Public Summary Document

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

Applicant: Pharmacy Guild of Australia

Date of MSAC consideration: 83rd MSAC Meeting, 25-26 November 2021

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, visit the MSAC website

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 of glycated haemoglobin (HbA1c) was received from the Pharmacy Guild of Australia by the Department of Health.

2.   MSAC's advice to the Minister

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness and cost-effectiveness, MSAC deferred providing advice on the comparative clinical and cost-effectiveness of pharmacy-based opportunistic screening for T2DM using AUSDRISK and HbA1c point-of-care (PoC) testing. MSAC considered that this service could address an unmet clinical need if targeted to people who are not currently accessing screening through general practitioners (GPs), particularly in underserved areas, The service could also support more equitable access to comprehensive, co-ordinated and integrated care (including access to prior screening tests results by pharmacists and GPs).

The Pharmacy Diabetes Screening Trial (PDST) did not compare pharmacy-based screening with usual care (opportunistic intermittent screening through the general practitioner). For this reason, the trial could not demonstrate the potential benefits of adding pharmacy-based screening to existing services. However, the PDST provided some evidence that AUSDRISK followed by HbA1c PoC testing and referral may lead to more people being diagnosed with T2DM and benefiting from treatment. MSAC considered the intervention should be targeted to people who are not adequately screened through existing primary care services. For this population, the comparator would be no opportunistic screening.

MSAC recalled it had previously considered PoC testing for HbA1c to be unreliable for diagnosis (but useful for monitoring). MSAC noted the importance of accuracy of PoC testing for screening purposes to guide appropriate referral for confirmation (or otherwise) of

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the diagnosis and management where appropriate. MSAC considered that the performance of HbA1c PoC testing has likely evolved since MSAC's last consideration of the technology and requested further assessment of the analytical validity of the PoC test compared with laboratory-based tests.

MSAC advised that the modelled cost effectiveness of the proposed intervention was highly uncertain as discussed in the commentary and the ESC report. MSAC recognised that the management of T2DM is more cost effective than letting undiagnosed T2DM run its course. In this context, MSAC considered a cost consequence analysis which took into account the full costs of the proposed screening service using AUSDRISK with HbA1c PoC testing and with the application of appropriate underlying prevalence of T2DM, would be informative. Further, MSAC requested that a comparison with other programs such as the Quality Assurance for Aboriginal and Torres Strait Islander Medical Services (QAAMS) be undertaken. MSAC also requested updated financial implications of programmatic funding which includes various scenarios of targeted delivery of the service.

Consumer summary

This application was from the Pharmacy Guild of Australia to publicly fund a community pharmacy-based screening program for people who have not been diagnosed with type 2 diabetes or pre-diabetes.

Diabetes is a chronic disease that affects how the body uses glucose (a type of sugar). When there is too much glucose in the bloodstream (high blood sugar levels) over time it can result in serious complications such as heart disease, kidney disease and eye problems. There are various types of diabetes, the main one being type 2 (typically occurring in older overweight people and often asymptomatic) and type 1 (which presents quickly with symptoms such as thirst and increased urination). Pre-diabetes is when blood sugar levels are mildly raised, but not high enough to be considered type 2 diabetes. Pre-diabetes may develop into diabetes if left untreated.

The application was based on the Pharmacy Diabetes Screening Trial that looked at three different pharmacy screening services. All three services used the Australian Type 2 Diabetes Risk Assessment Tool (AUSDRISK). The AUSDRISK is a free questionnaire with 10 questions that people can complete on their own. Research has shown that the AUSDRISK can identify whether a person has a low, intermediate, or high risk of developing type 2 diabetes in the next 5 years. The Pharmacy Diabetes Screening Trial compared AUSDRISK alone (Group A) or in combination with point-of-care testing for glycated haemoglobin (HbA1c; Group B) or small capillary blood glucose (blood glucose testing; Group C). HbAc1 and blood glucose testing were detected using point-of-care tests (finger prick blood tests) in the pharmacy. High HbA1c or blood glucose tests are suggestive of type 2 diabetes and these individuals would need further blood tests to confirm type 2 diabetes. In Group A, anyone with an AUSDRISK score of 12 or greater was referred to a general practitioner (GP). In Group B and C, anyone with an AUSDRISK score of 12 or greater then received either an HbAc1 (Group B) or a blood glucose test (Group C). Anyone found to have elevated levels of HbA1c or blood glucose were referred to a GP for further assessment and management.

MSAC noted that the trial provided some evidence that AUSDRISK followed by HbA1c point-of-care testing and referral may lead to more people being diagnosed with T2DM and benefiting from treatment. However, the trial did not compare AUSDRISK followed by

Consumer summary

HbA1c point-of-care testing with usual care, which is diabetes screening by a GP. For this reason, MSAC was uncertain whether AUSDRISK followed by HbA1c point-of-care testing provided additional benefits to usual care and whether it was good value for money. MSAC also recalled that it had previously found that HbA1c point-of-care tests were not as accurate as laboratory HbA1c tests used for diagnosing type 2 diabetes. MSAC acknowledged that HbA1c point-of-care tests may have improved but needed further information on this. MSAC acknowledged there are high numbers of people in Australia with undiagnosed type 2 diabetes, and that diabetes is a debilitating chronic condition that needs to be managed. Thus, MSAC considered it important that everyone with diabetes is identified so they can access treatment. However, MSAC considered the benefits of diagnosing pre-diabetes is unclear as the dietary and exercise advice to prevent diabetes is the same as for the general population

MSAC requested extra information about the proposed pharmacy diabetes screening program, so that it could make an informed decision about whether such a program is safe, effective and cost-effective to detect type 2 diabetes and pre-diabetes in undiagnosed people. MSAC requested more information about the details of the program, who would be screened and how much the screening would cost, to ensure that the program benefits the people who needed it the most. Therefore, MSAC deferred its decision until it receives and considers such information.

