terminal nodes**: • Diagnosed T2DM (+/-intensive Tx) • Undiagnosed T2DM • Diagnosed Pre-DM (+/- Lifestyle Tx) • No DM detected Long-term Markov cohort model **health states**: • No complication • Post CVD • End stage renal disease (ESRD) • Blindness • Amputation • Death
Cycle length	1 year (with half-cycle correction)
Discount rate	s47 for both costs and outcomes
Software	Microsoft Excel (Trial-based economic evaluation) TreeAge Pro (Short-term decision tree & Long-term Markov cohort models)

Source: Compiled based on the PDST Final Report and Appendices
Abbreviations: AUSDRISK - Australian type 2 diabetes risk assessment tool; DM – diabetes mellitus; PoC – point of care; Pre-DM – pre-diabetes mellitus; scBGT - small capillary blood glucose testing; Tx – treatment; T2DM – type 2 diabetes mellitus

Within-trial economic evaluation

The costs, which are applied to each cohort, included in the ADAR within-trial evaluation are:

1. Cost of community pharmacy screening
2. Cost of GP follow-up.

The ADAR included two alternative costing methods for the cost of community pharmacy screening – one in the within-trial economic evaluation, which is also used in the modelled

economic evaluation, and one in the financial impact analysis which applied a fee for pharmacy screening. The ADAR economic evaluation costs of community pharmacy screening significantly exceed that in the ADAR financial impact analysis.

The ADAR's approach to costing GP follow-up excludes participants who visited the GP but did not receive pathology testing according to Medicare. Therefore, the commentary considered the ADAR's approach may have underestimated the total cost of GP follow-up. In calculating these costs, the commentary considered the ADAR's within-trial economic evaluation takes a wider perspective, including the following costs that are not usually considered by MSAC for MBS reimbursement purposes:

- PDST establishment and recruitment costs
- PDST bonus paid to pharmacies for screening
- PoC device capital costs.

The commentary included a revised within-trial evaluation, removing these clinical trial and capital costs. This resulted in a revised cost of s47 per screened patient in Group B (AUSDRISK +HbA1c) including consumables. This was higher than the weighted average screening service cost of s47 in the financial estimates which excluded consumables. The ADAR did not address pathology coning of HbA1c tests. Previously, the MSAC executive considered it would be reasonable to assume between 60 - 90% of laboratory HBA1c tests will be coned out (p3, PSD Application 1431.1). Across all groups, s47 participants received diagnostic testing during GP follow-up according to Medicare data, whereas s47 participants self-reported receiving diagnostic testing. The commentary considered this difference was due to pathology coning, but the ADAR did not present any data to support this theory. The commentary considered that significant uncertainty regarding the costs remain.

Within-trial totals costs are compared to the number of T2DM diagnoses to generate the incremental cost-effectiveness results, presented for the ADAR and revised evaluations (removing costs trial and capital costs) in Table 7.

Table 7: Results of ADAR and revised within-trial evaluation – T2DM diagnoses (Incremental vs. Group A)

	Cost	Inc. Cost	T2DM Diagnoses	Inc. T2DM Diagnoses	ICER ($ per T2DM Diagnosis)
ADAR					
Group A (AUSDRISK only)	s47	s47	s47	s47	s47
Group B (AUSDRISK + PoC HbA1c)	s47	s47	s47	s47	s47
Group C (AUSDRISK + PoC scBGT)	s47	s47	s47	s47	s47
Revised (commentary)[a]					
Group A (AUSDRISK only)	s47	s47	s47	s47	s47
Group B (AUSDRISK + PoC HbA1c)	s47	s47	s47	s47	s47
Group C (AUSDRISK + PoC scBGT)	s47	s47	s47	s47	s47

Source: ADAR – PDST Final Report, Table 42, p151; Revised – MSAC 1677 Revised Within-trial.xlsx

Abbreviations: AUSDRISK - Australian type 2 diabetes risk assessment tool; ICER – incremental cost-effectiveness ratio; Inc. – incremental; PoC – point of care; scBGT – small capillary blood glucose testing; T2DM – type 2 diabetes mellitus

[a] *Revised screening cost per participant was* s47 *for Group A,* s47 *for Group B, and* s47 *for Group C.*

In the ADAR within-trial evaluation, Group C is dominated by Group A. Group B is associated with an ICER of s47 per additional T2DM diagnosis compared to Group A.

The removal of costs not normally considered in the revised within-trial evaluation did not significantly impact the within-trial cost per T2DM diagnosis. The revised cost of community pharmacy screening per participant screened is closer to that used in the ADAR's financial impact analysis.

The ADAR includes a series of univariate sensitivity analysis revealing the key drivers of the results of the within-trial economic evaluation. The within-trial economic evaluation is most sensitive to the HbA1c cut-off for referral, HbA1c PoC test strips unit price, HbA1c diagnostic threshold, AUSDRISK cut-off for referral and the definitions of DM and Pre-DM.

Modelled economic evaluation

The modelled evaluation included a short-term decision tree that mirrors the design of the PDST, with the eligible population screened at community pharmacy, referred to GP, diagnostic tested and then diagnosed. Long term outcomes were modelled using Markov cohort model has a similar structure to common reference models in T2DM, chiefly the United Kingdom Prospective Diabetes Study (UKPDS) model.[9]

The commentary noted that there is research suggesting the first UKPDS overestimates risk of T2DM-related health events in the Australian T2DM population.[10] The short-term decision tree does not define a consistent underlying prevalence of undiagnosed T2DM and Pre-DM at the start of the model for each group, the underlying prevalence is 'revealed' through the proportions that achieve a T2DM or Pre-DM diagnosis or remain undiagnosed at the end of the model. Undiagnosed Pre-DM is not considered and thus implicitly set to zero in the model.

Given this decision tree structure, estimates for two parameters were not available from the PDST:

1. The proportion of those not referred with T2DM (false negatives among non-referred)
2. The undiagnosed prevalence among those referred.

In the ADAR's modelled evaluation these are informed by AusDiab on recommendation from the PDST Expert Panel, presented in Table 8.

Table 8: Short-term decision tree parameters informed by AusDiab data

Parameter	Group A (AUSDRISK only)	Group B (AUSDRISK + PoC HbA1c)	Group C (AUSDRISK + POC scBGT)
False negative among non-referred	s47	s47	s47
Undiagnosed prevalence among referred	s47	s47	s47

Source: PDST Final Report, Appendix 12

Abbreviations: AUSDRISK - Australian type 2 diabetes risk assessment tool; PoC – point of care; scBGT - small capillary blood glucose testing

[9] UK Prospective Diabetes Study Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *The lancet*. 1998;352(9131):837-853.

[10] Davis WA, Colagiuri S, Davis TM. Comparison of the Framingham and United Kingdom Prospective Diabetes Study cardiovascular risk equations in Australian patients with type 2 diabetes from the Fremantle Diabetes Study. *Med J Aust*. 2009;190(4):180-184.

The commentary considered that it was inconsistent for each screening option to be associated with the same undiagnosed prevalence among referred participants (who then did not attend their GP). Given the screening options are not expected to have the same sensitivity, the commentary considered the prevalence of T2DM among those referred would not be the same.

Given these parameters, the assumed underlying prevalence of T2DM and Pre-DM is presented in Table 9 for the ADAR base case.

Table 9: Short-term decision tree outcomes

Outcome	Group A (AUSDRISK only)	Group B (AUSDRISK + PoC HbA1c)	Group C (AUSDRISK+ PoC scBGT)
T2DM	s47	s47	s47
Undiagnosed	s47	s47	s47
Diagnosed	s47	s47	s47
Intensive Tx [a]	s47	s47	s47
No Intensive Tx [a]	s47	s47	s47
Pre-DM	s47	s47	s47
Undiagnosed	s47	s47	s47
Diagnosed	s47	s47	s47
Lifestyle Tx	s47	s47	s47
No Lifestyle Tx	s47	s47	s47
No DM	s47	s47	s47

Source: Compiled from PDST_CEA_Model4.3.trex

[a] As in the UKPDS, Intensive Treatment comprised either sulfonylurea or insulin or, in overweight patients, metformin for glucose control. No Intensive Treatment was the conventional therapy, i.e., diet modification.

