The Royal College of Pathologists
Pathology: the science behind the cure

Best practice recommendations

The communication of critical and unexpected pathology results

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Contents

Foreword

Best practice recommendations (BPRs) published by the Royal College of Pathologists should assist pathologists in providing a high standard of care for patients. BPRs are systematically developed statements intended to assist the decisions and approach of practitioners and patients about appropriate actions for specific clinical circumstances. They are based on the best available evidence at the time the document was prepared. It may be necessary or even desirable to depart from the advice in the interests of specific patients and special circumstances. The clinical risk of departing from the BPR should be assessed and documented.

A formal revision cycle for all BPRs takes place every 5 years. The College will ask the authors of the BPR to consider whether the recommendations need to be revised. A full consultation process will be undertaken if major revisions are required. If minor revisions or changes are required, a short note of the proposed changes will be placed on the College website for 2 weeks for members' attention. If members do not object to the changes, a short notice of change will be incorporated into the document and the full revised version will replace the previous version on the College website.

This BPR has been reviewed by the Professional Guidelines team. It has been placed on the College website for consultation with the membership from 27 March 2025 to 24 April 2025. All comments received from the membership will be addressed by the authors to the satisfaction of the Clinical Director of Quality and Safety.

This BPR was developed without external funding to the writing group. The College requires the authors of BPRs to provide a list of potential conflicts of interest. These are monitored by the College's Professional Guidelines team and are available on request. The authors of this document have declared that there are no conflicts of interest.

1 Introduction

This document is published as 'advice to pathologists' and is offered as a basis on which pathologists can construct local guidelines after discussion with relevant stakeholders. It is vital that this document is seen as guidance for pathology providers to set their own criteria on how, when and why particular laboratory results are required to be communicated to clinical professionals in an expedited manner. It also explicitly encourages consultation with service users to set criteria which will directly influence the patient pathway.

This document will refer to the communication of laboratory results to all areas of clinical responsibility, including both primary and secondary care. Similarly, it will refer to within hours and out-of-hours (OOHs) periods where relevant. However, it must be acknowledged that local definitions will inevitably determine and define the explicit arrangements that are put in place for each individual pathology provider service. Cellular pathologists are expected to promptly communicate the results of autopsy examinations to clinical teams and the Coroner/Procurator Fiscal, but this is outside the scope of this advice.

Stakeholders

The following are stakeholders in facilitating the effective, rapid communication of critical or unexpected laboratory test results:

- pathologists (medical staff and clinical scientists)
- all other laboratory staff, including biomedical scientists
- general practitioners (GPs)
- secondary care clinicians and other staff
- OOHs providers of primary care.

2 Background

There are clearly many situations whereby the rapid communication or raised awareness of a critical or unexpected laboratory test result can significantly alter the time taken for appropriate medical care to be initiated that would otherwise have been delayed and in turn would likely to be detrimental to patient care and outcome. Therefore it would be expected that all pathology providers across the country would have systems in place to both identify and communicate such results. Having an appropriate system in place to cover such communication of results is an explicit requirement of ISO 15189:2022.

The main purpose of this document is to introduce a degree of consistency and to promote the general principle of the responsibility of laboratory services to organise a service to ensure the communication of critical or unexpected results to the clinical teams responsible in a timely manner.

3 Identification of laboratory test results for rapid communication

There are many reasons why specific laboratory test results may require more rapid communication. While this document is concerned mainly with such test results that may be life threatening or of immediate clinical significance and that require urgent action, it should also be acknowledged that rapid communication of results may also be required in several non-clinical situations, such as the need to meet or maintain patient flow targets within the wider organisation or to enable a more efficient use of healthcare resource. Administrative expediency should not however outweigh the need for accurate diagnosis. Consideration should be given to the balance between maintaining patient flow targets and managing laboratory and staff resources so that laboratories are not placed under unnecessary pressures.

