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Guideline

Title **Consensus Statement for the Management and Communication of High Risk Laboratory Results**

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The Australasian Association of Clinical Biochemists (AACB) and the Royal College of Pathologists of Australasia (RCPA) have developed these recommendations as a tool to assist laboratories in the reporting and management of high risk results. Each recommendation includes indicators of the strength of the recommendation (“needs to”, “should” and “may”), which reflect the consensus views of the expert working party. The use of these recommendations is subject to the judgement of individual laboratory practices.

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SUMMARY

Ineffective test follow-up is a major source of harm for patients around the world. Unreliable communication from medical laboratories (henceforth termed “laboratories”) to clinicians of results that represent critical or significant risk to patients (collectively termed “high risk results”) is a contributing factor to this problem. Throughout Australasia, management practices for such results vary considerably. The recommendations presented in this document are based on best practice derived from the published literature and follow consultation with a wide range of stakeholders. These recommendations were created to harmonise Australasian practices by guiding laboratories in the design and implementation of

safe and effective communication procedures for managing high risk results which require timely notification.

TERMINOLOGY

Medical Laboratory: A laboratory for the examination of materials derived from the human body for the purpose of providing information for the diagnosis, management, prevention and treatment of disease in, or assessment of the health of, human beings, and which may provide a consultant advisory service.¹ This definition is adapted from AS ISO 15189 and includes here any examinations performed near or at the site of the patient; “point-of-care” testing.

Test result: The result of an examination produced by a laboratory. This may be quantitative, semi-quantitative or qualitative.

Critical test: A test that requires immediate communication of the result irrespective of whether it is normal, significantly abnormal or critical.

Critical risk result: Results requiring immediate medical attention and action because they indicate a high risk of imminent death or major patient harm.²

Significant risk result: Results that are not imminently life-threatening, but signify significant risk to patient well-being and therefore require medical attention and follow-up action within a clinically justified time limit.²

High risk results: A collective term used to denote results that require communication in a timely manner; i.e. critical risk results, significant risk results and results of critical tests.

Alert threshold: The upper and/or lower threshold of a test result or the magnitude of change (delta) in a test result within a clinically significant time period, beyond which the finding is considered to be a medical priority warranting timely action.

Alert list: A list of critical tests and tests with alert thresholds for high risk results ideally reflecting an agreed policy between the laboratory and its users for rapid communication within a pre-specified time frame and according to a procedure.

User of laboratory: Medical Practitioner, nurses and other health care professionals directly involved in patient care.

Referral laboratory: An external laboratory other than the primary testing laboratory to which a sample is submitted for further examination.¹

Escalation procedure: An ordered list of alternative steps to be followed when the appropriate recipient(s) of a high risk result cannot be reached in a clinically appropriate time frame.

KEY RECOMMENDATIONS Laboratories and their users need to have shared policies and procedures, involving patients and their carers, for the effective communication and management of high risk results in order to ensure patient safety. To achieve this goal, the laboratory should:

- 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.

BACKGROUND

Laboratory test results support clinical decision making in the majority of clinical interventions.^{3,4} Thus when a high risk result is obtained on a patient, it is imperative that the clinician is alerted so that appropriate action can be taken to improve patient care and optimise clinical outcomes.

In 2008, a report published by the World Health Organization World Alliance for Patient Safety identified poor test follow-up as a major cause of harm for patients around the world.⁵ Poor test follow-up was found to manifest as delayed treatment or failure to treat inpatients with high risk laboratory results, and failure to forward such results to the primary care providers of discharged patients. In 2010, the Clinical Excellence Commission Patient Safety Team analysed incidence data from the NSW health system to identify contributing factors and possible solutions for failure to follow up diagnostic test results.⁶ Issues identified include: poorly defined time frames for test reporting; inconsistent mechanisms for clinicians to identify high risk results which have not been reviewed; and considerable variation in the process for communicating these unexpected results. Recommendations to improve test follow-up include: capability requirements for the electronic medical record system; the creation of management procedures to ensure timely and effective use of test results; and use of key performance indicators to monitor time frames for formal reporting.

The ISO 15189 accreditation standard requires that pathology laboratories communicate high risk results to clinical personnel responsible for the patient.¹ The standard offers little guidance

for laboratories on best practice and the actual procedures to be followed. A survey of Australasian laboratories revealed considerable variation in high risk result management practices.⁷ The procedures used by many of these laboratories for communicating high risk results do not reflect the various safe practice recommendations reported elsewhere.⁸⁻¹²

SCOPE AND PURPOSE

The purpose of this document is to provide Australasian laboratories and their users with guidance on how to design shared policies and procedures for the management of high risk results in order to improve the effectiveness and safety of care delivered to patients. The recommendations within this consensus statement are expected to facilitate harmonisation in the management of high risk results notification in Australasia, ensuring that all laboratories are able to achieve best practice. This should enable benchmarking leading to further improvements in the quality of service delivery.