Abbreviations: AUSDRISK - Australian type 2 diabetes risk assessment tool; DM – diabetes mellitus; Pre-DM – pre-diabetes mellitus; PoC – point of care; scBGT - small capillary blood glucose testing; T2DM – type 2 diabetes mellitus; Tx – treatment

In the ADAR base case, Group A has a higher prevalence of underlying T2DM and Pre-DM than both Group B and Group C. The commentary considered that this inconsistent underlying prevalence of T2DM and Pre-DM was the major driver of incremental costs and QALYs.

The probability of participation in Intensive Treatment for T2DM patients (80%) was an assumption, with no justification or threshold sensitivity analysis provided in the ADAR. The commentary highlighted that the ADAR's economic evaluation assumed that screening for T2DM only occurs once in a patient's lifetime, at a community pharmacy, and if they remain undiagnosed at this point, they will remain undiagnosed for the rest of their life. The commentary considered that this is unlikely and will overestimate incremental QALYs for community pharmacy screening vs. usual care. Instead, the commentary considered that it is probable that patients with undiagnosed T2DM would have been diagnosed by their GP at some later date if they had not been referred through community pharmacy screening. Therefore, the commentary considered implementing community pharmacy screening for T2DM may not diagnose many more patients, but simply diagnose T2DM earlier than under the usual care of opportunistic screening by GPs.

The commentary considered that there are also a number of other limitations that impacted the model's incremental results:

- The model does not explicitly capture undiagnosed Pre-DM.
- A coding error applying Intensive Treatment costs to the No Intensive Treatment arm. The pre-ESC response disagreed there was a coding error. The pre-ESC response considered that this could be rectified by applying a 5% difference between intensive treatment and no intensive treatment based on the UKPDS cost analysis.
- The use of costs from 2003 without inflation or consideration of the current price level.
- The unjustified use of a discount rate (s47) not recommended by MSAC guidelines.
- Costs not normally considered allocated to community pharmacy screening.
- An inconsistency in the cost of GP follow-up.
- The misinterpretation of all-cause mortality data from the literature.

Based on the available evidence, the commentary presented a revised base case to address these limitations in the ADAR's modelled economic evaluation.

Results

The results of the Markov cohort models are applied to the screening outcomes of the short-term decision tree to generate the ADAR base case results, presented in Table 9.

Table 10: Results of ADAR base case (Incremental vs. Group A)

	Cost	Inc. Cost	QALYs	Inc. QALYs	ICER ($/QALY)
ADAR base case					
Group A (AUSDRISK only)	s47	s47	s47	s47	s47
Group B (AUSDRISK + PoC HbA1c)	s47	s47	s47	s47	s47
Group C (AUSDRISK + PoC scBGT)	s47	s47	s47	s47	s47

Source: Compiled from PDST_CEA_Model4.3.trex and MSAC 1677 - Revised DTree (Incon Prev).trex
Abbreviations: AUSDRISK - Australian type 2 diabetes risk assessment tool; ICER – incremental cost-effectiveness ratio; Inc. - incremental; POC – point of care; scBGT - small capillary blood glucose testing

The commentary considered that these incremental results are driven by the inconsistent underlying prevalence of T2DM and Pre-DM across the groups.

Revised Base Case - Methods

The commentary developed a revised base-case, based on the available evidence, to provide MSAC with relevant information to inform the funding question. The key revisions included:

- A consistent underlying prevalence of T2DM and Pre-DM using the prevalence figures for Group A (AUSDRISK only) from the base case analysis (T2DM – s47 Pre-DM s47). This revision is presented for Group B in Figure 3, with revision for Group C performed in an identical manner. The commentary considered that the model was not sensitive to the overall underlying prevalence of T2DM and Pre-DM, only to the proportion that receive a diagnosis through screening.
- s47 of undiagnosed T2DM patients receive a delayed diagnosis three years later. Three-yearly screening is consistent with the RACGP guidelines. Consistent with the ADAR decision tree, 80% of those diagnosed with T2DM would receive Intensive Treatment. Based on this assumption, s47 remained undiagnosed for life.

- Incorporating a usual care group (Group D) into the short-term decision tree, presented in Figure 4. In this arm, patients do not receive community pharmacy screening and are allocated to Undiagnosed T2DM, Undiagnosed Pre-DM, and No DM, based on the underlying prevalence in the population. In this arm, the same proportion of T2DM patients s47) received a 'delayed diagnosis' after three years.
- Inflated the cost of T2DM-related health events to 2020 price levels
- Applied a 5% discount rate s47 in the ADAR).

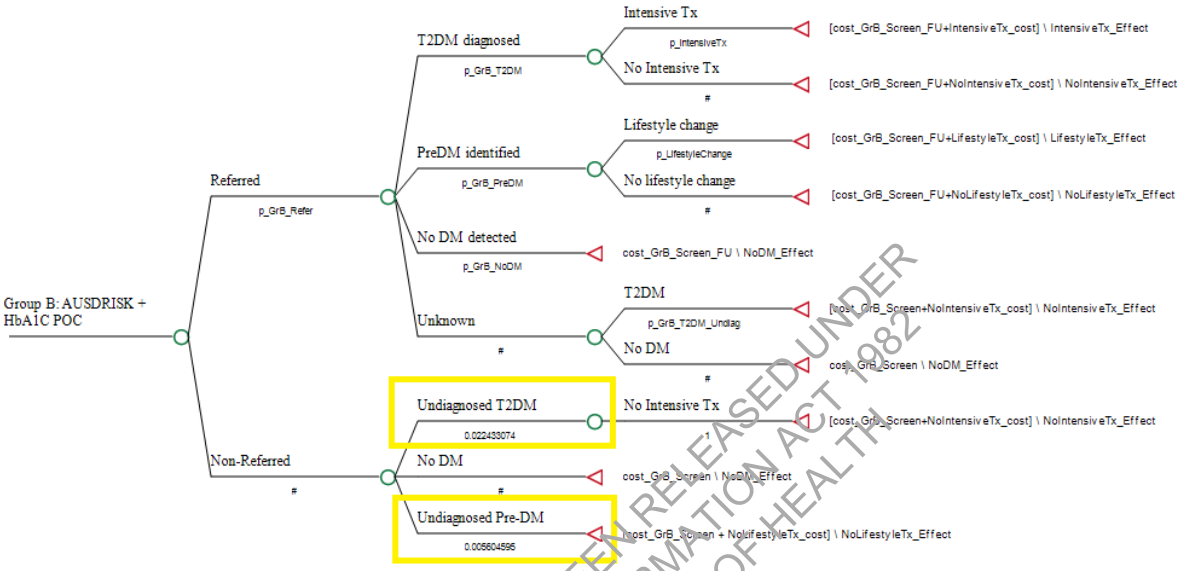

Figure 3: Revised base case – Undiagnosed Pre-DM

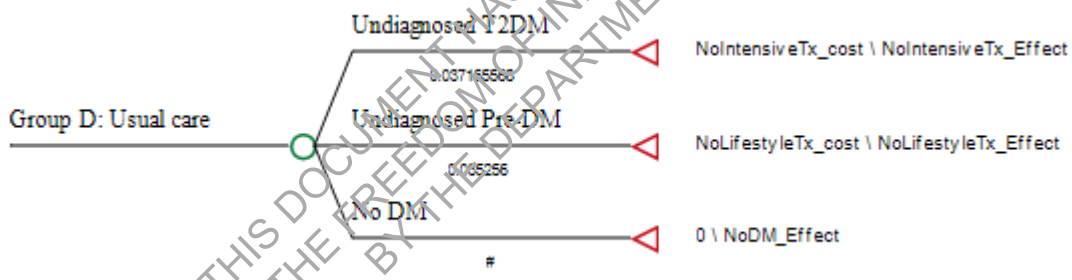

Figure 4: Revised base case - Usual care

ReI'sults

Table 11 presents the result of the analysis relevant to the funding question – a comparison against Group D (Usual care) with a consistent underlying prevalence of T2DM and Pre-DM applied across the groups.