MSAC's advice to the Commonwealth Minister for Health

MSAC deferred its advice on public funding of community pharmacy-based opportunistic screening program for type 2 diabetes and pre-diabetes, until it has enough information to determine if such a program is safe, effective and cost-effective.

3.   Summary of consideration and rationale for MSAC's advice

MSAC noted this application, from the Pharmacy Guild of Australia, sought public funding of community pharmacy-based opportunistic screening for pre-diabetes and type 2 diabetes mellitus (T2DM) in undiagnosed patients, including counselling and referral.

MSAC noted the trial was a part of the Pharmacy Trials Program (PTP) funded by the Australian Government under the Sixth Community Pharmacy Agreement. 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.

MSAC noted 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:

- AUSDRISK assessment of diabetes risk alone and GP referral for persons with an AUSDRISK score of ≥12 (Group A)

- AUSDRISK followed by a PoC glycated HbA1c test for persons with an AUSDRISK score of ≥12 and GP referral if persons had an HbA1c ≥ 39 mmol/mol (5.7%) (Group B)

- AUSDRISK followed by a PoC small capillary blood glucose test (scBGT) for persons with an AUSDRISK score of ≥12 or greater and GP referral if persons had a fasting blood glucose of ≥ 5.5 mmol/l or a random blood glucose of ≥ 7.0 mmol/l (Group C).

The applicant-developed assessment report (ADAR) requested public funding for AUSDRISK assessment followed by PoC HbA1c testing for persons with an AUSDRISK score of 12 or greater. MSAC noted that AUSDRISK provides a prognostic score (i.e. it calculates a risk of developing diabetes in the next 5 years) rather than a test that predicts a patient's risk of having asymptomatic T2DM at the time the AUSDRISK is performed. In the PDST, patients with an HbAc1 score of 5.7% or higher were referred to a GP. The ADAR presented an economic analysis exploring the impact of adopting a HbA1c cut-off ≥6.0%.

MSAC noted the fee proposed by the applicant was **$redacted** for AUSDRISK alone and **$redacted** for AUSDRISK and PoC HbA1c testing for eligible patients. However, the applicant also stated the fee per occasion of service would need to be reconsidered in the event capital expenditure cannot be considered for these devices. MSAC also noted the AUSDRISK is a free online tool and was unclear of the advantages of funding a pharmacy **$redacted** to complete the simple questionnaire on behalf of the patient.

The MSAC Executive had previously noted, and the ESC reiterated, that the PDST trial report does not provide information pertinent to MSAC decision making, particularly regarding cost-effectiveness, as the trial did not examine the value of a pharmacy-based service in addition to current services or compared to alternative options for screening undiagnosed T2DM. The ADAR did not present a comparison with usual care. MSAC agreed with ESC that this was a major limitation of the ADAR. MSAC considered that usual care, for most people, would be opportunistic screening by GPs.

MSAC noted the clinical need for identifying people with undiagnosed T2DM, as undiagnosed T2DM can lead to poor health outcomes. MSAC considered T2DM screening in general practice had improved over time. MSAC considered that over the course of three years, the majority of the population would have attended a GP as 82.4% of people saw a GP in 2020-21 [1]. MSAC considered most of the proposed population would have undergone opportunistic screening as 56% of the population receive a pathology service[2] and GPs frequently request fasting plasma glucose tests and an HbA1c. MSAC considered that pharmacies could play an important role in providing well-targeted screening that complements, rather than duplicates existing services such as GP-based screening. MSAC considered that the comparator for a pharmacy-based screening program targeted to people not accessing GP services would be no screening in primary care.

The ADAR did not define a screening population or nominate the frequency of testing. MSAC noted that the Royal Australian College of General Practitioners (RACGP) Guidelines recommend diabetes screening for individuals not at high risk every 3 years from 40 years of age using the AUSDRISK only, and that Aboriginal and Torres Strait Islander people should have blood testing annually from 18 years of age. MSAC considered that any pharmacy-based screening should be consistent with RACGP Guidelines. MSAC also noted the

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[1] Australian Bureau of Statistics (2020-21), Patient Experiences in Australia: Summary of Findings. https://www.abs.gov.au/statistics/health/health-services/patient-experiences-australia-summary-findings/latest-release#key-statistics, ABS Website.
[2] Australian Institute for Health and Welfare (2020). Specialist, pathology and other diagnostic services. https://www.aihw.gov.au/reports/australias-health/specialist-pathology-and-other-diagnostic-services

Australian position statement on screening and management of pre-diabetes in adults in primary care in Australia (Bell 2020[3]) which advised that re-testing should occur every 1–5 years, depending on the AUSDRISK score and blood test results. MSAC noted the position paper advised blood testing in people with an AUSDRISK ≥ 6 and noted that this differed from the RACGP Guidelines.

MSAC noted the ADAR did not include a clinical management algorithm; MSAC considered the algorithm proposed by the commentary and ESC (see Figure 1). MSAC noted that two positive tests are required to confirm a diagnosis of T2DM. MSAC considered that when GPs screen patients for T2DM, the confirmatory test typically occurs three months after the initial test.

