Review Article

Towards Harmonisation of Critical Laboratory Result Management - Review of the Literature and Survey of Australasian Practices

CA Campbell,[1] *AR Horvath[1,2,3]

[1]SEALS Department of Clinical Chemistry, Prince of Wales Hospital; [2]Screening and Test Evaluation Program, School of Public Health, University of Sydney; [3]School of Medical Sciences, University of New South Wales, Sydney, NSW 2031, Australia.
*For correspondence: Andrea Rita Horvath, rita.horvath@sesiahs.health.nsw.gov.au

Abstract

Timely release and communication of critical test results may have significant impact on medical decisions and subsequent patient outcomes. Laboratories therefore have an important responsibility and contribution to patient safety. Certification, accreditation and regulatory bodies also require that laboratories follow procedures to ensure patient safety, but there is limited guidance on best practices. In Australasia, no specific requirements exist in this area and critical result reporting practices have been demonstrated to be heterogeneous worldwide.

Recognising the need for agreed standards and critical limits, the AACB started a quality initiative to harmonise critical result management throughout Australasia. The first step toward harmonisation is to understand current laboratory practices. Fifty eight Australasian laboratories responded to a survey and 36 laboratories shared their critical limits. Findings from this survey are compared to international practices reviewed in various surveys conducted elsewhere. For the successful operation of a critical result management system, critical tests and critical limits must be defined in collaboration with clinicians. Reporting procedures must include how critical results are identified; who can report and who can receive critical results; what is an acceptable timeframe within which results must be delivered or, if reporting fails, what escalation procedures should follow; what communication channels or systems should be used; what should be recorded and how; and how critical result procedures should be maintained and evaluated to assess impact on outcomes.

In this paper we review the literature of current standards and recommendations for critical result management. Key elements of critical result reporting are discussed in view of the findings of various national surveys on existing laboratory practices, including data from our own survey in Australasia. Best practice recommendations are made that laboratories are expected to follow in order to provide high quality and safe service to patients.

Introduction

Clinical laboratories play an important role in promoting patient safety by timely release and communication of critical results that may have significant impact on medical decisions and subsequent patient outcomes. Due to improved pre-analytical systems, robotics and automation, laboratory results of higher analytical quality are produced faster. Paradoxically, post analytical processes and critical result notification practices are far less standardised and are more prone to human error or non-compliance and may threaten patient safety and potentially lead to litigation. Whilst information technology rapidly transforms the ways and improves the efficiency of communication between laboratories and the users of their services, there is increased awareness of information overload and resulting communication breakdowns that may cause harm to patients.[1] Recognising the complexity and importance of timely delivery of critical results, certification, accreditation and regulatory bodies require that laboratories have procedures in place to ensure patient safety, but there is limited information in the literature on best practices that work

most efficiently. In Australasia, no guidelines or standards exist in this area and critical result reporting practices have been demonstrated to be heterogeneous worldwide.

Therefore the Australasian Association of Clinical Biochemists (AACB) has undertaken a quality initiative to harmonise critical laboratory result management. Key elements of such harmonisation are to design specific recommendations or standards for best practice to support the implementation of uniform policies and procedures, and a master list of critical limits that are ideally based on scientific evidence, preferably derived from clinical outcome studies or, in the lack of such information, on the consensus of key stakeholders. Due to the lack of appropriate outcome data, currently there is no universal consensus on critical limits at which results should be urgently communicated to responsible caregivers. Furthermore, as laboratories serve different patient populations at various settings of care, critical limits must be determined accordingly and in agreement with clinicians. These factors make an ultimate master list of critical limits for use by all laboratories difficult to design. Acknowledging these difficulties and gaps in our current knowledge and evidence base, the AACB harmonisation project on critical result management focuses on a more pragmatic approach and aims to create a set of best practice recommendations for laboratories to use in their design of critical result management procedures. In addition, based on a systematic literature review and survey and consensus of laboratories, a 'starter set' of critical limits will be developed which individual laboratories can tailor according to their clients' needs.

In this paper we review the literature of current standards and recommendations for critical result management. Key elements of critical result reporting are discussed in view of the findings of various national surveys on existing laboratory practices, including some data from our own survey in Australasia.

Definitions

Before discussing critical result management in more depth a few terms need to be defined. So far there is no international consensus on the best terminology and many terms are used interchangeably in the literature. *Critical result* is defined by Lundberg as a result that is so extremely abnormal that it is considered life threatening or that could result in significant morbidity and which, therefore, requires urgent action.[1,2] Commonly used alternative terms are 'critical values', 'panic values', 'critical alarms' or 'alarm values'. Critical results can not only be quantitative or semi-quantitative values but also qualitative results that exceed actionable thresholds (i.e. critical limits) and therefore need urgent notification. Therefore we advocate the term critical results, rather than critical values. We discourage the use of the term 'panic value' as laboratories are expected to have carefully planned and well-designed systems in place for professionally managing critical results.

We differentiate life-threatening critical results from *significantly abnormal results*, i.e. non-life threatening results that need attention and follow up action as soon as possible, but for which timing is not as crucial as for a critical result.[1] These are also termed as 'vital' or 'life-altering' or 'markedly abnormal results of medical significance'. In the absence of an internationally agreed terminology, we use the term *significantly abnormal results* throughout this paper. *Critical test* refers to a test that requires rapid communication of the result irrespective whether it is normal, significantly abnormal or critical (e.g. Troponin results in all requests from the emergency department, or all paracetamol results).[1] *Critical limit* refers to the upper and/or lower boundary of a result or the change of a result within a critical time scale beyond which the finding is considered to be a medically urgent critical result that warrants prompt action. Other synonyms used include critical value, critical value limit, alert limit, critical or alert interval or range, and critical decision limit or threshold. We recommend using the simple term of critical limit.

