



Standardization of haematology critical results management in adults: an International Council for Standardization in Haematology, ICSH, survey and recommendations

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SUMMARY

Introduction: These recommendations are intended to develop a consensus in the previously published papers as to which parameters and what values should be considered critical. A practical guide on the standardization of critical results management in haematology laboratories would be beneficial as part of good laboratory and clinical practice and for use by laboratory-accrediting agencies.

Methods: A working group with members from Europe, America, Australasia and Asia was formed by International Council for Standardization in Haematology. A pattern of practice survey of 21 questions was distributed in 2014, and the data were collected electronically by Survey Monkey. The mode, or most commonly occurring value, was selected as the threshold for the upper and lower alert limits for critical results reporting.

Results: A total of 666 laboratories submitted data to this study and, of these, 499 submitted complete responses. Full blood count critical results alert thresholds, morphology findings that trigger critical result notification, critical results alert list, notification process and maintenance of critical results management protocol are described. This international survey provided a snapshot of the current practice worldwide and has identified the existence of considerable heterogeneity of critical results management.

Conclusion: The recommendations in this study represent a consensus of good laboratory practice. They are intended to encourage the implementation of a standardized critical results management protocol in the laboratory.

Keywords

Haematology, critical results, standardization, ICSH, recommendations

INTRODUCTION

Originally defined by Lundberg in 1972, critical results are test results so extremely abnormal that they represent a life-threatening condition for which some corrective actions should be taken promptly [1]. Laboratories are responsible for the notification of critical results to clinicians so that clinical interventions can be made in an appropriate time frame [2].

Automation and information technology advances in laboratory medicine managed by qualified laboratory professionals have significantly improved the quality of laboratory performance [3]. Nevertheless, the vast amount and rapid flow of data contribute to the information overload and communication failures and, as a consequence, to increasing medical error rates [4].

Although critical result reporting is widely known to be a determinant of patient outcomes [5], there is a lack of consensus in the published literatures as to which parameters and what values should be considered critical [6]. There are also differences in terminology and management processes. For these reasons, a practical guide on the standardization of critical results management in haematology laboratories would be beneficial as part of good laboratory and clinical practice and for use by laboratory-accrediting agencies.

The aim of the International Council for Standardization in Haematology (ICSH) was to survey the current practice and to develop recommendations for the standardization of haematology critical results management.

This is the first international survey looking at the current practice of critical results management in haematology.

MATERIALS AND METHODS

A working group with members from Europe, America, Australasia and Asia was formed by ICSH.

Study design

A pattern of practice survey of 21 questions was distributed in 2014 (Appendix S1). The data were collected electronically by Survey Monkey.

The survey was distributed internationally through the ICSH Critical Results Management Protocol working group members and with the help of various national/regional networks. The purpose of the survey was to develop an understanding of the process and management of full blood count (FBC) quantitative and qualitative critical results. Critical results for specific populations (based on age, gender, ethnicity or pregnancy) were not assessed.

For the survey, a critical result was defined as a result that is so abnormal that it is considered life-threatening and requires immediate corrective action to be taken.

The survey consisted of multiple choice questions and yes/no responses. The participants were able to include free-text comments depending on the question.

Participating laboratories without a Critical Results Management Protocol (CRMP) exited the survey after general information about the characteristics of the laboratory had been collected.

The recommendations included in this study are based on an analysis of data from the survey, a systematic review of the evidence in the published literature and the consensus opinion of the working group.

In this recommendation, the following terminology/terminology [7] and directive terms are used:

Critical result: A test result which may signify a pathophysiological state that is potentially life-threatening or that could result in significant patient morbidity or irreversible harm or mortality and therefore requires urgent medical attention and action.

Significantly abnormal result: A test result that is not-life threatening but that requires a timely medical

attention and follow-up action within a medically justified time-scale.

Alert thresholds: The upper and/or lower threshold of a test result or the magnitude of change in a test result within a critical or clinically significant time-scale beyond which the finding is considered to be a medical priority warranting urgent or timely action.

Alert list: A list of laboratory tests, including critical tests and noncritical tests with alert thresholds for critical and/or significantly abnormal results that reflect an agreed policy between laboratory and clinical staff for rapid communication within a pre-specified time frame and according to a procedure.

Must indicates a practice which is considered mandatory based on this working group's expert opinion.

Should indicates a practice which is recommended and where compliance would be expected for good clinical practice, but for which alternative practices may also be acceptable. Individual laboratories may elect to increase the level of compliance to mandatory by substituting 'must' within their own policies.

May indicates a practice which is permissible within the limits of these recommendations.

Statistical analysis

Descriptive statistics were determined using Microsoft Excel 2010 (Microsoft Corporation, Redmond, WA, USA). The mode, or most commonly occurring value, was selected as the threshold for the upper and lower alert limits for critical results reporting.

A wide range of results for the requested parameters was received, and some of the results may have been clerical errors.

For haemoglobin concentration, the results showed a bimodal distribution of both upper and lower alert thresholds, with modes that differed by a factor of 10. This is consistent with a difference in the units of measurement used for reporting (g/L and g/dL). To avoid confusion, the thresholds used in this study for haemoglobin concentration are expressed in g/L.