MSAC noted that comprehensive consultation feedback had been received for this application and the majority of consultation feedback was supportive (see Section 7 of this PSD). MSAC noted the consultation feedback highlighted the trial did not consider some high-risk populations such as Aboriginal and Torres Strait Islander people and younger people at high risk of T2DM. MSAC noted the feedback from medical organisations emphasised the importance of continuity of care.

MSAC advised that a quality assurance program is needed for pharmacies and pharmacists providing PoC HbA1c testing for implementation. MSAC noted that a program similar to the QAAMS (Quality Assurance for Aboriginal & Torres Strait Islander Medical Services) Program which provides training for Aboriginal health workers and other health professionals in the use of PoC testing would be suitable for this purpose.

MSAC noted that, in the PDST, there were **redacted** new diagnoses of T2DM and **redacted** new diagnoses of pre-diabetes from 14,093 people screened in **redacted** pharmacies. In Group B, which examined AUSDRISK and PoC HbA1c testing, there were **redacted** new diagnoses of T2DM and **redacted** diagnoses of pre-diabetes out of **redacted** participants. MSAC noted that the proportion diagnosed was consistent with other population-based estimates such as the 2011-12 Australian Health Survey which estimated 1.2% of the adult population had previously undiagnosed diabetes. MSAC noted the imbalance in risk factors among the three PDST groups as Group B (and Group C) had more risk factors for T2DM. MSAC considered this would have contributed to more T2DM diagnoses in the HbA1c arm (Group B). MSAC noted there were fewer participants recruited into the trial from regional and remote areas than planned and there were few diagnoses of T2DM outside metropolitan areas.

MSAC considered the intervention in Group C (AUSDRISK and random blood glucose testing) was an inappropriate screening intervention for T2DM as it is an unreliable measure of whether a person may have diabetes.

MSAC discussed the clinical value of a diagnosis of pre-diabetes. MSAC acknowledged pre-diabetes is associated with worse cardiovascular outcomes. Although lifestyle interventions can reduce or delay the onset of T2DM, there is insufficient data that identifying pre-diabetes improved clinical outcomes such as mortality or cardiovascular disease [4]. MSAC noted that a person identified as having pre-diabetes may be a motivating

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[3] Bell K *et al.* A position statement on screening and management of prediabetes in adults in primary care in Australia. *Diabetes Res Clin Pract*. 2020;164:108188.

[4] 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.

factor to undertake lifestyle interventions. However, MSAC also noted that the dietary and exercise interventions to prevent diabetes did not differ from those recommended for the broader population.

Because the PDST did not compare pharmacy-based screening with usual care (opportunistic intermittent screening through a GP), the trial could not demonstrate the potential benefits of adding pharmacy-based screening to existing services. In its pre-MSAC response, the applicant reiterated that this was not the purpose of the PDST; rather, it aimed to compare pharmacy models that could complement GP services. MSAC noted that the PDST provided some evidence that Group B – AUSDRISK followed by HbA1c PoC testing and referral – may lead to more people being diagnosed with T2DM and benefiting from treatment.

MSAC recalled that it had previously considered PoC testing for HbA1c to be unreliable for diagnosis but useful for monitoring diabetes (MSAC 1431 Public Summary Document). MSAC noted the importance of accuracy of PoC testing for screening purposes to guide appropriate referral for confirmation (or otherwise) of the diagnosis and management of diabetes, where appropriate. In the pre-ESC response the applicant provided a citation Sobolesky 2018[5] that reported that 97.1% of the Afinion PoC device results and 94.5% of routine laboratory results fell within the target value of ±6% of the National Glycohemoglobin Standardization Program (NGSP) reference method results. MSAC agreed with the ESC that the publication (Sobolesky 2018) appeared to show some degree of underestimation compared with laboratory testing for samples with lower HbA1c values. MSAC noted that most HbA1c PoC devices are not registered for diagnosis of T2DM, however the Afinion PoC device used in the trial has been registered in the United States for diagnosis of T2DM. MSAC considered the precision of PoC HbA1c testing platforms for values between 5.5% and 7.5% is most relevant for screening, rather than broadly across HbA1c values. MSAC considered the performance of HbA1c PoC testing has likely evolved since MSAC's last consideration of the technology and requested further assessment of the analytical validity of the HbA1c PoC testing platforms compared with laboratory-based tests. MSAC considered this updated assessment would be relevant to opportunistic screening using HbA1c PoC testing in all primary care settings. MSAC considered the accuracy of PoC tests would be an important issue for consumers. MSAC considered most consumers would want a diagnosis confirmed by the most accurate test available.

MSAC noted 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, on lifetime costs and quality adjusted life years (QALYs). The ADAR also presented several cost-utility models. The commentary presented the ADAR's preferred model as the base case model. MSAC considered there were numerous issues with the economic analyses presented in the ADAR and the applicant's pre-ESC response.

MSAC noted the ESC concern that a pharmacy-based screening program would "double up" services if patients were already screened by GPs. Additionally, two tests are required for confirmation of the diagnosis (as recommended by the World Health Organization). Previously, the MSAC Executive considered it would be reasonable to assume 60–90% of laboratory HBA1c tests will be coned out (p3, PSD Application 1431.1) and the MBS would

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[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

not pay for the cost of these tests. The applicant did not address this matter in its pre-MSAC response.

MSAC noted the ESC concern that use of inconsistent underlying prevalence of T2DM (due to the recruitment into the trial) is a major flaw and a significant driver of the results. Costs used are inappropriate and have errors. Transition probabilities used in the model are derived from data that may not be appropriate – specifically, they are from the first UKPDS diabetes model (not the updated second UKPDS model), which overestimates risk of T2DM-related health events in the Australian T2DM population.