Key Elements of Critical Result Management

A critical result management system involves the consideration and work-up of a number of key components (Table 1) which need to be organised into a consistently and reliably operating system of several complex processes. Critical result management presents a communication challenge at the laboratory-clinical interface and only achieves its ultimate goal if appropriate clinical decisions and actions follow the communication of results. The World Health Organisation's World Alliance for Patient Safety has identified poor follow-up of critical or significantly abnormal test results.[3] A recent systematic review also found that 20-60% of inpatient test results were overlooked and unattended, and most of these errors were encountered with critical results, particularly when patients moved across health care settings. The most important adverse outcomes were missed diagnosis and inappropriate or delayed treatment decisions.[4] Therefore successful implementation of a critical result management system can only be achieved if a shared policy and procedures are developed, implemented, and monitored by all stakeholders.

Review of Critical Result Management Policies and Procedures

Timely communication of critical results is an accreditation

Table 1. Key critical result management procedures developed by the laboratory in agreement with clinicians.

Key Management Procedures
• Definition of critical tests and critical limits
• Critical result notification procedures
– How are critical results identified?
– Timeliness of reporting
– How and via what communication channels are critical results notified?
– Who can report critical results?
– Who can receive critical results?
– How is receipt of results acknowledged?
– What should be recorded?
– Escalation or fail-safe procedures if reporting is unsuccessful within the predefined timescale
• Procedures for the maintenance of critical results management procedures and monitoring the outcomes.

requirement worldwide. However, accreditation standards are rather generic. Several countries have surveyed their laboratories and identified large variations in practices, which has resulted in the development of a few national guidelines. Below we review some initiatives that are most relevant to the AACB Harmonisation Project.

Accreditation Standards

ISO 15189 international standard

Three subclauses within the ISO 15189 accreditation standard address the management of critical results.[5] Subclause 5.8.7 states that a 'laboratory shall have procedures for the immediate notification of clinical personnel responsible for patient care when examination results for critical properties fall within established critical intervals'. Subclause 5.8.8 requires a laboratory to 'determine the critical properties and their critical intervals in agreement with the clinicians using the laboratory'. Subclause 5.8.10 demands that records be maintained of actions in response to critical results, with difficulties in meeting these requirements also recorded and reviewed during audits. Thus, apart from seeking agreement with clinicians, there is no specific guidance given for managing critical results and thus heterogeneous practices may be accredited in different laboratories.

Accreditation requirements in Australia and New Zealand

In Australia, the National Pathology Accreditation Advisory Council (NPAAC) issues guidance to laboratories and accrediting agencies and sets minimum standards considered acceptable for good laboratory practice.[6] In relation to critical results, no specific requirements are mentioned but the topic is indirectly covered in commentary 7.1 under Standard 7 for recording any telephone or verbal communications. This requires that laboratories record the reasons for reporting (e.g. critical results), by whom and to whom results are communicated, and the date and time of the call. NPAAC requirements for information communication, in reference to Standard 5.2, provide guidance (G5.2.c) on how laboratories should phone or fax urgent or critical results if electronic result notifications fail and the recipient does not acknowledge receipt of results within one hour. It also refers to appropriate documentation of all actions taken in such cases.[7]

International Accreditation New Zealand sets out specific requirements in addition to the general requirements of ISO 15189 for medical testing laboratories.[8] Explanatory comment 5.8.8 of this standard indicates that laboratories may have separate critical limits for hospital and community patients. Apart from this no further specific requirement is formulated for critical result management.

Accreditation standards in the USA

The Joint Commission accredits and certifies health care organisations in the United States. In 2002, the Joint Commission introduced a set of National Patient Safety Goals (NPSGs) that healthcare organisations must comply with in order to gain or maintain their accreditation status.[9] Each year these NPSGs are re-evaluated to determine which goals should be continued or replaced with new initiatives. The 2012 NPSGs include clause 02.03.01: 'Report critical results of tests and diagnostic procedures on a timely basis'.[10] The elements of performance for NPSG 02.03.01 are as follows. Organisation leaders must collaborate to develop written procedures for managing critical results that address the definition of critical test results; by whom and to whom results are reported; and the acceptable length of time

between availability and reporting of critical results. Further criteria relate to the implementation of these procedures, and evaluation of the timeliness of reporting.[10]

The College of American Pathologists laboratory accreditation inspection checklist items 41320-41340 include criteria for written 'procedures for immediate notification of responsible caregivers when results of certain tests fall within established critical ranges'. Critical limits should be defined by the laboratory director in consultation with clinicians, and different critical limits can be established for specific patient subpopulations. There are clear requirements for a read-back policy; for the content of records to be kept (i.e. date, time, responsible laboratory individual, person notified and test results); and for procedures and preventive actions for any problems encountered in transmitting critical result information.[11]

Accreditation standards in the UK

Clinical Pathology Accreditation (UK) Ltd issues its own accreditation standards for medical laboratories which are based on ISO 15189.[12] Standard G3.1 refers to general procedures for telephoned results. This requires written procedure(s) for giving reports by telephone under predefined circumstances (e.g. critical results) which include mutual identification of the patient and recording the nominated individuals who may give or receive such calls, confirmation of correct transmission, the maintenance of confidentiality, and the process of sending a follow up final laboratory report.

