
MSAC Application
1385

Final Protocol to
guide the assessment
of shared medical
appointments for
management of Type
2 diabetes mellitus

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MSAC and PASC

The Medical Services Advisory Committee (MSAC) is an independent expert committee appointed by the Australian Government Health Minister to strengthen the role of evidence in health financing decisions in Australia. MSAC advises the Commonwealth Minister for Health on the evidence relating to the safety, effectiveness, and cost-effectiveness of new and existing medical technologies and procedures and under what circumstances public funding should be supported.

The Protocol Advisory Sub-Committee (PASC) is a standing sub-committee of MSAC. Its primary objective is the determination of protocols to guide clinical and economic assessments of medical interventions proposed for public funding.

Purpose of this document

This document is intended to provide a draft decision analytic protocol (DAP) that will be used to guide the assessment of shared medical appointments for patients with Type 2 diabetes mellitus

The draft protocol will be finalised after inviting relevant stakeholders to provide input. The final protocol will provide the basis for the assessment of the intervention.

The protocol guiding the assessment of the health intervention has been developed using the widely accepted "PICO" approach. The PICO approach involves a clear articulation of the following aspects of the research question that the assessment is intended to answer:

Patients – specification of the characteristics of the patients in whom the intervention is to be considered for use;

Intervention – specification of the proposed intervention;

Comparator – specification of the therapy most likely to be replaced by the proposed intervention; and

Outcomes – specification of the health outcomes and the healthcare resources likely to be affected by the introduction of the proposed intervention.

Purpose of application

An application requesting Medicare Benefits Schedule (MBS) listing of shared medical appointments for patients with Type 2 diabetes mellitus was received from the Australian Lifestyle Medicine Association by the Department of Health in March 2014. This proposal relates to two new consultation items not currently listed on the MBS.

The Assessment Group at Griffith University, as part of its contract with the Department of Health, has drafted this DAP and may undertake an independent assessment of the evidence base on the safety, effectiveness and cost-effectiveness of the proposed intervention in order to inform MSAC's decision-making regarding public funding of the intervention.

Background

Current arrangements for public reimbursement

There are currently no formal arrangements for public reimbursement for shared medical appointments in Australia. There have been a substantial number of papers published on shared medical appointments internationally [1], many of which have shown positive evaluations for the process ranging from patient satisfaction, to reduced use of other services and even reduced health costs. However at this time, there are no published Australian outcome evaluation trials. Two recent Australian publications report the findings of the first phase of a Royal Australian College of General Practitioners (RACGP) funded study [2, 3] designed to assess patient and provider satisfaction with SMAs before considering more extensive evaluation of the process, as has been carried out overseas, in the Australian environment. The report was of findings from focus groups of potential health practitioners and patient support for shared medical appointments. In the past year, a number of shared medical appointments representing 220 patient visits have been performed in Australia in this research setting to gauge patient and provider satisfaction with such a process. Outside of this research setting, shared medical appointments are currently not being widely used in Australia.

Regulatory status

Since this type of care can be given routinely in everyday practice by health professionals in their various roles, shared medical appointments do not require approval from Australian regulatory bodies.

There are no barriers to a general practitioner (GP) setting up a private shared medical appointment clinic with allied health professionals. Patients would not be able to claim Medicare benefits. A practice nurse working under the direction of a GP is not covered by a separate Medicare item.

Currently GP attendance items listed on the MBS require one GP attending to one patient. In G.12.1., MBS Cat 8 of the *Health Insurance Regulations 1975* it specifies that the following medical services will attract benefits only if they have been personally performed by a medical practitioner on not more than one patient on the one occasion (i.e. two or more patients cannot be attended simultaneously, although patients may be seen consecutively) unless a group session is involved (i.e. Items 170-172) (a) All Category 1 (Professional Attendances) items (except 170-172, 342-346).

Intervention

Description

Shared medical appointments

Shared medical appointments are medical appointments carried out in a group of consenting patients by a GP and other health professionals. The role of the GP is the same as in an individual appointment, that is, to provide individual patient care, but in the presence of fellow sufferers. Delineation of duty of care between health professionals also remains the same as in other multi-disciplinary interactions such as team care arrangements.

Patient confidentiality is addressed by ensuring patients consent to participate in the shared medical appointments. They are also required to sign a confidentiality agreement to prevent private medical details to be circulated more widely throughout the community. As some people may not feel comfortable discussing their health in front of other patients, shared medical appointments would be voluntary, and standard GP visits would remain available to those who want them.

Although the health professionals involved in shared medical appointments can vary, the model proposed here would include a minimum of 6 and maximum of 12 patients, an accredited GP and at least a trained Facilitator (e.g., practice nurse, diabetes educator, dietitian, psychologist, or other allied health professional). Proposed Facilitators will have knowledge in T2DM in the course of their professional duties (e.g., nursing, exercise science, dietetics etc). Diabetes educators trained in the SMA process can bring extra skills to the process. The Facilitator could act as the documenter for the shared medical appointment. Shared medical appointments bridge a gap between individual one-on-one consultations, which often lack time for the educational process, and group education, which often lack medical input [4].

Each shared medical appointment is expected to last up to 120 minutes. The GP is not necessarily present for the entire appointment, but is in attendance for up to 80 minutes. The content and conduct of each shared appointment is expected to vary within a loose arrangement providing some structural consistency.

The indicative breakdown in time and health professional participation is provided below. These components occur consecutively but the total duration of the shared medical appointment is 120 minutes:

- The Facilitator (usually but not necessarily a Practice Nurse) will use 20-30 minutes/per group to take vital signs and blood as necessary. This occurs in a 'break out' room or a screen and can continue even after the doctor enters the room. Taking these measurements is not always necessary as many patients have recent records that can – with permission – be noted on the white board. The test results of patients who have signed a confidentiality agreement will be recorded on a white board in the room. Patients will have the option to withdraw consent for their test results to be shared at any time during the appointment. The Facilitator is responsible for group dynamics and encourages group discussion throughout the appointment.

- The GP enters the room about 20 minutes into the meeting and would remain for up to 80 minutes. The GP conducts a standard medical consultation with patients sequentially, making sure that all patients are consulted within the time period available. Patients who require more specific or personalized attention can then be advised to come back for a personalized assessment outside the SMA if necessary.
- The GP leaves the room and the Facilitator continues the group discussion for between 20-30 minutes.

The documenter or Facilitator will detail medical records in real time. This would typically involve taking required chart notes as care is being delivered. Generally the doctor will advise what needs to be written, and this can include referrals and/or prescriptions, but is usually an update to the medical records. It is important that the doctor is not distracted from the consultation by looking at a computer screen, except to check certain things, like medication use.

The group's patient composition may stay constant over many appointments to aid familiarity, or it may vary.

Shared medical appointments are beginning to be used internationally in the management of chronic illnesses. Health outcomes for people with chronic illnesses often depend on self-directed strategies for a healthy lifestyle, vigilant and competent self-monitoring, and appropriate long-term management of medications. Shared medical appointments can increase the likelihood of these things happening in the following ways [4]: They can function as a support group, allowing patients to share experiences and reinforce each other's determination;

- By listening to other patients, they can learn the answers to questions they had not thought to ask;
- They can receive attention from different expert health practitioners (including the doctor) in the same session. This may be prohibitively expensive in a single patient appointment;
- Patients set goals in front of the group, increasing accountability and receiving support and validation from the group;

- They can reduce the waiting time for a medical appointment; and
- They can make the medical appointment much more enjoyable for the patient.

They can also be beneficial from the point of view of medical practitioners for the following reasons:

- They reduce the need to repeat the same information to different patients on multiple appointments;
- They allow greater specialisation within the appointment, with doctors receiving help from the multidisciplinary team and enabling better coordinated care;
- They reduce costs by allowing patients to be seen more quickly and efficiently than current practice; and
- They provide more time for the doctor (and Facilitator where appropriate) to contribute educational/prescriptive advice to the patient.