Table 11: Results of revised base case (Incremental vs. Group D)

	Cost	Inc. Cost	QALYs	Inc. QALYs	ICER ($/QALY)
Group D (Usual care)	s47	s47	s47	s47	s47
Group A (AUSDRISK only)	s47	s47	s47	s47	s47
Group B (AUSDRISK + PoC HbA1c)	s47	s47	s47	s47	s47
Group C (AUSDRISK + PoC scBGT)	s47	s47	s47	s47	s47

Source: Constructed during the evaluation (MSAC 1677 - Revised DTree (Con Prev).trex)
Abbreviations: AUSDRISK - Australian type 2 diabetes risk assessment tool; ICER – incremental cost-effectiveness ratio; Inc. - incremental; POC – point of care; scBGT - small capillary blood glucose testing

In this analysis, incremental QALYs are very low for all community pharmacy screening options versus usual care, leading to ICERs over s47 /QALY. The commentary did not perform sensitivity analyses was performed on the ADAR's modelled economic evaluation. The commentary considered the ADAR and revised base case analyses contained several limitations worth noting:

- The long-term Markov models remains populated with cost data from 2003 for the intensive treatment of T2DM and benefit data from 1998 or 2008 for the treatment of T2DM and Pre-DM, which were the key drivers of incremental costs and QALYs. The costs of some diabetes treatments will have changed since then and newly funded treatments for diabetes have since been added to the PBS.
- In the revised base case, patients who progress from Pre-DM to T2DM were not modelled in the same way as T2DM patients diagnosed at community pharmacy screening (i.e., not exposed to T2DM-related health events).
- The concept of delayed diagnosis by GPs after a time lag of three years was not informed by trial data. In addition, there was evidence of a 'legacy' effect such that early intensive treatment for T2DM may translate into future benefits even after the delayed diagnosis. There remains significant uncertainty around the size of the benefits of earlier diagnosis.
- The participation rate for Intensive Treatment for T2DM remained an assumption.

These limitations notwithstanding, the commentary considered the revised base case provides valuable, relevant information to inform MSAC's consideration of whether public funding of community pharmacy-based screening would be cost effective compared to usual care. The pre-ESC response disagreed with the commentary's revised base case and considered that it was unrealistic to assume that s47 of patients with undiagnosed T2DM would receive a delayed diagnosis by a GP after 3 years. This was based on the pre-ESC response's claim that GPs diagnose only 15-20% of T2DM cases.

The pre-ESC response presented a revised base case removing the adjustment for delayed diagnosis and incorporating higher treatment costs for intensive treatment (Table 12). This resulted in ICERs less than s47 per QALY for the pharmacy screening strategies.

Table 12: Revised base case vs. Group D (pre-ESC response)

Intervention	Cost	Inc. Cost	QALYs	Inc. QALYs	ICER ($ per QALY)
Group D (Usual care)	s47	s47	s47	s47	s47
Group A (AUSDRISK only)	s47	s47	s47	s47	s47
Group B (AUSDRISK + PoC HbA1c)	s47	s47	s47	s47	s47
Group C (AUSDRISK + PoC scBGT)	s47	s47	s47	s47	s47

Source: Table 2, pre-ESC response
Abbreviations: AUSDRISK - Australian type 2 diabetes risk assessment tool; ICER – incremental cost-effectiveness ratio; Inc. - incremental; POC – point of care; scBGT - small capillary blood glucose testing

The pre-ESC response presented a third analysis (Table 13), in which the costs of usual care arm (Group D) were added to the pharmacy screening arms, resulting in ICERs of approximately s47 /QALY.

Table 13: Revised base case PDST in the context of usual care (pre-ESC response)

Intervention	Cost	Inc. Cost	QALYs	Inc. QALYs	ICER ($ per QALY)

Group D (Usual care)	s47	s47	s47	s47	s47
Group A (AUSDRISK only) + Group D	s47	s47	s47	s47	s47
Group B (AUSDRISK + PoC HbA1c) + Group D	s47	s47	s47	s47	s47
Group C (AUSDRISK + PoC scBGT) + Group D	s47	s47	s47	s47	s47

Source: Table 3, pre-ESC response
Abbreviations: AUSDRISK - Australian type 2 diabetes risk assessment tool; ICER – incremental cost-effectiveness ratio; Inc. - incremental; POC – point of care; scBGT - small capillary blood glucose testing

Conclusions

The commentary considered inconsistencies in the ADAR model were the key drivers of its incremental cost-effectiveness results. After adjusting, and comparing with the appropriate comparator, usual care, none of the community pharmacy screening options appeared to be cost-effective, noting that considerable uncertainties remain regarding the evidence.
A higher cost per QALY may be acceptable if wider screening in community pharmacies would lead to more equitable access to Intensive Treatment for T2DM, but no evidence on this has been presented.

12. Financial/budgetary impacts

The ADAR used an epidemiological approach to estimate the proportion of the population who would be eligible for community pharmacy screening for T2DM. The ADAR used Group B (AUSDRISK + PoC HbA1c) as the funded programme in the financial impact analysis.

The ADAR assumed the population eligible for community pharmacy screening for T2DM is people aged 35-74 who have not been diagnosed or screened for diabetes in the last 12 months. This implied that individuals could be screened yearly - at a higher frequency of screening than that suggested by the RACGP, who recommend every 3 years in their guidelines for the management of T2DM.

Table 14 presents the population parameters used in the financial impact analysis. The commentary considered the uptake of the eligible population is the key parameter that influences the overall financial impact. This was estimated by expert opinion in the ADAR analysis. The commentary considered uptake is also likely to be heavily influenced by the financial reimbursement offered to pharmacies to undertake T2DM screening. The ADAR estimated that s47 of the total aged 35-74 Australian population would be eligible for community pharmacy screening. The assumed eligible population relied on criteria for how often individuals should be screened.

The commentary noted that based on the epidemiological estimates, 1.7% of the eligible population has undiagnosed T2DM. This is below all of the estimates provided in the ADAR's economic base case and scenarios s47 to s47).

The ADAR's financial impact analysis assumed that community pharmacy screening is not associated with cost offsets of reduced GP screening for T2DM.

Table 14: Population data sources applied in financial estimates

Data	Source and value
Population of Australia aged 35-74	ABS – 12,051,931
Prevalence of T2DM diabetes, aged 35-74	AIHW - 5.7%
Prevalence of Pre-DM, aged 35-74	AIHW - 13.0%
Percentage of T2DM already diagnosed	The Boden Institute – 71.0%
Percentage of Pre-DM already diagnosed	Estimate (PDST) – s47
Percentage of people already screened in the last 12 months	Estimate (Expert) – s47
Undiagnosed T2DM	s47
Undiagnosed Pre-DM	s47

Source: Budget Impact Analysis - Pharmacy Diabetes Screening Service Final for Submission

[1] The population of interest can be calculated as s47 The subsequent estimate of undiagnosed T2DM is s47

[2] The population of interest can be calculated as s47 The subsequent estimate of undiagnosed Pre-DM is s47

Abbreviation: ABS - Australian Bureau of Statistics; AG – assessment group; AIHW – Australian Institute of Health and Welfare; Pre-DM – pre-diabetes mellitus; PDST – pharmacy diabetes screening trial; T2DM – type 2 diabetes mellitus

Table 15 presents the pharmacy data used in the ADAR financial impact analysis.