National Surveys

Most of these general accreditation standards can be interpreted or translated to practice in many ways. It is no surprise therefore that a number of national surveys investigating existing policies highlighted large variations and gaps in practices. The College of American Pathologists have conducted a number of surveys through their Q-probes program.[13-15] These included surveys covering critical result policies and procedures, critical limit comparisons, and notification of critical results. Two Italian national surveys analysing critical result policies have been reported.[16,17] Other countries that have published national survey data on critical limits and reporting practices include Spain and Thailand.[18-19] Adult and paediatric critical limits used by laboratories were surveyed in the United Kingdom[20] and Canada,[21,22] respectively.

Guideline Recommendations

More specific recommendations for the development or refinement of critical result management policies can be found in national or local guidelines. Recognising the paucity of clear and specific standards and good practice recommendations, the Clinical and Laboratory Standards Institute (CLSI) is currently preparing an international guideline on the topic which is expected to provide the most comprehensive guidance and will significantly help harmonising critical result management policies and procedures worldwide. However, the CLSI guideline will not recommend a list of critical tests or limits. We review below four published recommendations and discuss the findings from the Australasian survey in view of their criteria.

Massachusetts recommendations

The Massachusetts hospitals collaborated in a state-wide patient safety initiative to improve the communication of critical results in a timely and reliable fashion. The consensus group developed two major products: 'Safe Practice Recommendations' to promote efficient communication of critical results, and a 'starter set' of critical limits.[23]

Veterans Affairs Medical Center recommendations

Eight recommendations for effective policies on communication of critical and significantly abnormal results were developed at the Veterans Affairs Medical Center (VAMC) in Houston based on policy refinement, institutional experience, and findings from research performed locally and elsewhere.[1] The recommendations suggested that policies should specify (1) clear definitions of key terms; (2) provider responsibilities; (3) procedures for fail-safe communication of abnormal results; (4) verbal and/or electronic reporting procedures; (5) 'critical tests' and acceptable length of time between their ordering and reporting; (6) time lines between the availability of test results and patient notification, and preferred mechanisms for patient notification. (7) Policies must be of 'real world' value and written with feedback from key stakeholders. (8) Policies should establish responsibilities for monitoring and evaluating communication procedures.

Italian recommendations

The joint study group of three major Italian laboratory organisations has issued a consensus document for the detection and management of critical results in clinical laboratories which makes explicit and specific recommendations for best practice.[24]

British recommendations

The Royal College of Pathologists in the UK has also released a set of recommendations for the out-of-hours communication of critical results of patients referred by general practitioners. These guidelines present some consensus critical limits in biochemistry, haematology, immunology, microbiology and virology to guide local discussions with clinicians.[25]

Australasian Laboratory Practice Compared to International Recommendations

A review of current practices is essential in providing a rationale for any national harmonisation initiative. Therefore, a survey was conducted in 2011 by the AACB Critical Results Working Party to identify potential practice variations and gaps within Australasia. The survey focused on the key elements of critical result management, as described in Table 1, and on what critical tests and limits laboratories use in practice. The survey was circulated to all laboratories participating in the external quality assurance program of the Royal College of Pathologists of Australasia. Assuming internally harmonised practice and to avoid a biased interpretation of survey results, we requested one response from large laboratory networks covering various regions and states. A total of 58 laboratories responded to the survey (50 from Australia, 6 from New Zealand and 2 from Hong Kong). Participating laboratories were typically either publicly (48%) or privately owned (45%). General practitioners were the most common clients of the laboratories surveyed (91%), with specialist outpatient clinics (74%), private hospitals (72%), and public hospitals (68%) also serviced by most respondents. As laboratory accreditation is a prerequisite of funding laboratory services in the Australasian region, all respondents were accredited organisations.

Definition of Critical Tests and Critical Limits

The Massachusetts recommendation proposes that the laboratory's critical limit list contains different categories for different levels of urgency and patient settings, references to existing standards and evidence sources, and is reviewed annually.[23] At the VAMC, the clinical executive board creates and maintains the critical limit list, which is reviewed at least annually.[1] The Italian and British guidelines recommend that the list constituents must be agreed with clinical colleagues, and that critical limits must be established by each laboratory, since sample types and analytical platforms may differ.[24,25]

In the Australasian survey, 97% of laboratories include critical results and 81% incorporate significantly abnormal results in their list. Some laboratories have different policies for outpatients (21%), tests performed out-of-hours (27%), physicians external to their institution (8%), and tests performed on behalf of referral laboratories (4%). Table 2 shows the resources used by Australasian laboratories to compile their critical limit list. Of most interest is the fact that only 41% of laboratories stated that they compiled their list in consultation with doctors, even though this is an ISO 15189 accreditation requirement. This figure is higher than in Italy (21%)[16,17] and Spain (10%)[18] but considerably lower than found in the US surveys (73%).[13-15] In Australasia 68% of laboratories review their critical limit list on a regular basis as part of their standard procedures, while 55% review their list when new information from any source is obtained. Nine percent stated that they review their list in response to the burden of handling an increased number of critical results.

Table 2. Australasian survey responses to 'resources used to compile the laboratory's critical limit list'.