Shared medical appointments are intended to complement the judicious use of individual consultations, and cut back on the number of these required, rather than replace standard consultations. They offer an adjunct model of care that may be more appropriate for chronic conditions and which may provide benefits for both clinicians and patients [2, 3]. In particular it is believed that shared medical appointments may also be attractive for patients with low levels of health literacy, including the aged, migrant groups, the Indigenous and lower socioeconomic groups.

Type 2 diabetes mellitus (T2DM)

Burden of T2DM

T2DM is a major public health issue in Australia and is a National Health Priority Area. T2DM is a chronic metabolic disorder characterised by insulin resistance and hyperglycaemia. It is associated with hereditary and lifestyle factors, such as insufficient physical activity, poor diet, and being overweight or obese [5].

T2DM is an increasing public health problem throughout the world [6], as well as in Australia, where it is estimated that more than one million people suffer from the disease, and another 3.4 million may have pre-diabetes [7]. In Australia, T2DM adds an additional \$14.6 billion per year to total healthcare costs [8].

In 2012, the cost for a person with T2DM without complications was estimated at \$4,025 per year, but this rose to \$9,645 if the person developed macrovascular complications [9]. Hospital separations where the primary cause was diabetes (all types, though T2DM constitutes the majority) rose from 31,135 in 1997 to 66,716 in 2004 [10]. To the year ending June 2012, the total cost of PBS-listed diabetes medications (all types, though T2DM constitutes the majority) was \$470 million [11].

Diabetes was the underlying cause in 3% of all deaths in Australia in 2011. Of these, 91% were from either T2DM or the type of diabetes was not specified. In 10% of cases, diabetes was listed as either an underlying or associated cause of death. Death rates from diabetes (where diabetes is listed as the underlying or associated cause of death) have remained practically unchanged over the last 30 years [12]. Currently, the Australian diabetes mortality rate is also slightly greater than the OECD average [12].

Impact of T2DM on health

Diabetes significantly affects the health of many Australians and can result in a range of complications. Untreated or poorly managed diabetes can lead to complications including coronary heart disease, stroke, kidney failure, limb amputations and blindness. In 2011, diabetes was the sixth leading cause of death in Australia [13]. Cardiovascular disease is the major cause of death in people with diabetes, accounting for approximately 50% of all fatalities [14]. Hypertensive and cerebrovascular diseases (e.g. stroke), and kidney failure, are also common causes of death [15].

In the short term, extremely high blood sugar levels can cause a hyperosmolar hyperglycaemic state, and accompanying decreased level of consciousness usually requiring hospitalisation. As the disease progresses, macrovascular and microvascular complications from T2DM can damage the heart, blood vessels, eyes, kidneys and nerves, as well as diminishing quality of life. T2DM increases the risk of:

- heart disease and stroke
- diabetic neuropathy (nerve damage), and reduced blood flow and blood vessel damage, resulting in foot ulcers and limb amputation

- diabetic retinopathy, which can cause blindness resulting from long term accumulated damage to the small blood vessels in the retina (microaneurysms)
- nephropathy (kidney disease), which can lead to kidney failure
- death [16].

After 15 years of having T2DM, approximately 2% of people become blind and 10% develop severe visual impairment. It is one of the leading causes of kidney failure and this condition is the cause of death in 10–20% of people with diabetes. Diabetic neuropathy affects up to 50% of people with diabetes with common symptoms including tingling, pain, numbness, or weakness in the feet and hands [16].

High-risk groups for T2DM

Death from T2DM is 2.5-fold more common in people with lower socio-economic status than in people of higher socio-economic status. There is also significant regional inequality, with remote and very remote areas suffering a diabetes death rate more than twice that of major cities. Aboriginal and Torres Strait Islander people have a T2DM rate over three times the national average, and a diabetes death rate 2.7 times as high. The burden of diabetes accounts for much of the difference in life expectancy between indigenous and non-indigenous Australians [12].

The RACGP/Diabetes Australia guidelines consider the following people at high risk of T2DM:

- People with impaired glucose tolerance or impaired fasting glucose;
- All patients with a history of a cardiovascular event;
- People aged 35 and over from the Pacific Islands, Indian subcontinent or China;
- People aged 40 years and over with BMI ≥ 30 kg/m² or hypertension;
- Women with a history of gestational diabetes mellitus;
- Women with polycystic ovary syndrome who are obese; and
- Patients on antipsychotic medication.

Individuals at high risk and those with impaired glucose tolerance or impaired fasting glucose should be tested with fasting blood glucose, 2-hour glucose or glycated haemoglobin (HbA_{1c}) [17], see Table 1. For the purposes of this application, the following definition of T2DM is proposed and based on widely used tests and definitions (Table 1).

Table 1: Criteria for patients with Type 2 diabetes mellitus in contrast to impaired glucose states

	Fasting glucose (mmol/l)	2 hour glucose (mmol/l)	Glycated haemoglobin (HbA _{1c} % or mmol/mol)
Type 2 diabetes mellitus	>7.0	>11.0	≥6.5 (48 mmol/mol)
Impaired glucose tolerance	<7.0	7.8-11.0	6.0-6.4
Impaired fasting glucose	6.1-6.9	<7.8	N.A.

Source: General practice management of type 2 diabetes – 2014–15. Melbourne: The Royal Australian College of General Practitioners and Diabetes Australia, 2014.

People who do not meet the criteria for T2DM, but have either impaired glucose tolerance or impaired fasting glucose are considered to have pre-diabetes. People with pre-diabetes often continue to develop T2DM [18]. Since early initiation of therapy is correlated with better patient outcomes [19], there are benefits to detecting diabetes in its earliest stages [20]. Early intervention in patients with pre-diabetes can reduce the chance of developing T2DM by 60% [9].

Use of shared medical appointments

Managing T2DM requires vigilant and ongoing self-discipline by the patient, and skilled attention to all aspects of their health. Patients can benefit from information on the best available methods of monitoring their condition, and appropriate drug regimens. While medications and compliance with medical prescription are important, other lifestyle changes are critical to the success of regulating blood sugar levels and reducing risk factors [21]. Adherence to diabetes guidelines has historically been poor, and there is little evidence of improvement over the past 20 years [22].

Moral support from other patients in the same situation has been shown to be beneficial in achieving diet, weight loss and exercise goals [23]. Shared medical appointments should thus help patients manage their own condition through peer support, improved knowledge and enhanced empowerment. As part of the group education component of the shared medical appointments, patients should be reminded of the need to have their eyes checked for retinopathy regularly. A group setting may allow patients to air concerns about their own health challenges, and listen to the experiences of others.

Delivery of the intervention

The intervention could be on an occasional, one-off, or ongoing (e.g. two monthly) basis. The appointment would involve, at a minimum, an accredited GP, and a group Facilitator. It may also include a practice nurse, and a documenter who may all be the same person as the group Facilitator. The number of appointments attended by the patient would be expected to be limited to a maximum of six meetings per 12 month period.

The key to the success of shared medical appointments, based on the US experience and preliminary Australian work, is the Facilitator needs training in the particularities of shared medical appointments (including group dynamics). Other providers (doctor, nurse, documenter) do not need specific training [4]. The Australian Lifestyle Medicine Association has developed a shared medical appointment training manual for Facilitators for this purpose. It has not yet been independently evaluated or accredited. Dr Ed Noffsinger, the originator of shared medical appointments from the US, has travelled to Australia to conduct training workshops on this topic in 2013 [24] and Dr Marianne Sumego, Manager of Shared Medical Appointments at the Cleveland Clinic in Ohio has conducted similar workshops at the instigation of Australian Lifestyle Medicine Association and the Australian and New Zealand Obesity Society in 2014. Training would also be provided to reception staff to deal with large bookings.

The proposed place for shared medical appointments is a consulting or meeting room of a clinic or in a residential aged care facility. The main limitation is space, as the room needs to accommodate 6-12 patients and 2-3 health professionals. However, as patients are seated for the duration, the room does not have to be extensive. There may also need to be a 'break-out' room for patients who wish for some aspects of their case to be discussed privately or to be used in the case of the physical shared medical appointment. The only other requirements are a whiteboard (or butcher's paper on the wall) and a computer with medical records (unless notes are taken by hand and entered later).

