

Simplifying diabetes screening: Kimberley HbA_{1c} Study

Why was this study done?

- Diabetes is a major health issue in the Kimberley. Earlier diagnosis and treatment leads to better outcomes, but around 50% of people with diabetes are undiagnosed.
- Screening remains problematic; current screening models in Australia rely on fasting glucose measurements. In contrast glycated haemoglobin A (HbA_{1c}), which is used in the management of diabetes, requires no fasting. In late 2009 the American Diabetes Association added HbA_{1c} to their screening model.
- We wanted to see if a combination of point-of-care (POC) and laboratory (lab) HbA_{1c} testing, in real world settings, is an effective method of screening for diabetes in Kimberley Aboriginal people compared to the existing glucose screening model.

How was this study done?

- From September 2011 to November 2013, 255 Aboriginal and Torres Strait Islander patients over 17 years old without confirmed diabetes and due for screening were enrolled in the study. This was done by clinic staff on an opportunistic basis depending on clinic resources.
- We compared POC capillary HbA_{1c} with venous HbA_{1c} levels measured in a reference lab (n=241). A train-the-trainer model was used to train staff in how to operate POC analysers.
- At the same time clinic staff screened patients for diabetes using:
 - 1) **existing glucose screening model** (normal: < 5.5 mmol/L; indeterminate: fasting 5.5 - < 7.0 mmol/L or random 5.5 - < 11.1 mmol/L and follow-up tests not completed; impaired glucose tolerance: oral glucose tolerance test (OGTT) 2-hour glucose 7.8 - 11.0 mmol/L; diabetes: a diagnostic OGTT or 2 diagnostic glucose: fasting ≥ 7.0 mmol/L, random ≥ 11.1mmol/L); and
 - 2) **HbA_{1c} screening model** (normal: POC < 5.7%; prediabetes: lab 5.7 - 6.4%; diabetes: two results (POC and/or lab) ≥ 6.5%).
- Participants were classified independently using both diabetes screening models for comparison.

What did we find?

POC HbA_{1c} testing is sufficiently accurate to be used in the HbA_{1c} screening model:

- Concordance (agreement) between POC and lab results was good ($\rho=0.88$).
- The POC value for screening for diabetes or a high risk of developing diabetes was ≥ 5.7% (sensitivity, 91%; specificity, 76.7% for lab measurements ≥ 6.0%).
- Staff trained by other clinic staff 'on the job' performed as well as people with formal accredited training.
- Staff reported difficulty in maintaining formal accreditation.