Characteristics of participating laboratories

The participating laboratories were located throughout the world, including Europe (347, 52.1%), Australasia (119, 17.9%), East Asia (89, 13.4%), South East Asia

(45, 6.8%), North America (25, 3.8%), Africa (23, 3.5%), the Middle East (13, 2.0%) and other (5, 0.8%).

A total of 666 laboratories submitted data to this study and, of these, 499 submitted complete responses and 115 laboratories did not have a CRMP.

Four hundred and forty-one (66.2%) of the participating laboratories were public hospitals, 170 (25.5%) were private hospitals, and 39 (5.9%) were not-for-profit organizations. A total of 16 (2.4%) were others including public and private institutions, research facilities, external quality assessment providers, military or government centres and blood bank services.

Laboratories provided services to the following service users: specialists (483, 72.5%), primary care physicians (470, 70.6%), public hospitals (414, 62.1%), private hospitals (251, 37.7%), nurses (265, 39.8%), allied health professionals (170, 25.5%) and others (41, 6.2%).

Five hundred and fifty-one (82.7%) of the surveyed laboratories had a CRMP. The majority (479, 86.9%) of these were accredited. A minority, (115, 17.3%), had no CRMP. Of these, 64.3% (74) were accredited.

Table 1 indicates the characteristics of the laboratories according to CRMP status.

RESULTS

Four hundred and ninety-nine laboratories submitted complete responses, including 115 laboratories that did not have a CRMP. The complete response returned rate was 74.9%. The results below were based on the responses from 384 laboratories that had a CRMP.

Full blood count critical results alert thresholds

The laboratories submitted their upper and lower critical results alert thresholds for four parameters: haemoglobin concentration, total leucocyte count, neutrophil count and platelet count. For all four parameters, fewer respondents reported an upper-than-a-lower alert threshold. This was especially true for neutrophils, where 62% of respondents did not provide an upper alert threshold. A greater emphasis was placed on the total leucocyte count, for which 75% of respondents provided an upper alert threshold.

Lower alert thresholds were provided by 374 (97.4%) laboratories for haemoglobin, 267 (69.5%)

Table 1. Characteristic of 666 laboratories according to their Critical Results Management Protocol (CRMP) status

| CRMP | Number (%) | Type of laboratories | Number (%) | Accredited number (%) |
|------|------------|----------------------|------------|-----------------------|
| Yes | 551 (82.7) | Public | 362 (65.7) | 479 (86.9) |
| | | Private | 147 (26.7) | |
| | | Not for profit | 32 (5.8) | |
| | | Other | 10 (1.8) | |
| No | 115 (17.3) | Public | 79 (68.7) | 74 (64.3) |
| | | Private | 23 (20.0) | |
| | | Not for profit | 7 (6.1) | |
| | | Other | 6 (5.2) | |

for leucocytes, 295 (76.8%) for neutrophils and 378 (98.4%) for platelets. Upper alert thresholds by contrast were given by 241 (62.8%) laboratories for haemoglobin, 290 (75.5%) for leucocytes, 145 (37.8%) for neutrophils and 274 (71.4%) for platelets.

The most commonly reported alert thresholds (the modes) for each parameter are shown in Table 2.

Morphology findings that trigger critical result notification

The morphology findings that would trigger a critical result notification in this survey are listed in Table 3. A total of 24 laboratories with quantitative critical results thresholds selected 'not applicable' as a response for morphology findings and 22 of these 24 submitted no comments with the response. The remaining two reported that they did not examine blood films.

'Other' as a response was selected by 80 (20.8%) laboratories and seven of the 80 ticked 'other' as their only response. The remaining 73 participating laboratories had submitted a combination of choices and listed the following morphological findings in their comments: TTP/HUS, haemolysis, sickle cells, hyperviscosity, HELLP, blasts, other major haematological conditions, any haematological malignancy, abnormal lymphocytes, atypical lymphocytes, lymphoma, severe sepsis, neonate with >50% cells showing toxic changes, severe pancytopenia, any patients aged <15 years with results outside normal reference ranges, lymphoma, blasts or unexpected findings, blasts >5%, Pelger anomaly, neutrophil degranulation and unspecified/unclassifiable cells.

Table 2. Critical results alert thresholds among the 384 laboratories

| Parameter | Mode | Respondants reporting this value/total respondents that provide thresholds (%) |
|--|---------------|--|
| Lower alert thresholds | | |
| Leucocytes* ($\times 10^9/L$) | 1.0 | 102/267 (38.2) |
| Neutrophils [†] ($\times 10^9/L$) | 0.5 | 172/295 (58.3) |
| Haemoglobin [‡] (g/L) | 70 | 127/374 (33.9) |
| Platelets [§] ($\times 10^9/L$) | 50 | 124/378 (32.8) |
| Upper alert thresholds | | |
| Leucocytes* ($\times 10^9/L$) | 30 | 93/290 (32.1) |
| Neutrophils [†] ($\times 10^9/L$) | Indeterminate | ~ |
| Haemoglobin [‡] (g/L) | 200 | 126/241 (52.3) |
| Platelets ($\times 10^9/L$) | 1000 | 155/274 (56.6) |

*For leucocytes, another 63/267 (23.6%) of participants selected $2 \times 10^9/L$ as the lower alert threshold and 41/267 (15.4%) selected $1.5 \times 10^9/L$. For the upper alert threshold, another 65/290 (22.4%) gave $50 \times 10^9/L$ and 41/290 (14.1%) gave $20 \times 10^9/L$.