Table 15: Pharmacy data applied in the financial estimates

Data	Source and value	Justification
Screened and referred	PDST – s47 p.a.	-
Referral uptake	PDST – s47 p.a.	Conditional on screened and referred
Diagnosis testing	PDST – s47 p.a.	Conditional on referral uptake
T2DM diagnosis	PDST – s47 p.a.	Conditional on diagnosis testing
Pre-DM diagnosis	PDST – s47 p.a.	Conditional on diagnosis testing
Expected number of eligible pharmacies	Pharmacy Guild - s47	Reflects the proportion of pharmacies expected to meet eligibility criteria.
Measuring tape unit cost	PDST - s47	-
PoC test device	PDST - s47	-
PoC & measurement device cost per pharmacy per annum	s47	**Used in the final financial impact calculation**
PoC consumables cost per participant screened	s47	**Used in the final financial impact calculation**
PoC test consumables	PDST - s47	Total consumables based on the trial expenses provided by the Pharmacy Guild. Higher than $10/test in MSAC 1431.1 (p15, 1431 PSD)
Short consultation - AUSDRISK & counselling service cost	PDST - s47	Participants with AUSDRISK < 12 who did not receive PoC testing
Standard consultation - AUSDRISK + HbA1c PoC testing, counselling & referral	PDST - s47	Participants with AUSDRISK ≥ 12 who did receive PoC testing
Cost of community pharmacy screening per participant screened	PDST - s47	Weight average of short and standard consultation **Used in the final financial impact calculation**
GP Consultation	MBS item 23 - $38.75	-
T2DM Pathology testing	MBS - various	-
Cost of GP follow-up per T2DM and Pre-DM diagnosis	Calculation - s47	**Used in the final financial impact calculation**

Source: Budget Impact Analysis - Pharmacy Diabetes Screening Service Final for Submission
Abbreviations: ABS - Australian Bureau of Statistics; AIHW – Australian Institute of Health and Welfare; Cum – cumulative; DM – diabetes mellitus; Inc. - incremental; MBS – Medicare benefits schedule; p.a. – per annum; PEI – patient episode initiation; PDST – pharmacy diabetes screening trial; PoC – point of care; scBGT - small capillary blood glucose testing; T2DM – type 2 diabetes mellitus

The ADAR financial impact analysis includes the same PoC device capital cost as the ADAR within-trial economic evaluation. The commentary presented a revised financial impact that removed the PoC device capital and consumable costs.

The number of Group B (AUSDRISK + HbA1c PoC) participants who received a short and standard consultation used in the financial impact analysis do not match Figure 11 of the PDST Final Report which shows s47 and (s47 -s47) s47 , respectively. The commentary noted the GP follow-up costs in the ADAR's financial impact analysis is per diabetes (T2DM or Pre-DM) diagnosis, which resulted a significantly higher GP follow-up cost than that in the economic analysis (i.e. s47 vs s47). In the revised financial impact analysis, the cost of GP follow-up was revised to align with how the GP follow up costs calculated for the economic analysis.

Table 16 presents the financial impact calculations.

Table 16: Financial implications of community pharmacy screening for T2DM for the first 5 years

Parameter	Year 1	Year 2	Year 3	Year 4	Year 5
Number of participants					
Eligible	s47	s47	s47	s47	s47
Screened	s47	s47	s47	s47	s47
AUSDRISK ≥ 12 + PoC	s47	s47	s47	s47	s47
Referred	s47	s47	s47	s47	s47
Visit GP	s47	s47	s47	s47	s47
Diagnosis tested	s47	s47	s47	s47	s47
T2DM diagnosed	s47	s47	s47	s47	s47
Pre-DM diagnosed	s47	s47	s47	s47	s47
Financial Impact					
Pharmacy Screening costs	s47	s47	s47	s47	s47
PoC device & consumables	s47	s47	s47	s47	s47
Screening service	s47	s47	s47	s47	s47
GP Follow-up costs	s47	s47	s47	s47	s47
Total (p.a.)	s47	s47	s47	s47	s47
Cumulative	s47	s47	s47	s47	s47
Revised Financial Impact (net cost to government)					
Pharmacy Screening costs	s47	s47	s47	s47	s47
GP Follow-up costs [a]	s47	s47	s47	s47	s47
Total (p.a.)	s47	s47	s47	s47	s47
Cumulative	s47	s47	s47	s47	s47

Source: ADAR - Budget Impact Analysis - Pharmacy Diabetes Screening Service Final for Submission; and revised financial implications estimated by the commentary (Revised – MSAC 1677 – Revised Financial Implications.xlsm)
Abbreviations: GP – general practitioner; p.a. – per annum; PoC – point of care; T2DM – type 2 diabetes mellitus
[a] For patients who visit their GP

The ADAR's financial impact analysis suggested the 5-year cumulative financial impact of adopting community pharmacy screening for T2DM using the AUSDRISK + PoC HbA1c would be approximately s47 . The revised financial impact analysis calculated int eh commentary suggested this figure is significantly lower, approximately s47 over 5 years. The commentary considered the financial impact of community pharmacy screening is heavily influenced by the proportion of the eligible population that use the service which was informed by expert opinion. Doubling the proportion of eligible patients who receive screening (which was based on expert opinion) almost exactly doubles the revised financial impact. Therefore, the commentary considered there was considerable uncertainty as to the true financial impact. The numbers screened per year is likely to depend on whether the financial reimbursement to pharmacies is high or low compared to the work involved.

The ADAR analysis also does not include the additional costs related to the increased use of Intensive Treatment for T2DM or Lifestyle Treatment for Pre-DM, respectively.

Australian Government
Medical Services Advisory Committee

MSAC Meeting
25-26 November 2021

Application 1677 – Pharmacy Diabetes Screening Trial

ACTIONS

That MSAC:

1. DISCUSS the following key questions/concerns raised by ESC:
   a. The appropriateness of the proposed use of opportunistic HbA1c Point of Care (PoC) testing in community pharmacies as a screening tool for patients with an AUSDRISK score of 12 or greater.
   b. The appropriateness of the economic model and financial estimates provided pertinent to MSAC decision-making.

2. DISCUSS the following key issues raised by the Department:
   a. eligibility of patients for the intervention.
   b. frequency of testing and potential over-diagnosis.
   c. service fee arrangement for the intervention.
   d. appropriateness of comparator used for trial.
   e. appropriateness of pharmacy and pharmacist accreditation.
   f. scope of practice.
   g. public consultation feedback.

3. NOTE that MSAC has:
   a. supported the MBS listing of new item # 73812 for the quantitation of glycated haemoglobin via Point of Care testing in the management of established diabetes.
   b. rejected an application for PoC glycated haemoglobin testing as an alternative to HbA1c testing in an accredited laboratory for the diagnosis of diabetes in asymptomatic patients.

BACKGROUND

With the rising prevalence of type 2 diabetes in Australia, screening and earlier diagnosis is needed to provide opportunities to intervene with evidence-based lifestyle and treatment options to reduce the individual, social and economic impact of the disease. It is estimated that there are 500,000 Australians with undiagnosed Type 2 Diabetes Mellitus (T2DM).

Implemented between October 2017 and November 2019, the objectives of the Pharmacy Diabetes Screening Trial (PDST) were to compare the clinical effectiveness and cost-effectiveness of three screening models for T2DM in a previously undiagnosed population. The application proposed referring patients with a HbA1c of 5.7% or greater to a GP for further T2Dm testing.

The trial included the following pharmacy-based models:

i. The paper-based Australian Type 2 Diabetes Risk Assessment Tool (AUSDRISK) assessment of diabetes risk, alone and GP referral for persons with an AUSDRISK score of 12 or greater Group A);
ii. AUSDRISK followed by a point-of-care (PoC) glycated haemoglobin (HbA1c) test (Group B) for persons with an AUSDRISK score of 12 or greater; and
iii. AUSDRISK followed by a PoC small capillary blood glucose test (scBGT) for persons with an AUSDRISK score of 12 or greater (Group C).

The PDST was not designed to determine whether any of the above options was effective compared with usual care, which for most patients is likely to be opportunistic screening for T2DM by GPs using AUSDRISK every 3 years for patients not at high risk according to *The Royal Australian College of General Practitioners (RACGP)* standards for PoC.

