Australian Government
Medical Services Advisory Committee
Protocol Advisory Sub-committee

Feedback Survey

Application 1431- HbA1c point of care testing for the diagnosis and management of diabetes mellitus

Thank you for taking the time to complete this feedback form on a draft protocol to consider the options by which a new intervention might be subsidised through the use of public funds. You are welcome to provide feedback from either a personal or group perspective for consideration by the Protocol Advisory Sub-Committee (PASC) of MSAC when the draft protocol is being reviewed.

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

This feedback form should take 10-12 minutes to complete.

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

Responses will be provided to the MSAC , its subcommittees and the applicant with responses identified unless you specifically request deidentification.

While stakeholder feedback is used to inform the application process, you should be aware that your feedback may be used more broadly by the applicant.

Please reply to the HTA Team

Postal: MDP 959, GPO 9848 Canberra ACT 2601

Fax: 02 6289 5540

Phone 02 6289 7550

Email: HTA@health.gov.au

*Your feedback is requested by **15 July 2016** to enable the collation of responses to be provided to PASC to consider during its deliberations.*

PERSONAL AND ORGANISATIONAL INFORMATION

1. What is your name? Dr Gary Deed
2. Is the feedback being provided on an individual basis or by a collective group?

❑ Individual

x Collective group. Specify name of group (if applicable) RACGP

What is the name of the organisation you work for (if applicable)? _____

4. What is your e-mail address? _____qualitycare@racgp.org.au_____
5. Are you a:
    a. General practitioner X
    b. Specialist
    c. Researcher
    d. Consumer
    e. Care giver
    f. Other (please specify) _____

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MEDICAL CONDITION (DISEASE):

PROPOSED INTERVENTION:

HbA1c point of care test

CLINICAL NEED AND PUBLIC HEALTH SIGNIFICANCE

1) Describe your experience with the medical condition (disease) and/or proposed intervention relating to the draft protocol?

   The RACGP promotes best practice management of type 2 diabetes and we support POCT to reinforce clinical care pathways at diagnosis and for monitoring, see our diabetes guideline for more information: http://www.racgp.org.au/your-practice/guidelines/diabetes/

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2) What do you see as the benefits of this proposed intervention for the person involved and/or their family and carers?

   Point of care HbA1c testing is likely to improve convenience and overall experience of care by providing immediate results that can feed into the treatment and care of a patient. POCT will also assist in the reinforcement of diabetes goals in the patient. It will also assist in prompting the clinician to intensify treatment of a patient who is not at their HbA1c goal.

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3) What do you see as the disadvantages of this proposed intervention for the person involved and/or their family and carers?

   There may still be high risk patient groups who do not regularly attend general practice for clinical care who will not gain access to any benefit. This is no different to the current process of availability of testing. If the POCT is available but not fully publically funded equality of access will be an issue and 'out of pocket' expenses for patients may increase at the time of testing.

   There is a potential for loosing track of when an HbA1c test has been performed if POC test becomes the default action when patient arrives for a consultation about diabetes. Exceeding 4 tests a year is a possible consequence with patient or tester being out of pocket when the new POC Medicare item is claim is rejected.

   One advantage of Lab results are that they are available to other providers (with patient consent).

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4) How do you think a person's life and that of their family and/or carers can be improved by this proposed intervention?

POCT allows an immediate diagnosis which means patients will have immediate access to clinical support without delay. For patients with existing diabetes, its mean the results can immediately influence treatment and management. This reduces the need for additional follow up appointments.

POCT supports the "general practice medical home model" that brings benefits of enhanced chronic disease management services to patients. See RACGP's vision for sustainable health system: http://www.racgp.org.au/support/advocacy/vision/

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5) What other benefits can you see from having this proposed intervention publicly funded on the Medicare Benefits Schedule (MBS)?

Reduction in delays of medical care by eliminating the need to send a patient away for a test and then return for another consultation.

POCT will reduce the costs of care, by reducing the need for these additional consultations and tests.

POCT will also greatly improve the patient experience by improving convenience and providing more timely care and treatment.

INDICATION(S) FOR THE PROPOSED INTERVENTION AND CLINICAL CLAIM

Flowchart of current management and potential management with the proposed intervention for this medical condition can be found on page 13-14.

6) Do you agree or disagree with the eligible population for the proposed intervention as specified in the proposed management flowcharts?

x Strongly agree
❑ Agree
❑ Disagree
❑ Strongly disagree

Why or why not?