Resource	
Laboratory's professional experience	62%
Published literature	59%
International guidelines	41%
In consultation with doctors	41%
National guidelines	40%
Critical limits have been decided internally	31%
Manufacturer's recommendations	28%
Internal studies	24%
Adopted from another laboratory	17%
Don't know	16%

Out of 58 laboratories, 36 provided their critical limits. Table 3 shows the median and range of critical limits used by the laboratories for a selected group of analytes. Various national surveys have also demonstrated that critical test and limit lists vary grossly.[17-20,22] While differing patient populations, settings and laboratory methods may explain these variations, many critical limits are simply different because there is a lot of subjective element and traditional practice behind compiling these lists. With lack of outcome studies or a broader consensus, this is not at all surprising. Some laboratories regard amylase, blood gases, cerebrospinal fluid glucose, paracetamol, salicylate and troponin as critical tests that need to be communicated irrespective of their results (Table 3).

With the lack of convincing evidence and clear recommendations, how should laboratories establish their critical limits? The guiding principle should be that critical limits are clinical decision thresholds that should trigger appropriate actions. Therefore critical limit lists should neither be too inclusive nor exclusive. Critical limits that are too conservative may put unnecessary burden on both laboratory staff and clinicians and may lead to annoyance or inertia at the end-user level, which can result in truly critical results being ignored and thus fatal outcomes. When a laboratory seeks consensus with local physicians it is worth sending out a starter set that at least represents some national or international consensus or, wherever possible, with limits based on literature. Such documents are currently available for family practice settings in the UK[25] and from various published surveys[14,16,18-22] or publications.[26-28] The AACB

Critical Results Working Party is currently synthesising the data in the literature and aims to publish a review of commonly used critical limits to facilitate local discussions.

Separate lists are needed for neonatal, paediatric[21,22,26] and adult care as well as for various ward or outpatient settings (e.g. there is no need to phone a high Troponin result to the cardiac surgery unit in a post-operative case; or a high creatinine to a renal ward or dialysis unit, or repeatedly elevated liver enzymes which are already known to the doctors). Rapid or unexpected changes in patient results may also qualify for urgent communication and thus could be added as a rule to the critical limit list. For example, a result that rapidly became normal should ring alarm bells and generate rapid communication as it could signal the deterioration of or harm to patients (e.g. a rapidly falling sodium concentration in a chronic hypernatraemic patient due to overzealous fluid therapy).

Critical Result Notification Procedures

Identification of critical results

Critical results are identified in laboratories by technical staff when releasing results from analysers. Therefore laboratory staff must be appropriately trained to identify, verify and handle critical results. Laboratories may have different levels of alarms and procedures in place to check the validity of critical results. Most errors are related to pre-analytical problems, such as potential mix-up of samples, inappropriate sampling for microclots in the specimen, common interferences such as haemolysis, icterus or lipaemia, interferences by certain medications, and analytical problems such as results being out of linearity limits or high-dose hook effects, etc. Most of these pre-analytical or analytical problems are easily spotted by double checking patient identification details and by automated analysers that have built in software to detect these common interferences.

It is common practice in clinical laboratories that critically abnormal results are automatically repeated. Several authors investigated whether repeat testing before critical results are reported identifies true errors and is a safe practice. In a recent study routine repeat testing of critical haematology and coagulation results were indicated in 2.2% of cases but no errors were detected on re-measurement. Therefore automated repeats did not offer any advantage over a single run.[29] In a larger study related to general chemistry, tests errors were found in 2.6% of all repeated tests but only one sixth of these were values within the analytic measurement range. With this practice, reporting of critical results was delayed by 5 (blood gases) to 17 (glucose) minutes.[30] With the advancement of automation and pre-analytical robotic systems with clot detection and common interference indices, and automated flags for potential analytical errors, repeat testing is becoming more and more redundant and only delays the timely delivery of critical results. Whilst double-checking is still considered safe laboratory practice, many laboratories have procedures in place whereby critical results are immediately phoned to doctors while informing them that these preliminary results will be confirmed by repeat testing and a final confirmatory call or report. This allows clinicians to make rapid clinical judgments whether the test result fits the patient's condition and gives them time to prepare for appropriate actions when it is clinically justified.

Laboratories may also employ different levels of alarm systems, based on the clinical significance of the actual critical or significantly abnormal results and the clinically required urgency of notification. For example, the Massachusetts laboratories identified red, orange and yellow zone results, where the 'red zone' refers to results that indicate imminent danger of death, or significant morbidity and therefore clinicians must be notified and treatment must be initiated immediately or, at a maximum, within 1 hour. 'Orange zone' results indicate significant abnormalities that do not qualify for clinical emergency and physicians should be notified within 6–8 hours. **'**Yellow zone' results indicate a significant abnormality that may threaten life or cause significant morbidity, complications, or serious adverse consequences at some stage, unless diagnosis and treatment is initiated in a timely and reliable manner. Physician notification and acknowledgement occurs within three days in such cases.[23] Laboratory information management systems may assist in setting up these categories and assembling different alarm lists that can be channelled to different personnel with differing consultative skills.

Timeliness of reporting

The Massachusetts recommendation proposes that the timeliness of reporting should be achieved by: setting notification time parameters according to the level of urgency as described above; utilising a fail-safe plan to identify an alternate clinician when the ordering clinician can not be contacted; and setting conditions where notification of a critical result is not necessary.[23] VAMC recommends that policies should define timelines between the availability of test results and patient notification, and institutions should specify preferred mechanisms for patient notification. For fail-safe communication all mentioned guidelines recommend the use of structured algorithms for sustaining communication attempts including the use of alternate care-givers to receive results after repeated failures, particularly in after-hours situations.[25] Those involved in reporting results must have access to regularly updated contact information for ordering providers and their surrogates.[1,25] The Italian

Table 3. Critical limits in adults from 36 Australasian laboratories.