GUIDELINE METHODOLOGY

The Royal College of Pathologists of Australasia (RCPA) and the Australasian Association of Clinical Biochemists (AACB) formed a working party with the aim of promoting best practice and harmonisation of high risk result management throughout Australasia.

The members of the working party are listed in Appendix 1.

To develop these best practice recommendations, the working party undertook a literature search to identify international accreditation requirements, guideline and best practice recommendations and current practices for managing high risk results. The key elements of a results notification management system, as published elsewhere, provided the framework for developing these recommendations. The first draft of these recommendations was produced on the basis of evidence and information gathered from the literature. The working party reviewed the draft, and amendments were made by consensus.

A wide range of experts and organisations representing the relevant stakeholders, including a broad range of laboratory, clinical, patient and patient safety groups, were then invited to make formal comments on the draft (see Appendix 2). The working party reviewed and discussed all comments and amended the final draft of the document accordingly. The final draft was then sent to RCPA and AACB for endorsement and official release.

In these recommendations the terms ‘needs to’, ‘should’, and ‘may’ are used in reference to the strength of the recommendation in descending order. This grading reflects the weight the working party assigned on the basis of the potential impact of the recommendation on patient safety. Recommendations using the word:

- 'needs to' represent approaches where national harmonisation is necessary for patient safety and/or medico-legal reasons (where relevant); these recommendations are expected to be implemented without modification.
- 'should' represent approaches where national harmonisation is desirable for best practice but some variations may be acceptable, provided they fulfil the main aims of the recommendation.
- 'may' represent approaches where national harmonisation is not essential and laboratories may choose to depart from or modify the recommendation.

TARGET GROUP

This consensus statement targets stakeholders who are involved in developing procedures for managing high risk results:

- Pathology service staff • General Practitioners and their staff • Medical Specialists and their staff
- Nurses and midwives
- Carers of patients
- Patients and/or patient representatives
- Patient safety committees or organisations
- Laboratory accreditation bodies and assessors
- Health information specialists

RECOMMENDATIONS

Laboratories and their users need to have shared policies and procedures for the effective management of high risk results in order to ensure patient safety. Such policies and procedures should cover the key items below:

- 1) The laboratory should compile an alert list(s) in consultation with its users. •**
 - The alert list(s) needs to contain 1) the name of the tests; 2) the reporting unit of the test; 3) the alert thresholds (e.g. upper, lower and/or delta thresholds) beyond which results require notification; 4) the timeframe of notification.^{8, 11-18}
 - Alert list(s) should be developed in consultation with the representative clinicians using risk assessment principles.^{7, 9, 14-16, 18-27}
 - Where feasible, separate lists or separate entries on a list may be created for different patient groups and settings.^{8, 16, 18, 20, 28-30}

Eg age-specific, ward-specific, inpatient, community setting, specialist referrals, etc.

Laboratories are discouraged from having unique alert lists and/or thresholds for individual clinicians as this will add complexity and potentially compromise the process of communication.

- The list(s) may be divided into categories based on the degree of clinical risk, with each category assigned a clinically appropriate time frame within which results need to be communicated.^{8, 11, 15, 17, 31}

Eg A serum potassium of 7mmol/L requires immediate communication, while new hyperthyroid results may be communicated on the next working day.

- The alert thresholds (e.g. upper, lower and/or delta thresholds) should preferably be determined on the basis of clinical outcome data using published literature sources, or expert consensus (e.g. published in national or international guidelines) where available.^{7-9, 14, 21, 23, 24, 26, 27} Any literature or other sources used should be documented.
- The alert thresholds selected for the list(s) may be modified based on local patient population and consensus.^{7, 14, 27, 29} If those alterations are adopted by the laboratory, the rationale and source should be documented.⁹
- Conditions under which it is decided not to communicate results within the limit(s) normally requiring notification need to be pre-determined in consultation with clinicians.^{8, 9, 20, 29, 32} These conditions need to be clearly specified and a record kept of the reasons for such decisions.

Eg It may be pre-determined that there is no need to urgently communicate a result which is similar to that obtained previously in the same patient, or where a result is expected for a given diagnosis.