The *primary clinical hypothesis* was that the addition of either a HbA1c PoC test (Group B) or a PoC scBGT test (Group C) to the AUSDRISK assessment would be associated with a statistically significant increase in the proportion of newly diagnosed T2DM cases compared with AUSDRISK assessment alone. Additional clinical hypotheses related to the primary hypothesis were that compared with Group A, Groups B and C would be associated with a lower rate of referral to the GP and higher rates of referral uptake, and subsequent newly diagnosed prediabetes, (i.e., Impaired Fasting Glycaemia (IFG) or Impaired Glucose Tolerance (IGT)) or a composite of diabetes or prediabetes.

The *core economic analysis hypothesis* was that the addition of either a HbA1c PoC test after AUSDRISK screening, followed by a referral to GP, if appropriate, was 'cost-effective' in comparison to AUSDRISK screening alone from a health funder's (i.e. the Department/Government) perspective. The cost-effectiveness of a community pharmacy based AUSDRISK based opportunistic screening program compared to current practice has not been assessed.

The trial-based economic evaluation supported the Group B option (AUSDRISK followed by a PoC HbA1c test) as the preferred option for T2DM screening in pharmacies as it dominated AUSDRISK screening alone, having regard to longer term health and patient outcomes.

MSAC has *supported* the listing of new MBS Item 73812 for the quantitation of glycated haemoglobin via Point of Care testing in the management of established diabetes. This is with a maximum of three PoC tests in a 12 month period (and a maximum of 4 glycated haemoglobin tests in total (PoC plus laboratory testing) in a 12 month period. The fee allocated is $11.80 Benefit (75%=$8.85) which does not include capital costs or the costs of consumables.

The MSAC has *rejected* an application for PoC glycated haemoglobin testing as an alternative to HbA1c testing in an accredited laboratory for the diagnosis of diabetes in asymptomatic patients.

In addition, MBS Item 701(fee of $61.75) for a GP consultation is used for a health assessment lasting <30 mins in patients aged 40-49 with a high risk of developing T2DM as assessed by the AUSDRISK score.

POLICY AND IMPLEMENTATION ISSUES

a. Eligibility for proposed screening

MSAC is requested to consider appropriate eligibility for the intervention. ESC notes that the ADAR did not explicitly nominate a population for the proposed service. The PDST entry requirements included people aged 35-74 years, who did not have a history of diabetes or pre-diabetes and had not undergone screening for diabetes in the past 12 months. Those with a AUSDRISK score of 12 or greater were either referred to a GP, underwent HbA1c, or, undertook random blood glucose, as this score is accepted as an indication of high risk for developing diabetes.

ESC considered that the trial population did not align with the RACGP Guidelines which recommend AUSDRISK screening every 3 years for patients over 40 years and not at high risk. ESC considered that it may be appropriate to align the eligible population with the RACGP Guidelines, which would also include Aboriginal and Torres Islander people receiving testing, given their high prevalence for T2DM at younger ages. There were concerns in some public consultation feedback unavailable at the ESC meeting, that Aboriginal and Torres Strait Islander people may not have adequate access to diabetes screening.

MSAC is requested to consider the appropriate GP referral threshold – the application proposed referring patients with a HbA1c of 5.7% or greater to a general practitioner (GP) for further T2DM testing. ESC noted an alternative threshold of 6% which is recommended in the RACGP Guidelines.

The PDST also did not define 'screening' in the entry requirements. Screening may include HbA1c, fasting blood glucose or glucose tolerance testing. Furthermore, pharmacies would need to identify whether patients had undergone screening for diabetes in the past 12 months or even whether diabetes had been diagnosed. Consideration should also be given to pharmacists accessing My Health Record for patients to determine if prior testing or other evidence is available to determine eligibility.

An identified issue is whether the persons undergoing screening in community pharmacies will be people less likely to visit GPs, and whether in this group (not defined) earlier diagnosis of diabetes may be the result with anticipated better health outcomes.

MSAC is requested to consider whether the entrance eligibility should be people aged 40 or greater who have an AUSDRISK score of 12 or greater (this aligns with MBS Item 701). Since the prevalence of T2DM in the Aboriginal and Torres Strait Islander population is much higher including a higher aged-matched prevalence of diabetes, consideration may be given to lowering the entry age, eg. to 25 years, for this population.

MSAC is requested to consider whether patient eligibility should be restricted to those:

- who have not been previously diagnosed with diabetes or prediabetes;
- who have not been screened for diabetes in the last 12 months;
- who have not enrolled in any lifestyle change programs for T2DM or programs that may duplicate services/treatment;
- who do not have a terminal illness or certain blood disorders;
  (including severe haematological diseases, e.g. thrombocytopaenia, leukaemia; shorter erythrocyte lifespan, e.g. renal anaemia, chronic and haemolytic anaemia, acute blood loss, and recent transfusion; haemoglobinopathy and red cell turnover disorders; and iron deficiency anaemia); and

- who are not pregnant;
- have the capacity to provide informed consent to undergo the service.

b. Frequency of testing and potential over-diagnosis

MSAC is requested to consider the appropriate frequency of testing. ESC noted that the ADAR did not nominate a specific frequency of testing. ESC advised that the screening could be aligned with RACGP standards for PoC testing for patients 40 years and over who are not at risk of T2DM to be screened every 3 years by AUSDRISK. However, negative test bias would need to be considered for more frequent testing. In addition, individuals with risk factors for diabetes should be tested with fasting blood glucose or HbA1c every 3 years.

MSAC is requested to consider whether the trial testing interval for participants of 'no screening in the last 12 months' is appropriate, given this is more frequent than RACGP recommendations. MSAC is requested to note ESC's suggestion that this rate could lead to over-testing, over-diagnosing pre-diabetes, and additional costs to the health system for patients who had an AUSDRISK of 12 or greater but who had a 'normal" HbA1c level.

c. Service fee arrangement (see Financial Impact)

d. Comparator used for the Trial

MSAC is requested to consider the appropriateness of the comparator for the intervention. ESC noted that the ADAR did not include relevant clinical or economic evidence using a comparator as usual care. The comparator used in the trial was referral to a GP for patients with an AUSDRISK score of at least 12. ESC considered whether the appropriate comparator should have been usual care, that is, *opportunistic monitoring* by a GP. The RACGP recommendation is screening for diabetes in non-high risk patients aged 40 years and over by monitoring AUSDRISK scores every 3 years. ESC considered the lack of a usual care comparator to be a major limitation of the ADAR.

MSAC is requested to note ESC's consideration of the revised base case from the Commentary, which considered the comparator should be usual care given that community pharmacy screening is intended to *complement* existing screening. This is consistent with the 2017 MSAC Guidelines (p19) regarding primary comparisons. The Commentary considered usual care for most patients is likely to be opportunistic screening by GPs. A 2014-15 Patient Experience Survey by the Australian Bureau of Statistics noted that 83% of respondents had visited a GP at least once in the previous year[1]. This implies that the population inaccessible to GP screening for T2DM is unlikely to be large, but that diagnosis under usual care may take longer. The Commentary's economic evaluation suggests that pharmacy-based screening is not cost-effective.

The pre-ESC response provided estimated incidence of T2Dm which could not be verified. (The pre-ESC response claimed that GPs detect 15-20% of T2DM cases, based on National Diabetes Services Scheme registrations, and estimates of T2DM incidence in an adult population.)

e. Accreditation of pharmacies and pharmacists

MSAC is requested to consider its position on appropriate HbA1c testing and accreditation standards for pharmacies and pharmacists for the intervention. ESC noted the ADAR which stated that pharmacists who participated in the PDST were required to undertake an

1 Australian Institute of Health and Welfare. *Primary health care in Australia*. 2016. Accessed 22 Aug 21

education program and satisfy certain criteria, and pharmacies needed to satisfy specific training and accreditation requirements. MSAC is advised that although community pharmacies that perform PoC testing fall outside the scope of the proposed NPAAC Requirements for Point of Care Testing (First Edition 2015), the requirements would provide guidance on good practice for the performance of PoC testing in other health care settings such as pharmacies.

