Final s54 Report from the Health and Community Services Complaints Commissioner (SA) on the Identified Systemic Concerns regarding the Use and Reporting of the HbA1c Test for Diabetes.

hcscc

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1. **Date of final report:** 20 May 2014

2. **HCSCC Reference # :** 011047 LP

3. **Background:**

In June 2009, a complaint was made to the Health and Community Services Complaints Commissioner (HCSCC) about the misdiagnosis of the complainant's diabetes[1] status. The complainant claimed that the misdiagnosis was due to the fallibility of the HbA1c blood test and the treating health professionals failure to firstly, consider the test results in context and secondly, to understand the HbA1c[2] test and its limitations.

In November 2012, after seeking independent expert advice on the substance of the complaint, HCSCC determined there was a need to deal separately with the individual's issues of complaint on the one hand and on the other, the identified systemic issues of concern regarding the use and reporting of HbA1c. The complaint was split and a full investigation into the systemic issues of concern surrounding the use and reporting of HbA1c commenced; alongside continued HCSCC inquiries into the concerns affecting the complainant as an individual.

In September 2013, the Commissioner released a report on the investigation into the identified systemic issues of concern surrounding HbA1c. In brief summary, the systemic issues identified and reported in September 2013, were:

1. Many practitioners are unaware of the fallibility of HbA1c and rely solely on a patient's HbA1c "score" as an indication as to whether the patient's diabetes is under good control.

2. Blood tests for HbA1c and BGL[3] appear to be processed in different laboratories by different pathologists, greatly reducing the chance of a pathologist providing comment on the "glycaemic gap" between the results of the two tests.

3. The results for HbA1c and BGL tests are printed on separate pages of a two page report, increasing the chance that a "glycaemic gap" will go unnoticed by pathologists and/or treating medical practitioners interpreting the results.

4. Pathologists carry out blood tests without access to a patient's "diabetic history" and therefore provide comment without context. This increases the chances that abnormalities, or extraordinary results for a particular individual, will go unnoticed.

5. Pathology reports carry a misleading legend as to the meaning of HbA1c results. Conditions affecting the lifespan of red blood cells can cause lower or higher HbA1c results. HbA1c results of < 6.0 are not always an indication of non diabetic levels.

6. Many practitioners, diabetes educators, pathologists and others working in the diabetes field are unaware that haemoglobinopathies and other conditions affecting the lifespan of red blood cells may confound HbA1c, causing false, low scores. Although those practicing in the field receive updates, they are not audited and are not required to comply with a set of standards that would ensure the information they provide to patients is accurate and up to date.

7. Those receiving Performance Incentive Payments in diabetes care do not always have the specialised skills and experience required to provide diabetes patient care.

The Commissioner determined to send out copies of the report and ask for feedback on the recommendations made as a result of HCSCC's investigation into the identified issues listed above. Peak organisations from all over Australia, representing those involved in diabetes diagnosis, testing, treatment, care and education; as well as those organisations involved in the development and maintenance of relevant service standards, were sent a copy of the report for review. They were asked to comment on the recommendations made by the Commissioner as a result of the investigation, which were:

1. More information and training on the nature of HbA1c to be provided to those working in general practice, and;

2. Develop a baseline standard of practice specifically for those working with diabetic patients; with practitioners reviewed to ensure the agreed service standards are met, and;

3. Support consumers to become health literate about diabetes and HbA1c so they can actively participate in their own treatment and care, and;

4. Improve education about HbA1c and its fallibilities and what might affect HbA1c results for all those working in the diabetes field, and;

5. Take up the opportunity offered by the introduction of new unit measures (mmol/mol) for HbA1c, to provide training on the nature of HbA1c, how it works and its fallibilities, and;

6. Update and improve PIP (Performance Incentive Payment) scheme to ensure that practitioners who qualify for those payments are assessed and can provide the appropriate diabetes care, and;

7. Review reporting processes in relation to pathology, with a specific view to improving pathology reporting by printing the results for HbA1c and BGL on the same page, and;

