

## Safe reading of chemical pathology reports: the RCPAQAP Report Assessment Survey



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### Summary

Pathology reports are a vital component of the request-test-report cycle communicating pathology results to doctors to support clinical decision making. This should be done in a comprehensive, safe and time-efficient manner. As doctors may receive reports from different laboratories these goals can be achieved more readily if reports are formatted in the same way.

This study evaluates the formatting of paper reports produced by Australian laboratories for numerical biochemistry results. As part of the RCPAQAP Liquid Serum Chemistry program in 2015, laboratories were invited to supply a routine paper report displaying the results. A total of 37 reports were received for analysis. These reports were assessed for variation in a range of components and, where possible, against relevant Australian standards and guidelines. In summary, there was a wide variation in most of the report components assessed including test names, result alignment, result flagging, sequence of data elements on the page, date formatting and patient name formatting. In most components there was also variation from the Standards.

In order to ensure safe result transmission by printed reports there is a need to promote the adoption of current reporting standards and monitor compliance with similar external quality assurance programs.

*Key words:* Pathology report; APUTS; quality assurance; standardisation; Australian standards and guidelines; report rendering..

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### INTRODUCTION

The purpose of a pathology report is to communicate the results of the testing in a clear and unambiguous manner. It is clearly a patient safety issue if a report is misread in a way that may lead to an incorrect understanding of the results. A survey of physicians in the United States in 2011 found that 8.3% had uncertainty in the interpretation of pathology reports. Challenges included different names for the same test, tests not available except as part of a test panel and different tests included in panels with the same names. With more than 500 million primary case patients' visits per year, the level of

uncertainty reported in this study potentially affects 23 million patients per year and raises significant concerns.<sup>1</sup>

Additionally if a report is difficult to read, there can be valuable time lost in trying to correctly identify the key elements of the results. As noted by Stephen Ruby in 2000: 'The elements found to influence the understanding of a report's content include spacing, highlighting, formatting and font selection. These items, in and of themselves do not contribute to the content of the report; however they do appear to contribute substantially to the comprehension of that report.'<sup>2</sup> In the modern era doctors commonly receive pathology reports from a range of different laboratories. Examples include tests requested by a specialist, results from a hospital, results obtained while travelling or results from a different laboratory attended by the patient for convenience or other reasons. Against this background it can be seen that uniformity of reporting formats amongst laboratories can be beneficial in making the review of pathology reports easier and safer, irrespective of the testing laboratory.<sup>3</sup>

Guidelines aimed at improving the effectiveness of testing have been the subject of standardisation between medical groups for a very long time.<sup>4</sup> While there has been focus on communication using electronic systems,<sup>5,6</sup> paper reports remain in common use and rendered reports [e.g., PDF or PIT (Pathology Information Transfer protocol) formats] are very widely used in Australia.

In 2013 an initial Standard was published by the Royal College of Pathologists (RCPA) Pathology Units and Terminology Standardisation Project (APUTS). After public feedback, edits and finalised comments, the Standards and Guidelines were released in 2014 to assist in the requesting and reporting of pathology.<sup>7</sup> As highlighted in the introduction,<sup>7</sup> pathology reports have evolved from being department-specific to covering a whole patient episode and are distributed more widely and it is current practise for clinicians to receive reports from multiple laboratories. Errors related to the non-analytical aspects of pathology processes are widely described and are often a large portion of the risk in misinterpretation. There is anecdotal evidence that variation in report formats has led to misunderstanding and misreading of results which is a clinical safety issue. In order to facilitate uniformity there is a need to work at the detail level including location of columns of data, test names and importantly the flagging of abnormal results to bring these to the clinician's attention.<sup>8</sup>

Other guidance on report formatting has come from the National Association of Testing Authorities (NATA) Medical Field Application Document for ISO 15189.<sup>7,9</sup>

The RCPA Quality Assurance Programs (RCPAQAP) sought to review the current practise and adherence to the Standards and Guidelines by requesting participants enrolled in the Liquid Serum Chemistry Program to generate a hard copy report using the Liquid Serum Chemistry External Quality Assurance (EQA) results.