Co-administered and associated interventions

A preliminary service for shared medical appointments is a GP consultation attendance (MBS item 23) as it provides the GP with the opportunity to identify suitable patients that might benefit from a shared medical appointment. An MBS item for HbA_{1c} testing (#66841) for the diagnosis of T2DM in asymptomatic patients with undiagnosed diabetes who are considered at high risk of the disease, was listed on 1st November 2014.

Listing proposed and options for MSAC consideration

Proposed MBS listing

Table 2 presents details of the proposed MBS listing.

Table 2: Proposed MBS item descriptor for Shared medical appointments

Category 1 - Professional Attendances
<p>MBS xxxx</p> <p>Shared medical appointment for patients with <u>Type 2 diabetes mellitus</u>. The number of patients is a minimum of 6 and maximum of 12 per appointment and the duration is up to 120 minutes. The appointment is to be conducted at general practitioner rooms or a residential aged-care facility. The medical professionals present will include at least the following:</p> <ul style="list-style-type: none">• 1 accredited GP;• 1 trained Group Facilitator (e.g., practice nurse, diabetes educator, exercise physiologist, clinical psychologist or dietitian); and• 1 documenter, who could be the same person as the above group Facilitator. <p>Fee: \$47.30 per patient</p> <p>The maximum number of appointments per patient is six per 12 month period.</p>

The definition of T2DM would be specifically defined in the 'Notes' of the MBS descriptors and these align with those detailed in Table 1.

Patients are not required to attend a minimum number of shared medical appointments and therefore may attend one appointment or up to six appointments per 12 month period. There is no known threshold number of sessions below which shared medical appointments are ineffective.

Shared medical appointments would be for people with T2DM. Patients are identified as suitable for shared medical appointments during a GP consultation and would have the option of following up with the comparator (MBS item 23 or 36) or a shared medical appointment. Eligibility would be determined by HbA_{1c} or other accepted measures of glucose intolerance.

The proposed MBS schedule fees of \$47.30 per patient is based on payments that might be expected using items 23 (\$37.05) and 10997 (\$12.00). If applied to a group of 12 patients, this would cost the MBS \$567.60 per session. Shared medical appointments are intended to incur MBS costs equal to or less than current GP care. There are however a number of other item numbers that could arguably be used (705, 723, 900, 10987, 10991) if a standard rate is not provided. The suggested rate of \$47.30 is calculated to provide sufficient reimbursement to rule out the use of the extra MBS item numbers. It is anticipated that the SMAs would be bulk billed.

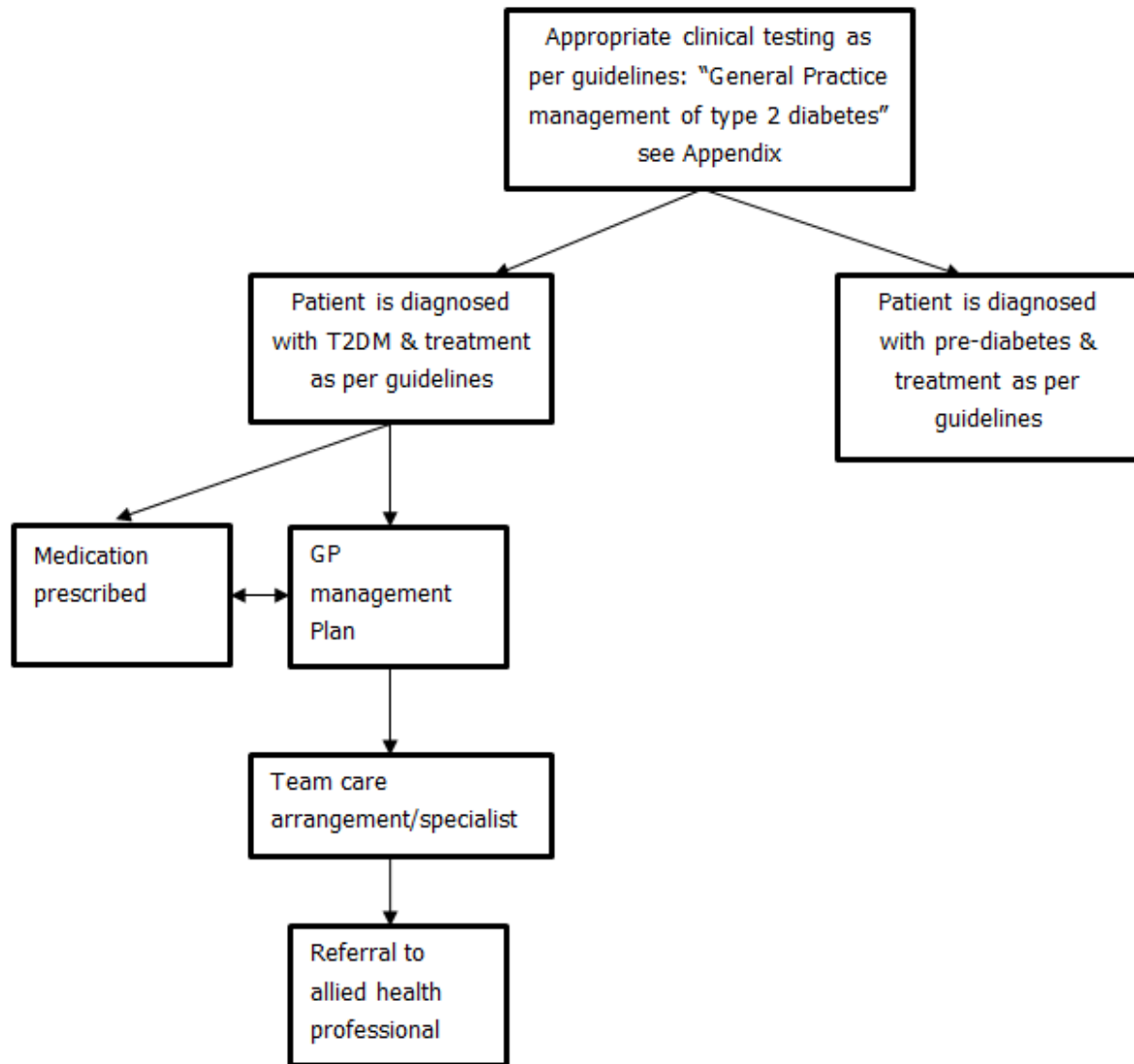
The Facilitator or nurse practitioner is intended to be reimbursed through the proposed item number. The proposed item fee cannot be designated for payment of allied health professionals, if these are used as the Facilitator. If they are not the Facilitator, the allied health professionals will be reimbursed through the proposed item number, where allowed. Health professionals unwilling to work under this arrangement will not participate in shared medical appointments. Co-billing on the same day (or week) should be excluded.

Clinical place for proposed intervention

Shared medical appointments would form part of an overall strategy for managing T2DM (see clinical practice guidelines algorithm in Appendix A). It is proposed shared medical appointments would replace some regular one-to-one appointments with a usual GP. Therefore the proposed intervention is intended to be a partial substitute for usual care.