8. Require diabetes education material to be updated to include accurate information regarding the fallibility of HbA1c, with information on what might affect an HbA1c score, and;

9. Revise tables and legends and information proliferated for education purposes and remove "< 6 = non diabetic" unless accompanied with a reference to circumstances where this is not the case, and;

10. Revise tables and legends for HbA1c results to include the words - Check for red blood cell conditions - next to levels indicated for 6.5% and below, and;

11. Revise tables and legends for HbA1c results and require that information be noted in pathology reports about the fallibilities of HbA1c and the imprudence of relying on an HbA1c score as a sole measure of diabetes control, and;

12. Implement system wide changes that require any request for pathology for a diabetic patient to include their "diabetic history". A "diabetic history" might include such information as:

    - Type 1 or 2
    - Number of years diagnosed with diabetes
    - Self monitoring data (collected by the patient)
    - Individual symptoms
    - Comments / Queries / Concerns

4. Discussion

The process of seeking comment on a list of preliminary recommendations made at the completion of the HCSCC investigation into the use and reporting of HbA1c, from those with experience and expertise in the diabetes field was aimed at gaining feedback on the recommendations so they may be accepted, improved or discarded.

HCSCC is grateful for the advice and information received from those organisations and specialists in the field; this information has provided HCSCC with a better understanding of the issues, in particular the issues relating to the Commissioner's recommendations and how affective, or otherwise, they may prove to be in practice.

This process enabled HCSCC to distil the recommendations into a form that may be best placed to suggest and encourage change; bringing about system-wide improvements for everyone working in the field, as well as those patients receiving diabetes services.

For your information a brief discussion of the responses as they relate to each of the recommendation follows:

Recommendation 1- **More information and training on the nature of HbA1c to be provided to those working in general practice, and;**

It was generally agreed that there should be more information and training on HbA1c provided to those working in general practice. Many organisations commented that they have been actively working on specific projects to improve the information currently available to those providing diabetes care. The Australian College of Nursing suggested that the Australian Diabetes Educators Association, the Australian Diabetes Society and other peak professional bodies such as the Australian College of Nursing who have the technical expertise, may be able to seek out funding for this project and draw on their professional networks for wider dissemination of this information.

Recommendation 2 - **Develop a baseline standard of practice specifically for those working with diabetic patients; with practitioners reviewed to ensure the agreed service standards are met, and:**

On consideration, practice standards, specifically related to diabetes care and applied to anyone working with diabetic patients, would meet with approval in the field. There are currently standards which apply to some areas of work such as those for Credentialed Diabetes Educators. The Australian Commission on Safety & Quality in Health Care observed that there may be value in making those organisations already producing or endorsing clinical practice guidelines aware of the limitations of HbA1c so that this information could be included and disseminated within already existing, relevant guidelines. It was noted that further improvements in the standardisation of HbA1c measurements would likely be achieved after implementation of a national whole blood external quality control program under the Royal College of Pathologists of Australia Quality Assurance Program.

Recommendation 3 - **Support consumers to become health literate about diabetes and HbA1c so they can actively participate in their own treatment and care, and;**

It is evident from the response to Recommendation 3 that health literacy is considered to be a necessary and important avenue to pursue and that in the future, patients must be better engaged and educated so they may play a more active role in their own diabetes care. The Australian College of Nursing believes that Credentialed Diabetes Educators and nurses, particularly those in general practice with special education in diabetes care, are ideally placed to educate consumers and improve health literacy. The Australian Commission on Safety and Quality in Health Care advises that they have initiated a discussion on health literacy in Australia, with the aim of raising awareness and prompting national action on the issue; currently the Australian Commission on Safety and Quality in Health Care are developing tools and resources that will enable health care organisations to tackle health literacy within their own systems and practices.