[†]For neutrophils, another 96/295, (32.5%) participants selected $1.0 \times 10^9/L$ as the lower alert threshold. The upper alert threshold was indeterminate. The three most commonly stated values were 20×10^9 , 30×10^9 and $50 \times 10^9/L$.

[‡]For haemoglobin, there was a mixture of units of measurement (g/L and g/dL). The most common lower alert thresholds were 70 (g/L) or 7 (g/dL), and the upper alert thresholds were 200 (g/L) or 20 (g/dL). For the purpose of this table, results have been reported in g/L only.

[§]For platelets, another 97/378 (25.7%) of participants selected $20 \times 10^9/L$ as the lower alert threshold and 66/378 (17.5%) selected $30 \times 10^9/L$.

Table 3. Morphology findings that trigger critical result notification among the 384 laboratories

| | Number of laboratories (%) |
|---------------------------------|----------------------------|
| Acute leukaemia | 323 (84.1) |
| Malaria | 322 (83.9) |
| Plasma cell leukaemia | 238 (62.0) |
| Other parasites | 193 (50.3) |
| Blood film showing schistocytes | 177 (46.1) |
| Blood film showing bacteria | 137 (35.7) |
| Other | 80 (20.8) |
| Not applicable | 24 (6.3) |

Characteristics of the critical results alert list

The majority of the participating laboratories used more than one resource to compile the critical results alert list (CRAL). The most frequently cited methods were the laboratory's professional experience (273, 71.1%), followed by departmental or internal review (189, 49.2%), published literature (188, 49.0%), international guidelines (138, 35.94%) and national guidelines (133, 34.6%). Some other resources cited included a protocol adopted from another laboratory (56, 14.6%) and manufacturer's recommendation (22, 5.7%). A small number (23, 6.0%) of the participating laboratories mentioned 'other' as the resource used to compile the CRAL. Thirteen (3.4%) responders did not know the resources used to compile their CRAL.

Two hundred and forty-six (64.1%) laboratories compiled the CRAL in consultation with referring clinicians.

Regarding the notification of a critical result to the referring clinicians, 115 (29.9%) laboratories do not allow exception. Nevertheless, 196 (51.0%) allow exception for a repeat critical result within a set time frame, 115 (30.0%) for specific patient groups, 69 (18.0%) for specific wards, 62 (16.2%) for a specific doctor group, 54 (14.1%) for doctor requests and 4 (1.0%) for referral works. Thirty (7.8%) chose 'other' as the reason to allow exception (as the only response in nine and in a combination of choices in 21).

Delta checking is used to decide whether a result should be considered critical in 174 (45.3%) laboratories.

Characteristics of the notification process for critical results

Communication of a critical result to the referring clinician is made mainly by telephone (377, 98.2%). Less commonly used means of communication included Fax (71, 18.5%), email (41, 10.7%), SMS to mobile (20, 5.2%), paper (14, 3.7%) and others (30, 7.8%), which are mainly computer communication.

The notification is undertaken by scientists (249, 64.8%), pathologists (226, 58.9%) and technical assistants (134, 34.9%). Call centre staff (22, 5.7%) and other personnel (6, 1.6%), including site support staff and clerical staff, are less commonly used.

For hospital inpatients, the critical result is communicated mainly to physicians (367, 95.6%) and nurses (304, 79.2%). Other personnel considered appropriate to receive critical results for hospital inpatients included clerical staff (47, 12.2%), allied health professionals (41, 10.7%), medical students (31, 8.1%) and others (18, 4.7%). 'Not applicable' was noted in 5 (1.3%) responses.

For community outpatients, the critical result is communicated mainly to physicians (356, 92.7%) and nurses (239, 62.2%). Other personnel considered appropriate to receive critical results for community outpatients included clerical staff (82, 21.4%), allied health professionals (37, 9.6%), medical students (17, 4.4%) and others (15, 3.9%). 'Not applicable' was noted in 21 (5.5%) responses.

Two hundred and ninety-eight (77.6%) laboratories have a read-back policy: 256 (85.9%) of this number keep a record of this and 42 (14.1%) do not.

The majority of the laboratories have a procedure if they are unable to find an appropriate person to accept the critical result. This process varies greatly from 'continue across the following shifts/days until the result is delivered' (201, 52.3%), 'passed on and up to the discretion of the pathologist' (170, 44.3%), 'contact the patient directly' (75, 19.5%), 'call police' (34, 6.3%), 'abandon call after a predefined period of time' (13, 3.4%) and other (79, 20.6%).