The RACGP guidelines outline additional groups of people considered to be at high risk of type 2 diabetes

- All patients with a history of a cardiovascular event (acute myocardial infarction, angina, peripheral vascular disease or stroke)
- People aged 35 and over originating from the Pacific Islands, Indian subcontinent or China
- People aged 40 years and over with body mass index (BMI) ≥ 30 kg/m2 or hypertension
- Women with a history of gestational diabetes mellitus (GDM)
- Women with polycystic ovary syndrome (PCOS)
- Patients taking antipsychotic medication
- People of any age with IGT or IFG

The USPTF Recommendation statement on Screening for abnormal blood glucose and type 2 diabetes Mellitus (October 2015) suggested screening adults 40-70 who are overweight or obese. The RACGP has not adopted this recommendation within the next edition of our guidelines (due for publication late August 2016) but is contemplating supporting this change.
(http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/screening-for-abnormal-blood-glucose-and-type-2-diabetes#copyright
http://annals.org/article.aspx?articleid=2466368)

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7) Do you agree or disagree with the comparator for the proposed intervention as specified in the current management flowchart?

❑ Strongly agree
X Agree
❑ Disagree
❑ Strongly disagree

Why or why not?

Australian expert guidance for the appropriate 'cut-offs' for HbA1c in 'pre-diabetes' is absent, leaving some patients who may have some impairment of glucose metabolism without access to appropriate lifestyle intervention and support from the primary care services (note the RACGP rejects the legitimacy of the term pre-diabetes and refers to impaired glucose tolerance and impaired fasting glucose). Some reference to the appropriate use of fasting glucose and Oral Glucose Tolerance test in high risk patients may assist – see http://www.racgp.org.au/your-practice/guidelines/diabetes/.

No footnote is included to illustrate when HbA1c lacks specificity and sensitivity such as haemoglobinopathies (see box below) and acute hyperglycaemic states at diagnosis which gives rise to instances of discordant results where HbA1c is in the normative range but elevated fasting glucose in the diabetes range is present. Wording describing this is within the RACGP guidelines. http://www.racgp.org.au/your-practice/guidelines/diabetes/

Other causes of variances to HbA1c:
Abnormally low HbA1c

- Haemolytic anaemia: congenital (eg spherocytosis, elliptocytosis), haemoglobinopathies, acquired haemolytic anaemias (e.g. drug-induced such as with dapsone, methyldopa)
- Recovery from acute blood loss
- Chronic blood loss
- Chronic renal failure (variable)

Abnormally high HbA1c

- Iron deficiency anaemia99
- Splenectomy
- Alcoholism
- Steroid therapy, stress, surgery or illness in the last 3 months

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8) Do you agree or disagree with the clinical claim (outcomes) made for the proposed intervention?

x Strongly agree
❑ Agree
❑ Disagree
❑ Strongly disagree

Why or why not?

The statement is evidence based

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9) Have all associated interventions been adequately captured in the flowchart ?

❑ Yes
X No

If not, please move any misplaced interventions, remove any superfluous intervention, or suggest any missing interventions to indicate how they should be captured on the flowcharts. Please explain the rationale behind each of your modifications.

See above notes on 'pre-diabetes' HbA1c cut offs. Additionally the words "patients at high risk of diabetes" using Ausdrisk needs to clarify the lack of specificity of this tool in Aboriginal and Torres Strait Islander subpopulations and the different age range of use compared to other populations. The words "or at risk according to guidelines" needs clarification - which guidelines are being referred to as there is no link or footnote?

The general HbA1c target in people with type 2 diabetes is HbA1c ≤7% (53 mmol/mol). Due to the natural variation of HbA1c test results, a target HbA1c of 7.0% would be achieved by laboratory results being in a range of 6.5–7.5% (48–58 mmol/mol). This should be reflected in the flow chart.

It would be helpful in the flow charts to have “lifestyle risk management and annual re-test” as an action for those patients at high risk of diabetes and those with HbA1c at a level not needing medication. This would emphasise prevention of diabetes complications as a consequence of immediately available POC test result.

ADDITIONAL QUESTIONS SPECIFIC TO THIS PROPOSAL

10) Should point of care testing for HbA1c provided under the Quality Assurance for the Aboriginal and Torres Strait Islander Medical Services (QAAMS) be included as a comparator?

The unique clinical setting of this application serves as an example that may not be helpful to compare with.

ADDITIONAL COMMENTS

11) Do you have any additional comments on the proposed intervention and/or medical condition (disease) relating to the proposed intervention?

The new 2016-2019 RACGP General Practice management of type 2 diabetes guidelines will be published in August 2016.

POCT within general practice offers many benefits in terms of early diagnosis and intervention and in delivering ongoing care and management. The benefits of POCT stem from the ongoing relationship GPs and their teams have with patients within the framework of a medical home model. Encouraging POCT outside of general practice will most likely contribute to greater fragmentation of care and generate more costs to the health system. POCT testing needs to be delivered by medical professionals who understand the therapeutic context and the goals and priorities of their patients.

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12) Do you have any comments on this feedback form and process? Please provide comments or suggestions on how this process could be improved.

Feedback Survey

Thank you again for taking the time to provide your valuable feedback.

If you experience any problems completing this on-line survey please contact the HTA Team

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