S54 Investigation Report by Health and Community Services Complaints Commissioner

Health & Community Services Complaints Commissioner

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1. **Date of Report -** 2 February 2016

2. **Date of de-identified version of Report –** 17 February 2016

3. **HCSCC Reference # -** M15 / 00004

4. **Date of s29 Determination to investigate –** 14 November 2014

5. **Service Provider –** All pathology services

6. **Service User/s –** Patients accessing pathology services – particularly those requesting HbA1c and/or Cholesterol testing

7. **Background to the decision to investigate –**

7.1 On 6 June 2014, the Health and Community Services Complaints Commissioner (HCSCC) received a complaint from Mr X. Mr X complained that for some time he had been suspicious of blood test results received from two different laboratories. Mr X alleged that blood test results received from one laboratory, for HbA1c and Cholesterol tests, were generally higher than his blood test results, for the same tests, from the other laboratory.

7.2 When Mr X went to see his GP for a three monthly check, Mr X claims there was a marked difference between the two pathology results. Mr X claims that while he had a 'normal' result of around 7% from the first laboratory, his HbA1c test result from the second laboratory was higher at 7.7%.

7.3 Mr X complains that he was confused by receiving different results from the different pathology laboratories for the same tests; and concerned that his GP would not have the correct information on which to base his treatment decisions.

7.4 Mr X was advised by his treating specialist, an endocrinologist, to always use the same laboratory to process all requests for bloodwork; as experience had shown that using different pathology laboratories gives rise to different results that could not be compared.

7.5 Mr X's GP advised him that there was no national testing procedure for Type 2 diabetes; but when Mr X questioned a third pathology laboratory about this, he was told this was not strictly accurate as there are strict guidelines in place for pathology services, nationally, and these are regularly audited to ensure that pathology services meet the expected standards.

7.6 Mr X complains that pathology seems to be a guessing game and requested an answer to his questions – which pathology results were right; and which results should his GP use to decide his treatment?

7.7 After receiving Mr X's complaint, HCSCC contacted the Royal College of Pathologists Australasia (RCPA) for advice. In response the RCPA commented that in general, if there are marked variations in results between two different laboratories, the two laboratories would need to discuss the different results and work out the possible causes for the differences. RCPA advised that in Mr X's case, the two pathology laboratories involved used different methods for measuring his HbA1c and both methods were valid.

7.8 In the RCPA response, in an email to the GP, a leading pathologist stated that: *"Unfortunately there is no "gold standard" method which is free of all interference so results need to be interpreted together with the patient's clinical status and other results such as blood glucose. Both sets of results appear to be internally consistent compared to other results from the same laboratory, suggesting Mr X's glycaemic control was unchanged for at least the past 18 months."*

7.9 After receiving advice from RCPA, HCSCC contacted Mr X's GP. The GP advised HCSCC that he was concerned that 5-10% of those with diabetes were borderline and it was these people who would be affected by a 0.7 difference in their results. This could mean a significant difference in diabetes care and this was concerning for the GP and his fellow GPs.

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8. Summary of issues /concerns under investigation -

8.1 On 14 November 2014, HCSCC determined to conduct an investigation, under Part 6, section 43, of the Health and Community Services Complaints Act 2004 (the Act), into why Mr X had received different results from different pathology laboratories, for the same blood tests; and HCSCC determined to investigate the GP's concern that the differences in the blood test results, for Mr X's HbA1c and Cholesterol tests, were significant enough to affect the decisions made about treatment and diabetes care.

8.2 In order to determine whether or not the pathology laboratories involved in this matter were meeting the generally accepted standards, HCSCC decided to identify the applicable standards set for pathology services and request information from relevant authorities actively monitoring and auditing the standards; and if the pathology services were found to not be meeting the generally accepted standards, to investigate how pathology services could improve their services to ensure they would meet the generally accepted standards in the future.