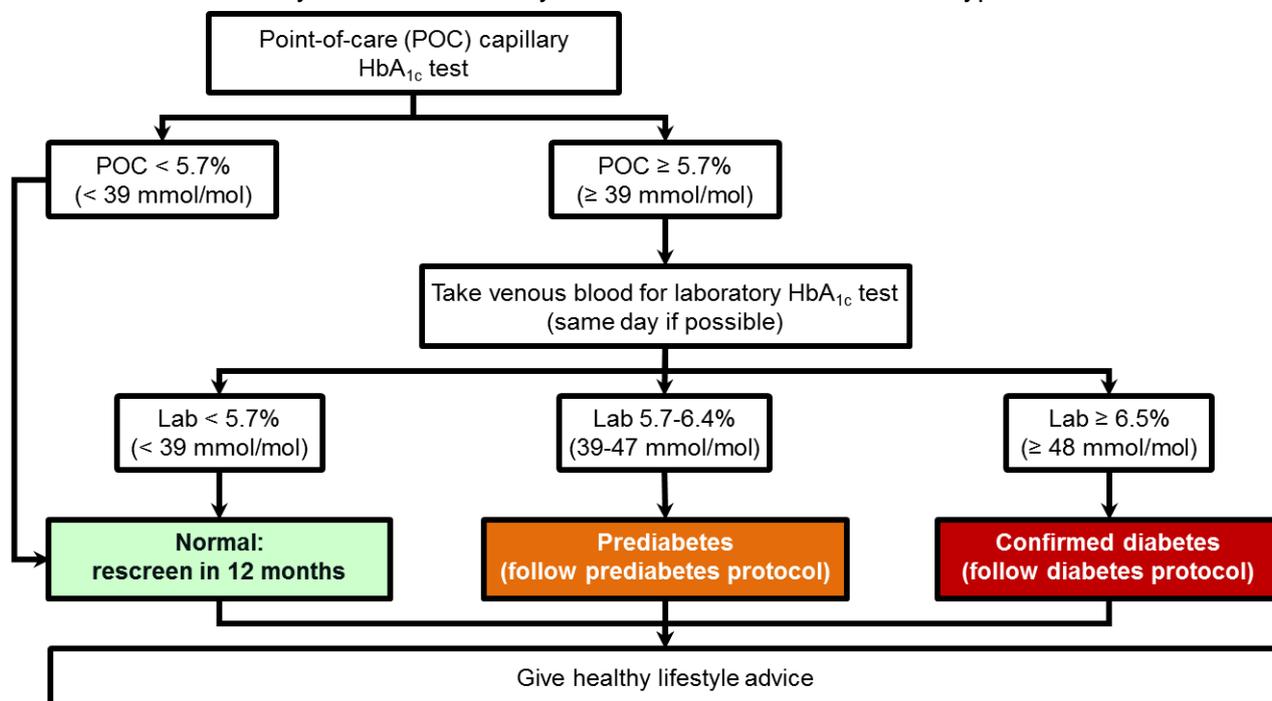
The HbA_{1c} model was better for screening and diagnosing diabetes than the glucose model:

- Participants were more likely to have a definitive result using the HbA_{1c} than the glucose model (250 v 214; $p < 0.001$).
- HbA_{1c} results were also much more timely with only 6 (2.4%) participants not having a result within seven days compared to 56 (22.0%) participants using the glucose model ($p < 0.001$).
- Participants were more likely to be diagnosed with diabetes using HbA_{1c} than the glucose model (15 v 4; $p = 0.003$):
 - For everyone with diabetes that we found using the glucose model we missed two: 8 participants who were classified as normal with the glucose model had diabetes.
 - Normal POC HbA_{1c} measurements (<5.7%) did not miss anyone with diabetes.



What happens now?

- In late 2014 an MBS rebate for diagnosing diabetes using a single lab HbA_{1c} test was introduced in Australia – this is different to the rebate for HbA_{1c} tests for managing diabetes.
- As a result of this we have dropped the requirement for an additional lab HbA_{1c} test to confirm diabetes and have included the simplified Kimberley HbA_{1c} diabetes screening and detection model in the recently revised Kimberley Chronic Disease Protocol for Type II Diabetes.



Barriers and enablers to implementing HbA_{1c} screening:

- We want to see how well the new Kimberley HbA_{1c} diabetes screening and detection model is implemented. Some of issues that may need to be addressed include:
 - FUNDING: the MBS rebate for is for lab not POC HbA_{1c} – we need to show that using POC testing as an initial screening measure is more cost effective than only using a single lab test.
 - EDUCATION:
 - Awareness of the new screening model: lab HbA_{1c} 6.5-6.9% is not normal.
 - Developing resources for clinicians to explain the new tests to patients.
 - TRAINING: adding POC HbA_{1c} analyser training to existing regional training programs.
 - UPDATING PROTOCOLS: adding POC HbA_{1c} to routine tests for people due for screening.
 - HARDWARE: ensuring clinics have POC HbA_{1c} analysers.
 - MONITORING: developing a regional quality assurance program.
- Adoption of the Kimberley HbA_{1c} diabetes screening and detection model should simplify the testing process in those previously undiagnosed and provide a timelier and more accurate diagnosis of diabetes for Aboriginal people and other high-risk remote populations.

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