One hundred and eighty-four (47.9%) of participating laboratories have no set time limits for delivery of a critical result, but with a comment of 'as soon as possible' (ASAP) in 25 of the 27 laboratories which submitted a comment. In contrast, 53 (13.8%) have set 15 min, 43 (11.2%) 30 min, 51 (13.3%) 1 h, 10 (26.0%) 2 h and 6 (1.6%) 3 h as their time limits for

delivery of a critical result. 'Other' time limits constituted 36 (9.4%) of responses, with most mentioning ASAP/immediately in their comments.

Characteristics of the maintenance of Critical Results Management Protocol

The frequency of review of the CRMP varies. The majority of participating laboratories review the protocol yearly (155, 40.4%) or every 2 years (86, 22.4%). However, review frequency is 3 yearly in 26, (6.8%) and not sure in 96 (25%) laboratories. Those 20 (5.2%) laboratories that selected 'other' as their response submitted comments that included 'as required', 'not specified', 'we do not' or 'with new guideline'.

The CRMP is audited by 246 (64.1%) laboratories.

DISCUSSION AND RECOMMENDATIONS

Critical results management is an important laboratory quality indicator as it reflects clinical effectiveness, patient safety and operational efficiency. It is thus in the accreditation standards of many countries that a documented policy is required [2, 8–12].

Regional/national recommendations have been made in an attempt to provide guidance for the critical results management [13–19]. Despite this, previous regional/national surveys have identified large variation in the practice of critical results management [6, 20–32]. This international survey provided a snapshot of the current practice worldwide and has identified the existence of considerable heterogeneity of critical results management.

Responses from the survey indicate that the majority (82.7%) of participating laboratories have a

procedure for critical results reporting (a CRMP). This is greater among laboratories with accreditation compared with those without (86.8% versus 63.7%). However, there remain 17.3% of the participating laboratories without a CRMP.

It is important to have clear definitions of key terms and these key terms should be standardized to ensure that the policy is credible and facilitates understanding among users [13]. Currently, there is a wide range of terminology and definitions used [7].

Among the laboratories participating in the survey, only 49% used published literature to establishing the CRAL. This may be due to the wide ranges of critical results alert thresholds in the published literature [6, 15–20, 22, 23]. Whilst our data were difficult to analyse, the threshold values derived and the range of results reported are consistent with those from other surveys. The wide range may reflect differences in local patient populations or test methods, but it is more likely that the critical result alert thresholds at different institutions reflect different levels of patient risk. Tables 4 and 5 summarize the critical results alert thresholds from selected published surveys or recommendations and the results of this survey.

It is noteworthy that 64.1% of the participating laboratories compiled the CRAL in consultation with referring clinicians. The College of American Pathologists checklist states that the laboratory director, in consultation with the clinicians served [9], should define critical results. This is also the recommendation from some regional/national bodies [13, 15, 17]. The compilation of the CRAL in consultation with referring clinicians was 73% in USA, 21% in Italy, 10% in Spain, 41% in Australia and 13% in China from

GENERAL RECOMMENDATIONS

The laboratory must have a clearly written policy in regards to the management of the critical results of tests that addresses the following:

- The definition of critical results of tests.
- The procedures for urgent notification of clinical personnel responsible for the patient's care when the results of designated tests exceed the established alert thresholds.
- The ongoing review and audit process.

This policy should be realistic and written with feedback from key stakeholders. The key stakeholders include but are not restricted to laboratory staff, pathologists, and clinicians.

Table 4. Lower critical results alert thresholds from selected surveys and recommendations

| | ICSH Mode | Kost 1990 [16] Mean | US 2002 [22] Median | US 2007 [23] Median | Croatia CCMB 2015 [32] | Emancipator 1997 [19] Median | Italy 2010 [28] Median | South Africa 2013 [20] Mean | IQMH 2015 [6] Median | UK RCPath 2010 [15] |
|---------------------------------|--------------|------------------------------|------------------------------|------------------------------|---------------------------------|------------------------------------|---------------------------------|---|-------------------------------|------------------------------|
| Leucocytes ($\times 10^9/L$) | 1.0 | 2 | 2 | | 2 | 2 | | 2 | 2 | |
| Neutrophils ($\times 10^9/L$) | 0.5 | | | | | | | | | 0.5 |
| Haemoglobin (g/L) | 70 | 66 | 70 | 70 | 66 | 70 | 66 | 60 | 69 | 50–70 |
| Platelets ($\times 10^9/L$) | 50 | 37 | 40 | 31 | 20 | 40 | 30 | 41 | 50 | 30 |

ICSH, International Council for Standardization in Haematology; UK RCpath, UK The Royal College of Pathologists; IQMHO, Institute for Quality Management in Healthcare Ontario.