9. **Summary of investigation process –**

9.1 To begin the investigation, HCSCC asked the GP and Mr X if they would submit samples of Mr X's blood to a number of pathology laboratories on the same day and request HbA1c and Cholesterol tests. This was done to provide the investigation with a place to start; a comparison between the results for the same tests, taken at the same time, from the same person, by the same doctor, but then processed by different pathology services. Having the samples taken on the same day, at the same time, by the same GP, was to limit the number of variables in the process.

9.2 In February 2015, the GP organised the results from this process into a table so they could be easily compared. (Attachment A).

9.3 The GPs overall review of the February 2015 results was that a 0.6 spread between test results was significant and presented issues for diagnostics and treatment. The GP commented that this was not an acceptable range for GPs; they could not have confidence in the results and would not know which results to rely on. The GP advised that these latest results were another set of results for Mr X that had shown a marked difference between laboratories. The GP said he had consistently found these differences in Mr X's results, over the three years he had been treating Mr X.

9.4 In pursuit of the relevant standards applicable to laboratories providing pathology services; and in particular the standards relevant to the testing of blood for HbA1c and Cholesterol; HCSCC contacted Medicare Australia. Medicare Australia is the relevant, national, regulation authority for pathology laboratories and every operational pathology laboratory must be registered with Medicare Australia. Medicare Australia advised HCSCC that, as this was a matter of quality and auditing and these functions are carried out for Medicare Australia by NATA, the National Authority of Testing Authorities, HCSCC would need to contact NATA.

9.5 Medicare Australia advised that NATA is contracted by Medicare Australia to provide accreditation and auditing of pathology laboratories throughout Australia. NATA audits against the relevant international standards and against the relevant national standards set by the Department of Health. Each operational, pathology laboratory is regularly assessed by NATA; on average every 3 – 4 years, when each pathology laboratory must meet the standards in every aspect of their work if they are to remain accredited to provide pathology services in Australia. Medicare Australia is aware of approximately 40 documents which provide the international and national standards relevant to providing pathology services in Australia.

9.6 In a meeting with NATA on 12 May 2015, HCSCC was informed that NATA does conduct the accreditation and auditing process for pathology laboratories in Australia; assessing the laboratories against the international and national Department of Health standards to ensure that their services and tests are up to standard and valid for purpose. NATA advised HCSCC that they do not set the standards; NATA's role is to ensure the standards are met.

9.7 NATA advised HCSCC that the RCPA (Royal College of Pathologists Australasia) and/or the Australasian Association of Clinical Biochemists (AACB) could provide HCSCC with information on the expected variations in specific blood test results and therefore what the applicable standards are. NATA advised that there are different options for pathology laboratories and they can choose to use different instrumentation or different methods; as long as the tests they use are fit for purpose and provide results within the range of the expected standards. Given this, the results provided by each laboratory for Mr X may be acceptable. Given different assays or equipment may have been used, Mr X's results may all fall within the acceptable range and meet the expected standards.

9.8 When contacted, an AACB biochemist advised HCSCC that there are numerous variables. Blood is not stable and therefore if it is not properly handled – through collection, transport, storage - even the same blood can give different results. In Mr X's example the 0.6 difference in HbA1c assays, did not appear to be an unexpected difference. This kind of difference may occur even testing the same sample of blood, in the same laboratory. The numbers of variables, called pre analytical problems, which may affect results, are countless; and include variations in how the samples were collected, how they were treated, if the sample sat around for any length of time etc. When samples are run a number of times there should be a <2% variation in the results for HbA1c (although some may be around 3%, they should try for better than 3%). This means (without doing a complete review for a more accurate and definitive answer) that all of Mr X's results appear to be within the expected range.

9.9 In June 2015, HCSCC approached the RCPA again regarding Mr X. HCSCC requested the RCPA comment on whether or not the differences measured in Mr X's case were significant; either for Mr X as an individual or systemically where differing results from different laboratories could affect the diagnosis and treatment options of treating specialists.

9.10 HCSCC also requested advice from RCPA regarding the relevant standards and whether or not the RCPA believed that pathology services had met the generally accepted standards in Mr X's case.