MSAC noted the economic evaluations did not present a comparison with usual care, which for most people is most likely to be opportunistic screening by GPs. Therefore, the economic evaluations presented in the ADAR do not inform whether public funding of pharmacy-based screening using AUSDRISK and HbA1c PoC would be a cost-effective addition to usual care. The commentary's calculations resulted in ICERs of **$redacted**–**$redacted** per QALY, which was still uncertain due to the limitations of the models used.

MSAC advised that the modelled cost effectiveness of the proposed intervention was highly uncertain as discussed in the commentary and the ESC report. MSAC recognised that management of T2DM is more cost-effective than letting undiagnosed T2DM run its course. In this context, MSAC considered a cost-consequence analysis would be informative. MSAC considered this could be based on the PDST data to determine the number and cost per additional diagnosis made (diabetes and pre-diabetes), accounting for the full costs of delivering the proposed pharmacy screening service and applying an appropriate underlying prevalence of T2DM. MSAC considered the intervention should be targeted to people who are not adequately screened through existing primary care services. For this population, the comparator would be no opportunistic screening. MSAC requested that a comparison with alternative approaches such as the QAAMS Program be undertaken.

MSAC noted the financial impact used an epidemiological approach and assumed the eligible population is people aged 35–74 who have not been diagnosed or screened for diabetes in the past 12 months. MSAC noted this implies that people could be screened every year, which is more often than recommended in the RACGP guidelines. MSAC also noted that uptake of the eligible population, the key parameter that influences the overall financial impact, was based on expert opinion. MSAC considered the financial estimates to be highly uncertain, and that uptake would be largely influenced by the financial reimbursement offered to pharmacies to undertake T2DM screening. The ADAR estimated that **redacted**% of the Australian population aged 35–74 years would be eligible. The financial impact analysis did not include any cost offsets for reduced GP screening for T2DM.

MSAC noted the ADAR estimated the 5-year cumulative financial impact of adopting community pharmacy screening for T2DM using the AUSDRISK + PoC HbA1c would be approximately $20 million to < $30 million. The commentary revised this base case to exclude the cost of consumables and the cost of PoC devices. MSAC noted this reduced the cost to government to approximately $10 million to < $20 million over 5 years.

MSAC noted that with an eligible population aged 40-74 years, no reimbursement for AUSDRISK alone, and inclusion of the Aboriginal and Torres Strait Islander people aged

20-39 years (eligible for HbA1c without AUSDRISK) the net cost to government would reduce to $0 to < $10 million over 5 years.

After considering the available evidence presented, MSAC deferred providing advice on the comparative clinical and cost-effectiveness of pharmacy-based opportunistic screening for T2DM using AUSDRISK and HbA1c PoC testing to seek updated information regarding the analytical validity of HbA1c PoC testing compared with laboratory-based tests, a cost-consequence economic analysis and further financial analyses to inform its advice. MSAC considered that although the PDST could not demonstrate the potential benefits of adding pharmacy-based screening to existing services, it provided some evidence that AUSDRISK followed by HbA1c PoC testing, and referral may lead to more people being diagnosed with T2DM and benefiting from treatment.

MSAC advised that if pharmacy-based opportunistic screening of T2DM was to be publicly funded, it should be targeted to people who are not currently accessing screening through GPs, particularly in underserved areas. MSAC requested updated financial implications of programmatic funding which includes scenarios of targeted delivery of the service. These scenarios may include different proposed populations and different referral thresholds.

MSAC considered that such a service should form a part of a comprehensive, coordinated and integrated system of primary care. MSAC advised that access to prior screening tests results by pharmacists and GPs was essential for the delivery of screening practices that are consistent with clinical guidelines. In this regard, MSAC considered that access to test results from pharmacy-based screening is essential information for the patient's GPs. MSAC considered that a pharmacy-based screening service could address an unmet clinical need if targeted to people not accessing existing services. MSAC considered that a subsidised pharmacy-based T2DM service should facilitate equitable access to care. MSAC emphasised the importance of pharmacy-based diabetes screening integrating with general practice and other primary care providers involved in diagnosing T2DM.

MSAC noted that no quality assurance measures were proposed in the ADAR. MSAC considered that a quality assurance program would be needed for implementation. MSAC noted there may be difficulties in implementing this service and the feasibility of uptake in different pharmacy practices would need to be assessed.

4. 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 **$redacted** Which is a weighted average of **$redacted** for administering AUSDRISK and **$redacted** for administering both AUSDRISK and HbA1c PoC testing.
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

5.   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%).

6.   Proposal for public funding

The ADAR did not present an explicit fee proposal. The pre-ESC response clarified that the fee proposal was **$redacted** for AUSDRISK alone and **$redacted** 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	$11.80

MBS item	Descriptor (abridged)	Fee and benefit [a]
	(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	
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: 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

7.   Summary of public consultation feedback/consumer issues

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[6] 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 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.

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

The PDST surveyed participants three months after their screening date. Surveys were sent to **redacted** referred participants and **redacted** responses were received (response rate **redacted**). A further **redacted** surveys were emailed to all non-referred participants and **redacted** responses were received (response rate **redacted**). The key findings included:

- more than **redacted** of respondents rating the service as professional or very professional;
- more than **redacted** of respondents stating that they would recommend the screening service to a family member or friend;
- more than **redacted** 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 **redacted** of respondents reported making healthy lifestyle changes since attending the pharmacy screening service.

8. Proposed intervention's place in clinical management

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.