MSAC may wish to consider appropriateness of requirements similar to those for MBS Item 73812 (listed 1 November 2021) in regard to the use of a certified instrument for testing. Other options may include, but are not limited to, those currently applied for non-pharmacy PoC testing (eg conducted by external agency such as Flinders University), or through accreditation by the Pharmaceutical Society of Australia and/or the Pharmacy Guild of Australia.

MSAC is requested to consider appropriate quality assurance processes for participating pharmacies for effective uptake and delivery of the intervention. ESC noted, however, that the ADAR did not detail the nature of the quality assurance system. Participating pharmacies would also need to adhere to Departmental requirements such as recordkeeping of AUSDRISK and test results, and referral records. Appropriate auditing of programs was also reflected in consultation feedback (Attachment A).

f. Scope of practice

MSAC is requested to consider the scope of practice for pharmacists providing this service, and whether there are any states or territories where pharmacists may not be able to provide the service.

The Australian Medical Association (AMA) raised their concerns on this matter in their feedback to the public consultation process (Attachment A). The AMA considered that non-medicine related tasks such as screening would expand the scope of practice of pharmacists.

MSAC is requested to consider:

- AMA's public consultation comments in which strong concerns were raised about some health services provided by pharmacists that may not have the appropriate level of assessment for delivery etc. The AMA stated that is does not support the evidence provided in the application to continue pharmacy diabetes screening programs when there is already an evidence-based screening process in place in general practice.

- AMA's recommendation that MSAC consult with the Pharmacy Board to determine their views on scope of practice relevant to medical services, including screening. The Pharmacy Board, in their Guidelines on Practice-specific issues Item 7 on Screening and Risk Assessment state "Pharmacists who conduct screening and risk assessment tests are expected to follow established practice and quality-assurance standards, including relevant guidelines issued by professional associations and state and territory pharmacy premises registering authorities".

The AMA sees merit in community pharmacy programs undergoing assessment, monitoring, evaluation and auditing similar to medical services under the MBS, given that they provide

health services rather than dispense medicines, as such.

g. Public consultation feedback

A summary of feedback received from the public consultation process is at Attachment A.

Feedback was received from:

- Australian Diabetes Society, Australian Diabetes Educators and Diabetes Australia (collective response)
- Australian Medical Association
- Pharmaceutical Society of Australia
- Diabetes South Australia
- Royal Australian College of General Practitioners
- Pharmacist and naturopath s22

MSAC is requested to consider key issues raised in the consultation feedback. These include:

- The majority of feedback received supported the proposed screening.
- There may be flow-on benefits to the proposed screening – public awareness, support and encourage preventive care and activities etc.
- Need to consider scope of practice for pharmacists providing screening and other 'non-medicinal' health care.
- Access to the screening may address lack of access in rural and remote areas.
- Indirect costs of delayed or missed diagnoses may lead to higher health care costs.
- The trial did not address the needs of high risk population such as Aboriginal and Torres Strait Islander populations, or emerging populations such as younger persons with T2DM (AUSDRISK lower cut-off at 35 years).
- RACGP states that pharmacies can provide the service only if two trained pharmacists on duty, therefore an inequitable model of access based on pharmacy staff levels.
- Some feedback considered AUSDRISK tool as appropriate to estimate a person's risk of developing T2DM however RACGP Guidelines recommend a different screening interval to that of the proposed screening.
- Consider misdiagnosis from false positives or negatives although these can be mitigated.
- As aligned with the Australian National Diabetes Strategy, *screening and early detection and treatment* may reduce undiagnosed T2DM and complications associated with diabetes.
- Consider how to mitigate duplication of tests, for example, how pharmacists can identify a patient's recent diabetes test or rely on patient's own records.
- Appropriateness of comparator, lack of reported data, lack of peer-reviewed research.
- Lack of information about risk-reducing lifestyle information provided to participants.
- Need for independent auditing of such screening services.
- Perceived conflict of interest with the PDST lead organisation, the Pharmacy Guild of Australia.

FINANCIAL IMPACT

The applicant's **financial impact analysis** estimated s47 over five years, if the second screening model (AUSDRISK plus PoC HbA1c) was to be publicly funded. This amount included capital costs for pharmacies, but did not include the additional costs related to the increased use of Intensive Treatment for T2DM or Lifestyle Treatment for Pre-DM, respectively.

After removing capital costs to pharmacies, the estimated cost to government would be s47 over 5 years.

MSAC is requested to consider issues in the financial impact analysis and the economic model which are contained in the ESC Report. Overall, ESC considered the financial impact to be uncertain. The financial impact analysis was problematic as it included capital costs, the number of trial participants across groups differed, and the eligible undiagnosed population figures in the analysis did not match those in the base case and scenarios.

The financial estimates were uncertain and sensitive to the proportion of the eligible population who would use community pharmacy screening, which was based on expert opinion.

MSAC is requested to consider that the ADAR costing method for costing GP follow-up excludes participants who visited a GP but did not receive pathology testing (according to Medicare data). This would seem to underestimate the total cost of GP follow-up. The ADAR also did not address pathology coning of HbA1c tests. Doubling the proportion of eligible patients who receive screening almost exactly doubles the revised financial impact.

Considerable uncertainty remains regarding the actual financial impact. The numbers screened per year is likely to depend on whether the financial reimbursement to pharmacies is high or low compared to the work involved.

MSAC is requested to noted ESC's comments in relation to the **economic analysis** also presented problems in the costs applied. These included screening intervention costs unmatched to the proposed service fee. Further, the ADAR compared different population across intervention groups and contained poorly justified assumptions, for example, different underlying prevalence of T2DM across the intervention groups. ESC also noted that the model used a s47 rate not aligned with that in the MSAC Guidelines (5%).

MSAC is requested to note ESC's advice that the decision tree structure was over-simplified, and did not provide for a sensitivity analysis of alternate thresholds for AUSDRISK and PoC test results.

ESC considered that the economic models presented in the ADAR were not informative for MSAC as they did not assess whether pharmacy-based opportunistic screening was cost-effective. The ADAR presented a number of alternative cost-utility models, with the preferred model not comparing pharmacy-based screening with usual care.

Appropriate Service Fee and Structure

MSAC is requested to note ESC's advice that the ADAR did not present an explicit fee proposal. The pre-ESC response clarified that the fee proposal was s47 for AUSDRISK alone and s47 for AUSDRISK and PoC HbA1c testing. Excluding a GP consultation fee (for example, Item 701), would provide for s47 of the proposed MBS item fee for the use of PoC HbA1c testing in the diagnosis of diabetes, or s47 of an Item 701 plus a PoC test. In

addition, consideration needs to be given to aligning the consistent principles for the fee structure for the conduct of a PoC HbA1c test irrespective of where the test is conducted.

However, the pre-ESC response fee per occasion of service would need to be reconsidered in the event capital expenditure cannot be considered for these devices. This was consistent with the screening service fees in the financial estimates. The modelled economic evaluation did not use the same cost of community pharmacy screening as the financial impact analysis. The pre-ESC statement may suggest that additional reimbursement would be sought for capital costs.

During the trial, pharmacists were paid $10.00 for the AUSDRISK evaluation, $10.50 for the PoC test, and $11.00 for a referral. Additionally, pharmacies were paid a bonus of $750 upon reaching their specified target screenings provided the data was completed according to the protocol.

MSAC is requested to consider whether, for testing in pharmacies, the cost of administering the AUSDRISK tool should be publicly funded/reimbursed at all, or whether the only fee payable should be equal to the MBS Item 73812 which is for a PoC test for people who have a high risk as evidenced by an elevated AUSDRISK score.

s47C

There may be a risk of some pharmacies over-servicing eligible patients and duplicating GPs' MBS health assessments. However, it has been predicted by MSAC Executive that 60-90% of laboratory HbA1c tests will be coned out.

This risk could be mitigated by including measures of patient experience (i.e. when conducting a screening assessment, the pharmacist should be required to ensure the individual does not already have a diagnosis of T2DM and has not been tested for T2DM with a valid screening test in the previous 12 months).

s47C

Table 2 presents the MBS fees for potentially comparable pathology and consultation items. As noted earlier, MSAC is requested to advise on the appropriate reimbursed fee for the proposed intervention.