## METHOD

The Liquid Serum Chemistry (LSC) program involves sending two serum samples to enrolled laboratories in Australia and New Zealand. In 2015, data were managed for over 50 analytes and seven calculations based on measured results (e.g., anion gap, serum globulins). An additional component of the LSC program for 2015 was a request for a copy of a paper report as though the samples were routine patient requests and the report was being sent to the requesting doctor. The two samples were identified as one male and one female, both 40 years of age. The reports were reviewed manually under the headings covered by the APUTS standards<sup>7</sup> (Table 1) and assessed for differences between reports and compliance against the following standards: RCPA Pathology Units and Terminology Standardisation Project (APUTS) Standards and Guidelines,<sup>7</sup> and NATA Medical Field Application Document for ISO 15189.<sup>9</sup> Additional areas of variation in reporting not specified in current standards were identified and reported. A schematic of a report indicating the location of the items assessed is shown in Fig. 1.

## RESULTS

Of 176 laboratories enrolled in the LSC program in 2015, 37 (21%) returned a hard copy report to the program organisers. There were 23 different pathology providers that supplied results, of which six were pathology networks which supplied multiple reports results through a number of different sites.

### Concordance with specific standards

#### *Horizontal alignment of columns of numerical results*

*APUTS Standard 7.01: Numeric results must be right justified (when shown in columns) and have corresponding guidance values (e.g., reference interval) and units if these exist.*

One-third of the columns of numerical results were right aligned (34%) in conformity with the standard, while the

other two-thirds were evenly distributed between left alignment (33%) and central alignment (34%). Adherence to this guideline facilitates identification of an abnormal flag to the right of a set of vertically aligned digits (see below).

#### *Leading zeros for numerical results*

*APUTS Standard 7.02: Numeric results must have a leading zero where there is no number in the units place (i.e., 0.7 not .7).*

All reports had a leading 0 when there was no number in the units place. The results for serum urate (in mmol/L) was an example of this type of result. This standard avoids the risk of misinterpretation due to missing a decimal point at the start of a numerical value.

#### *Time direction across and/or down the page*

*APUTS Standard 7.03: For columnar cumulative reports the latest results must be shown in the furthest right column of results (i.e., time must go from left to right across the page) or at the top for cumulative reports shown in rows (i.e., time must go from the bottom to the top of the page).*

*APUTS Standard 7.04 reads as follows: The latest result must be differentiated from earlier results by at least two methods, one of which is a heading 'Latest Results'.*

As only five reports included cumulative results there were insufficient data to assess time direction and flagging of the most recent results.

#### *Formatting reference values*

*APUTS Standard 7.06: Guidance values must be bound by parentheses and have no spaces.*

Sixty-eight percent of reports had the numbers indicating the lower and upper reference limits bound by parentheses as stated in the standard, while 32% of reports did not. This type of formatting is aimed at clearly identifying the reference (guidance values).

**Table 1** APUTS Standards

APUTS Standards
S7.01: Numeric results must be right justified (when shown in columns) and have corresponding guidance values (e.g. reference interval) and units if these exist.
S7.02: Numeric results must have a leading zero where there is no number in the units place (i.e. 0.7 not .7).
S7.03: For columnar cumulative reports the latest results must be shown in the furthest right column of results (i.e. time must go from left to right across the page) or at the top for cumulative reports shown in rows (i.e. time must go from the bottom to the top of the page).
S7.04: The latest result must be differentiated from earlier results by at least two methods one of which is a heading 'Latest Results'.
S7.06: Guidance values must be bound by parentheses and have no spaces.
S7.07: The column showing units must be headed 'Units', be left justified and be to the immediate right of the 'Reference' column. Following this recommendation, the correct order for display of the report should be: Analyte Name, Result, Reference Interval, and Unit.
S7.08: The numbers used for guidance must be rendered with the same number of decimal places as the related result.
S7.09: Results are considered outside the guidance values if after rounding to the format of the displayed result (and the guidance) the result is greater than the higher number or less than the lower number of the guidance values. All reports followed this Guideline.
S7.10: Results outside the guidance values must be highlighted by at least two methods one of which is either an 'L' or 'H' one space to the right of the result ('L' for a result lower and 'H' for a result higher).
CS7.10a: A single asterisk (*) and the '+' and '-' characters should not be used for flagging results.
CS7.10b: Underlining of results should not be used for highlighting results.
CS7.10c: Colour was preferred by most respondents in the survey but because of colour blindness and possible loss of colour in some communications, if colour is used, then the font should also be bolded.
CS7.10d: Multi-level flagging may be used in which case 'LL' or 'HH' should be used for the second level.
S7.11: Headings must be differentiated from test names.
S7.12: Dates must be shown in the form 30-Jan-14 (i.e. not in the form 30/01/14).

S refers to standards and C refers to commentary related to the standard.

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