Analyte	Measuring units	No. of labs performing test	Lower critical limit		Upper critical limit		No. of labs phoning all results for test
			Median (Range)	No. of labs using lower limit	Median (Range)	No. of labs using upper limit	
ALT	U/L	36	2	1	500 (350–3000)	19	–
Ammonia	µmol/L	17	–	–	150 (50–200)	7	–
Amylase	U/L	35	–	–	350 (90–1000)	24	2
Arterial pCO_2	mmHg	28	23 (20–32)	4	60 (42–70)	8	8
Arterial pH		28	7.20 (7.00–7.35)	11	7.55 (7.45–7.60)	9	7
Arterial pO_2	mmHg	29	60 (40–75)	7	80* (60 - 99)	2	7
AST	U/L	34	2	1	750 (200–3000)	14	–
Bicarbonate	mmol/L	34	15 (10–18)	23	40 (40–45)	17	–
Bilirubin	µmol/L	36	1	1	100 (100–500)	9	–
Calcium (corrected)	mmol/L	32	1.75 (1.50–2.00)	20	3.00 (2.80–3.50)	20	–
Calcium (ionised)	mmol/L	27	0.80 (0.70–1.12)	11	1.50 (1.35–1.60)	11	–
Calcium (total)	mmol/L	34	1.78 (1.50–2.10)	20	3.00 (2.60–3.50)	21	–
Carbamazepine	mg/L	26	2* (0.2–4)	2	15 (9–24)	22	–
CK (total)	U/L	36	–	–	1000 (195–20000)	23	–
Creatinine	µmol/L	36	–	–	300 (180–618)	24	–
CRP	mg/L	35	–	–	100 (80–300)	10	–
Digoxin	µg/L	30	0.4* (0.4–0.5)	2	2.0 (1.0–3.0)	28	–
Glucose (blood)	mmol/L	36	2.5 (1.5–3.0)	36	20.0 (8.0–30.0)	36	–
Glucose (CSF)	mmol/L	24	2.2 (2.0–2.2)	3	8.25* (5.5–11.0)	2	4
Lactate	mmol/L	26	–	–	5.0 (3.4–12.0)	14	–
Lithium	mmol/L	26	0.4* (0.2–0.5)	2	1.5 (1.0–3.5)	24	–
Magnesium	mmol/L	34	0.4 (0.2–0.6)	30	2.0 (1.4–4.0)	24	–
Osmolality	mmol/kg	21	255 (240–260)	6	309 (305–330)	6	–
Paracetamol	mg/L	26	–	–	21 (4–106)	10	6
Phenobarbitone	mg/L	18	1 (1–7)	3	48 (35–60)	12	–
Phenytoin	mg/L	29	1 (1–10)	3	25 (20–63)	24	–
Phosphate	mmol/L	36	0.4 (0.3–0.6)	23	3.0 (2.5–4.0)	15	–
Potassium	mmol/L	36	2.8 (2.2–3.0)	36	6.0 (5.4–6.9)	36	–
Salicylate	mg/L	20	–	–	325 (200–497)	12	1
Sodium	mmol/L	36	125 (120–130)	35	155 (150–160)	34	–
Theophylline	mg/L	20	1 (1–8)	3	23 (20–31)	14	–
Triglyceride	mmol/L	35	–	–	20 (10–50)	10	–
Troponin I	µg/L	19	–	–	0.05 (0.02–0.10)	7	3
Troponin T	ng/l	21	–	–	15 (14–100)	9	5
Urea	mmol/L	36	1	1	30 (12–45)	19	–

*Result expressed as average

recommendation proposes that laboratories should consider adopting the policy that critical results should be communicated in less than 60 minutes after validation, and that laboratories should consider a non-communication policy for tests that have a guaranteed defined response time and the result is available to the recipient promptly.[24] Such examples could be blood gases or cardiac markers in emergency or intensive care settings.

According to the Australasian survey, critical results must be delivered within set time limits in 54% of Australasian laboratories. These figures are comparable to the Spanish (38%) and the US (61%) survey results. A list of physicians' contact details is maintained by 78% of laboratories. Table 4 reveals the circumstances in which Australasian laboratories do not deliver critical results.

How to notify critical results?

Most guidelines and surveys demonstrate that phoning directly by lab staff or via call centres is still the most utilised method of communication of critical results. In Massachusetts it is recommended to incorporate modern information technology solutions into the system to improve its capabilities.[23] The VAMC recommendation asserts that verbal notification of critical results is essential, while at a minimum some form of mandatory electronic notification is necessary for significantly abnormal results.[1] The Italian recommendation is that the communication may be performed electronically and/or verbally and in the latter, details of the communication should be documented.[24] The methods Australasian laboratories use to deliver critical results are presented in Table 5.