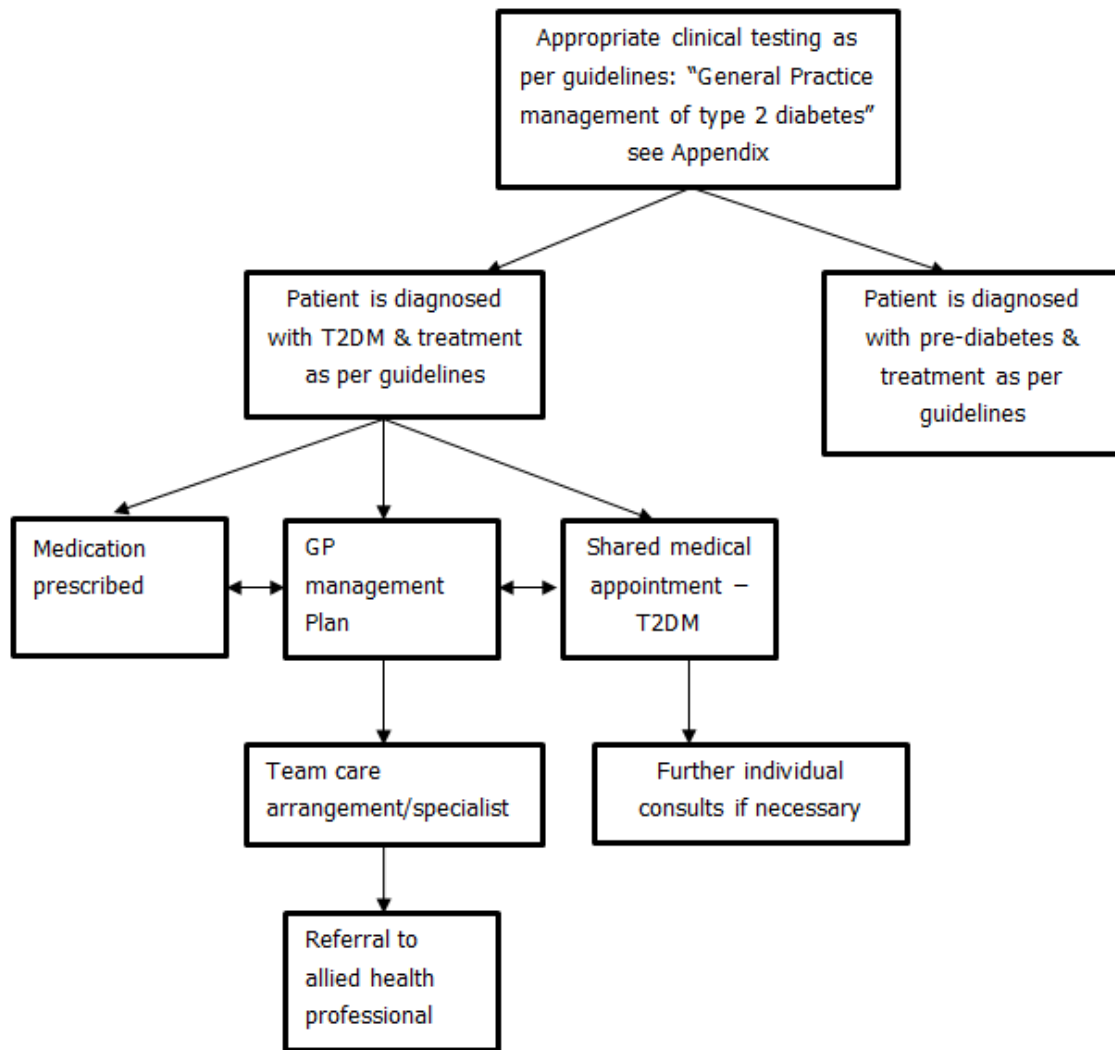
Figures 1 and 2 illustrate the current and proposed management algorithm using shared medical appointments for T2DM respectively. There can be no requirement for a patient to attend for a shared medical appointment rather than choosing to see a GP on a one-on-one basis. There is no denial of patient access to any aspect of current usual care.

Figure 1: Current management algorithm



GP=general practitioner, T2DM = Type 2 diabetes mellitus

Figure 2: Proposed management algorithm



GP=general practitioner, T2DM = Type 2 diabetes mellitus

Under the current management plan in Figure 1, individuals with blood glucose levels below the recommended guidelines receive standard care as recommended in current Diabetes Australia guidelines (Figure A1, Appendix). Under the proposed plan, everyone with T2DM would be entitled to attend shared medical appointments. The main difference in the two algorithms is that with shared medical appointments, patients have an expanded option to receive healthcare for T2DM. The strategy is designed to directly replace many GP visits in the management of T2DM with other chronic conditions.

In June 2014, an estimated 981,202 people were living with diagnosed T2DM [25]. The population prevalence of pre-diabetes was estimated in a study involving 11,247 participants more than 25 years old across Australia [26]. Their results suggest that 17.4% of men over 25 years and 15.4% of women have pre-diabetes. Given the current population of men and women over 25, this translates to an estimated 2.5 million (2,563,891) Australians with pre-diabetes. This estimate assumes that pre-diabetes is negligible for people under 25 and the prevalence is similar to that from over 10 years ago, both which may be underestimated today. According to other studies, the true figure may be higher; up to 3.4 million [7]. Up to 58% of T2DM cases may be preventable with optimal management in the pre-diabetic stage [27].

In a preliminary study on shared medical appointments carried out in Australia in 2014 [2], a high proportion (e.g., >60%) of T2DM patients invited by their doctor to attend a shared medical appointment did so. After attending at least two shared medical appointments, over 90% claimed they would like to continue with this type of consult, suggesting that word-of-mouth would mean a high demand, over the long-term, for this type of management. Comparative research carried out overseas suggests that shared medical appointments result in improved self-management and health outcomes in a reduced time required through conventional one-to-one consulting [28].

Comparators

There are two relevant comparators:

1. 'usual GP care' described as standard care and applies to 1:1 medical consults, and
2. Group allied health services for Type 2 diabetes (MBS items 81100 to 81125).

Usual GP care involves a doctor seeing a patient in a one-on-one setting to discuss nutrition, physical activity and foot care. They would typically assess blood glucose levels, and comorbidities such as hypertension, hyperlipidaemia, and cardiovascular disease. They may also check the appropriateness of current medication, and write prescriptions [29]. The Medicare comparator is MBS item numbers 23 and 36, "professional attendance by a GP" lasting less than 20 minutes or more than 20 minutes respectively. Monitoring and support is specified by the nursing MBS item number 10997. Table 3 provides the MBS item descriptors for the comparators.

Table 3: MBS item descriptors for 23 and 36

Category 1 – Professional Attendances	
<p>MBS 23</p> <p>Professional attendance at consulting rooms</p> <p>Fee: \$37.05</p> <p>Professional attendance by a general practitioner (not being a service to which any other item in this table applies) lasting less than 20 minutes, including any of the following that are clinically relevant:</p> <ul style="list-style-type: none"> 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; <p>in relation to 1 or more health-related issues, with appropriate documentation.</p>	
Category 1 – Professional Attendances	
<p>MBS 36</p> <p>Professional attendance at consulting rooms</p> <p>Fee: \$71.70</p> <p>Professional attendance by a general practitioner (not being a service to which any other item in this table applies) lasting at least 20 minutes, including any of the following that are clinically relevant:</p> <ul style="list-style-type: none"> a) taking a detailed patient history; b) performing a clinical examination; c) arranging any necessary investigation; d) implementing a management plan; e) providing appropriate preventive health care; <p>in relation to 1 or more health-related issues, with appropriate documentation.</p>	
Category 8 –Miscellaneous services	
<p>MBS 10997</p> <p>Provision of monitoring and support for a person with a chronic disease by a practice nurse or Aboriginal and Torres Strait Islander health practitioner</p> <p>Fee \$12.00</p> <p>Service provided to a person with a chronic disease by a practice nurse or an Aboriginal and Torres Strait Islander health practitioner if:</p> <ul style="list-style-type: none"> (a) the service is provided on behalf of and under the supervision of a medical practitioner; and (b) the person is not an admitted patient of a hospital; and (c) the person has a GP Management Plan, Team Care Arrangements or Multidisciplinary Care Plan in place; and (d) the service is consistent with the GP Management Plan, Team Care Arrangements or Multidisciplinary Care Plan <p>to a maximum of 5 services per patient in a calendar year</p>	

It is acknowledged that 'Usual care' as described by the one-to-one doctor-patient consultation is likely to be the most common scenario however it may also include several other varieties such as group allied health services for T2DM (items 81100 to 81125), individual allied health services (items 10950 to 10970) with item 721, individual practice nurse or ATSI health practitioner services (item 10997) and HbA_{1c} (item 66841).