Table 5. Upper critical results alert thresholds from selected surveys and recommendations

| | ICSH mode | Kost 1990 [16] Mean | US 2002 [22] Median | US 2007 [23] Median | Croatia CCMB 2015 [32] | Emancipator 1997 [19] Median | Italy 2010 [28] Median | South Africa 2013 [20] Mean | IQMH 2015 [6] Median | UK RCPath 2010 [15] |
|------------------------------------|---------------|------------------------------|------------------------------|------------------------------|---------------------------------|------------------------------------|---------------------------------|---|-------------------------------|------------------------------|
| Leucocytes ($\times 10^9/L$) | 30 | 37 | 30 | | 50 | 30 | | 46 | 40 | |
| Neutrophils ($\times 10^9/L$) | Indeterminate | | | | | | | | | 50 |
| Haemoglobin (g/L) | 200 | 199 | 200 | 200 | 199 | 200 | 199 | 200 | 200 | 190 |
| Platelets ($\times 10^9/L$) | 1000 | 910 | 999 | 999 | 1000 | 999 | 900 | 1000 | 1000 | 1000 |

ICSH, International Council for Standardization in Haematology; IQMHO, Institute for Quality Management in Healthcare Ontario; RCpath, UK The Royal College of Pathologists.

previous surveys [21, 22, 25, 28, 31]. Whilst it is good practice to compile a CRAL in consultation with referring clinicians, this process may have contributed to the wide variation in local definitions of critical results. It may also be impractical to implement this in centralized practices that service multiple institutions across a wide geographical region.

The practice of repeat testing on the same samples with critical results has been questioned recently. Previous studies have shown repeat analysis of samples with critical results rarely produced clinically discrepant results; it is unnecessary with today's automated laboratory analysers [33–36] and contributes to delay reporting.

The Joint Commission (JC) [10] has commented on issues regarding repeatedly and chronically critical

results. It states for chronically critical results that, 'Each health care organization may define for itself what the "Critical Values" are. Provisions may be made for certain patient-specific situations in which values that would be "critical" for most patients are not critical for a particular patient or for patients with a particular diagnosis. The parameters must be objectively defined and are known to all staff that is involved in the process of reporting values'.

For repeatedly critical results, it states, 'this is a matter of definition and each organization can define for itself the circumstances under which a test result is considered "critical." It is permissible to define "critical results" differently for repeat tests. For example, this may be represented as different "panic value" limits for repeat tests or may be based on the direction of change

in the subsequent test results. The default, however, should be to treat the repeat result as a critical result'.

A significant number of laboratories allowed exceptions in the notification of critical results in this survey. The main exception was for repeat critical results within a set time (51%). There were also exceptions allowed for specific patient/ward/doctor groups.

A standardized approach is needed for these specific situations. Increasing critical results notification workload has made it important to achieve efficient use of laboratory's resources and to avoid overloading the requesting clinicians with information. The marginal clinical usefulness versus marginal cost of resources should be considered carefully when the limits or exceptions are determined. A CRAL that includes results that do not meet the criterion of the imminent danger standard may dilute the urgency of the call and lead to unnecessary interruption for clinicians. In many clinical settings (e.g. chemotherapy) in which the critical result is expected, reporting the value as critical may not contribute to improve patient care. On the other hand, clinicians may not fully understand why certain apparently critical results are not notified, which may lead to adverse patient outcome. It is also simpler for the laboratory to report all critical results, especially when the laboratory may not have the clinical details and cannot know whether the repeated result is expected or not. A previous Q-Tracks study has found this approach was associated with improved overall performance in critical results reporting [29]. Advances in information technology may allow the laboratories to develop CRALs designed for a specific clinic or clinician in the future.

The working group has drafted a CRAL with suggested critical results and alert thresholds for FBC. The working group recognizes that it is difficult to achieve complete harmonization on these and there should be some degree of flexibility for modification by each individual laboratory. One of the ways of determining the alert thresholds is to ascertain the practice pattern of the majority and use this pattern as the standard of practice. The committee has used this as the basis for our recommendations for those alert thresholds with consistent data across the surveys/recommendations. However, the upper alert threshold for leucocytes and lower alert threshold for platelets showed a considerable variation. The current literatures have suggested

a platelet transfusion trigger of $10 \times 10^9/L$ in the absence of other risk factors for bleeding [37]. The working group has suggested a platelet count of $20\text{--}50 \times 10^9/L$ as the lower alert threshold for notification so that it can be taken into account alongside patient's clinical condition. Hyperleucocytosis is usually defined as a leucocyte count above $100 \times 10^9/L$ [38]. This can lead to leucostasis with its associated complications. This has been used as our suggestion for leucocytes' upper alert threshold. The laboratory should use this only as a guide to establish a local CRAL to suit the local patient populations and clinical needs, and may also include other significantly abnormal results for urgent notification. The CRAL should not override the timely communication of results marked as urgent by the referring clinicians.