A markedly abnormal test result that may be deemed urgent or critical is one that may signify a pathophysiological state that may be life threatening or of immediate clinical significance. The classification and explicit definition of such results are likely to be different, depending on the clinical setting and scenario. This needs to be defined and agreed at local level through direct discussion with key stakeholders in both primary and secondary care. Other factors clearly need to be taken into account, such as whether the markedly abnormal laboratory test result is a new first-time occurrence, an unexpected result for that particular clinical setting or if an unacceptable time delay would normally occur if the decision to more rapidly communicate the said result was not made.

The Royal College of Pathologists' Specialty Advisory Committees have drafted commentary and, where possible, created lists of suggested tests and triggers for expediting communication to both primary and secondary care (see Appendices A–E). It is advised that pathologists should use these lists as a starting point, with modification being made as a result of local negotiation and to address local clinical circumstances.

Where possible, pathology providers should use electronic mechanisms for the automatic selection of results for urgent communication based upon absolute results or associated changes from previous results.

In cellular pathology, relatively few reports require urgent communication. Examples of those that do are given in the discipline-specific guidance in Appendix A.

4 Definitions

The following definitions have been modified from Masood and Karim (2020)[1]:

- unexpected result: A result which would not be routinely expected. This may be an out-of-range result or one that in unexpected for the patient given their clinical condition e.g. a positive mycobacterium tuberculosis result from thumb tissue in a patient who presented with a traumatic injury to their thumb.
- urgent result: test results that are significantly outside the normal (reference) range, but which do **not** indicate an immediate dangerous or life-threatening state.
- critical result: test results that are significantly outside the normal (reference) range and which indicate an immediate dangerous or life-threatening state.

This guidance is focusing on the handling of critical results.

5 Methods for rapid communication

Traditionally the route of communication of rapid results has been by telephone, however developments in technology now exist and more will be available in the future. If available, pathology providers should use automated electronic systems that provide real-time rapid alerts for critical or unexpected laboratory test results. The use of real-time rapid electronic alerts will reduce the risk of transcriptions errors and should also have a feedback mechanism to allow the laboratory to ascertain whether any such alert has been received, read, understood and even actioned. It is the joint responsibility of laboratory and clinical teams to ensure that such a process is audited to ensure that there are no missed results.

Development of such automated electronic alert systems is currently in its infancy and therefore it remains likely that the mainstay of communication will be direct verbal communication, either in person or via a telephone call between the laboratory and the clinical teams.

As stated previously, it is important that laboratory services negotiate directly with all clinical areas to ascertain the specific classification of critical or unexpected laboratory test results relevant to their service, and to identify exceptions to any rules that may be put in place. It is likely that a balance will need to be struck to avoid saturation of the system and not put unnecessary demands upon both the laboratory service having to make the calls and the clinical units having to receive them and take action. The communication between

laboratory and clinical areas needs to be balanced against unnecessary demands on the laboratory service and the need to ensure patient safety at all times.

6 Result communication content

When rapid communication of a laboratory test result is indicated, the information in the following list should be provided to the clinical team:

- name and date of birth of the patient, together with any unique patient identifier
- the critical or unexpected test results with units, along with any reference range if relevant or requested
- the date and time of the request (noted that a variety of parameters can be recorded)
- the name of the requesting clinician or primary care practitioner – this is usually only relevant if the patient has moved from the location where the sample was taken e.g., the emergency department (ED).
- any relevant clinical history that may be available (if the patient is unknown to the clinician receiving the result) or relevant past laboratory test results
- a contact address for the patient and any telephone number if known for primary care patients and notification to the local health protection team.

The circumstances and setting of the clinical team receiving the communication needs to be considered; the type of information required by an OOHs provider of primary care will be very different to that required by an intensive care department with live electronic availability of laboratory results which can result in a reduced need for verbal communication.

The rapid communication of such information could be provided by consultant pathologists, clinical scientists, trainees or biomedical scientists. Further interpretation and appropriate clinical advice should, however, also be available from the relevant consultant pathologist or clinical scientist as appropriate, or from a trainee after consultation with a senior member of their team, and where this has been made available, either within the same or next normal working day.