Group allied health services under MBS items (81100 to 81125) are collectively a second relevant comparator for patients with T2DM. These items apply to services provided by eligible diabetes educators, exercise physiologists and dietitians, on referral from a GP. Services available under these items are in addition to the five individual allied health services available to patients each calendar year (refer to items 10950 to 10970). Patients are eligible for these services if the patient has in place a GP Management Plan (item 721); OR for a resident of a residential aged care facility, the GP must have contributed to, or contributed to a review of, a care plan prepared for them by the facility (item 731). Unlike the individual allied health services under items 10950 to 10970, there is no additional requirement for a Team Care Arrangement (item 723) in order for the patient to be referred for group allied health services.

Table 4 provides the MBS items for 81100 (assessment) and 81105 (treatment services) for a diabetes educator. In the interests of space, the corresponding items for exercise physiologists (81115 & 81120) and dietitians (81120 & 81125) are not presented here. These are identical assessment and treatment service items but relate to exercise physiologists and dietitians

Table 4: MBS item descriptors for 81100 and 81105

Category 8 – Miscellaneous services
<p>MBS 81100</p> <p>DIABETES EDUCATION SERVICE - ASSESSMENT FOR GROUP SERVICES</p> <p>Diabetes education health service provided to a person by an eligible diabetes educator for the purposes of ASSESSING a person's suitability for group services for the management of type 2 diabetes, including taking a comprehensive patient history, identifying an appropriate group services program based on the patient's needs, and preparing the person for the group services, if:</p> <p>(a) the service is provided to a person who has type 2 diabetes; and</p>

(b) the person is being managed by a medical practitioner (including a general practitioner, but not a specialist or consultant physician) under a GP Management Plan [ie item 721 or 732], or if the person is a resident of an aged care facility, their medical practitioner has contributed to a multidisciplinary care plan [ie item 731]; and

(c) the person is referred to an eligible diabetes educator by the medical practitioner using a referral form that has been issued by the Department of Health, or a referral form that contains all the components of the form issued by the Department; and

(d) the person is not an admitted patient of a hospital; and

(e) the service is provided to the person individually and in person; and

(f) the service is of at least 45 minutes duration; and

(g) after the service, the eligible diabetes educator gives a written report to the referring medical practitioner mentioned in paragraph (c); and

(h) in the case of a service in respect of which a private health insurance benefit is payable - the person who incurred the medical expenses in respect of the service has elected to claim the Medicare benefit in respect of the service, and not the private health insurance benefit.

Benefits are payable once only in a calendar year for this or any other Assessment for Group Services item (including services to which items 81100, 81110 and 81120 apply).

Fee: \$79.85 Benefit: 85% = \$67.90

Category 8 – Miscellaneous services

MBS 81105

DIABETES EDUCATION SERVICE - GROUP SERVICE

Diabetes education health service provided to a person by an eligible diabetes educator, as a GROUP SERVICE for the management of type 2 diabetes if:

(a) the person has been assessed as suitable for a type 2 diabetes group service under assessment item 81100, 81110 or 81120; and

(b) the service is provided to a person who is part of a group of between 2 and 12 patients inclusive; and

(c) the person is not an admitted patient of a hospital; and

(d) the service is provided to a person involving the personal attendance by an eligible diabetes educator; and

(e) the service is of at least 60 minutes duration; and

(f) after the last service in the group services program provided to the person under items 81105, 81115 or 81125, the eligible diabetes educator prepares, or contribute to, a written report to be provided to the referring medical practitioner; and

(g) an attendance record for the group is maintained by the eligible diabetes educator; and

(h).in the case of a service in respect of which a private health insurance benefit is payable - the person who incurred the medical expenses in respect of the service has elected to claim the Medicare benefit in respect of the service, and not the private health insurance benefit;

- to a maximum of eight GROUP SERVICES (including services to which items 81105, 81115 and 81125 apply) in a calendar year.

Fee: \$19.90 Benefit: 85% = \$16.95

Listed in November 2012, the total number of services provided for eligible Australians through group allied health items 81100 to 81125, was 118,268 (Nov 2012 to Sept 2014) with MBS funding of \$3.2 million. The majority were for services by exercise physiologists (81,564 services) followed by dietetics (7,984 services) (https://www.medicareaustralia.gov.au/statistics/mbs_item.shtml).

Interventions vs the comparators

The following table compares shared medical appointments with the comparator services currently billable under the MBS.

Table 5: Shared medical appointments versus comparators

Intervention	Shared medical appointments	GP care			Group allied health	
		MBS 23	MBS 36	MBS 10997	MBS 81100 or 81110 or 81120	MBS 81105 or 81115 or 81125
Fee (per patient)	\$47.30	\$37.05	\$71.70	\$12.00	\$79.85	\$19.90
Duration	90-120 minutes	<20 mins	≥20 mins		≥45 mins	≥60 mins
Ratio of health prof to patient	Many to many (2:12)	1:1	1:1	1:1	1:many (1:12)	1:many (1:12)
Number of patients	6-12	1	1	1	2-12	2-12
Types of medical officials present	1 GP for 40-80 minutes 1 Group Facilitator 1 Documenter (can be the Group Facilitator)	1 GP	1 GP	1 practice nurse or registered Aboriginal Health Worker	Eligible diabetes educator, or exercise physiologist, or dietitian	Eligible diabetes educator, or exercise physiologist, or dietitian
Eligible patients	Type 2 diabetes who have attended a GP consultation for referral				Type 2 diabetes, item 721 or resident of aged care home and item 731	Assessment under item 81100, or 81110, or 81120

Another MBS item which could be considered a comparator is item 44 (Professional attendance at consulting rooms – Level D - < 40 mins). The fee of MBS item 44 is \$105.55.

Outcomes for safety and effectiveness evaluation

Clinical outcomes

Studies from overseas suggest that shared medical appointments have superior efficacy and lower costs than the comparators [23, 30-33]. Based on this literature, it is expected that implementation of shared medical appointments will lead to improved self-management of T2DM through;

- 1) improved patient education;
- 2) increased peer support from fellow sufferers;
- 3) improved integration between GPs, nursing staff, and allied health;
- 4) reduced number of standard visits per annum;
- 5) appropriate management through pharmacotherapy; and
- 6) reduced costs to the health system of ~20-30%.

The first three of these are outcomes relating to patient health literacy and better healthcare delivery. Item 3) has a beneficial effect on both health outcomes and costs. Better integration between health care professionals could improve overall diabetes management (captured by lowering HbA_{1c}), and increase the chance that adverse events are identified in their earlier, more treatable stages. Thus, the effect of item 3) would be to reduce both the number and severity of adverse events, as well as to reduce total costs. Items 4) to 6) relate to cost reduction. In an economic evaluation, all costs would be considered for both treatments and the results compared.

Surrogate outcomes

The primary surrogate clinical outcome for persons with T2DM will be reduction in HbA_{1c}. For a person with established T2DM, this could be HbA_{1c} ≤7.0% (range 6.5-7.5) or ≤53 mmol/mol (range 48-58). However, in clinical practice this specific target is individualised for the patient. It should be as low as reasonably possible with a balance between hyper- and hypoglycaemia [17].

HbA_{1c} indicates a person's average plasma glucose concentration over the last several months. In a person with T2DM, these concentrations are higher than in the general population. The Pharmaceutical Benefits Advisory Committee has considered a reduction of 0.3-0.4% to be clinically relevant [34] and is considered to produce clinically significant improvements. One older but large trial indicated that a reduction of 1% in HbA_{1c} was linked to 21% fewer deaths, 14% fewer non-fatal myocardial infarctions and a reduction in microvascular complications (such as retinopathy and nephropathy) by 37% [35].

There are several other surrogate clinical outcomes applying to persons with T2DM with direct effect on patient health. These outcomes are presented in Table 6.