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 pre-diabetes 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. The commentary suggested that

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.
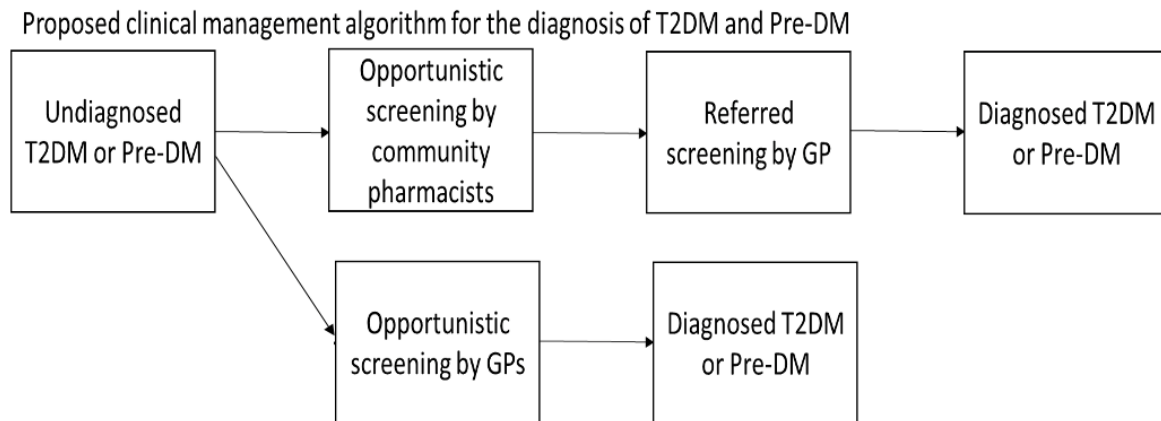
Proposed clinical management algorithm for the diagnosis of T2DM and Pre-DM

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.

9. Comparator

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 pre-diabetes 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.

10. 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 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).

11.   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	**redacted**	**redacted**	**redacted**
AUSDRISK ≥ 12	**redacted**	**redacted**	**redacted**
Referred to GP	**redacted**	**redacted**	**redacted**
Visited GP (Self-reported)	**redacted**	**redacted**	**redacted**
Tested (Self-reported)	**redacted**	**redacted**	**redacted**
Tested (Medicare data)	**redacted**	**redacted**	**redacted**
Diagnosed T2DM	**redacted**	**redacted**	**redacted**
Diagnosed Pre-DM[1]	**redacted**	**redacted**	**redacted**

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: **redacted** of T2DM and **redacted** Pre-DM across the 14,093 participants screened (**redacted** and **redacted** respectively).

The commentary considered that this is low, given the expected prevalence of undiagnosed T2DM used in the sample size calculation (**redacted**). The Preliminary Evaluation, however,

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[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.

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.

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[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
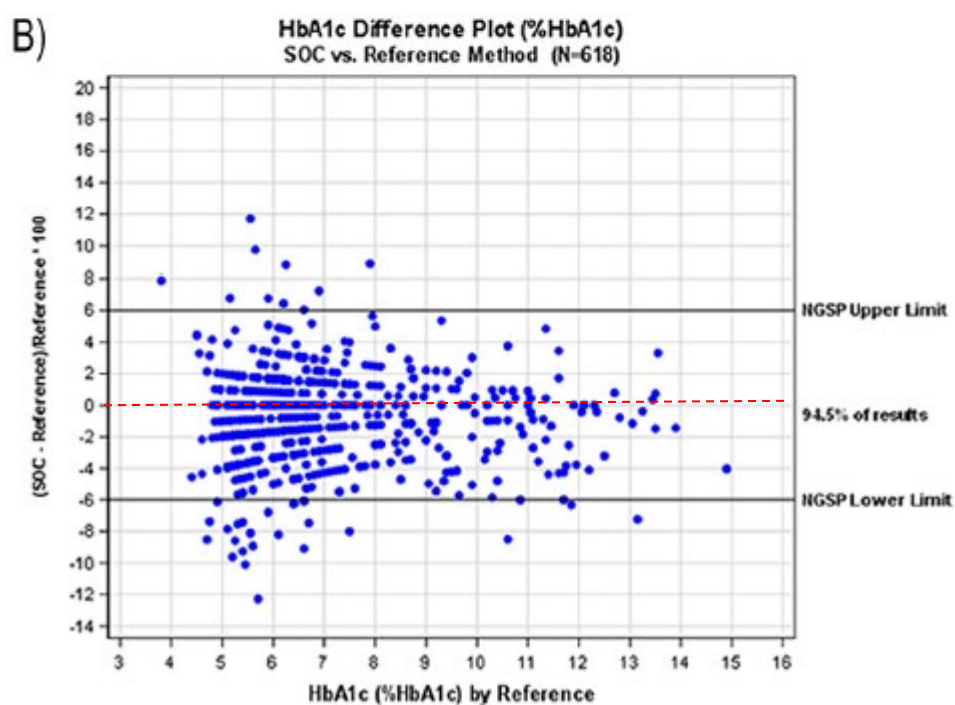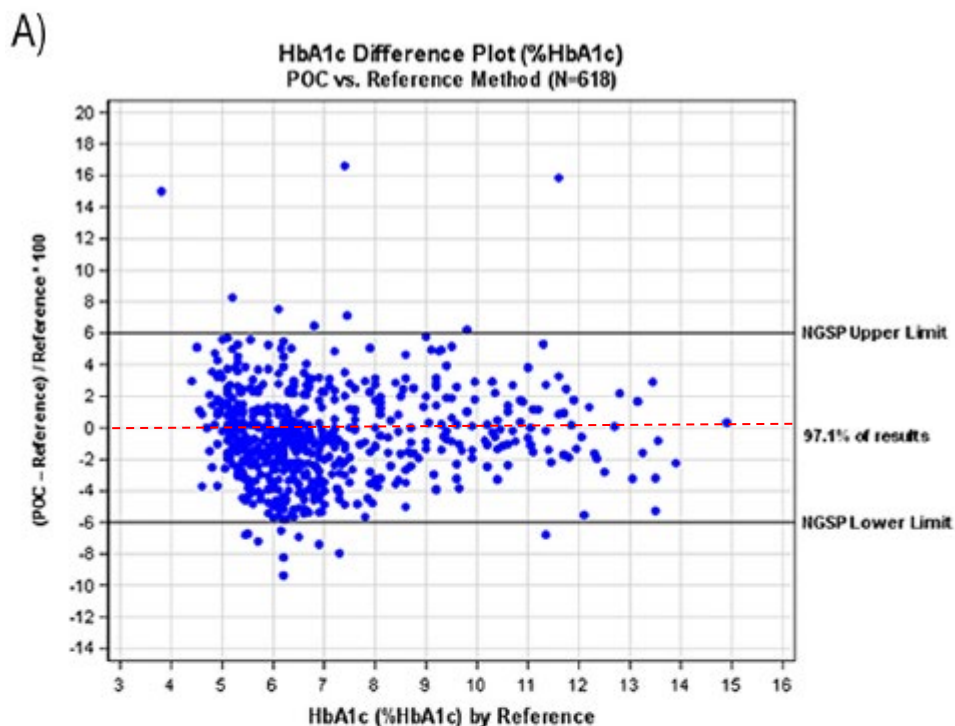
Figure 2 Difference plots comparing point of care and routine laboratory standard-of-care HbA1c results with an NGSP reference method. Limit lines of ±6% are illustrated on the graph. (a) The POC device versus the mean results from the reference method. (b) SOC laboratory result versus the mean reference 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.