In this survey, the telephone (98.2%) remains the most frequent mode of notification. This is similar to previous surveys [21, 22, 25, 27, 28, 31, 32]. The verbal notification process represents a significant workload for the laboratory that diverts the attention from other laboratory work. Laboratories should explore new modes of notification including electronic technology notification which can improve timeliness of reporting [39]. Electronic modes of notification will need acknowledgement and confirmation of receipt. CAP [9] stipulates that transmission of critical results by electronic means (fax or computer) is acceptable, but the laboratory should confirm receipt of the result by the intended recipient (e.g. by a phone call). In the UK, the proposed key performance indicators (KPI) from The Royal College of Pathologists (RCPath) note that electronic delivery of critical results to an electronic post box that will trigger urgent clinical review and action is acceptable [40]. In Australia, National Pathology Accreditation Advisory Council (NPAAC) stipulates [41]: Receipt of a 'failure' acknowledgement message or failure to receive any acknowledgement within an appropriate time frame for messages containing urgent results should initiate immediate action to deliver reports through an alternative channel, such as phone or fax for urgent or clinically significant reports. The modes of notification will change as electronic technology evolves, providing better management of acknowledgement and confirmation of receipt. This can ease the laboratory workload and reduce clerical errors. The electronic trail captured

RECOMMENDATIONS ON CRITICAL RESULTS AND THE ALERT LIST

The laboratory must have a clearly written policy defining what tests must be on the alert list and what results must be communicated urgently to clinical personnel responsible for patient care.

The alert list must contain:

- Name of the tests
- The units of measurement
- Alert thresholds
- Time limit of notification

Critical results should be defined by the laboratory director in consultation with the clinicians served that pertain to its patient population. The alert list should refer to existing standards or published literatures and sources should be documented. Rationale and sources should be documented if there are local modifications.

The laboratory must have documented procedures in place to exclude possible pre-analytical and analytical errors before releasing the critical results.

The laboratory should use delta check to look for dangerously rapid changes in test results within an appropriate/specified time frame.

The laboratory may establish different critical results for specific patient subpopulations (for example, patients on chemotherapy, inpatients versus outpatients) in consultation with the clinicians served. This must be clearly specified on the alert list and the reason should be documented.

The laboratory may establish a policy for dealing with repeatedly critical results. The laboratory may define critical results that always need to be communicated urgently or only at 'first' presentation. The laboratory must determine the appropriate time frame for 'first' presentation in consultation with the clinicians served. This must be clearly specified on the alert list and the reason should be documented.

Allowing clinical personnel responsible for patient care to 'opt out' of receiving critical results should be discouraged.

The laboratory staff may decide to communicate urgently other abnormal test results at their discretion. This may apply where milder abnormalities may require urgent notification if it is felt that action is required.

The laboratory should ensure all stakeholders are familiar with the alert list and their responsibilities. The list should be readily available to all the users.

will also facilitate audit and thus improve performance monitoring and evaluation. Surprisingly in this survey, some still use paper notification (3.7%) for critical results reporting.

Most of the notification is performed by scientists, technical assistants or pathologists in this survey, similar to previous surveys [20–24, 32]. Despite the increased workload, call centres are seldom used (5.7%). A previous systematic review has found call centres are effective in improving the timeliness and accuracy of critical result reporting in an inpatient care setting [39]. This will free the laboratory personnel from the time-consuming diversion of locating the

clinician and improve productivity. The communication of critical results though should be a part of the service in interpretive laboratory medicine and where a call centre is used, the staff must be properly trained and with access to qualified laboratory personnel. The use of call centres may require additional communication with laboratory staff when a clinician requires additional information that call centre staff are unable to provide. This situation may result in a delay of treatment whilst the appropriate laboratory staff member is located.

The personnel considered appropriate to receive critical results are similar for both hospital inpatients

RECOMMENDATIONS ON CRITICAL RESULTS ALERT LIST[†]

| | Lower alert thresholds | Upper alert thresholds |
|---|------------------------|------------------------|
| Leucocytes ($\times 10^9/L$) | 2.0 | 100 |
| Neutrophils ($\times 10^9/L$) | 0.5 | 50 |
| Haemoglobin (g/L) | 70 | 200 |
| Platelets ($\times 10^9/L$) | 20-50 | 1000 |
| Morphology findings that trigger critical result notification | | |
| Acute leukaemia (>20% blasts)* and Acute Promyelocytic leukaemia* | | |
| Parasites including Malaria* | | |
| Blood film suggestive of Thrombotic micro-angiopathic anaemia* | | |
| Blood film showing bacteria* | | |

*Urgent notification of laboratory haematologist of these cases is also required.

[†]This should be used only as a guide to establish a local CRAL to suit the local patient populations and clinical needs and may also include other significantly abnormal results for urgent notification.

and community outpatients in this survey. They are mainly physicians and nurses, but some deem clerical staffs (especially in community setting), medical students and allied health professionals to be appropriate. It is important for guidelines to clarify who are deemed appropriate to receive critical results as the definition appears to vary. ISO [2] defines this as a physician (or other authorized health professional). The Joint Commission [10] stipulates this as a responsible licensed caregiver or authorized agent (if the organization can demonstrate that there will be no significant delays in getting the test result to the responsible licensed caregiver so that patient can be promptly treated). CAP [9] defines this as a physician (or other clinical personnel responsible for the patient's care). In the UK Clinical Pathology Accreditation standard [11], the appropriate personnel are the responsible clinicians. NPAAC [12] deems this as a requesting practitioner or others delegated by the requesting practitioner responsible for the patient's immediate care and management either directly or through a third party such as a practice nurse or receptionist. Previous Q-Tracks study has found that if unit secretarial/clerical staff were not authorized to accept critical results, this was associated with improved overall performance in critical result reporting [28]. The practice of calling someone rather than the 'licensed' caregivers/authorized agent should be discouraged.