Table 1: MBS fees for relevant pathology and consultation items

MBS item	Descriptor (abridged)	Fee and benefit [a]
Pathology testing items		
66841	Quantitation of HbA1c (glycated haemoglobin) performed for the diagnosis of diabetes in asymptomatic patients at high risk.	$16.80 Benefit: 85% = $14.30
73839	Quantitation of HbA1c (glycated haemoglobin) performed for the diagnosis of diabetes in asymptomatic patients at high risk - not more than once in a 12 month period. (QAAMS item)	
73812	Quantitation of glycated haemoglobin (HbA1c) performed in the management of established diabetes when performed: (a) as a point-of-care test; and (b) by or on behalf of a medical practitioner who works in a general practice that is accredited against the point of care testing accreditation module under the National General Practice Accreditation Scheme; and (c) using a method and instrument certified by the National Glycohemoglobin Standardization Program (NGSP), if the instrument has a total coefficient variation less than 3.0% at 48 mmol/mol (6.5%) Applicable not more than 3 times per 12 months per patient	$11.80
66500	Quantitation in serum, plasma, urine or other body fluid (except amniotic fluid), by any method except reagent tablet or reagent strip of glucose [or other specified substances]- 1 test	$9.70 Benefit: 85% = $8.25
66542	Oral glucose tolerance test for the diagnosis of diabetes mellitus that includes: (a) administration of glucose; and (b) at least 2 measurements of blood glucose.	$18.95 Benefit: 85% = $16.15
Consultation items (general practitioners)		
3	Professional attendance by a general practitioner for an obvious problem characterised by the straightforward nature of the task that requires a short patient history and, if required, limited examination and management-each attendance	$17.90

MBS item	Descriptor (abridged)	Fee and benefit [a]
23	Professional attendance by a general practitioner lasting less than 20 minutes including any of the following that are clinically relevant: (a) taking a patient history; (b) performing a clinical examination; (c) arranging any necessary investigation; (d) implementing a management plan; (e) providing appropriate preventive health care; for one or more health-related issues, with appropriate documentation-each attendance	$39.10
Consultation items (nurse practitioners)		
82200	Professional attendance by a participating nurse practitioner for an obvious problem characterised by the straightforward nature of the task that requires a short patient history and, if required, limited examination and management.	$10.00 Benefit: 85% = $8.50
82205	Professional attendance by a participating nurse practitioner lasting less than 20 minutes and including any of the following: a) taking a history; b) undertaking clinical examination; c) arranging any necessary investigation; d) implementing a management plan; e) providing appropriate preventive health care, for 1 or more health-related issues, with appropriate documentation.	$21.80 Benefit: 85% = $18.55
Consultation items (other medical practitioners)		
53	Professional attendance at consulting rooms of more than 5 minutes in duration but not more than 25 minutes (other than a service to which any other item applies)-each attendance, by: (a) a medical practitioner (who is not a general practitioner); or (b) a Group A1 disqualified general practitioner, as defined in the dictionary of the General Medical Services Table (GMST).	$21.00

Source: MBS Schedule July 2021

[a] 85% benefit presented as the proposed service is not expected to be rendered to a patient as part of an episode of hospital treatment or hospital-substitute treatment

Applicant:	The Pharmacy Guild of Australia
Clinical experts consulted and their expertise:	Emeritus Professor Lloyd Sansom AO
Co-dependency (if applicable):	Not applicable
Date of PASC consideration:	8 March 2016
Date of ESC consideration:	7 October 2021
Date of previous MSAC consideration (if applicable):	Not applicable
Professional bodies/ organisations/consumer groups consulted during targeted consultation:	Australian Diabetes Educators Association Australian Medical Association Australian Diabetes Society Diabetes Australia (including States and Territories) Diabetes support groups Diabetes Strategy Refresh – Expert Advisory Group Members Juvenile Diabetes Research Foundation Royal Australian College of General Practitioners Pharmaceutical Society of Australia Consumer Health Forum

Contact: s22

Cleared by: David Laffan
Assistant Secretary
Pharmacy Branch

Application 1677: Pharmacy Diabetes Screening Trial (PDST)

Summary of public consultation feedback/consumer issues

Prior to MSAC consideration (and subsequent to the ESC), consultation feedback was received from five health professional organisations, two consumer organisations and one health professional individual (pharmacist). The seven organisations that provided input on the application were:

- Australian Diabetes Educators Association (ADEA)
- Australian Diabetes Society (ADS)
- Australian Medical Association (AMA)
- Australian Pharmaceutical Society of Australia (PSA)
- Diabetes Australia (DA)
- Diabetes South Australia (SA)
- Royal Australian College of General Practitioners (RACGP).

Consultation feedback from five of the seven organisations (ADS, ADEA, DA, Diabetes SA and PSA) and the individual were mostly supportive of the proposed service: community pharmacy-based opportunistic screening for pre-diabetes and T2DM. Collectively, the supportive responses considered the benefits of the proposed service included early identification of individuals at high risk of T2DM (pre-diabetes) and/or with undiagnosed T2D, enabling timely referral to a General Practitioner (GP) and if appropriate referral to a credentialled diabetes educator and accredited practising dietitian (and other allied health professionals) for education regarding the self-management. The responses expect that this would lead to earlier lifestyle intervention which would reduce the risk of developing T2DM and delay or prevent diabetes-related complications such as heart disease, stroke, kidney disease, blindness, anxiety, depression and amputations. The ADS, ADEA and DA also considered the proposed service aligns with the *Australian National Diabetes Strategy*. Consultation feedback from the AMA and RACGP acknowledged the importance to improve the identification and management of people with diabetes but was not supportive of the application, expressing a number of concerns with the proposed medical service and the evidence from the PDST.

The following considerations were raised in the consultation responses:

- *Proposed service is outside pharmacist scope of practice*
  The AMA recommended MSAC consult the Pharmacy Board to determine their views and if necessary, conduct a consultation on expanding pharmacist scopes of practice into medical services.

- *Proposed service may fragment patient care and reduce the comprehensiveness of care*
  The AMA and RACGP expressed concern that the proposed medical service encourages one-off, opportunistic screening for a single medical condition without the background biopsychosocial information of the individual and without the history of previous screening. The AMA and RACGP highlighted that GPs provide

comprehensive patient care whereas the proposed pharmacy service model has the potential to fragment patient care and that poorly coordinated patient care within the health system and inadequate links between health and social services results in poorer health outcomes and increased health care cost. The AMA considered there were more useful models of care involving pharmacists that should be considered as part of a patient-centred medical home model rather than further fragmenting care.

- *Pharmacists ability to confirm diabetes status and testing history*
  The AMA and RACGP raised concern that it is unclear how pharmacists plan to confirm whether an individual has had a recent diabetes test which was likely initiated by a GP, which is crucial to determine whether costs and services are being duplicated.

- *Alignment with clinical guidelines for managing T2DM*
  The AMA and RACGP noted that the PDST allowed anyone aged 35-74 to be screened, as long as a diabetes screening test has not been conducted in the past 12 months. This differed to the clinical guidelines on the management of T2DM2 which recommend patients without a high risk of type 2 diabetes to be screened using AUSDRISK every three years from when they reach 40 years of age.

- *Populations at high risk of T2DM*
  Feedback from ADS, ADEA, DA, PSA and Diabetes SA raised that Aboriginal and Torres Strait Islander people have higher rates of undiagnosed diabetes and therefore culturally sensitive screening programs (along with lifestyle information and support) should be supported to enable earlier detection intervention to delay or prevent diabetes-related complications. However, Diabetes SA and the RACGP expressed that the PDST protocol did not target Aboriginal and Torres Strait Islander populations and did not address other populations at higher risk of T2DM or emerging populations who are younger than the 35 year age cut-off in the PDST.