12. 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) – **redacted** / **redacted** Group B (AUSDRISK + PoC HbA1c) – **redacted** / **redacted** Group C (AUSDRISK + PoC scBGT) – **redacted** / **redacted**
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	**redacted** 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

<u>Within-trial economic evaluation</u>

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 **$redacted** per screened patient in Group B (AUSDRISK +HbA1c) including consumables. This was higher than the weighted average screening service cost of **$redacted** 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, **redacted** participants received diagnostic testing during GP follow-up according to Medicare data, whereas **redacted** 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)	$redacted	-	redacted	-	-
Group B (AUSDRISK + PoC HbA1c)	$redacted	$redacted	redacted	redacted	$redacted
Group C (AUSDRISK + PoC scBGT)	$redacted	$redacted	redacted	redacted	redacted
Revised (commentary) ª					
Group A (AUSDRISK only)	$redacted	-	redacted	-	-
Group B (AUSDRISK + PoC HbA1c)	$redacted	$redacted	redacted	redacted	$redacted
Group C (AUSDRISK + PoC scBGT)	$redacted	$redacted	redacted	redacted	redacted

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 $redacted for Group A, $redacted for Group B, and $redacted for Group C.

In the ADAR within-trial evaluation, Group C is dominated by Group A. Group B is associated with an ICER of **$redacted** 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

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[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 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	redacted	redacted	redacted
Undiagnosed prevalence among referred	redacted	redacted	redacted

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

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	redacted	redacted	redacted
Undiagnosed	redacted	redacted	redacted
Diagnosed	redacted	redacted	redacted
Intensive Tx ª	redacted	redacted	redacted
No Intensive Tx ª	redacted	redacted	redacted
Pre-DM	redacted	redacted	redacted
Undiagnosed	redacted	redacted	redacted
Diagnosed	redacted	redacted	redacted
Lifestyle Tx	redacted	redacted	redacted
No Lifestyle Tx	redacted	redacted	redacted
No DM	redacted	redacted	redacted

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 (**redacted**) 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)	$redacted	-	redacted	-	-
Group B (AUSDRISK + PoC HbA1c)	$redacted	$redacted	redacted	redacted	$redacted
Group C (AUSDRISK + PoC scBGT)	$redacted	$redacted	redacted	redacted	$redacted

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 – **redacted**, Pre-DM **redacted**). 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.
- **redacted**% 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, **redacted**% 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 (**redacted**%) received a 'delayed diagnosis' after three years.

- Inflated the cost of T2DM-related health events to 2020 price levels
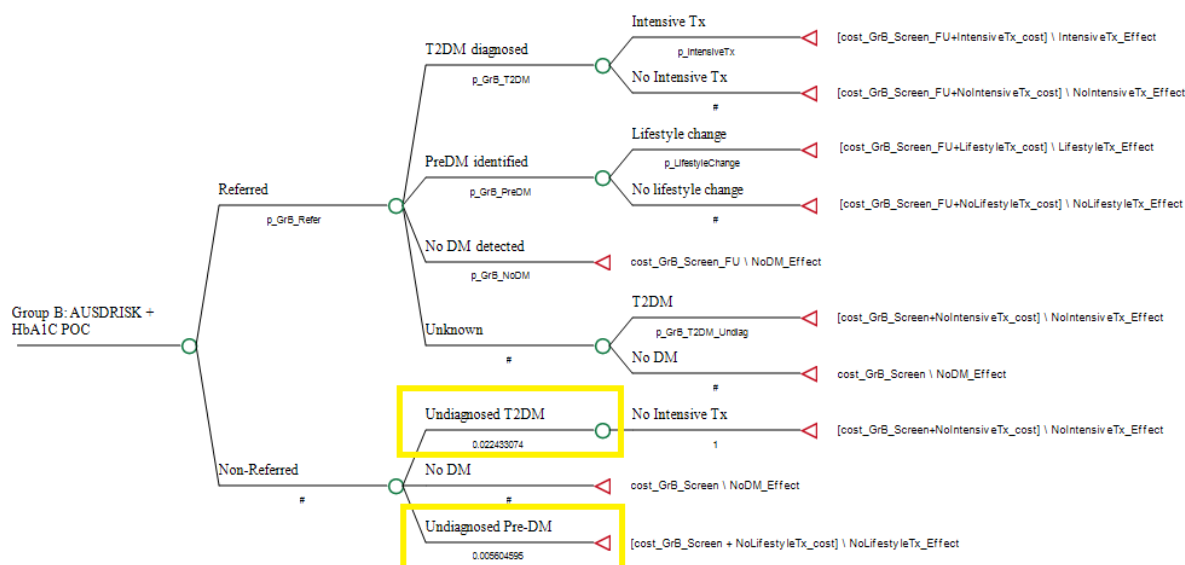- Applied a 5% discount rate (**redacted**% in the ADAR).