9.11 The RCPA responded with a detailed explanation of Measurement Uncertainty and Measurement Error. The components of measurement error are bias (a systematic error in measurement data) and imprecision (random error in measurement data). The RCPA advised that pathology laboratories aim to eliminate bias and reduce imprecision.

9.12 RCPA advised that most methods have a 'gold standard' to refer to, so that results from different methods can be compared; however the 'gold standard' is generally impractical for routine use. Careful analytical testing, machine maintenance, local standards and controls within the laboratory, aim to address imprecision; but it is not possible to eliminate it entirely.

9.12 In practical terms, the RCPA commented that different methods have different Measurement Uncertainties (MU). With HbA1c, one commonly used method has a MU of 1.4% while another has a MU of 3.6%. At a value of 7 the former instrument has a 95% confidence interval of 6.8 – 7.2 and the latter 6.5 – 7.5; and changes within this range of results may not represent any real biological difference.

9.13 There is always variability in results. In an individual laboratory there is MU to be considered, however, as in the case with Mr X, when using multiple laboratories there is both MU and bias to be considered. It would seem from the results that a range of results between 6.8 and 7.2 is not significant; as it is within the 95% interval for results. However such differences are hard to interpret between different laboratories; it is possible that there is evidence of bias in the matrix of Mr X's results. It is possible that one method was used by the first two laboratories, while the other laboratories were using another method. This would explain the clustering of Mr X's results. It does appear that the results from all the laboratories are within the same uncertainty limits.

9.14 RCPA advised that it is good practice to request tests, such as HbA1c, from the same laboratory, or if from different laboratories, at least from laboratories that utilise the same method.

9.15 After reviewing the RCPA response, the GP commented that it was unhelpful. The differences in Mr X's results had clearly impacted on Mr X's management. Mr X's specialist had chosen one laboratory over all others and was making recommendations for therapy based on different results to those received by Mr X's GP, from another laboratory.

9.16 Mr X was provided with the information received from the RCPA. Mr X commented that he was still unable to understand which results were accurate; and given all of the information provided, he still felt unable to tell which results gave his GP better insight into his condition or which result was the best basis for his treatment.

9.17 HCSCC asked the Chief Medical Officer (CMO) of SA Health to review the complaint documents and provide advice. The CMO advised HCSCC that in his opinion there was nothing further HCSCC could do to resolve this matter; HCSCC had sought information and advice from all the relevant and appropriate organisations involved in setting, maintaining and auditing the standards that apply. From the complaint documents and from experience, the CMO advised HCSCC that there will invariably be problems with measuring some tests. The issue is to know when this is the case, to identify the errors, or the chance of errors, and to take this into account in the results. It is impossible to measure biological processes precisely. It is impossible to get the exact same results from any sample, let alone from different samples that may have been processed in different laboratories.

9.18 The CMO explained that therefore the aim is that for 95% of the time, the results should be within a certain range. This becomes the standard, the only kind of standard you can have and the one you need each laboratory to aim for and attain. But it also means that we have to recognise that we can't do anything about the results that fall outside this range – 5% of the time. This is an underlying problem with measuring biological results; and the variability occurs, invariably.

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10. **Findings/ Conclusions –**

10.1 After investigating this matter with the relevant authorities, HCSCC has found that countless variations can occur during the process of blood sample testing; and this is the reason Mr X received different results from different pathology laboratories for the same blood tests.

10.2 During collection, transport and storage of a blood sample for testing, there can be many variations involved that will affect the results; and then during the testing other variables that may cause results to deviate from accuracy. As it is known that there are countless variations that will affect results and cause them to vary, the measure of error must be taken into account.

10.3 It is impossible to measure biological samples accurately, therefore the standard must necessarily be set as a range, in which the result must fall within; results must fall within a certain range a certain percentage of the time. It appears that in the case of HbA1c, the results must fall within the expected range 95% of the time.