Table 6: Surrogate outcomes

Outcome	Optimum control	Minimum clinically relevant change
Weight loss in overweight or obese patients	BMI<25 [36]	5-10% of total body weight [36]
Blood pressure	<130/80 mmHg [17]	10 mmHg systolic [37]
LDL cholesterol	<2.0mmol/L [17]	0.5mmol/L [38]
Triglycerides	< 2.0mmol/L [17]	0.5 mmol/L [39]

Patient-relevant outcomes

In addition, there are a number of other outcomes applying to both persons with T2DM that may be considered depending on those available in the evidence base for shared medical appointments including:

- Reduced mortality
- Fewer T2DM-related hospitalisations & other health services
- Improved quality of life/anxiety scores
- Fewer major cardiovascular events
- Fewer microvascular events (e.g. retinopathy, neuropathy, nephropathy)
- Fewer emergency department visits
- Reduced/better medication use
- Greater reliance on self-management principles

Evidence for the effectiveness of shared medical appointments

A non-exhaustive search located several studies reporting on the effectiveness of shared medical appointments. In addition to a large body of clinical studies, there are at least three existing literature reviews on the efficacy of shared medical appointments for treatment of patients with T2DM [1, 29, 40]. Table 7 presents a summary of prospective randomised control trials (RCTs) comparing shared medical appointments with usual GP care for treatment of patients with T2DM. Every trial measured reduction in HbA_{1c} as the primary outcome and a number of trial-specific secondary outcomes. These trials appear relevant to the evidence base on shared medical appointments for Australia and will contribute to the main clinical evidence. No Australian trials were identified but an initial trial of patient and provider satisfaction has been completed [2] and grant applications have been made for further research.

The applicability of the trial population results to the proposed MBS population will be assessed at the evidence stage.

Table 7: Overview of prospective RCTs involving T2DM and Shared medical appointments

RCTs	Primary clinical outcome	Secondary clinical outcomes	Frequency/duration of shared medical appointment	Comparator	Duration of trial	Subjects	Setting
Rygg (2012)[41]	Reduction of HbA _{1c}	Patient activation, diabetes knowledge, BP, weight, BMI, total and HDL cholesterol, triglycerides, creatinine, oral glucose-lowering medication, visits with health care personnel in past 3 mth, treatment satisfaction, EQ-VAS	Fortnightly or 3 wkly/5hrs Depending on site	Usual GP care	6 wks – 9 wks Depending on site 12 mth follow up	146 patients with type 2 diabetes Age > 18 yr;; consultation with general practitioner in past 3 yr	GP clinics in Central Norway
Naik (2011)[42]	Reduction of HbA _{1c}	Diabetes self-efficacy, knowledge and understanding tests	3 wkly/ 70 mins	Usual GP care	3 mths with 1 year follow-up	87 patients with diabetes whose HbA _{1c} levels > 7.5% from veterans affairs medical centre	Diabetes clinic
Trento (2010)[23]	Reduction of HbA _{1c}	Total cholesterol, LDL cholesterol, triglycerides, blood pressure, BMI, serum creatinine, HDL cholesterol, health behaviours, quality of life, knowledge of diabetes	3 mthly/ 1 hour	Usual GP care	4 yrs	815 non-insulin-treated patients aged < 80 years diagnosed for at least 1 year	13 hospital-based diabetes clinics in Italy

Clancy (2007)[43]	Reduction of HbA _{1c}	Blood pressure, lipid profiles, adherence to US guidelines	Mthly/ 2hrs	Usual GP care	12 mths	186 Adult patients with type 2 diabetes, HbA _{1c} > 8.5%	Adult primary care centre, medical university of South Carolina
Trento (2004)[33]	Reduction of HbA _{1c}	Knowledge of diabetes, problem solving ability, quality of life, health problem identification, progression of retinopathy	3 mthly/~2 hrs	Usual GP care	5 yrs	112 patients with diabetes	Diabetes clinic
Clancy (2002)[30]	Reduction of HbA _{1c}	Lipid profiles, Trust in Physician scale, patient care assessment tool	Mthly/ 2hrs	Usual GP care	6 mths	120 Adult patients with type 2 diabetes, HbA _{1c} > 8.5%	Adult primary care centre, medical university of South Carolina
Wagner (2001)[44]	Reduction of HbA _{1c}	Specialty and emergency room visits, bed disability days, Short-Form 36 general health	3 mthly to 6 mthly/~ 2 hrs	Usual GP care plus group education	2 yrs	707 patients with diabetes, age > 30	Health management organisation
Sadur (1999)[32]	Reduction of HbA _{1c}	Reduction in hospital admission rates, self-efficacy, treating hypoglycaemia, managing glucose when ill	Mthly/2 hrs	Usual GP care	6 mths	~142-156 patients with diabetes with HbA _{1c} > 8.5%	Health management organisation

Adverse events from T2DM that could be assessed are [21]:

- Hypoglycaemic events (all, serious, nocturnal)
- Cardiovascular events
- Amputations;
- Microvascular events (retinopathy, neuropathy, nephropathy rates); and
- Mortality rates.

However, these events may be too rare, or may happen over too long a time horizon, to be properly captured in any prospective RCT.

Other indicators relating to patient quality of life which could be considered would be:

- Knowledge of diabetes/ health literacy
- Quality of life/anxiety score
- 'Trust in physician' score

Safety

There is no safety concerns associated with the intervention. There may be a concern with confidentiality, as some people may not feel comfortable discussing their health in front of other patients. For this reason, shared medical appointments would be voluntary, and standard GP visits would always be available to those who want them. An additional potential concern could be the possibility for private medical details to be circulated more widely throughout the community by other members of the group. However, a requirement of a shared medical appointment is that confidentiality agreements are signed before every shared medical appointment. This was not shown to be an issue in the Australian study [45] or in over 100,000 visits recorded in the US [24].

Summary of PICO to be used for assessment of evidence (systematic review)

Tables 8 and 9 provide a summary of the PICO used to:

- (1) define the question for public funding,
- (2) select the evidence to assess the safety and effectiveness of shared medical appointments for patients with T2DM, and
- (3) provide the evidence-based inputs for any decision-analytical modelling to determine the cost-effectiveness of shared medical appointments for patients with T2DM.

Table 8: Summary of PICO for T2DM population

Patients	Intervention	Comparators	Outcomes to be assessed
<p>People with T2DM defined as HbA_{1c} ≥ 6.5% or 2 hr glucose >11.0 mmol/l or fasting glucose >7.0 mmol/l.</p>	<p>Shared medical appointments with 6-12 patients, at a minimum: 1 accredited GP, 1 group Facilitator, 1 documenter who could be the Facilitator</p> <p>Duration: 90-120 minutes</p> <p>Location: GP clinic with sufficient space, residential aged-care facility.</p> <p>Limited to six appointments per patient per 12 months</p>	<p>1. Usual care by GP in primary clinical practice.</p> <p>2. Group allied health services</p>	<p><u>Effectiveness</u></p> <p><u>Surrogate outcomes:</u></p> <ul style="list-style-type: none"> • Reduction in HbA_{1c} • Weight loss in overweight or obese patients towards a BMI<25 • Reduction of blood pressure in patients with hypertension towards <130/80 • LDL cholesterol reduction towards < 2.0 mmol/L • Tg reduction towards <2.0 mmol/L <p><u>Patient-relevant outcomes</u></p> <ul style="list-style-type: none"> • Hyper-/hypoglycaemic events • Mortality • Hospitalisations • Health-related quality of life • Amputation rates • Major cardiovascular events • Microvascular events (e.g. retinopathy, neuropathy, nephropathy) • Emergency department visits • Medication use <p><u>Cost-effectiveness</u></p> <p>Cost per QALY gain</p> <p>Cost per life year saved</p>
<p><u>Questions</u></p> <ol style="list-style-type: none"> 1. In patients with T2DM, how effective are shared medical appointments relative to GP usual care or group services? 2. In patients with T2DM, how cost-effective are shared medical appointments relative to GP usual care or group services? 			

BP = Blood Pressure, HbA_{1c} = Glycated haemoglobin Tg = triglycerides, HDL-C = High-density lipoprotein, LDL = Low-density lipoprotein, FG =Fasting glucose, QALY =quality-adjusted life years

Clinical Claim

The clinical claims made in the application with respect to the comparative effectiveness and safety is that for persons with T2DM:

1. Shared medical appointments are superior in terms of comparative efficacy with usual care by GP consult or group allied health sessions;
2. Shared medical appointments are non-inferior in terms of comparative safety with usual care by GP consult or group allied health sessions.

