High Risk Results –
Update for Harmonisation 2019

Dr Que Lam
Chemical Pathologist, Austin Health
AACB Harmonisation meeting 2\textsuperscript{nd} May 2019
Aims:

1. **Recommendations** for the process of critical laboratory* results identification and notification.

2. “**Starter list**” of critical tests and values for laboratories to use as a basis for their own.

* Potential to apply to other pathology specialties.
Consensus Statement

AUSTRALASIAN ASSOCIATION OF CLINICAL BIOCHEMISTS INC

5/85 Bourke Rd, Alexandria NSW, 2015
Telephone: +61 2 9669 6600 Facsimilo: +61 2 9669 6607 Email: office@aacb.asn.au

Guideline

<table>
<thead>
<tr>
<th>Title</th>
<th>Consensus Statement for the Management and Communication of High Risk Laboratory Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Document Number:</td>
<td>2015 GD01</td>
</tr>
<tr>
<td>Publication date:</td>
<td>May 2015, February 2016</td>
</tr>
<tr>
<td>Next review date:</td>
<td>May 2020</td>
</tr>
<tr>
<td>Owner:</td>
<td>AACB/RCPA Critical results working party</td>
</tr>
</tbody>
</table>

Released in 2015.
Later that year, CLSI guidelines released.

Contains 8 key recommendations for laboratories.
Outlined terminology - endorsed use of “high risk”, “critical risk”, “significantly abnormal”.
“High Risk” Results

GP2.2 E High-risk (seriously abnormal and life-threatening) results identified outside normal opening hours are managed by our practice.

You must:

• give diagnostic services the contact details of the practitioner who ordered the investigation
• have a process for managing high-risk results identified outside of normal opening hours.

You could:

• educate practice team members about how anyone who provides diagnostic services or receives high-risk results outside of normal opening hours can contact the practice team members who have access to the patient’s health record
• provide current contact details to diagnostic services
• provide the contact details of the practice team members who can be contacted outside of normal opening hours when a diagnostic service receives high-risk patient results outside of normal opening hours.

Follow up of high-risk (seriously abnormal and life-threatening) results identified outside of normal opening hours

Your practice must manage seriously abnormal and life-threatening results identified outside of normal opening hours so you can provide prompt and adequate follow-up.

Your practice must have a process so that pathology and diagnostic services can contact the practice in urgent circumstances so information about the patient can be accessed.

You need to explain to deputising doctors what you expect them to do if they receive urgent and life-threatening results for one of your patients, as they have a responsibility to contact the general practice in such circumstances. This could be documented in a formal agreement between your practice and the service providing after-hours care.

Criterion GP2.2 – Follow-up systems

Indicators

GP2.2 A Pathology results, imaging reports, investigation reports, and clinical correspondence that our practice receives are:
• reviewed
• electronically notated, or, if on paper, signed or initialed
• acted on where required
• incorporated into the patient health record.

GP2.2 B Our practice recalls patients who have clinically significant results.

GP2.2 C Our patients are advised of the practice’s process for follow-up of tests and results.

GP2.2 D Our practice initiates and manages patient reminders.

GP2.2 E High-risk (seriously abnormal and life-threatening) results identified outside normal opening hours are managed by our practice.
“Starter” Alert List

- Evidence-based
- Hierarchy of Evidence defined.
- Priority list of analytes.
- Adoption of CLSI “risk assessment” model for determining alert thresholds.
- Defined steps to be undertaken including seeking endorsement from laboratory community and clinical colleges.

- Supported by AACB membership:
  - Shared alert lists, harmonisation meeting presentations.
High Risk Results: 2019 Update

KIMMS pilot program

Systematic reviews of critical values in key laboratory analytes Project
High Risk Results –
KIMMS Pilot 2019

Dr Que Lam
Chemical Pathologist, Austin Health
AACB Harmonisation meeting 2nd May 2019
# GP47

**Management of Critical- and Significant-Risk Results**

--

**Guideline**

<table>
<thead>
<tr>
<th>Title</th>
<th>Consensus Statement for the Management and Communication of High Risk Laboratory Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Document Number:</td>
<td>2015 GD01</td>
</tr>
<tr>
<td>Publication date:</td>
<td>May 2015, February 2016</td>
</tr>
<tr>
<td>Next review date:</td>
<td>May 2020</td>
</tr>
<tr>
<td>Owner:</td>
<td>AACB/RCPA Critical results working party</td>
</tr>
</tbody>
</table>