Recommendation 4 - **Improve education about HbA1c and its fallibilities and what might affect HbA1c results for all those working in the diabetes field, and;**

It was generally agreed that improved education about HbA1c and its fallibilities for those working in the field would be invaluable and would improve the care provided to diabetic patients. The Australian Diabetes Association in particular commented that if and when it is decided that HbA1c can be used as a diagnostic tool as well as for monitoring diabetes care, it would be especially advisable to conduct a major education campaign on HbA1c and the assay issues discussed, such as the affect red blood cell conditions have on HbA1c results.

Recommendation 5 - **Take up the opportunity offered by the introduction of new unit measures (mmol/mol) for HbA1c, to provide training on the nature of HbA1c, how it works and its fallibilities, and;**

Clinpath Laboratories have commented that the opportunity for further education on HbA1c, offered by the introduction of new unit measures (mmol/mol) for HbA1c, still exists. Although the new measures were to have been completed by July 2013 – most laboratories are still reporting dual units, providing relevant information about the new measures as well as the old percentage units and how they compare. The Australian College of Nurses adds that the recent introduction of new unit measures for HbA1c offers an excellent opportunity for education on how HbA1c forms and the different contributions fasting and post prandial blood glucose make to HbA1c.

Recommendation 6 - **Update & improve PIP (Performance Incentive Payment) scheme to ensure that practitioners who qualify for those payments are assessed & can provide appropriate diabetes care, and;**

Regarding Performance Incentive Payments (PIP), the Australian Diabetes Educators Association agrees there is inconsistency in the education and management of diabetes by some primary care practitioners. The Australian Diabetes Educators Association puts forward the argument that Credentialed Diabetes Educators (CDE) because of their specialist education and experience should be used as primary support for people with diabetes and that this should be reflected in PIP.

Recommendation 7 - **Review reporting processes in relation to pathology, with a specific view to improving pathology reporting by printing the results for HbA1c and BGL on the same page, and;**

Generally, it was felt that the recommendation that HbA1c and Blood Glucose Level results should be printed in closer proximity or on the same page in pathology reports, that this would seem to assist with highlighting disparities, it was pointed out that HbA1c and Blood Glucose Level are separate tests; they may not be requested simultaneously and the results, given the huge range of possible variations, may not be at all relevant to each other. Also, it was noted that increased general use of electronic data systems for recording and storing patient data may circumvent the issues found in dealing with printed pathology reports. The Royal College of Pathologists of Australia advise that they are in the process of establishing a working group to develop a position statement on HbA1c testing and reporting and that this statement will include discussions on the accuracy of testing when other diseases such as Haemoglobinopathy, Chronic Renal Disease and Anaemia are present.

Recommendation 8 - **Require diabetes education material to be updated to include accurate information regarding the fallibility of HbA1c, with information on what might affect an HbA1c score, and;**

It was generally agreed that diabetes educational material should be continually updated to include accurate information. With regards to improving educational material by including current information about the fallibility of HbA1c and what might affect HbA1c results, it was noted that this would be helpful, as long as the information was concise, in context, was not confusing and did not cause patients to be unjustifiably cautious of accepting HbA1c results. Diabetes SA suggested that this should be addressed by the Australian Diabetes Educators Association; although the Australian Diabetes Educators Association itself commented that this information is already available and there should be clarification of the numbers affected before implementing further expensive, system wide changes.

Recommendation 9 - **Revise tables, legends & information proliferated for education purposes & remove "< 6 = non diabetic" unless accompanied with a reference to circumstances where this is not the case, and;**

Revising tables and legends to remove indicators and advice, such as "< 6 = non diabetic" unless accompanied by a reference to circumstances where this is not the case, was generally accepted. Clinpath Laboratories noted that this may be the single most important item within the recommendations as it provided an opportunity to deliver clear and definitive information to requesting practitioners on the interpretation of all HbA1c results, regardless of any other confounding factors.