- Users of the laboratory service should be provided with ready access to the alert list(s).

Eg the laboratory could make the list(s) available over the internet.^{9, 20}

2) The laboratory should have procedures to ensure that high risk results are reliably identified.

- The laboratory should have procedures which include an alert system to inform laboratory staff when a high risk result has been generated.^{14, 15, 26, 27} The system should distinguish high risk results from other results.
- The laboratory should have procedures for identifying potential errors in the testing process in order to communicate only valid results.^{7, 9, 14, 18, 20, 33} If an initial result is deemed critical risk the laboratory may communicate a

preliminary result to allow for early clinical intervention.⁷ In such cases the user is informed that the result is preliminary and will be confirmed by repeat or further testing.

3) The laboratory should specify, in agreement with its users, the modes of transmission for the communication of high risk results.

- For patient safety, reliable modes of transmission (verbal/non-verbal) which enable immediate notification and acknowledgement of receipt are preferred, especially for critical risk results.^{8, 20, 21, 28, 34}
- Verbal notification should be performed by an adequately trained individual who is judged to be competent.¹⁴ The list and competence of personnel authorised to communicate high risk results should be monitored and regularly updated.
- Non-verbal modes of transmission may also be acceptable forms of communication provided that they are secure, reliable, and have been agreed upon by the users of the laboratory's services.^{35, 36}
- For referred tests, the referral laboratory should be responsible for communicating high risk results.
- The laboratory needs to include a provision for confidentiality of communications within its protocols. However, consideration should be given to situations where patient safety may take precedence over normal confidentiality conventions.

E.g. In situations where clinical staff cannot be contacted and the results are from a child, the parent(s) should be contacted to initiate appropriate action in response to the results.

4) The laboratory should specify, in agreement with its users, who is authorised to receive high risk results.

- Notification of a high risk result should, where feasible, be made to the clinician immediately responsible for the patient's care.^{7, 8, 10, 11, 13, 15, 17, 20, 21, 31, 37-39}
- An escalation procedure needs to be established to guide laboratory staff in locating a suitable recipient for the result.^{7, 8, 11, 14, 15, 17, 18, 21, 39} For community based patients there may be a need to contact the patient or carer in event that their clinician is uncontactable and the result is critical.^{7, 39} (see Appendix 3 for examples)
- The laboratory and its users should endeavour to keep the database of contact details for result notification up-to-date.^{7, 11, 14, 20, 22}
- The laboratory should have procedures which request that current patient contact phone numbers are provided on request forms.¹⁰

5) The laboratory should define what data needs to be communicated to the recipients of high risk results.^{9-11, 14}

- The information communicated to the recipient of a high risk result should include the:
 - i) identity of the notifier;
 - ii) identity of the patient tested;
 - iii) date and time that the sample was collected
 - iv) test that was performed;
 - v) test result (with the units of measurement where relevant).

Additional information available to a recipient upon request should include the:

- vi) sample type;
 - vii) reported reference interval or clinical decision limit(s) for the test.
 - viii) Offer of pathologist assistance or explanation as appropriate, especially for unexpected critical results
- 6) **The laboratory should develop a system for the acknowledgement of the receipt of high risk results to confirm that results were accurately communicated.**
- The laboratory should develop a system for the acknowledgement of the receipt of high risk results and to confirm that the result was accurately communicated.
 - In verbal communications, the notifier should confirm that the information has been received and understood correctly.^{7-9, 11, 13, 14, 19, 22, 24, 26, 39-45}

Eg results (with their units of measurement where relevant) can be repeated back by the recipient.

- Non-verbal modes of communication of high risk results should be established in such a way that the recipient acknowledges receipt of results within an appropriate pre-determined time period.^{8, 15, 21, 36, 46-48}

Note: High risk results communicated by facsimile need to be followed up by a telephone call from the laboratory to the recipient to confirm receipt of the faxed report.

- 7) **The laboratory should ensure that every high risk result notification is appropriately documented.**
- Laboratory record systems or data source should contain the:
 - i) date and time that the notification was made;
 - ii) identity of the patient tested;
 - iii) date and time that the sample was collected;
 - iv) test that was performed;
 - v) test result with the units of measurement;
 - vi) identity of the recipient of the notification;

- vii) date and time of the acknowledgement of receipt of the result.^{8, 9, 11, 14, 19-21, 36, 43, 49}

- For verbally communicated high risk results, the laboratory record or data source should also contain the identity of the notifier.^{8, 9, 11, 14, 19-21, 49}
- Records of any forms of communication should be documented in real time and need to remain traceable in the laboratory information or quality records systems for a period of time as specified by relevant regulations.²⁰

Note: For example, within Australia, this is a minimum of 7 years for adult patients and longer for paediatric patients or particular pathology disciplines.⁵⁰

- Any difficulties in meeting the requirements for result notification should be documented within the record.^{1, 11, 14, 19, 10, 28, 51}

8) The laboratory should have procedures that involve its users in maintaining and monitoring the outcomes of its high risk result management practices.