About 77.6% of participating laboratories in this survey have a read-back policy. Read-back policy rates in previous surveys were 90% in Ontario [6], 91% in USA [42], 81% in Thailand [27], 62% in Italy [28] and 46% in Australia [31]. This requirement is in the CAP [9] check list and is also the recommendation from some regional/national bodies [13, 14, 17]. A previous study [42] showed that 3.5% of verbal communications that are not confirmed by a read-back policy are shown to be inaccurate.

The participating laboratories in this survey have various procedures in place if an appropriate person cannot be contacted for critical results. These range from the result being passed on to the pathologist to abandoning the call. It can be particularly difficult to find someone to accept results afterhours, at night or over the weekends in the community setting. It is crucial to ensure caregivers' contact data is complete and up to date. A previous study has found that it takes more than twice as long to communicate critical results for outpatients than for inpatients and slightly more than 5% of critical results phone calls were abandoned [22]. The UK RCPATH publication of out-of-hours reporting of laboratory results requiring urgent clinical action to primary care is a welcome addition [15]. However, out-of-hours provider services in some countries will

not normally accept the responsibility of critical results. There is a need for well-documented and properly thought-out escalation procedure for this scenario which may involve contacting the patient directly, for example as stipulated in NPAAC [12]. There should be a clear line of communication with a failsafe system. Clinicians who use the laboratory service should, when completing request forms, be encouraged to consider the possibility that the request may generate an abnormal result that may have to be communicated to another doctor or directly to the patient.

Almost half of the surveyed laboratories (47.9%) do not have a documented set time for notifying critical results but mentioned 'ASAP' as their aim. Most of the rest have variable set time limits that vary from 15 min to 3 h, which may be too long for life-threatening results. ISO [2] stipulates immediate notification of critical results. The Joint Commission [10] requires an acceptable length of time between the availability and reporting of critical results of tests. The timeliness for patient notification was also recommended by others [13, 14]. The proposed UK RCPATH KPI recommends notification within 60 min of the result becoming available [38]. Previous surveys have identified that 54% of Australia, 38% of Spanish and 61% of US laboratories have set time limits [24, 25, 31]. Whilst it is the intention of most laboratories to establish contact ASAP, it is best to document the time limits together with a documented algorithm if contact with a caregiver cannot be made in that time frame. A previous study has found that the median

laboratory required a median of 5 min for staff to notify someone about a critical result once testing was complete [24]. Timely reporting should lead to timely clinical interventions and improve health outcomes. This timeliness can be measured and audited as a quality indicator.

According to ISO [2], the laboratory has to ensure 'records are maintained of actions taken that document date, time, responsible laboratory staff member, person notified and examination results conveyed, and any difficulties encountered in notifications' of critical results.

The frequency of review of the CRMP varies in this survey with only 40.4% of participating laboratories reviewing it annually and a substantial percentage of participating laboratories (35.4%) did not audit the CRMP. In previous survey, 50% of Ontario [6] laboratories have annual review. Audit was done by 42% of laboratories in the Australia survey [31].

The Joint Commission [10] requires laboratories evaluating the timeliness of reporting the critical results. The CRMP policy should provide guidance on what other key review criteria should be monitored and/or audited apart from timeliness of reporting. A previous Q-Probes study [24] had suggested more fruitful areas for monitoring and quality improvement which included (i) results that are not called or calls that are abandoned; (ii) the time it takes caregivers to respond to findings of critical abnormalities; (iii) the fidelity of communication; and (iv) problems communicating critical results for

RECOMMENDATION ON NOTIFICATION PROCESS

The laboratory must establish a documented procedure for the release of critical results in a clear, secure and timely manner, including details of who should release results.

The laboratory must establish a reliable process by which staff identify critical results and should have a system to identify critical results that are yet to be notified.

The laboratory should establish, in agreement with its users, who should be notified urgently of critical results. This should be the requesting clinician or other authorized health professional responsible for the patient's care either directly or through a third party such as a nurse or receptionist provided if the organization can demonstrate that there will be no significant delays in getting the test result.

The laboratory should have fail-safe communication modes of notification for critical results including verbal or nonverbal modes of communications. The laboratory should specify preferred modes of communication for critical result notification, in agreement with its users.

The laboratory must define the timeliness of reporting for critical results. In general, failure to achieve a successful notification within 1 h of critical result becoming available should prompt a review action by the laboratory. The time frame may need to be customized according to the institution.

The laboratory must establish a documented procedure for giving critical result by telephone which should include the following:

- The individuals who may give result. That person should be a qualified healthcare professional or an individual deemed competent to explain the significance of the results by the laboratory.
- The individuals who may receive result.
- A method of mutual identification of the patient between reporter and receiver. There should be a minimum of two patient identifiers.
- The date and time that the sample was collected.
- The abnormal test result with the unit of measurement and reference range.
- The urgency or significance of the result must be made clear.
- A confirmation of correct transmission with 'read-back'.
- The maintenance of confidentiality.
- Result provided verbally shall be followed by a usual paper or electronic report.