Recommendation 10 - **Revise tables and legends for HbA1c results to include the words - Check for red blood cell conditions - next to levels indicated for 6.5% and below, and;**

The response to the recommendation that tables and legends for HbA1c test results should include the words – *Check for red blood cell conditions* – next to levels indicated as 6.5% or below, was mixed. It was agreed, as per Recommendation 9 above, that there is a need for a generic statement qualifying HbA1c results and providing some guidance as to their interpretation. However as the Royal College of Pathologists of Australia pointed out, 99% of all patients with HbA1c results that are < 6.5% would not have any cell abnormality affecting their results.

Recommendation 10 – **Continued**

Therefore a simple statement such as that suggested, – *Check for red blood cell conditions* – in circumstances where HbA1c is poorly understood, would be more likely to cause alarm with the resulting confusion leading to unnecessary testing and/or treatments. Clinpath Laboratories felt that, to be truly informative, the comment should be more comprehensive and less ambiguous. Clinpath put forward the following suggestion as to the wording of a note to appear as a footnote on all HbA1c reports:

> NB: Misleadingly low HbA1c levels may occur in: anaemia, B12 & folate deficiency, recent transfusion, haemoglobinopathies, haemolysis, or any chronic disease with reduced red cell survival including chronic liver disease, cirrhosis and renal failure. Severe iron deficiency may result in higher levels.

Recommendation 11 - **Revise tables & legends for HbA1c results & require that information be noted in pathology reports about the fallibilities of HbA1c & the imprudence of relying on an HbA1c score as a sole measure of diabetes control, and;**

It was generally felt that Recommendation 11, which recommended that pathology reports be changed to include information on the fallibilities of HbA1c, with statements advising practitioners against relying on an HbA1c score as a sole measure of diabetes control, was in most part addressed through the responses provided to Recommendations 9 and 10, above. The Australian Diabetes Educators Association advises that HbA1c is a robust and accurate test in most cases and as such there is no need to list all the potential fallibilities of HbA1c on a results report. If this was necessary for HbA1c, it would therefore be necessary for all blood tests which would increase the risk that recipients of such reports would ignore them.

Recommendation 12 - **Implement system wide changes that require any request for pathology for a diabetic patient to include their "diabetic history". A "diabetic history" might include such information as:**

- **Type 1 or 2**
- **Number of years diagnosed with diabetes**
- **Self monitoring data (collected by the patient)**
- **Individual symptoms**
- **Comments / Queries / Concerns**

Pathologists agreed that the inclusion of a diabetic history on pathology forms would assist pathologists in their interpretation of HbA1c results. The Australian College of Nurses agreed but added that only relevant information should be included. The Royal College of Pathologists of Australia suggested that information provided on a request form is rarely that good and therefore not often useful; however the Royal College of Pathologists of Australia is aware of the issue and is looking to develop a position statement on HbA1c Testing and Reporting to try and assist with addressing these kinds of concern.

4. Conclusion

After investigating the use and reporting of HbA1c, HCSCC has learnt that the system supporting patients with diabetes in Australia is a very large and complicated one. We have learnt that HbA1c, like all tests, is subject to variability and that although there are confounders for HbA1c, it remains a reliable and very important part of monitoring and managing diabetes.

However, patients with shortened red blood cell survival for whatever reason, will have lower HbA1c results than the normal population. This statement remains at the heart of this investigation and necessarily underpins the findings and the recommendations that follow.

These recommendations have been blended from the information and feedback provided to HCSCC as part of this investigation process; and are therefore supported by those living and working with diabetes. These recommendations are practical and achievable and their implementation will improve the complicated system that is diabetes care in Australia; for those working in the field, for those who live with diabetes, but especially for those who may have diabetes and another condition that affects their individual HbA1c score.