An electronic means of recording when results are urgently communicated should be in place, which should also record the name of the person to whom the result was

communicated, the name of the laboratory person communicating the result, and the date and time of the communication. As described above, this could be achieved using local LIMS.

7 Responsibilities for the rapid communication of critical or unexpected test results

Pathology providers have a responsibility to put mechanisms in place that allow the identification and rapid communication of critical and unexpected laboratory test results. It would also be expected that pathology providers negotiate with secondary care clinicians, GPs, other members of the clinical team and OOHs primary care providers to ensure robust mechanisms are in place so that appropriate action is taken following rapid communication of such results. There is also a responsibility placed upon the users of the service to ensure clear requesting instructions, contact information and awareness of self-checking of results once requested, in an appropriate and timely manner and in line with pathology providers' user information. It is the responsibility of the pathology providers to ensure that user information is kept up to date, especially with contact details.

It is also vital that local guidelines are in place, especially in primary care, to deal with patients with critical results. Any failures or gaps in the system that may lead to suboptimal patient care should be reported directly back to the employing organisations.

Pathology providers should have protocols in place to cover contingencies when a member of the referring team or surrogate is not contactable.

8 Reporting of results directly to patients

Our recommendation remains that critical results are only communicated with the requesting clinical team. However, in recent years, healthcare policy has been moving towards the concept of patients being able to receive their pathology test results directly. While this is currently largely focussed on patient access via primary care portals, it is likely that pathology providers may need to consider the communication of some laboratory test results directly to patients, and this may include the need for rapid communication methods for critical or unexpected results. This document will not seek to cover these aspects.

9 References

1. Masood A, Karim MY. The Clinical Approach on Receipt of an Unexpected Laboratory Test Result. *Int J Gen Med* 2020;13:969–976.
2. NHS. *Notifiable diseases.* Published November 2023. Accessed January 2025. Available at: www.infectionpreventioncontrol.co.uk/wp-content/uploads/2023/12/GP-10-Notifiable-diseases-November-2023-Version-3.00-2.pdf
3. Ratnaraja N, Davies AP, Atkins BL, Dhillon R, Mahida N, Moses S *et al.* Best practice standards for the delivery of NHS infection services in the United Kingdom. *Clin Infect Pract* 2021;12:100095.

Appendix A Clinical Biochemistry

The guidance shown in the table overleaf, incorporating suggested cut points/thresholds for communication of critical results to users should be viewed in the context of the specific services to which they apply, these should focus on the clinical outcome and whether any action will be taken based on these results. Deviation may of course be justified and discussion with clinical services locally is encouraged.

Local decisions also need to be made as to the circumstances whereby rapid communication is made OOHs to GP services or as a result of a sample from outpatient departments. It would be envisaged, that results requiring communication would have a direct impact on patient care during the OOHs period. It is appreciated that service provision does vary, and the process will depend on the nature of the OOHs cover provided and the timing of the sample. It has been suggested that for some tests, direct communication the next working day will be adequate; this assumes the result in question is identified on a Sunday–Thursday, OOHs only, otherwise more immediate communication may be justified. Communication type B in the table suggests communication within 24 hours to a GP or GPs' OOHs service.

Laboratories may also consider, following local consultation, less stringent thresholds for OOHs communication for some of the analytes. Where service users have alternative electronic mechanisms for urgent alerting, this may replace or be interchangeable with phoning the result.

Note that the following guidance is relevant for adult patients only, unless otherwise stated.

Notes for the table overleaf:

a) action limits: assume lower and upper cut points are ≤ or ≥ respectively.

b) communication type

- A = rapid communication within 2 hours, usually by telephone
- B = OOHs then communication within 24 hours to GP/GP OOHs service

c) 354 umol/L cut point aligned with the National AKI Algorithm (www.england.nhs.uk/akiprogramme/aki-algorithm/)

d) please see 'Comments' column of the table for explanation

e) please see 'Comments' column of the table for explanation.