The laboratory must establish a documented procedure for giving critical results electronically according to local communication standards, which includes policy of patient privacy. Where critical results have been sent electronically, there must be an acknowledgement and confirmation of receipt within the specified timeframe. Receipt of a 'failure' acknowledgement message or failure to receive any acknowledgement within the specified time frame must initiate immediate action to deliver reports through an alternative mode of notification, such as phone. The laboratory must remain proficient in the use of an alternative mode of notification.

The laboratory should establish a documented procedure for making contact with the out-of-hours medical deputizing service with critical results if the requesting clinician has engaged this out-of-hours service. When reporting critical result to deputizing service, laboratory staff should give the following additional information:

- The name of the requesting clinician and/or the practice number.
- As much clinical history as is available, including relevant past results.
- The contact address for the patient, and telephone number if known.

The laboratory must establish a documented procedure for the action required in the event that the requesting clinician or other authorized health professional responsible for the patient's care cannot be contacted for critical results within the specified time frame. This may include an attempt made by the laboratory to contact the patient directly to arrange management. The procedure in this case must define how results are given to the patient and by whom, to avoid undue anxiety and distress. These critical results should be telephoned to the requesting clinician at the first opportunity within normal working hours.

The laboratory should have a procedure in place to ensure that interpretation and clinical advice are available from a consultant pathologist or clinical scientist; and laboratory staff must be able to contact senior members of the department for advice at all times.

Requesting clinicians have a responsibility to ensure contact details are clear and should be encouraged to provide after-hours contact numbers or to arrange proper handover arrangements. The laboratory should have a register of these contact details and keep it regularly updated.

Requesting clinicians have a responsibility to ensure providing adequate patient information with the request. The laboratory should confirm the contact details for the patient at the time of collection.

RECOMMENDATIONS ON DOCUMENTATION

The laboratory must maintain records showing urgent notification of critical results.

These records should include the following:

- The identity of the individual who delivered the result, if verbally communicated.
- The identity of the recipient of the result.
- The identity of the patient tested.
- The date and time that the sample was collected.
- The test that was performed.
- The abnormal test result with the unit of measurement and reference range.
- The date and time that the communication was made or acknowledgement of receipt of the result.
- Other relevant factors, such as difficulties encountered in result delivery or whether 'read-back' of verbally communicated result was obtained.

The laboratory must retain the records of documentation for the specified time period according to local accreditation regulation. Ideally, records should be stored electronically within a database to allow for statistical analysis of the data.

RECOMMENDATIONS ON REVIEW AND AUDIT

The laboratory should review and update the CRMP every 2 years or earlier if recommendations on action points change.

The laboratory should conduct internal audits at planned intervals to determine whether all activities in the management system:

- conform to the requirements established by the laboratory, and
- are implemented, effective and maintained including testing of electronic notification systems.

This should be performed on at least an annual basis. It is not necessary that internal audits cover each year, in depth, all elements of the management system. The laboratory may decide to focus on a particular activity without completely neglecting the others.

Useful quality indicators for measuring laboratory compliance to critical result notification procedures include the following:

- The percentage of critical results requiring communication that were not communicated.
- The average time taken to communicate a critical result (from the time the result was first available).
- The percentage of verbally communicated critical results for which 'read-back' was received.
- The percentage of notification that were not documented by the laboratory.

The laboratory should ensure that appropriate corrective action is promptly undertaken when nonconformities are identified and other relevant findings from the audit should be used to improve the management system.

outpatients. These audits are crucial to identify areas for improvement. The lack of quality indicators of the critical results audit process may mean some important aspects are not revealed.

CONCLUSION

Effective critical results management is an essential part of the laboratory service. It will reduce harm, improve patient safety and should be mandatory for laboratory accreditation. Adherence to critical results management guidelines has continued to improve as shown in this survey, but the process should be further developed and harmonized.

The laboratory must have a documented policy for the communication of critical results to the responsible clinician or carer and it is essential that this includes a read-back policy in verbal notification to avoid errors of transcription. The critical results management policy should be regularly reviewed and audited.

The recommendations in this paper represent a consensus of good laboratory practice. They are intended to encourage implementation of a standardized critical results management protocol in the laboratory. This should encourage consistency of practice between pathology providers and provide standardization of service expectations for clinicians. It should also encourage better provision of contact information and responsiveness to critical results by clinicians.

Improved critical results management should result in a reduction in medico-legal challenges and, more importantly, better patient care. On the other hand, it is important not to give a false sense of security to

clinicians, resulting in a reduction in their sense of responsibility for review and follow-up of the investigations they have requested. When establishing a critical results management policy, the laboratory must consider the resources required to sustain the desired level of service, as a loss or reduction in the service could have severe, adverse effects on patient care.

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CONFLICT OF INTEREST

This study was financially supported by the ICSH. The ICSH is a not-for-profit organization sponsored by unrestricted educational grants from its corporate and affiliate members who are listed in Appendix S2.

Gini Bourner works as a consultant for Phoenix Airmid Biomedical. All other authors declare that they have no conflict of interests.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1: Pattern of Practice Survey.

Appendix S2: ICSH Corporate and Affiliate Members