5. Recommendations

The Health and Community Services Complaints Commissioner South Australia recommends that:

1. Peak professional bodies such as the Australian College of Nursing, the Australian Diabetes Society and the Australian Diabetes Educators Association, singly or in partnership, seek support to fund, develop and provide education programs on HbA1c which includes current and accurate information on the part played by HbA1c in the diagnosis and monitoring of diabetes, its fallibilities/limitations and the new unit measures introduced in 2013. There should be general and specific education programs and material developed to ensure that information on HbA1c targets those in general practice caring for diabetic patients; and those patients with co-morbidities that may affect their HbA1c results, and;

2. Organisations, such as Therapeutic Guidelines Ltd, the National Health and Medical Research Council and the relevant Colleges of practice, already producing or endorsing clinical practice guidelines, should be made aware of, and include, information about the limitations of HbA1c in clinical practice guidelines; to allow information about HbA1c to be disseminated widely within existing guidelines, and;

3. Eligibility for PIP (Performance Incentive Payments) must be improved so that practitioners receiving PIP have the necessary training and are accredited to provide diabetes care, and;

4. "< 6 = non diabetic" should be generally removed from educational material, reports, information and advice regarding HbA1c scores unless accompanied by a disclaimer that explains when this may not be the case, and;

5. Revise and update all educational material, reports, information and advice regarding HbA1c scores to include a written subscript related to scores of 6.5% and below, such as or similar to:

   Note: Misleadingly low HbA1c levels may occur in: anaemia, B12 & folate deficiency, recent transfusion, haemoglobinopathies, haemolysis, or any chronic disease with reduced red cell survival including chronic liver disease, cirrhosis and renal failure. Severe iron deficiency may result in higher levels.

6. Implement changes to HbA1c pathology request forms so that they include the space for referring practitioners to provide pathologists with a "diabetic history" for the patient being tested.

HCSCC intends to contact the recipients of this report (being those organisations, associations and colleges of learning listed in attachment A) in 12 months time to request an update on the progress made with regards to the implementation of the above recommended changes.

Steve Tully
Health and Community Services Complaints Commissioner
Date: 22/5/14

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[1] **Diabetes Mellitus** is a chronic condition in which the levels of glucose (sugar) in the blood are too high. Blood glucose levels are normally regulated by the hormone insulin, which is made by the pancreas. In people with diabetes, the pancreas doesn't produce enough insulin, or there is a problem with how the body's cells respond to it.

[2] **Glycated haemoglobin** (*haemoglobin A1c, HbA_{1c}, A1C*, or *Hb_{1c}*; sometimes also **HbA1c**) is a form of haemoglobin that is measured primarily to identify the average plasma glucose concentration over prolonged periods of time. Normal levels of glucose produce a normal amount of glycated haemoglobin. As the average amount of plasma glucose increases, the fraction of glycated haemoglobin increases in a predictable way. This serves as a marker for average blood glucose levels over the previous months prior to the measurement.

[3] **Blood Sugar Levels (BSL) or Blood Glucose Levels (BGL)** is the amount of glucose (sugar) present in the blood of a human or animal. The mean normal blood glucose level in humans is about 5.5mmol/L, however this level fluctuates throughout the day. Glucose levels are usually lowest in the mornings before the first meal of the day (termed "the fasting level") and rise after meals for an hour or two by a few millimolars.

Attachment A

List of Organisations, Associations and Colleges of Learning to receive a copy of Final Report of the Investigation by the Health and Community Services Complaints Commissioner SA into the Use and Reporting of HbA1c

Australian Diabetes Educators Association (ADEA)

Diabetes Australia Research Trust

Australian Diabetes Council

Coalition of National Nursing Organisations (CoNNO)

Royal Australasian College of Physicians

Rural Doctors Association of Australia

National Association of Testing Authorities

Australian Diabetes Society

Diabetes Australia

Royal College of Nursing Australia

Endocrine Society of Australia

Royal Australasian College of General Practitioners

Royal College of Pathologists of Australia

The Royal Australasian College of Physicians

The Royal Australian College of General Practitioners

The Royal College of Pathologists of Australasia

RCPAQAP Chemical Pathology

SA Pathology

Australian College of Rural and Remote Medicine

Clinpath Laboratories

Healthscope Pathology

Adelaide Pathology Partners

SA Health and Ageing

Australian Commission on Safety and Quality in Health Care

Australian General Practice Network

Diabetes SA

Therapeutic Guidelines Limited

National Health and Medical Research Council

National e-Health Transition Authority