10.4 In pathology, in general, the method used is to have a 'gold standard'. The 'gold standard', though impractical for routine use, will set the bar by which to measure the efficiency of other methods. The results from a given method must fall within the range of the 'gold standard' most of the time. In the case of HbA1c it appears that the applicable standard requires that HbA1c results will fall within a certain range (and the range to aim for is >2%) 95% of the time. This is the generally accepted standard and pathology laboratories conducting HbA1c tests are audited to this standard. It is important to remember that it is impossible to accurately measure biological samples and there may be results, 5% of the time, which may not fall within the expected range.

10.5 On advice and information provided to HCSCC in the course of this investigation, the learned opinions canvassed suggest that the range of results for Mr X were all within the generally expected range - for results, of the specific tests, requested for Mr X. Therefore there was no pathology service that provided a result outside the expected range and all the pathology services provided to Mr X were services that met the generally accepted standards.

10.6 The issue for Mr X and his GP seems to be that the likelihood of variations influencing Mr X's results to a point of concern is increased when the specialist uses a different laboratory to that used by his GP. Using the same laboratory, while still subject to variations, will decrease the level of error; because the tests will be done using the same method, on the same equipment and likely in the same manner, following the same procedures.

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11. **Recommendations / Outcome –**

11.1 After investigating this matter, HCSCC has determined there are applicable standards for the work carried out by pathology laboratories and these standards are documented in international and national standards, monitored and audited by NATA (National Authority of Testing Authorities). It is apparent that each operational pathology laboratory is registered with Medicare Australia and to provide pathology services in Australia, each pathology laboratory must provide services according to the relevant standards.

11.2 Biological tests, such as blood tests for HbA1c and Cholesterol, are vulnerable to variations and it is therefore accepted that it is impossible to calculate the results with 100% accuracy. The standard for measuring results of biological tests is therefore determined as a range; with the results expected to be within the expected range 95% of the time.

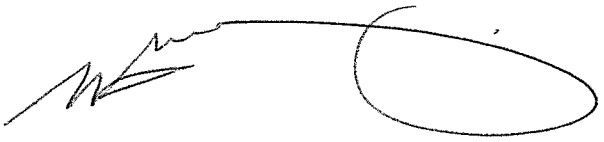
11.3 In this case, Mr X was provided with services that met the generally accepted standards as all the test results were deemed by the experts in the field, to have fallen within the generally accepted standards, within the expected range.

11.3 On the basis of the findings of this investigation it is recommended that HCSCC release a public statement regarding the advice that it is better practice to use the same pathology provider and not more than one pathology service provider. Using one provider gives results that can be more easily compared and reduces the number of variations that may be involved in the process.

11.4 In Mr X's case there would be better outcomes for Mr X if his GP and specialist agreed upon a pathology service provider and requested blood tests and results from the same provider. It is clear that this has been a problem in the past and the solution may lie in Mr X's health team collaborating to eliminate as many of the variables as possible from his blood test results and to have an agreed platform on which to base treatment decisions.

11.5 After investigating this matter thoroughly and on the basis that HCSCC has found that the services provided to Mr X met the generally accepted standards; and that there have been no obvious systemic issues of concern identified; it is recommended that HCSCC close this investigation and take no further action on this complaint.

11.6 It is recommended that a copy of this report - which outlines the reasons HCSCC has determined to close this investigation and take no further action with regards to it – is provided to Mr X, Mr X's GP and Mr X's treating specialist. With Mr X's permission or in a de-identified form, this report should also be provided to other parties that HCSCC believes would benefit from receiving this report; such as RCPA, AHPRA (Australian Heath Practitioner Regulation Agency) and NATA.

Signed: 

Health and Community Services Complaints Commissioner

Date: 18th February 2016

GLOSSARY of ABBREVIATIONS:

AACB	– Australasian Association of Clinical Biochemists
AHPRA	– Australian Health Practitioner Regulation Agency
CMO	– Chief Medical Officer
GP	– General Practitioner, doctor
HbA1c	– blood test used to measure glycated haemoglobin
HCSCC	– Health and Community Services Complaints Commissioner
MU	– Measurement Uncertainty
NATA	– National Authority of Testing Authorities
RCPA	– Royal College of Pathologists Australia