On the basis of the clinical claims, the type of economic evaluation expected to be provided in the application will be a cost-utility or cost-effectiveness analysis.

Table 9: Classification of an intervention for determination of economic evaluation to be presented

		Comparative effectiveness versus comparator					
		Superior		Non-inferior	Inferior		
Comparative safety versus comparator	Superior	CEA/CUA		CEA/CUA		Net clinical benefit	CEA/CUA
						Neutral benefit	CEA/CUA*
						Net harms	None^
	Non-inferior	CEA/CUA		CEA/CUA*		None^	
	Inferior	Net clinical benefit	CEA/CUA	None^		None^	
		Neutral benefit	CEA/CUA*				
Net harms		None^					

CEA = cost-effectiveness analysis; CUA = cost-utility analysis

Outcomes and health care resources affected by introduction of proposed intervention

Outcomes for economic evaluation

A literature review revealed few full economic evaluations of shared medical appointment in T2DM compared with usual doctor visits, but several costing studies exist. However, the search identified an economic analysis of shared medical appointments for other chronic illnesses, for instance one study assessed shared medical appointments for dermatology patient counselling [46].

Aligning with the clinical evidence, the comparative clinical performance of shared medical appointments versus GP usual care should be measured principally using HbA_{1c} levels. Groups of HbA_{1c} levels could then be linked to health utility values with the purpose of estimating quality-adjusted life years (QALYs). This has previously been performed and published in at least one Australian cost-utility analysis for patients with existing T2DM (but not for a shared medical appointment) [47]. Therefore the main outcome for the economic evaluation is incremental cost per QALY gained.

Health care resources

Table 11 provides a list of the healthcare resources whose utilisation will be considered in the assessment of shared medical appointments.

Table 11: List of resources to be considered in the economic analysis

	Provider of resource	Setting in which resource is provided	Proportion of patients receiving resource	Number of units of resource per relevant time horizon per patient receiving resource	Disaggregated unit cost					
					MBS	Safety nets*	Other govt budget	Private health insurer	Patient	Total cost
Resources provided to identify eligible population										
Brief Health assessment (MBS item # 701)	GP	GP clinic	x	1	\$59.35	\$178.05			\$0.00	\$59.35
Standard Health assessment (MBS item # 703)	GP	GP clinic	x	1	\$137.90	\$413.70			\$0.00	\$137.90
Long Health assessment (MBS item # 705)	GP	GP clinic	x	1	\$190.30	\$500.00			\$0.00	\$190.30
Prolonged Health assessment (MBS item # 707)	GP	GP clinic	x	1	\$268.80	\$500.00			\$0.00	\$268.80
HbA _{1c} test (MBS item #66841)	Pathologist		x	x	\$12.60 (75%)	N.A.			\$4.20	\$16.80
Fasting plasma glucose test (MBS item # 66500)	x	x			\$7.30 (75%)				\$2.40	\$9.70
Oral glucose tolerance test (MBS item # 66542)	x	x			\$14.25 (75%)				\$4.70	\$18.95
Resources provided to deliver proposed intervention										
Shared Medical appointment	GP, group Facilitator, at least 1 practice nurse, Documenter	Clinic, or aged-care facility	x	x	\$47.30	x			\$0.00	\$47.30
Resources provided in association with proposed intervention										
GP management plan (MBS item # 721)	GP	GP clinic	100%	1	\$108.20	\$432.75			\$36.05	\$144.25

	Provider of resource	Setting in which resource is provided	Proportion of patients receiving resource	Number of units of resource per relevant time horizon per patient receiving resource	Disaggregated unit cost					
					MBS	Safety nets*	Other govt budget	Private health insurer	Patient	Total cost
Resources provided to deliver comparator										
Standard GP visit (<20 mins) (MBS item # 23)	GP	GP clinic	x	x	\$37.05	\$111.15			\$0.00	\$37.05
Extended GP visit (20-40 mins) (MBS item # 36)	GP	GP clinic	x	x	\$71.70	\$215.10			\$0.00	\$71.70
Extended GP visit (>40 mins) (MBS item # 44)	GP	GP clinic	x	x	\$105.55	\$316.65			\$0.00	\$105.55
Monitoring person with a chronic disease care plan. (MBS item # 10997)	Practice nurse, or Aboriginal and Torres Strait Islander health practitioner	GP clinic	x	x	\$12.00	\$36.00			\$0.00	\$12.00
Group allied health MBS item 81100	Diabetes educator		x	x	\$67.90	\$239.55			\$11.95	\$79.85
Group allied health MBS item 81105	Diabetes educator		x	x	\$16.95	\$59.70			\$2.95	\$19.90
Group allied health MBS item 81110	Exercise physiologist		x	x	\$67.90	\$239.55			\$11.95	\$79.85
Group allied health MBS item 81115	Exercise physiologist		x	x	\$16.95	\$59.70			\$2.95	\$19.90
Group allied health MBS item 81120	Dietitian		x	x	\$67.90	\$239.55			\$11.95	\$79.85
Group allied health MBS item 81125	Dietitian		x	x	\$16.95	\$59.70			\$2.95	\$19.90

* Include costs relating to both the standard and extended safety net.

Proposed structure of economic evaluation (decision-analytic)

In order to evaluate this proposal, an economic evaluation will be conducted, combining evidence on both clinical and healthcare resource data. Since T2DM is a chronic, non-communicable disease, a lifetime health state transition (Markov) model would be appropriate. The model will compare the health and economic outcomes of a strategy of shared medical appointments versus usual GP care in patients with T2DM.

The model will closely mirror the management algorithm proposed for the shared medical appointment and it will be based on the best available evidence to populate the necessary cost, clinical and utility values. The methodology will be guided by current good practice guidelines for state-transition modelling [48, 49].

The model will link the evidence for shared medical appointments and it is expected that shared medical appointments will lead to improved patient health behaviours through improved clinical care and self-management of HbA_{1c} levels. In turn this will lead to lower HbA_{1c} levels, improved health outcomes, quality of life and the accompanying costs.

A Markov model consists of a cohort of patients, initially beginning in a health state typified by patients with T2DM. In discrete time steps, patients move into different health states with fixed transition probabilities or remain in the same health state. Each health state would correspond to a different level of disease (or groups of HbA_{1c} levels), with associated risks, costs, and utilities. This approach was used previously in Australia for another intervention for people with established T2DM [47]. The clinical evidence will be used to provide transition probabilities between health states, which will populate the economic model along with estimates of other economically relevant variables.

Data estimates

There are a number of Australian sources available for utilities, costs, probabilities, and mortality. The risk of mortality will be extracted from Australian estimates of all-cause mortality for individuals with various levels of hyperglycaemia [50]. In every health state, there is an age-dependent risk of mortality. This could be measured as a 'relative risk,' as reported in the Australian 'AusDiab' study [7]. Therefore, Australian data is available on excess mortality in people with elevated HbA_{1c} levels over a 7-year follow up. In addition to