Analyte (serum/plasma)	Units	Action Limits[a]		Communication Type[b]		Comments
		Lower	Upper	Primary Care	Secondary Care	
Na	mmol/L	120 (130 if < 16 yrs)	160	A	A	Note particular concern of risk of death in children with hyponatraemia.
K	mmol/L	2.5	6.5	A	A	Exclude haemolysis/ old samples/ EDTA contamination first. Agree, by local consensus, higher thresholds for phoning results in patients with known kidney disease including those on dialysis.
Urea	mmol/L		30 (≥ 10 if < 16 yrs)	A	A	Agree, by local consensus, higher thresholds for phoning results in patients with known kidney disease including those on dialysis. Specific local cut points likely to be required for babies and neonates. Cut offs may be based on either urea and creatinine concentrations and/or AKI alerts.
Creatinine	umol/L		354[c] (≥ 200 if < 16 yrs)	A	A	
Glucose	mmol/L	2.5[d]	25 (≥ 15 if < 16 yrs)	A	A	Exact cut points and response should be determined locally. [d]Glucose results < 2.5 mmol/L from primary care may be less crucial to telephone immediately. For GPs and OPD, an upper cut off point of 30 mmol/L in known type 2 DM may be more appropriate.

Calcium (adjusted)	mmol/L	1.5	3.5	B[e]	A	[e] Primary Care: If OOHs then communication next day to GP or GP OOHs service. Calcium levels ≥ 3.5 mmol/L may warrant more immediate communication with Primary Care as agreed by local consensus.
Mg	mmol/L	0.4		B	A	
PO4	mmol/L	0.3		B	A	
AST	U/L		15 x ULN	A	A	Agree specific cut points with key users locally (A&E, Liver Unit/Medical Admissions, GI Medicine). Pathology departments should consider lower limits in specific circumstances or conditions (e.g. pregnancy).
ALT	U/L		15 x ULN	A	A	
Total CK	U/L		≥ 5000	A	A	
Amylase/ Lipase	U/L		5 x ULN	A	A	
Total Bilirubin (neonatal)	umol/L	300		A	A	In children <28 days old. Agree a specific threshold with neonatal clinicians based on the cutoff point at which they will act to request a newborn child is immediately re-admitted to hospital for treatment.
Digoxin	ug/L		2.5	A	A	Check timing >6hrs from last dose. More urgent if K+ < 3.0 mmol/L. Telephone immediately to primary care if overdose suspected (or K+ low).
Theophylline	mg/L		25	B	A	
Phenytoin	mg/L		25	B	A	
Lithium	mmol/L		1.5	B	A	
Triglycerides	mmol/L		30	A	A	Any new occurrence or when clinical details suggest patient may be at risk of pancreatitis.
CRP	mg/L		300	A	-	

Troponin (I or T)			Local cut off for MI	A	-	Exact cut point should be discussed with local clinicians in cardiology and Primary Care.
AKI			AKI-3	A	A	To be agreed with local renal clinicians.
AKI			AKI-2	A	A	To be agreed with local renal clinicians.
AKI			AKI-1	B	A	Only if K >6.0 mmol/L. – to be agreed with local renal clinicians.
Ammonia	umol/L		100	-	A	
Bicarbonate	mmol/L	10		-	A	
Cortisol	nmol/L	50		B	A	Unless part of overnight dexamethasone suppression test. If part of a short synacthen test then communicating may not be required if 30 min sample result is >250 nmol/L or agreed locally.
Ethanol	mg/L		4000	-	A	or 400 mg/dL − consider much lower threshold in paediatrics.
Paracetamol	mg/L		f	A	A	f − All detectable levels − Agree specific thresholds locally with acute admissions/A&E − especially for paediatric samples.
Salicylate	mg/L		300	A	A	Agree requirement and specific thresholds locally with acute admissions/A&E.