A recent systematic review and meta-analysis compared the effectiveness of automated alert systems *versus* call centre based telephone notification. The timeliness of reporting was better for automated alerts than for traditional laboratory-based communications in 62% of the time. For call centre *versus* laboratory-based communications, this figure went up to 89% of the time. Based on the size and quality of studies included in the meta-analysis, the authors' evidence rating for automated alerts is 'suggestive', while for utilising call centres in hospital settings it is 'moderate'.[31] These findings suggest that at the current state of information technology in most hospitals, dedicated call centres operated under the control of the laboratory with properly trained staff seem to offer a more feasible solution to improved communication of critical results. The benefit of call centres is that they free busy laboratory staff from the tedious and often frustrating task of locating the responsible caregiver and thus they can focus more on releasing high quality results for rapid communications. This reduces potential errors both in the laboratory and during critical result communications. A disadvantage of call centres is that clinical actions can be delayed when a critical result needs further consultation or additional testing in the laboratory. Laboratories can solve this problem by only referring those results to call centres which do not qualify for clinical emergency (e.g. 'yellow' or 'orange' zone results). With the advancement of information technology, it is

Table 4. Australasian survey responses to 'circumstances under which a critical result is not delivered'.

Circumstance	
When the critical result is not significantly different to a previously delivered result	80%
When the patient has a condition where that result is expected	51%
Where there is an arrangement with a particular physician/ward not to deliver certain results	51%
When the patient is from a ward where that result is expected	24%
Other	13%

Table 5. Australasian survey responses to 'mode of delivery of critical results'.

Mode of Delivery	Inpatients	Outpatients
Telephone the ward	96%	Not applicable
Telephone the doctor's rooms	56%	92%
Telephone the doctor's mobile	56%	81%
Send result by fax or email	40%	60%
Automated alert via EMR* system	4%	4%
Send result to physician's pager	4%	2%
SMS to the doctor's mobile	0%	2%
Other	19%	10%

*EMR: Electronic Medical Records

expected that automated alerts become more widespread and efficient, but laboratories should preserve 'manual' critical result notification systems for when electronic alerts are not acknowledged by the end user within a predefined time or for downtimes of hospital and laboratory information systems.

Who should receive the result?

The Massachusetts recommendations suggest that communication of the critical result must be directly to the responsible caregiver; all details of the notification should be documented; and confirmation should be received that the caregiver accepts responsibility for follow up. If the ordering clinician is unavailable, the result should go to the on-call primary care physician who was linked to the patient at admission. They also recommend that reliability must be designed into the system by forcing clinical information and clinician contact details to be provided during test ordering, and by utilising tracking systems to ensure that results are communicated and followed up.[23] The VAMC recommendation states that policies should clearly outline provider responsibilities, with the institution's own policy identifying the ordering provider as the person responsible for initiating follow-up of abnormal results. For fail-safe communication, the VAMC sends every mandatory test result to both the ordering provider and the permanent primary care provider assigned to each patient in the electronic medical record system.[1] The Italian recommendation declares that the result must be communicated promptly to a person who can take appropriate clinical and therapeutic action. The medical director of the laboratory must agree with the local clinicians on who is considered 'appropriate' to receive the results.[24] The UK guidelines specifically target out-of-hours notification in primary care and thus the patient's general practitioner (GP) or the GP deputising service should receive the results. In the case of the latter, the requesting GP should also be telephoned at the first opportunity within normal working hours the next day.[25]

According to Table 6, the vast majority of Australasian laboratories agree with the recommendations that the ordering physician is appropriate to receive the result (96%). However, most laboratories also consider the nurse responsible for the patient (75%) acceptable, which is reflected in the practice of the majority who deliver results to the wards rather than to the doctors directly (Table 5). Similarly high rates were found in US laboratories (91%). Some laboratories deliver results also to clerical staff (15%), which highlights the often encountered scenario of difficulties of locating a responsible caregiver in a timely fashion. Regarding the need for maintaining a reliable communication system, 27.5% of laboratories have a compulsory field for the physician's contact details in their request form, while 51% have a non-compulsory field. Regular follow-up and monitoring to identify critical results not yet delivered is performed by 33% of Australasian

Table 6. Australasian survey responses to 'personnel considered appropriate to receive a critical result'.

Personnel	
The physician who requested the test	96%
Any physician responsible for the patient	83%
Nurse responsible for the patient	75%
Any nurse on the ward or in the health care unit	58%
Clerical staff on the ward or in the health care unit	15%
The patient whom the test was performed on (when the requesting doctor has authorised it)	10%
Allied health professional treating the patient (physiotherapist, speech therapist, etc.)	4%
Medical student	4%

Table 7. Australasian survey responses to 'what do you do when it is difficult to find an appropriate person to accept a critical result?'

Action	
The responsibility for delivering the result is passed on to a senior person/pathologist	83%
We continue trying across following shifts/days until the result is delivered	46%
We document occurrences where delivery of a critical result has been abandoned	39%
If the patient is at home, we attempt to contact the patient directly	23%
For certain critical results, if the patient is at home and is not contactable, we arrange for the police or ambulance service to call in on the patient	15%
We abandon our attempts to deliver the result after a predefined period of time	0%
Other, please specify (this includes: we involve our local emergency department - 9.6%)	25%

laboratories. Laboratories' response to what they do when it is difficult to find an appropriate person to accept a critical result can be seen in Table 7. It was interesting to find that 23% of laboratories would attempt to contact the patient directly, and 15% of laboratories would arrange for the police or ambulance to call in on the patient.

Acknowledgement of the receipt of results

The Massachusetts guideline recommends that a shared policy must be established for the uniform communication of all results to all recipients. This includes a procedure for the read back of verbally communicated results or, in case of automated alerts, an electronic acknowledgement of receipt.[23] Clear identification and read-back procedures for verbal notification are recommended within the VAMC[1] and Italian[24] recommendations. According to international surveys, 91% of US laboratories, 81% of private laboratories in Thailand, and 62% of Italian laboratories require read back. The Australasian survey revealed that only 46% of laboratories ask the recipient to read back the results, and only 10% of laboratories keep records of this. Clearly this means that there is room for improvement in making communications error free and safer.