- The laboratory's alert list(s) and management procedures should be reviewed and updated where feasible in consultation with representative users of the service at least every 3 years or sooner if new information or technology arises.^{7, 8, 11, 14}
- Quality indicators should be used to monitor laboratory performance in communicating high risk results.^{7-10, 14, 16, 19, 51, 52} Parameters monitored should include the percentage of high risk results that were successfully communicated and the times taken to communicate results (from the time such results became available).^{7, 14, 16, 17, 19, 53-55}
- Auditing of the notification records should be performed to measure staff compliance with high risk result notification procedures and to identify any recurring difficulties met by staff in communicating high risk results.^{11, 16}

EXPIRY DATE This document will be reviewed in May 2020.

CONTRIBUTORS TO THESE RECOMMENDATIONS

These recommendations are endorsed by the AACB and RCPA.

Appendix 1 – Members of the RCPA-AACB working party:

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- Dr Grahame Caldwell, Chemical Pathology Director, Douglass Hanly Moir Pathology, NSW
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- Dr Penelope Coates, Clinical Director Chemical Pathology, South Australia Pathology, SA
- Mr. Robert Flatman, Assistant Manager Biochemistry, Sullivan Nicolaides Pathology, Qld
- A/Prof. Andrew Georgiou, Senior Research Fellow, Australian Institute of Health Innovation, University of New South Wales, NSW
- Prof. Andrea Rita Horvath, Clinical Director, Department of Clinical Chemistry and Endocrinology, South Eastern Area Laboratory Services, NSW Health Pathology, NSW
- Dr Alan McNeil, Chemical Pathologist, Head Biochemistry, Dorevitch Pathology, Vic.
- Prof. Hans Schneider, Director of Pathology, Alfred Pathology Services, Vic

Appendix 2 - Stakeholders invited to make formal comments on this paper:

- Australasian Association of Clinical Biochemists (AACB) Harmonisation Committee
- The Australasian College for Emergency Medicine (ACEM)
- Australian Commission on Safety and Quality in Health Care.
- Clinical Excellence Commission, New South Wales
- College of Intensive Care Medicine of Australia and New Zealand (CICM)
- Consumers Health Forum of Australia
- International Committee for Standardisation in Haematology (ICSH)
- National Association of Testing Authorities, (NATA) Australia
- National Coalition of Public Pathology (NCOPP)
- National E-Health Transition Authority (NEHTA)
- National Pathology Accreditation Advisory Council (NPAAC)
- National Prescribing Service Diagnostic Expert Advisory Panel
- Pathology Associations Council (PAC)
- Pathology Australia
- Pathology Information, Terminology and Units Standardisation Project (PITUS) Working group 3 - Safety in Pathology reporting, RCPA

- Public commenting (through the AACB and RCPA websites)
- Royal College of Pathologists of Australasia (RCPA)
- Royal Australian College of General Practitioners (RACGP)
- Standards Australia IT 14-6-5 Messaging Committee
- University of New South Wales (UNSW) Safety Unit

Feedback on this document in draft stage, was gratefully received from:

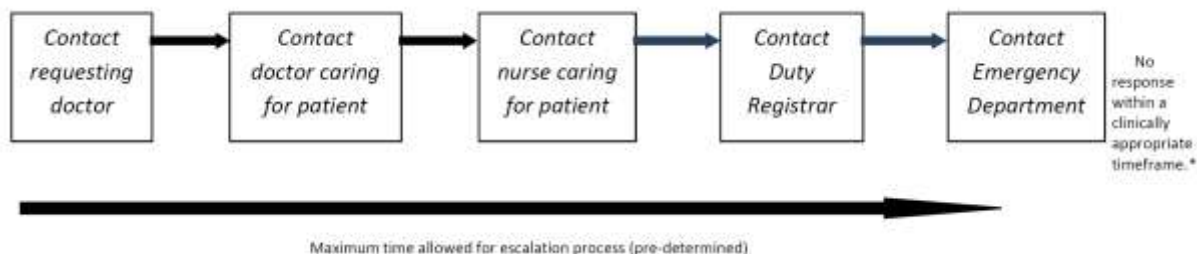
- A/Prof. Shane Carney, School of Medicine and Public Health, HNE Health, NSW.
- Prof. Mark Harris, UNSW Scientia Professor and Executive Director Centre for Primary Health Care and Equity and Director of COMPaRE-PHC (Centre for Obesity Management and Prevention Research Excellence in Primary Health Care).
- Tim Usherwood, Professor of General Practice, University of Sydney.
- A/Prof Michael Legg, Chair RCPA Informatics Committee.
- Dr Vincent McCauley, National eHealth Implementation Coordinator, Medical Software Industry Association (MSIA).
- Michael Cousins on behalf of Health Consumers Alliance of SA.
- Sally Crossing AM, Convenor, Cancer Voices Australia.
- Julie Marker, Acting Chair, on behalf of Cancer Voices South Australia.
- Priyanka Rai, Policy and Communications Officer, on behalf of Consumers Health Forum of Australia.
- Mrs Geraldine Robertson, Consumer.
- Janney Wale, RCPA Lay Committee member.
- Simon Benson FIBMS, President on behalf of Australian & New Zealand Society of Blood Transfusion (ANZSBT)
- Cathy Brehmer, Quality Officer on behalf of LabPlus, NZ
- Herb Carman, Manager Governance and Performance on behalf of PathWest Laboratory Medicine, WA.
- Peter Edwards, Section Head Haematology, Canterbury Health Laboratories, NZ.

- Linda Henshaw, Quality Team Manager, Canterbury Health Laboratories, NZ.
- Mr Alan Neal, Quality Manager, Pathology Associates, NZ.
- Angela Sanders, Quality Management Scientist on behalf of Northern Territory Government Pathology Service (NTGPS)
- Ms Jenny Sikorski, CEO on behalf of National Coalition of Public Pathology (NCOPP)
- Lesney Stuart, Section Head Biochemistry, Canterbury Health Laboratories, NZ.
- Mr Robert Wardrop, Senior Managing Scientist in Charge, QEII, PathWest Laboratory Medicine WA.
- Dr Trinia Gregory, GP and member of RACGP eHealth Committee and PITUS Project.
- Anthony Scander, Clinical Governance Unit – Clinical Functional Assurance Lead on behalf of NEHTA
- Dr Helen Wordsworth, member of Steering Committee of PUTS; Haematologist SNP.
- Dr Phillip Gray VMO (GP), Queanbeyan District Hospital, NSW.
- Dr Ross E. Hendry, General Practitioner , Queanbeyan, NSW
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- Dr Geoff Smith, Chemical Pathologist, Southern Community Laboratories, Dunedin, NZ
- Dr Janet Warner, Chemical Pathologist, Mater Pathology, Qld.
- A/Prof Graham White, Chief Clinical Biochemist, Flinders Medical Centre, SA Pathology
- Debra Graves, CEO on behalf of RCPA.

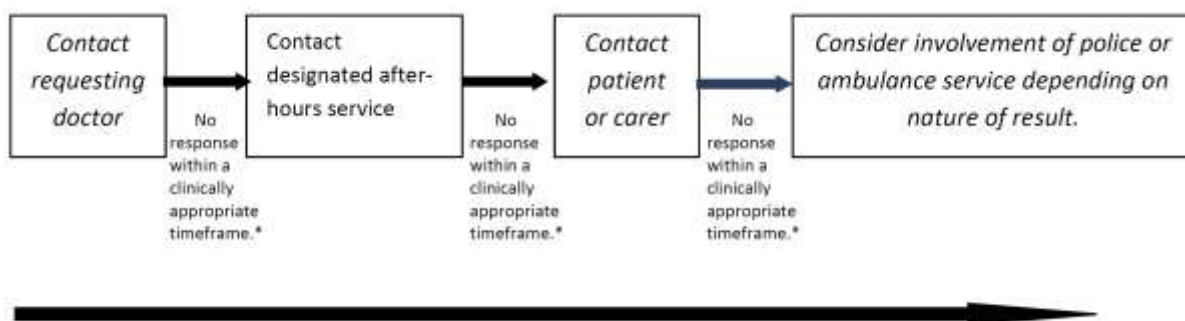
Appendix 3- Examples of Escalation Procedures

Note: These examples are for illustration only and may not be suitable for every laboratory and their users.

Example Escalation procedure for inpatients:



Example Escalation procedure for community patients: *



Clinically appropriate timeframes will differ between different categories of high risk results and should be pre-determined in the laboratory procedures.

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