Appendix B Haematology

A more rapid mechanism for communication of specific haematology tests may be required for both primary and secondary care to initiate the following action:

1. immediate medical intervention, including admission to hospital or change in the patient's treatment
2. urgent referral for assessment during next working day
3. urgent referral to an outpatient clinic.

While the decision to rapidly communicate any test result will be based solely on the numerical values obtained initially, the assessment and clinical decisions will depend on the clinical context and the input of the consultant haematologist with whom the result should be discussed.

If the patient is known to the department and has had a similar result within the previous 7 days, urgent contact is not necessary and the report can be processed as normal, whereas a de novo finding should always be responded to.

The following table shows suggested criteria that haematology laboratories could include in their own local standard operating procedures. These will also be influenced by the availability of previous results, together with the findings of a delta check of the relevant abnormality.

Full blood count parameters

Parameter	Unit	Level	Comment
Haemoglobin	g/L	<50	Microcytic or macrocytic anaemia
	g/L	<70	Normochromic, normocytic as this might suggest blood loss or bone marrow failure
	g/L	>190	Or haematocrit above 55 l/l. Only requires urgent referral if there appears to be compounding medical problems
White cell count			
Neutrophils	$x10^9$/L	<0.5	
	$x10^9$/L	>50	
Lymphocytes	$x10^9$/L	>50	Requires urgent but not immediate referral
Platelets	$x10^9$/L	<30	

Platelets	$x10^9/L$	>600	Requires assessment and referral
Platelets	$x10^9/L$	>1000	Requires urgent referral for assessment

Blood film

Presence of blasts or diagnosis suggestive of chronic myeloid leukaemia		Discuss with the covering haematologist prior to deciding what action should be taken
Malaria parasites	Positive	

Coagulation

INR		>5.0	For patients on warfarin
INR		>6.5	Requires urgent assessment

Appendix C Immunology

Diagnostic immunology laboratories do not, in general, offer routine sample testing on Saturday or Sunday or testing on a 24/7 basis in the UK. Most units operate routinely within normal working hours similar to those in primary care. However, this may change in the coming years, with the push being made towards full 24/7 basis of availability across healthcare sectors. It is therefore unlikely currently that many immunology-derived results will trigger the need for immediate clinical intervention. However, it is recommended that the requesting clinician or member of the team is contacted with test results in certain clinical situations as shown in the table.

Critical results should be communicated to the requesting clinician as soon as possible once a result is available. This should be communicated by a consultant immunologist, immunology registrar or clinical scientist/biomedical scientist.

To comply with ISO15189:2022 standards, an electronic record should be kept of all critical results that are communicated. The member of staff communicating the result should make note of the message in the appropriate patient record within LIMS. Minimum requirements for the record are:

- record which laboratory test result was communicated
- name of person communicating the result
- date and time the result was communicated to the clinical team
- name, job title and location of the person receiving the result.

Laboratories should have an escalation procedure in place for laboratory personnel with a responsible person cannot be contacted.

Laboratories should regularly audit the communication of critical results (e.g., through KPIs, QIPs and/or within audit cycles) and through UKAS ISO15189:2022 regular inspections.

Autoimmunity

Results that must be communicated at the earliest opportunity within autoimmunity include the following:

- new finding of positive **MPO** antibodies^{+}
- new finding of positive **PR3** antibodies^{+}

- new finding of positive anti-neutrophil cytoplasmic antibodies (**ANCA**)*
- new finding of positive **GBM** antibodies.

* New findings of a positive pANCA by IIF (MPO and PR3 negative) in the context of IBD/liver disease are unlikely to require urgent communication.

+ Low positive/equivocal ANCA/MPO/PR3 results should be interpreted in the clinical context and decision to communicate is based on whether features of small vessel vasculitis are present and locally devised decision thresholds in agreement with service users.

Liver antibodies

New finding of positive **LKM, SMA, SLA or LC-1** liver autoantibody in a child with very high ALT.