Maintenance and Monitoring the Outcome of Critical Result Management Practices

The Massachusetts guideline recommends maintaining the systems by performing ongoing education and monitoring of performance, including the effectiveness of the call schedule, feedback loops and tracking systems.[23] The VAMC recommendation states that policies should establish responsibilities for monitoring and evaluating communication procedures.[1] The Italian and British recommendations propose that the laboratory must regularly check for staff compliance with the procedures implemented for the identification and management of critical results.[24,25] These recommendations mean that communication processes and outcomes must be audited for compliance, and results of findings fed back to all stakeholders so that institutions can continuously learn from the consequences of their policies and practices. Regular monitoring of performance in the delivery of critical results is practiced by 42% of the Australasian laboratories surveyed.

The IFCC Working Group project on 'Laboratory Errors and Patient Safety' has developed a set of quality indicators.[32] Quality indicators for the postanalytical phase include the percentage of critical results communicated and the average time to notify critical results. Such indicators could be used for quality monitoring and improvement in the laboratory, as well as for national benchmarking. Monitoring the clinical effectiveness of critical result communication should be a joint initiative of the laboratory and clinicians. Findings of such audits should be used to improve critical result management practices.

Conclusions

Australasian critical result management policies vary greatly and often do not follow key international best practice recommendations. International and local surveys, procedures and recommendations published in the literature provide valuable guidance for clinical laboratories.[33] Nevertheless, clear guidance on standardised and harmonised practice is needed to improve patient safety and service quality. The Clinical and Laboratory Standards Institute is currently working on a consensus driven guideline on this topic, but publication is not expected for a year or two. To facilitate uniform practices in Australia and the region, we recommend the following actions:

- Laboratories must have shared policies and procedures for communicating critical results to responsible caregivers.
- Laboratories need to define critical tests and critical limits and compile their critical list based on published resources and, where available, on outcome studies or expert consensus. The source of critical limits must be recorded. A starter set of such values will be provided by the Working Party in the near future.
- These published values should facilitate clinical discussions, and critical limits as well as the procedures for reporting critical results should be agreed between the laboratory and the end users.
- Critical limits should be customised for various age groups or settings, if clinically indicated.
- Critical limits can also be categorised according to urgency of reporting and timeframes for notifications must be predefined for each category. Life threatening results must be communicated within one hour.
- Laboratories must define the circumstances where critical results do not need to be notified.
- Laboratories need to design procedures for identifying critical results and rules for confirming the validity of those results.
- Personnel responsible for giving out and receiving results must be defined.
- Fail-safe procedures and escalation algorithms must be designed for events when results cannot be communicated to the primary caregiver in a timely fashion.
- The laboratory must define the mode of transmission of critical results.
- Automated electronic alarm systems should be designed in such a way that recipients must acknowledge receipt of result within a short predefined time period and if such feedback is not received the laboratory must activate an alternative notification system to avoid harm due to delayed actions.
- Communication of critical results must be recorded and archived. The minimum requirement is to record the identification of the patient, the names of the persons

involved in and the time of the communication, the critical results given out and that the receipt of results was acknowledged by the recipient (e.g. by read back or electronic acknowledgement).
- Laboratories are required to update and monitor their critical result management procedures regularly and record and feed back any non-compliance to all stakeholders.
- Laboratories and clinicians must jointly audit and continuously improve their critical result management practices in order to provide safe and reliable care to patients.

Current critical result management practices leave much room for further improvements. We believe that advances in automation, laboratory and hospital information technologies, better awareness and education of laboratory and clinical staff, a shared care policy, together with harmonisation of critical limits and reporting practices will significantly contribute to better care and improved patient safety.

Acknowledgements: The authors acknowledge the support of AACB and Jill Tate for inspiring and helping this harmonisation initiative. We also wish to thank all laboratories in the Australasian region who replied to the survey. We are grateful to Jan Gill at the Royal College of Pathologists of Australasia Quality Assurance Program for preparing the electronic format of the survey and for its dissemination via RCPA QAP.

Competing Interests: None declared.