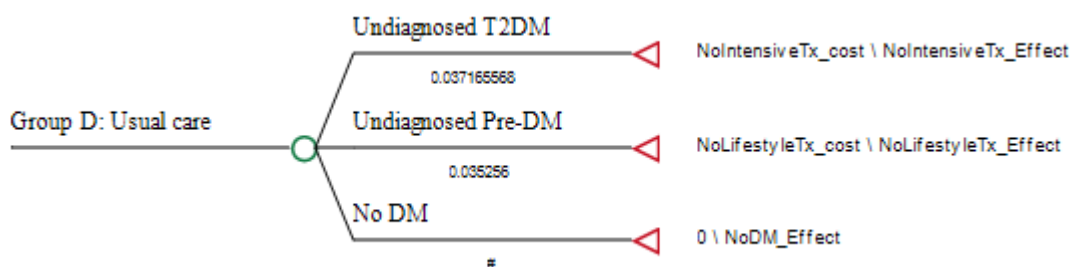**Figure 3: Revised base case – Undiagnosed Pre-DM**

Figure 4: 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)	$redacted	-	redacted	-	-
Group A (AUSDRISK only)	$redacted	$redacted	redacted	redacted	$redacted
Group B (AUSDRISK + PoC HbA1c)	$redacted	$redacted	redacted	redacted	$redacted
Group C (AUSDRISK + PoC scBGT)	$redacted	$redacted	redacted	redacted	$redacted

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 **$redacted**/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 **redacted**% 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 **$redacted** 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)	$redacted	$redacted	redacted	-	-
Group A (AUSDRISK only)	$redacted	$redacted	redacted	redacted	$redacted
Group B (AUSDRISK + PoC HbA1c)	$redacted	$redacted	redacted	redacted	$redacted
Group C (AUSDRISK + PoC scBGT)	$redacted	$redacted	redacted	redacted	$redacted

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 **$redacted** /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)	$redacted	-	redacted	-	-
Group A (AUSDRISK only) + Group D	$redacted	$redacted	redacted	redacted	$redacted
Group B (AUSDRISK + PoC HbA1c) + Group D	$redacted	$redacted	redacted	redacted	$redacted
Group C (AUSDRISK + PoC scBGT) + Group D	$redacted	$redacted	redacted	redacted	$redacted

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.

13.   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 **redacted**% 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 (**redacted** to **redacted**).

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) – **redacted**
Percentage of people already screened in the last 12 months	Estimate (Expert) – **redacted**
Undiagnosed T2DM	**redacted**%[1]
Undiagnosed Pre-DM	**redacted**%[2]

Source: Budget Impact Analysis - Pharmacy Diabetes Screening Service Final for Submission
[1] The population of interest can be calculated as **redacted** The subsequent estimate of undiagnosed T2DM is **redacted**.
[2] The population of interest can be calculated as **redacted** The subsequent estimate of undiagnosed Pre-DM is **redacted**
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 – **redacted** p.a.	-
Referral uptake	PDST – **redacted** p.a.	Conditional on screened and referred
Diagnosis testing	PDST – **redacted** p.a.	Conditional on referral uptake
T2DM diagnosis	PDST – **redacted** p.a.	Conditional on diagnosis testing
Pre-DM diagnosis	PDST – **redacted** p.a.	Conditional on diagnosis testing
Expected number of eligible pharmacies	Pharmacy Guild - **redacted**	Reflects the proportion of pharmacies expected to meet eligibility criteria.
Measuring tape unit cost	PDST - **redacted**	-
PoC test device	PDST - **redacted**	-
PoC & measurement device cost per pharmacy per annum	**redacted**	**Used in the final financial impact calculation**
PoC consumables cost per participant screened	**redacted**	**Used in the final financial impact calculation**
PoC test consumables	PDST - **redacted**	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 - **redacted**	Participants with AUSDRISK < 12 who did not receive PoC testing
Standard consultation - AUSDRISK + HbA1c PoC testing, counselling & referral	PDST - **redacted**	Participants with AUSDRISK ≥ 12 who did receive PoC testing
Cost of community pharmacy screening per participant screened	PDST - **redacted**	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 - **redacted**	**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 **redacted** and (**redacted** - **redacted**) **redacted**, 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. **redacted** vs **redacted**). 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	**redacted**	**redacted**	**redacted**	**redacted**	**redacted**
Screened	**redacted**	**redacted**	**redacted**	**redacted**	**redacted**
AUSDRISK < 12	**redacted**	**redacted**	**redacted**	**redacted**	**redacted**
AUSDRISK ≥ 12 + PoC	**redacted**	**redacted**	**redacted**	**redacted**	**redacted**
Referred	**redacted**	**redacted**	**redacted**	**redacted**	**redacted**
Visit GP	**redacted**	**redacted**	**redacted**	**redacted**	**redacted**
Diagnosis tested	**redacted**	**redacted**	**redacted**	**redacted**	**redacted**
T2DM diagnosed	**redacted**	**redacted**	**redacted**	**redacted**	**redacted**
Pre-DM diagnosed	**redacted**	**redacted**	**redacted**	**redacted**	**redacted**
Financial Impact					
Pharmacy Screening costs	$ **redacted**	$ **redacted**	$ **redacted**	$ **redacted**	$ **redacted**
PoC device & consumables	$ **redacted**	$ **redacted**	$ **redacted**	$ **redacted**	$ **redacted**
Screening service	$ **redacted**	$ **redacted**	$ **redacted**	$ **redacted**	$ **redacted**
GP Follow-up costs	$ **redacted**	$ **redacted**	$ **redacted**	$ **redacted**	$ **redacted**
Total (p.a.)	$ **redacted**	$ **redacted**	$ **redacted**	$ **redacted**	$ **redacted**
Cumulative	$ **redacted**	$ **redacted**	$ **redacted**	$ **redacted**	$ **redacted**
Commentary revised financial impact (net cost to government)					
Pharmacy Screening costs	$ **redacted**	$ **redacted**	$ **redacted**	$ **redacted**	$ **redacted**