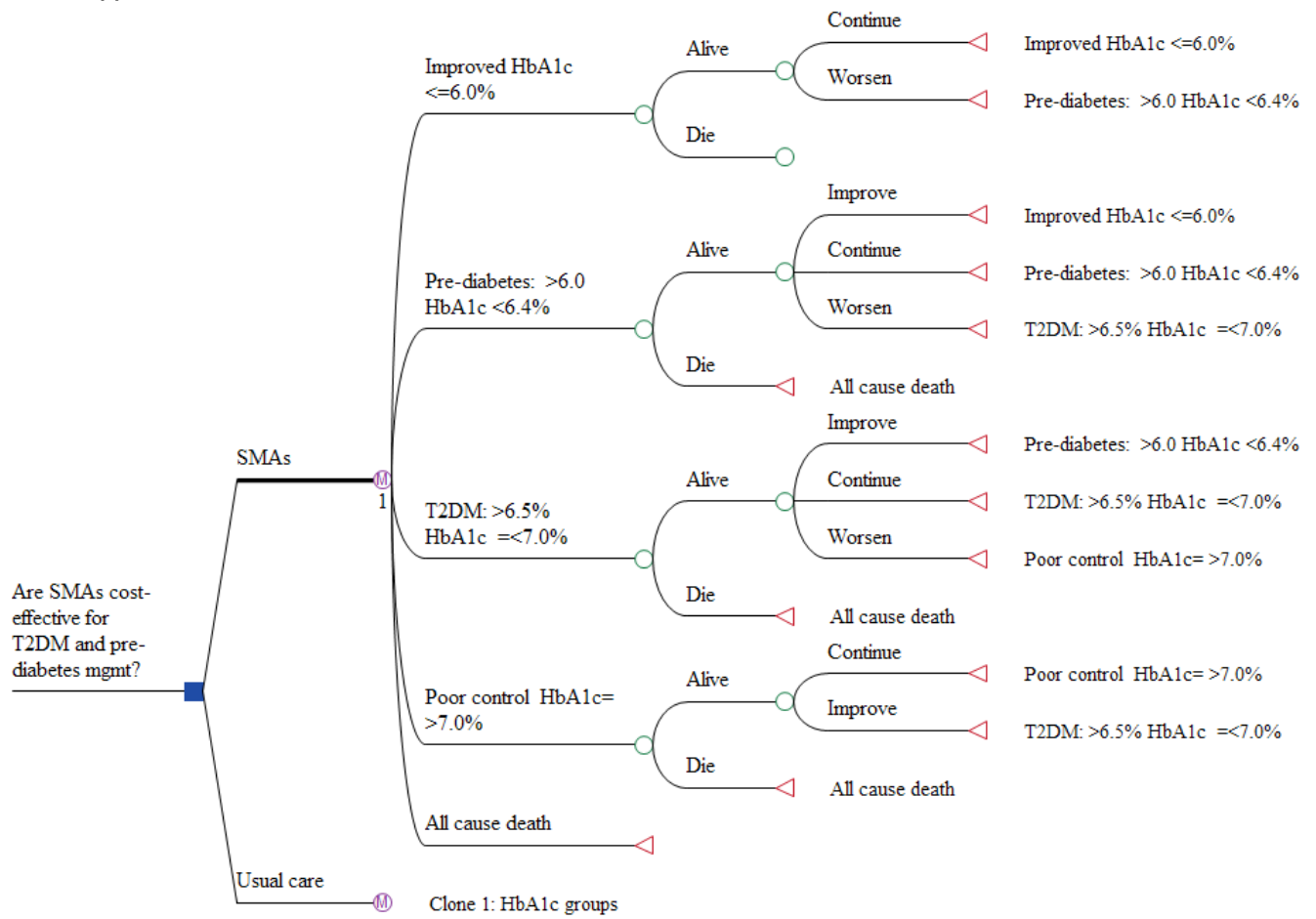
mortality, the risk of non-fatal adverse events for patients with various levels of glucose control is also reported [51], as well as overseas studies [35]. The risk of various other adverse health outcomes could be predicted in a similar way. These could include hypo- or hyperglycaemic events, retinopathy, neuropathy, nephropathy and amputations.

The costs of medical resources used will be derived from national price schedules [52-54]. Where possible, the economic evaluation will use Australian studies [55], which quantify the total cost (including direct healthcare costs, direct non-healthcare costs, and government subsidies) associated with T2DM.

The clinical data may suggest that shared medical appointments produce more vigilant monitoring, an earlier diagnosis of emerging problems and lower overall rates of these more severe health outcomes. This could be captured in the economic model by a reduced risk of these adverse outcomes for each health state in the treatment arm versus the control arm. The impact of removing this effect should then be tested in a sensitivity analysis. Comprehensive sensitivity analyses will be undertaken to address the uncertainty of the data estimates.

The figure below provides a possible Markov structure that could be a starting point from which to undertake the cost-utility analysis.

Figure 3: Possible structure of a Markov model to address the economic evaluation of shared medical appointments

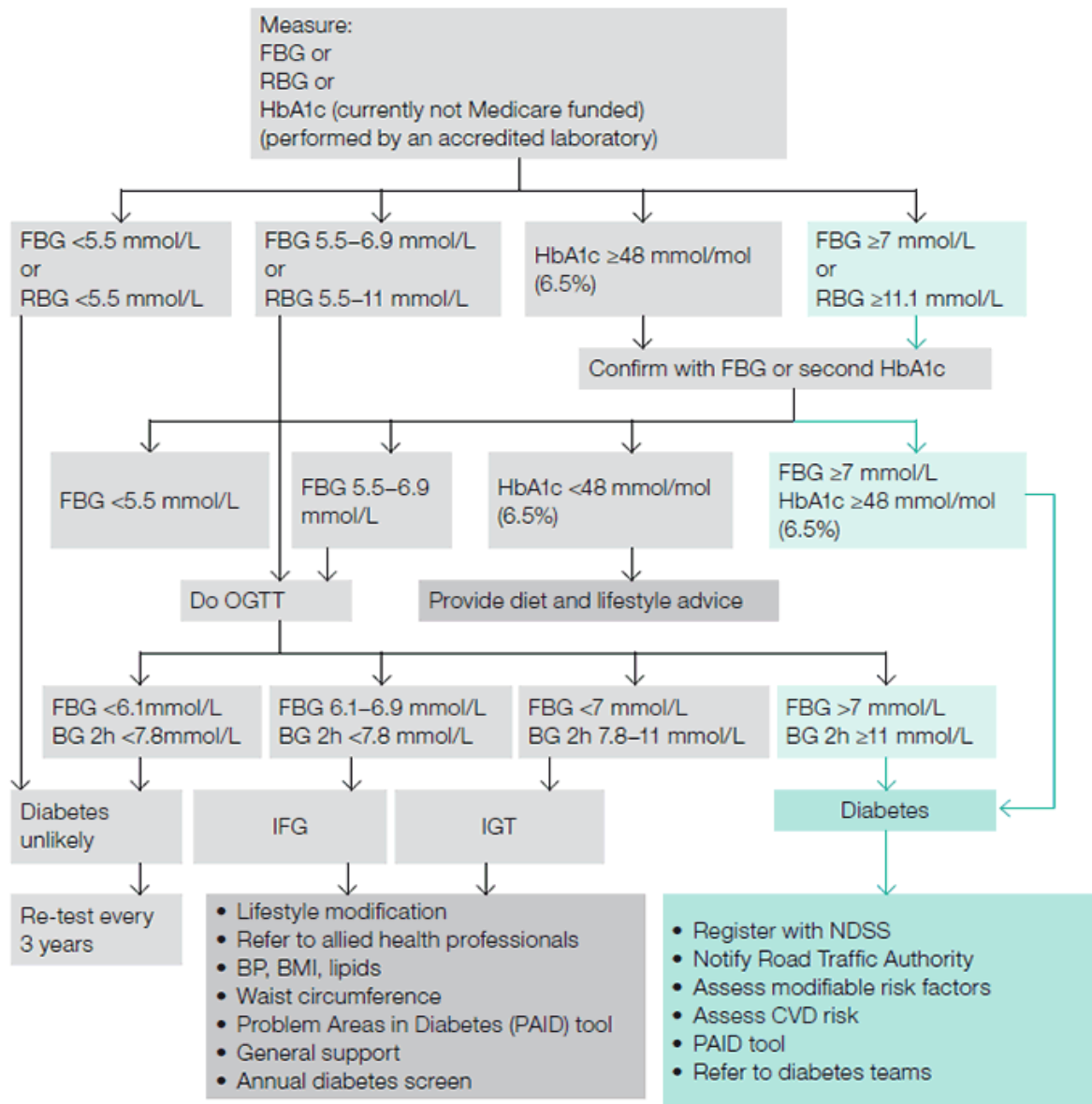


SMA=shared medical appointments, T2DM = Type 2 diabetes mellitus

Appendix

Figure A1 presents the current algorithm for T2DM screening and diagnosis.

Figure A1: T2DM: Screening and diagnosis algorithm



Source: General practice management of type 2 diabetes, Diabetes Australia 2014-2015

Table A1 presents the population specific thresholds for elevated waist circumference.

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