References

1. Singh H, Vij MS. Eight recommendations for policies for communicating abnormal test results. Joint Comm J Qual Patient Saf 2010;36:226-32.
2. Lundberg GD. Critical (panic) value notification: an established laboratory practice policy (parameter). JAMA 1990;263:709.
3. The Research Priority Setting Working Group of the World Alliance for Patient Safety. Summary of the Evidence on Patient Safety: Implications for Research. Geneva: World Health Organization; 2008. http://www.who.int/patientsafety/information_centre/20080523_Summary_of_the_evidence_on_patient_safety.pdf (Accessed 15 September 2012).
4. Callen J, Georgiou A, Li J, Westbrook JI. The safety implications of missed test results for hospitalised patients: a systematic review. BMJ Qual Saf 2011;20: 194-9.
5. International Organization for Standardization. ISO 15189:2009: Medical Laboratories – Particular requirements for quality and competence. Geneva, Switzerland: ISO; 2009.
6. National Pathology Accreditation Advisory Council. Requirements for pathology laboratories. Canberra, Australia: NPAAC; 2007.
7. National Pathology Accreditation Advisory Council. Requirements for information communication. Canberra, Australia: NPAAC; 2007.
8. International Accreditation New Zealand. AS LAB C7: Specific criteria for accreditation: Medical testing. 1st Edition. Auckland, New Zealand: International Accreditation New Zealand; 2011.
9. May KS. National Patient Safety Goals: a new patient safety initiative. Hosp Pharm 2003;38:490-6.
10. The Joint Commission: 2012 National Patient Safety Goals, Laboratory Accreditation Program. http//www.jointcommission.org/assets/1/6/NPSG_Chapter_Jan2012_LAB.pdf (Accessed 17 August 2012).
11. College of American Pathologists, Commission on Laboratory Accreditation, Laboratory Accreditation Program. Laboratory general checklist – questions related to reporting of results only, 2005. GEN.41320-41340 http://www.cap.org/apps/docs/pathology_reporting/LabGeneralChecklist_Reporting.pdf (Accessed 15 September 2012).
12. Standards for Medical Laboratories, Clinical Pathology Accreditation Ltd, UK; Version 2, November 2010. http://www.cpa-uk.co.uk (Accessed 17 August 2012).
13. Howanitz PJ, Steindel SJ, Heard NV. Laboratory critical values policies and procedures: a College of American Pathologists Q-Probes Study in 623 institutions. Arch Pathol Lab Med 2002;126:663-9.
14. Wagar EA, Friedberg RC, Souers R, Stankovic AK. Critical values comparison: a College of American Pathologists Q-Probes Survey of 163 clinical laboratories. Arch Pathol Lab Med 2007;131:1769-75.
15. Valenstein PN, Wagar EA, Stankovic AK, Walsh MK, Schneider F. Notification of critical results: a College of American Pathologists Q-Probes study of 121 institutions. Arch Pathol Lab Med 2008;132:1862-7.
16. Lippi G, Giavarina D, Montagnana M, Luca Salvagno G, Cappelletti P, Plebani M, et al. National survey on critical values reporting in a cohort of Italian laboratories. Clin Chem Lab Med 2007;45:1411-3.
17. Piva E, Sciacovelli L, Laposata M, Plebani M. Assessment of critical values policies in Italian institutions: comparison with the US situation. Clin Chem Lab Med 2010;48:461-8.
18. Llopis Diaz MA, Rioja RG, Funes VA, Bru CM, Rius MC, Meseguer NB, et al. Critical values reporting: Results of a Spanish laboratories survey [Spanish]. Publicado en Laboratorio Clinico 2010;3:177-82.
19. Sirisali K, Manochiopinij S, Leelahakul P, Ruengrai V, Sattayakom A, Sirisali S. Critical value of the clinical laboratory test in Thailand. J Med Assoc Thai 2010;93(Suppl 6):S22-7.

20. Tillman J, Barth JH. A survey of laboratory 'critical (alert) limits' in the UK. Ann Clin Biochem 2003;40:181-4.
21. Don-Wauchope AC, Chetty VT. Laboratory defined critical value limits: how do hospital physicians perceive laboratory based critical values? Clin Biochem 2009;42:766-70.
22. Gong Y, Adeli K on behalf of CSCC Pediatric Focus Group. A national survey on pediatric critical values used in clinical laboratories across Canada. Clin Biochem 2009;42:1610-5.
23. Hanna D, Griswold P, Leape LL, Bates DW. Communicating critical test results: safe practice recommendations. Jt Comm J Qual Patient Saf 2005;31:68-80.
24. Lippi G, Caputo M, Banfi G, Buttarello M, Ceriotti F, Daves M, et al; for the Intersociety Working Group SIBioC-SIMeL-CISMEL on Extra-Analytical Variability of Laboratory Data. Recommendations for the detection and management of critical values in clinical laboratories [Italian]. Biochim Clin 2008;32:209-16 and RIMeL/IJLaM 2008;4;28-35.
25. The Royal College of Pathologists (UK). Out-of-hours reporting of laboratory results requiring urgent clinical action to primary care: Advice to pathologists and those that work in laboratory medicine. London, UK: RCPath; 2010.
26. Kost GJ. Critical limits for emergency clinician notification at United States children's hospitals. Pediatrics 1991;88:597-603.
27. Thomas L. Critical limits of laboratory results for urgent clinician notification. eJIFCC 2003;14:1-8. http://www.ifcc.org/ifccfiles/docs/140103200303.pdf (Accessed 15 September 2012).
28. Kost GJ. Table of critical limits. Med Lab Observer CLR 2011-2012. http://www.clr-online.com/CLR201113-Table-of-Critical-Limits.pdf (Accessed 15 September 2012).
29. Toll AD, Liu JM, Gulati G, Behling EM, Kocher WD. Does routine repeat testing of critical values offer any advantage over single testing? Arch Pathol Lab Med 2011;135:440-4.
30. Deetz CO, Nolan DK, Scott MG. An examination of the usefulness of repeat testing practices in a large hospital clinical chemistry laboratory. Am J Clin Pathol 2012;137:20-5.
31. Liebow EB, Drezon JH, Fontanesi J, Favoretto AM, Baetz RA, Shaw C, et al. Effectiveness of automated notification and customer service call centers for timely and accurate reporting of critical values: A laboratory medicine best practices systematic review and meta-analysis. Clin Biochem 2012;45:979-87.
32. Sciacovelli L, O'Kane M, Skaik YA, Caciagli P, Pellegrini C, Da Rin G, et al. Quality Indicators in Laboratory Medicine: from theory to practice. Clin Chem Lab Med 2011;49:835-44.
33. Kost G, Hale KN. Global trends in critical values practices and their harmonization. Clin Chem Lab Med 2011;49:167-76.