---

AUSTRALASIAN ASSOCIATION OF CLINICAL BIOCHEMISTS INC

5/35 Bourke Rd, Alexandria NSW, 2015

Telephone: +61 2 9669 6600 Facsimile: +61 2 9669 6607 Email: office@aacb.asn.au
Managing high risk results


1) compile an alert list(s) in consultation with its users;

2) have procedures to ensure that high risk results are reliably identified;

3) specify, in agreement with its users, the modes of transmission for the communication of high risk results;

4) specify, in agreement with its users, who is authorised to receive high risk results;

5) define what data needs to be communicated to the recipients of high risk results;

6) develop a system for the acknowledgement of the receipt of high risk results to confirm that results were accurately and effectively communicated;

7) ensure that every high risk result notification is appropriately documented;

8) have procedures that involve its users in maintaining and monitoring the outcomes of its high risk result management practices.
KIMMS - Key Incident Management and Monitoring System

Pre- and Post- analytical errors are reported to account for up to 70% of errors in the Total Testing Cycle for Pathology. The KIMMS program is designed to monitor the Key Performance Indicators, or Quality Indicators, for the pre- and post-analytical areas. The pre-analytical area’s covered include Patient Identification, Collection, Transport, Storage and within-laboratory non-analytical errors, while the post-analytical area’s covered are incorrect reports released and reports sent to incorrect doctors. Turn around time failure rate is used as a QI for the total testing cycle. Other pre- and post-analytical areas are reviewed through one-off “audit surveys”, which are run 4 times per year. Reports are produced on a regular basis, and results discussed at bi-yearly workshops.

March 2018 – High Risk Results introduced at KIMMS Workshop
What can a QAP for HR results achieve?

- **Benchmarking**
  - Compare the number of results flagged & notifications required.
  - Compare time taken for notifications.

- **Compliance**
  - Compliance of procedures with consensus statement
  - Compliance of staff with procedures.

- **Identification of problems**
  - Is there adequate communication?
  - Is there adequate documentation?

- **Measure of improvement**
  - Are we improving?
  - What parameters should we monitor ourselves?
CAP Q-Tracks

• 180 Labs, 4 years; 2-16 quarters of participation.

• Aim: determine the level of successful critical value reporting in the general laboratory for inpatients and outpatients

• % of successful critical results notification (documented)

• Rate of undocumented critical results per 1000 results.

• Included analytes common to most alert tables: general haem, chem and coag.

<table>
<thead>
<tr>
<th>Table 6. Distribution of Cumulative Undocumented Critical Value Rates per 1000 Results for 180 Laboratories During the First Year of Participation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rate of Undocumented Critical Values per 1000 Results</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Total</td>
</tr>
<tr>
<td>Inpatient</td>
</tr>
<tr>
<td>Outpatient</td>
</tr>
</tbody>
</table>

**Table 2. Techniques or Processes Used by Best Performers That May Account for Higher Than Average Critical Values Reporting Rates**

- Written report is issued for failure to document critical value communication.
- Three times per day a computer report is generated to verify critical value notification; an additional report is generated the following morning to verify notification of all critical values from the previous day.
- For panic values, the laboratory computer system retrieves the physician’s name and telephone number and requires documentation of the notification.
- Frequent training is provided on the importance of critical values and the correct way to document notification, and follow-up on any failures.
KIMMS Survey

- Survey Monkey: link and pdf of survey questions.

- Questions written in a general format hopefully applicable to any test with critical risk results e.g. low platelets, positive blood cultures, biopsies with Cancer Dx.

- Customised for particular test e.g. Calcium – asked for a month of data (specified dates 1/1/2019 – 31/01/2019).

- “Road tested” the survey

- Questions categories:
  - Alert thresholds and no. of total and critical results
  - Notification; successful and not successful.
  - Complexity e.g. population, time required, need to escalate.
  - Barriers to successful notification.
Observations

• Note: Survey still open so this presentation contains my analysis of preliminary results (up to 29\textsuperscript{th} April 2019)

• Some survey questions were still confusing despite “road test”.
  • Despite introduction with definitions.

• Some incomplete surveys – had to make judgement as to whether attempt abandoned or could not supply information.

• More than one lab discovered that their IT rules for identification of high risk calcium results were not configured as they thought.

• Variation between laboratories as to exact level called e.g. 3.00 vs. 3.01 mmol/L.