- *Appropriateness of the comparator in the PDST*
  The AMA and RACGP highlighted that the PDST did not have an appropriate control group and did not research the effectiveness or cost-effectiveness in the context of wider public health or other more readily available and evidence-based medical services. Similarly, Diabetes SA and the individual pharmacist considered that the appropriate comparator for the proposed intervention would be diabetes screening in the GP setting.

- *Equitable access for rural and remote communities*
  Consultation feedback from ADS, ADEA and DA considered that access to traditional medical or clinic-led diabetes screening can be limited in rural and remote areas and by enabling pharmacy-led screening, there is potential to reduce this service gap. However, the RACGP noted that pharmacies can only provide the diabetes screening service if they have two trained pharmacists on duty at the same time, and a private room is available.

2 The Royal Australian College of General Practitioners. Management of type 2 diabetes: A handbook for general practice. East Melbourne, Vic. RACGP; 2020.

- *Potential for misdiagnosis*
  The ADS, ADEA and DA collectively expressed concerns that misdiagnosis as a result of either false positive or false negative screening results may be a potential issue, as with all screening programs. However, ADS, ADEA and DA considered that these risks may be minimized through appropriate education of pharmacists and quality control of testing apparatus, as well as referral of positive results to GPs. The AMA, Diabetes SA and PSA raised the potential risk of undermanaged 'diagnosis' if referrals are not made and that understanding the GP referral uptake rates (or lack of), particularly those diagnosed with diabetes would be informative.

- *Patient education and support*
  Diabetes SA noted that the report does not provide any detail about what education and support people in the trial received to assist them reduce their lifestyle risk factors. Diabetes SA considered it important to understand what people in the trial perceived to be their benefits and disadvantages of participating in this trial.

Issue raised during the Consultation Feedback	Consultation Feedback details	Guild and Project Partner Response
Proposed service is outside pharmacist scope of practice	The AMA recommended MSAC consult the Pharmacy Board to determine their views and if necessary, conduct a consultation on expanding pharmacist scopes of practice into medical services.	s47 Whilst disease screening services are recognised in the scope of practice for pharmacists, the **main barrier to pharmacists' routinely conducting screening is inadequate funding mechanisms for service activities provided**, requiring patients to cover the costs associated with these service activities. Enabling pharmacists' access to appropriate funding mechanisms for services that are equivalent to Government funded services provided by other healthcare professionals is required to ensure equitable access to services for all patients. s47
Proposed service may fragment patient care and reduce the comprehensiveness of care	The AMA and RACGP expressed concern that the proposed medical service encourages one-off, opportunistic screening for a single medical condition without the background biopsychosocial information of the individual and without the history of previous screening. The AMA and RACGP highlighted that GPs provide comprehensive patient care whereas the proposed pharmacy service model has the potential to fragment patient care and that poorly coordinated patient care within the health system and inadequate links	Community pharmacists, as the most accessible health professionals in the community, are well placed to triage consumers and refer them to other health professionals as necessary, depending on the level of care required. Community pharmacy can also be a gateway for health promotion and prevention measures, boosting distribution of self-help information and resources on physical and mental health and wellbeing. The PDST was designed to complement, not replace, usual care. s47

	between health and social services results in poorer health outcomes and increased health care cost. The AMA considered there were more useful models of care involving pharmacists that should be considered as part of a patient-centred medical home model rather than further fragmenting care.	s47
Pharmacists' ability to confirm diabetes status and testing history	The AMA and RACGP raised concern that it is unclear how pharmacists plan to confirm whether an individual has had a recent diabetes test which was likely initiated by a GP, which is crucial to determine whether costs and services are being duplicated.	s47

		s47
Alignment with clinical guidelines for managing T2DM.	The AMA and RACGP noted that the PDST allowed anyone aged 35-74 to be screened, as long as a diabetes screening test has not been conducted in the past 12 months. This differed to the clinical guidelines on the management of T2DM[1] which recommend patients without a high risk of type 2 diabetes to be screened using AUSDRISK every three years from when they reach 40 years of age.	s47
Populations at high risk of T2DM	Feedback from ADS, ADEA, DA, PSA and Diabetes SA raised that Aboriginal and Torres Strait Islander people have higher rates of undiagnosed diabetes and therefore culturally sensitive screening programs (along with lifestyle information and support) should be supported to enable earlier detection intervention to delay or prevent diabetes-related complications. However, Diabetes SA and the RACGP expressed that the PDST protocol did not target Aboriginal and Torres Strait Islander populations and did not address other populations at higher risk of T2DM or emerging populations who are younger than the 35-year age cut-off in the PDST.	s47

[1] The Royal Australian College of General Practitioners. Management of type 2 diabetes: A handbook for general practice. East Melbourne, Vic. RACGP; 2020.

Appropriateness of the comparator in the PDST.	The AMA and RACGP highlighted that the PDST did not have an appropriate control group and did not research the effectiveness or cost-effectiveness in the context of wider public health or other more readily available and evidence-based medical services. Similarly, Diabetes SA and the individual pharmacist considered that the appropriate comparator for the proposed intervention would be diabetes screening in the GP setting.	The objectives of the PDST were to compare the effectiveness and cost-effectiveness of three different pharmacy-based screening models to promote uptake of diagnostic testing in key groups (who otherwise would not get tested at all) for screening in community pharmacy - not to compare effectiveness relative to other avenues of screening e.g. general practice. As was clearly shown in the results of this trial, community pharmacy represents a complementary channel for screening, not a replacement for other screening venues, which was able to identify individuals with undiagnosed diabetes or pre-diabetes or individuals who were unaware of their condition and therefore not taking any preventive or treatment actions to reduce their risk of regression. **The PDST provides very solid evidence as to which pharmacy screening model will be most effective when offered in addition to existing screening opportunities.** Therefore, the appropriate comparison is "usual care plus PDST vs usual care". s47
Equitable access for rural and remote communities.	Consultation feedback from ADS, ADEA and DA considered that access to traditional medical or clinic-led diabetes screening can be limited in rural and remote areas and by enabling pharmacy-led screening, there is potential to reduce this service gap. However, the RACGP noted that pharmacies can only provide the diabetes screening service if they have two trained pharmacists on duty at the same time, and a private room is available.	To be eligible to deliver the screening service, a pharmacy needed to demonstrate that it had the following: • A separate counselling room or private counselling area • Two or more pharmacists on duty at the same time when delivering screening services • A minimum of one pharmacist with requisite training and competency to conduct screening • Appropriate documentation, software and suitable, regularly calibrated POC equipment and consumables s47
Potential for misdiagnosis	The ADS, ADEA and DA collectively expressed concerns that misdiagnosis as a result of either false positive or false negative screening results may be a potential issue, as with all screening programs. However, ADS, ADEA and DA considered that these risks may be minimized through appropriate education of pharmacists and quality control of testing apparatus, as well as referral of positive results to GPs. The AMA, Diabetes SA and PSA raised the	s47 Pharmacists who worked in a participating pharmacy were only eligible to participate if they: • Were currently registered by the Australian Health Practitioner Regulation Agency • satisfactorily completed a Continuing Professional Development (CPD)-accredited online training course and assessment • agreed to follow procedures outlined in the trial protocol • demonstrate competence in POC testing using the device supplied for the trial (groups B and C).

	potential risk of undermanaged 'diagnosis' if referrals are not made and that understanding the GP referral uptake rates (or lack of), particularly for those diagnosed with diabetes would be informative.	The content for the CPD-accredited online training course was developed by the project team and further developed for online delivery by the Guild Pharmacy Academy. The online training consisted of four modules: (1) trial overview; (2) about T2DM; (3) about screening; and (4) clinical protocol. Modules 1–3 were the same for all groups, while module 4 was specific to each group and supported by standard operating procedures detailing each step of the clinical protocol. Training in device use was delivered in the pharmacy by a trained technical support representative of the device manufacturer, with assessment using a competency checklist. s47
Patient education and support	Diabetes SA noted that the report does not provide any detail about what education and support people in the trial received to assist them reduce their lifestyle risk factors. Diabetes SA considered it important to understand what people in the trial perceived to be their benefits and disadvantages of participating in this trial.	s47

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