Parameter	Year 1	Year 2	Year 3	Year 4	Year 5
GP Follow-up costs [a]	$ redacted	$ redacted	$ redacted	$ redacted	$ redacted
Total (p.a.)	$ redacted	$ redacted	$ redacted	$ redacted	$ redacted
Cumulative	$ redacted	$ redacted	$ redacted	$ redacted	$ redacted
MSAC revised financial impact					
Eligible (aged 40-74yr)	6,689,124	6,779,209	6,856,336	6,924,325	6,986,992
Eligible (Aboriginal and Torres Strait Islander people 20-39 yrs)	275,138	282,066	288,666	295,219	302,092
Screened (uptake unchanged)	$ redacted	$ redacted	$ redacted	$ redacted	$ redacted
PoC test (AUSDRISK ≥ 12 or Aboriginal and Torres Strait Islander people)	$ redacted	$ redacted	$ redacted	$ redacted	$ redacted
*Pharmacy Screening costs (PoC test only - $ **redacted**)*	$ redacted	$ redacted	$ redacted	$ redacted	$ redacted

Source: ADAR - Budget Impact Analysis - Pharmacy Diabetes Screening Service Final for Submission; and revised financial implications estimated by the commentary *and the Department (as requested by MSAC).*
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 $20 million to < $30 million. The revised financial impact analysis calculated int eh commentary suggested this figure is significantly lower, approximately $10 million to < $20 million 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.

14. 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 **$redacted** for AUSDRISK alone and **$redacted** 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.
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[11] 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 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 **$redacted** for AUSDRISK alone and **$redacted** 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

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

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 **redacted**% 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 (**redacted** people were diagnosed with T2DM and **redacted** 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 AUSDRISK + HbA1c (Group B) vs AUSDRISK alone (Group A).

ESC noted that the clinical relevance of a diagnosis of pre-diabetes is controversial[12] 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 [13] which recommended screening for pre-diabetes and type 2 diabetes but found no direct evidence that screening for pre-diabetes improves clinical outcomes. The evidence for improvement in clinical outcomes for treating newly diagnosed T2DM was from the UK Prospective Diabetes Study (UKPDS) trial[14]. The UKPDS recruited patients before the diagnostic criterion for T2DM changed in 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

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[12] Lam K, Lee SJ. Prediabetes-A Risk Factor Twice Removed. *JAMA Intern Med*. 2021;181(4):520-521.

[13] 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.

[14] 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.

bias (as per the [MSAC 1431 Public Summary Document](#)), resulting in possible underdiagnosis. The applicant provided a citation (Sobolesky 2018[15]) 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-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.

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[15] 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

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 **redacted** 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 **$redacted** per QALY to nearly **$redacted**/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 **$redacted** 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.[16] 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 **redacted** of the eligible population has undiagnosed T2DM, which is less than the estimates provided in the ADAR's economic base case and scenarios (**redacted–redacted%**).

ESC considered that these issues resulted in a very uncertain financial impact, which was calculated at up to $0 to < $10 million 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 $0 to < $10 million in year 1 to $0 to < $10 million 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 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.

15.   Other significant factors

Nil

16.   Applicant comments on MSAC's Public Summary Document

Whilst disease screening services are recognised in the scope of practice for pharmacists the main barrier to pharmacists' routinely conducting screening is inadequate funding. Patients are required 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 will ensure equitable access to

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[16] 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.

services for all patients. This raises the question of which approach to screening is the most cost-effective. Thus 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 demonstrated in the results of the 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 Pharmacy Guild of Australia believe the PDST provides very solid evidence as to the pharmacy screening model that will be most effective when offered in adjunct to the variety of existing screening opportunities. Therefore the appropriate comparison is "usual care plus PDST vs usual care". The results of revised analysis has appropriately addressed the assertion of the PDST complementary role to usual care. Community pharmacists being 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. In the context of usual care, the future new intervention of includes the one-off diabetes screening in community pharmacy in parallel with usual care.

17.   Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website: visit the MSAC website