PDST - 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

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 <u>total screened population</u> was higher in Group B [*redacted*] than in Group A [*redacted*] and Group C [*redacted*]
- <u>Using referred participants</u> as the denominator, the rates of diagnosis of T2DM were: Group A [*redacted*]; Group B [*redacted*]; and Group C [*redacted*]
- Rates of <u>qualifying for referral</u> were lower in Groups B [*redacted*] and C [*redacted*] compared with Group A [*redacted*]
- Rates of <u>referral uptake</u> were higher in Groups B [*redacted*] and C [*redacted*] compared with Group A [*redacted*]

- The most common risk factors in participants diagnosed with T2DM were having a family history of diabetes [*redacted*], being on blood pressure medication [*redacted*], having low levels of exercise [*redacted*] or vegetable intake [*redacted*], and smoking [*redacted*]
- 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 [*redacted*] per person screened to [*redacted*] 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 [*redacted*] 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** [*redacted*] per new case of T2DM diagnosed and [*redacted*] 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)** **<u>AUSDRISK + HbA1c (Group B):</u> Dominates Group A** Under Model 3 and Model 4 (including 4.1-4.3) Group B is dominant over AUSDRISK alone (Group A). **<u>AUSDRISK + scBGT (Group C):</u> 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@** [*redacted*] **AUSDRISK + scBGT: No@** [*redacted*] **@** 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.	<u>**Results are variable by model, with Group B having stronger credentials than Group C**</u> **<u>AUSDRISK + HbA1c (Group B)</u>** # No, additional cost of [*redacted*] per person screened under Model 1 # Yes, saving of [*redacted*] per person screened under Model 3 # Yes, saving of [*redacted*] per person screened under Model 4.1 # Yes, saving of [*redacted*] per person under Model 4.2 and 4.3 **<u>AUSDRISK + scBGT (Group C)</u>** # No, additional cost of [*redacted*] per person screened (Model 1) # No, additional cost of [*redacted*] and [*redacted*] under Model 3 and Model 4.1, respectively

| | # Yes, saving of [*redacted*] per person screened (Model 4.2) |
| | # Yes, saving of [*redacted*] 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 [*redacted*] (from [*redacted*] in Group A; [*redacted*] in Group B; and [*redacted*] in Group C); with FN in non-referrals of Group A moving from [*redacted*] to [*redacted*] [based on AusDiab], Group B left unchanged at [*redacted*], and Group C moving from [*redacted*] to [*redacted*] [based on AusDiab]. **Model 4.3:** was based on 4.2 with the Group C referral rate increased to [*redacted*] and FN decreased to [*redacted*].

[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 $[*redacted*] for Group A (AUSRISK alone); $[*redacted*] for Group B (AUSDRISK +POC HbA1c); and $[*redacted*] 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 $[*redacted*] per additional new case of T2DM detected in Group B compared with Group A; or $[*redacted*] 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 [*redacted*], 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 $[*redacted*] per new confirmed case of T2DM; or $[*redacted*] with prediabetes included

- The <u>most sensitive parameters</u> 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:

    o <u>Model 1</u> 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 $[*redacted*] per QALY, while the Group B/Group A ICER was $[*redacted*] per QALY

    o <u>Model 2</u> 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

    o <u>Model 3</u> 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

    o <u>Model 4</u> 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 $[*redacted*] per person screened to $[*redacted*] per person screened, with only Model 1 predicting a net cost. For Group C the results are less promising, with Model 4.2 and Model 4.3 suggesting savings ($[*redacted*] to $[*redacted*] 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	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
Group B: AUSDRISK + HbA1C POC	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
Group C: AUSDRISK + BG POC	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
Decision Analytical Model 4.1 (based on Model 3 + using weighted lifetime costs and outcomes)					
Group A: AUSDRISK	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
Group B: AUSDRISK + HbA1C POC	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
Group C: AUSDRISK + BG POC	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
Decision Analytical Model 4.2 (based on Model 4.1 + using AusDiab data to update FN in Group A and C)					
Group A: AUSDRISK	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
Group B: AUSDRISK + HbA1C POC	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
Group C: AUSDRISK + BG POC	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
Decision Analytical Model 4.3 (based on Model 4.2 + changing referral rate in Group C)					
Group A: AUSDRISK	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
Group B: AUSDRISK + HbA1C POC	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
Group C: AUSDRISK + BG POC	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]

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 9.6% (from [*redacted*] in Group A; [*redacted*] in Group B; and [*redacted*] in Group C); with FN in non-referrals of Group A moving from [*redacted*] to [*redacted*] [AusDiab], Group B unchanged at [*redacted*], and Group C moving from [*redacted*] to 1.94% [based on AusDiab]. Uses weighted average lifetime costs and outcomes.
Model 4.3: Version 4.2, but with Group C referral rate increased to [*redacted*] and FN decreased to 1.5%. 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 [*redacted*] in Group A; [*redacted*] in Group B; and [*redacted*] in Group C); with FNs in non-referrals of Group A moving from [*redacted*] to [*redacted*] [AusDiab], Group B unchanged at [*redacted*][1], and Group C moving from [*redacted*]% to [*redacted*]% [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

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[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.

- 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. 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

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[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
RBG Cut off ≥7.0 mmol/L or FBG cut off≥ 5.5 mmol/L	[*redacted*]	[*redacted*]
RBG cut offs ≥6.5 mmol/L or FBG cut off≥ 5.5 mmol/L	[*redacted*]	[*redacted*]
RBG Cut off ≥6.0 mmol/L or FBG cut off≥ 5.5 mmol/L	[*redacted*]	[*redacted*]
RBG Cut off ≥5.5 mmol/L or FBG cut off≥ 5.5 mmol/L	[*redacted*]	[*redacted*]

Table Note: *Assumption due to no data available.

- 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 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 ([*redacted*] of the total screened population) compared to Groups A ([*redacted*]) and C ([*redacted*]). 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 [*redacted*] per additional confirmed case of T2DM detected in Group B (vs Group A), and [*redacted*] 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 <u>non-referral rates</u>; 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.

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[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	[*redacted*]	[*redacted*]
RBG cut offs ≥6.5 mmol/L or FBG cut off≥ 5.5 mmol/L	[*redacted*]	[*redacted*]
RBG Cut off ≥6.0 mmol/L or FBG cut off≥ 5.5 mmol/L	[*redacted*]	[*redacted*]
RBG Cut off ≥5.5 mmol/L or FBG cut off≥ 5.5 mmol/L	[*redacted*]	[*redacted*]

*Assumption due to no data available.

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
Group A $[redacted]	1st	**Group B** [redacted] [redacted]	1st	**Group B** [redacted] [redacted]	1st	Group A [redacted]	1st	Comparator	n/a in ICER
Group C [redacted]	2nd	Group A [redacted] [redacted]	2nd	Group A [redacted] [redacted]	2nd	**Group B** [redacted]	2nd	**Group B** [redacted] Models 3, 4.1. 4.3	1st
Group B [redacted]	3rd	Group C [redacted] [redacted]	3rd	Group C [redacted] [redacted]	Poor 3rd	Group C [redacted]	3rd	Group C [redacted]	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 $[redacted] per person screened to $[redacted] per person screened, with only Model 1 predicting a net cost ($[redacted] per person screened). For Group C versus Group A the results are less promising, with Model 4.2 and Model 4.3 suggesting savings ($[redacted] to $[redacted] per person screened), while Models 1, 3 and 4.1 all predict a net cost ($[redacted] to $[redacted] 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.

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[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.

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 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