• Less responses when more “manual” data extraction was required.
Response*

- **49** responses
  - Labs were asked to respond individually – more useful for benchmarking?
  - **All** had Critical Alert Thresholds (high and low) for serum Ca.

4. Is this for Total Calcium or Corrected Calcium?

- [ ] Total Calcium
- [ ] Corrected Calcium

*Up to 29/4/2019
Critical Alert thresholds - calcium

23 different sets of thresholds

**Critically High Calcium (Total and Adjusted) Thresholds (mmol/L)**
- Range = 2.80 – 3.51

**Critically Low Calcium (Total and Adjusted) Thresholds (mmol/L)**
- Range = 1.49 – 1.90
44/44 labs offered data on critically high calcium results reported.

Total Calcium results: 150 – 143000

Columns = no. of critical high results per 1000 Ca results

Actual no. of critical high results: 0 – 110
42/44 labs offered data on critically low calcium results reported.

Total Calcium results: 150 – 143000

Columns = no. of critical low results per 1000 Ca results

No. of critical low results: 0 – 30
Documentation of action.

11. Of those Calcium results that were outside your critical thresholds, how many notifications to referrers were:
   (please leave blank if you are unable to extract this data)
   Attempted - Successfully
   Attempted - Unsuccessfully
   Not attempted - lab decision rule
   Not attempted - non-conformance

• What evidence does the laboratory have?
  • Documentation
• Do results affected by pre-determined rules need documentation?
Failure to follow procedure

Unsuccessful Critical Calcium Results

Opportunity to ask why
Time take for notification.

12. Of those that were successfully notified, what was the median and range of time taken between when the result was ready for notification and when successful notification occurred.

If you are not able to supply this data, please enter NA.

Median result (in mins) 

Time range (in mins) 

Range: 0 – 90 mins
Questions that were too difficult?

13. Of those attempted unsuccessfully, how many involved your escalation procedure and, if known, what was the outcome for the patient? Please answer NA if you do not have an escalation policy, or leave blank if you are unable to extract this data.

14. For those results not notified due to non-conformance, please list reasons for the non-conformance.

Q 13. Attempt at using escalation procedures as a marker of complexity.

Some thoughts

• We need to think carefully about what is useful to measure and how that data is presented to labs.

• We need to think about minimising the work labs need to do to extract their data. The more automated the extraction, the wider the survey time period.

• Better to adopt CAP approach? Ask fewer questions e.g. just ask for undocumented critical results, but ask this for a number of analytes at a time e.g. K, Ca, Cortisol in the month of January.

• Over the year, a number of surveys to look at different aspects of data. e.g. Survey 1 concentrate on alert thresholds and no. of critical results for a few tests; Survey 2 concentrate on documentation—name, read-back etc.; Survey 3 concentrate on time taken for notification, time of day, inpt vs. outpt.
Acknowledgements

Stephanie Gay
Angela Sanders
Susan Benson
Tony Badrick
High Risk Results – Systematic reviews of critical values in key laboratory analytes

Dr Que Lam
Chemical Pathologist, Austin Health
AACB Harmonisation meeting 2\textsuperscript{nd} May 2019
A common list of alert thresholds

Approached from many angles.

- Evidence-based, risk assessment.
  - Essential for harmonisation.

- Surveys of thresholds

- List of essential analytes

- Personal literature review

Conclusion:

Systematic approach to reviewing evidence required.

Resources required.
“Systematic reviews of critical values in key laboratory analytes” Project

- Volunteers
- Participants will undergoing training in a full day workshop at MQU
  - Developing a research question, inclusion/exclusion criteria
  - Search strategies and key word/headings
  - Database searching
  - Using Endnote
  - How to perform literature screening
  - Data extraction and quality assessment
- In small groups, under supervision on MQU team, assigned 2-3 analytes to review (16 week)
- Reports presented to HR WP
- WP to review report and following further discussions, recommend alert threshold.
Support for the Project

1st Round is a “pilot” round.

Generous support by RCPA and AACB who have offered scholarships to help cover the cost involved especially use of MQU staff time.

If successful,

- Further rounds – more analytes
- Program could be utilised for other projects
- Ongoing funding

- “Proof of concept” – Wilson Punyalack
## Acknowledgements

**Macquarie University**
- Professor Andrew Georgiou
- Dr Rae-Anne Hardie
- Dr Nasir Wabe
- Dr Ling Li
- Mr Gorkem Sezgin
- Ms Julie Li

**Professor Rita Horvath**
- Dr Que Lam
- Craig Campbell
- Wilson Punyalack