Investigation of plasma cell dyscrasias (myeloma)

Results that must be communicated at the earliest opportunity relating to the investigation of plasma cell dyscrasias and multiple myeloma are recorded in the table below. This includes new serum monoclonal paraproteins, urinary Bence Jones proteins and abnormal serum free light chain (sFLCs) results that indicate diagnosis of plasma cell dyscrasias or B cell lymphoproliferative disease.

These criteria should be used as a guide only. Agreed communication pathways with local haematology departments should be established. Findings of new paraproteins/abnormal sFLCs ratios outside of these ranges with a strong suspicion of myeloma or LPD (e.g., CRAB features) should be communicated at the discretion of the reporting immunologist. Urgent communication should be by telephone or alternative method where receipt of the communication can be promptly acknowledged. Discussions with local haematology departments should be undertaken if results are not clear or there are any concerns.

Sample / test result	Referral type
Any paraprotein/abnormal sFLCs ratio with significant symptoms indicating an urgent problem (e.g., spinal cord compression, acute kidney injury)	Immediate referral to Haematology
Serum IgG paraprotein >15 g/L	Referral to Haematology
Serum IgA or IgM paraprotein >10 g/L	
IgD or IgE paraproteins regardless of concentration	
Light chain only kappa or lambda paraproteins in urine or serum	
Abnormal sFLCs ratio of >7 or <0.1 with involved light chain > 100mg/L or identification of BJP*	
An increase in paraprotein concentration of >25% and >5g/L in patients monitored in primary care	Referral to Haematology

*Cut-off values given for sFLCs are based on the FreeLite-specific assay – given significant analytical variation in sFLCs methods, laboratories should determine locally derived cut-off threshold in agreement with service users.

Suspected immunodeficiency

Results that must be communicated at the earliest opportunity for suspected immunodeficiency include the following:

- any result supporting a new finding of severe combined immunodeficiency (**SCID**) in a child should be communicated urgently to the local paediatric team and to the paediatric Immunology team at Great Ormond Street Hospital (GOSH) or Great North Children's Hospital, Newcastle (geography-dependent)
- **new severe lymphopenia**
- **marked hypogammaglobulinaemia**
- **absent T cells** by flow cytometry testing.

These criteria should be used as a guide only. Laboratory findings with a strong suspicion of any primary immunodeficiency can be communicated at the discretion of the reporting immunologist.

Appendix D Medical microbiology and medical virology

Introduction

Timely reporting of results to the responsible clinician is crucial for optimal patient management and care. Processing of microbiology specimens may take only a few minutes (e.g. Gram film) or days for batched and reference laboratory requests. Hence, the concept of 'critical' results in microbiology mainly applies to the more acute diagnostic results, with immediate implications for infection control and sepsis management.

However, for virology laboratories, urgent testing may be required, for example, for blood-borne virus exposure incidents, late booked pregnancies, varicella zoster virus (VZV) IgG or measles IgG testing in those at risk who have been exposed.

Other tests may be considered urgent but not time critical e.g. HIV and other blood-borne virus infections in a critical care setting, respiratory and gastroenteritis viral infections.

Evolution of the medical microbiologist's clinical role – more pressure on time, more emphasis on ward rounds, bedside consults, infection control, outpatient parenteral antimicrobial therapy (OPAT), etc – necessarily means less time in the laboratory and to telephone non-urgent results, so a very prescriptive list is not very helpful in microbiology (compared to the quantitative blood specialties) since so much depends on the clinical scenario. Timely administration of appropriate antimicrobials to septic and less acutely unwell patients in multiple specialties is the aim and is usually mostly achieved with empirical prescribing guidelines. However, unexpected results, e.g. Gram negatives seen in septic arthritis, where empirical antimicrobials may not cover, must be communicated quickly to the correct clinician. From a virological perspective, there is also more emphasis on multidisciplinary (MDT) meetings, bedside consultation, outpatient clinics as well as telephone advice from local and referral hospital staff.

Guidance must be framed within local arrangements and recommendations, not rules, and also reflect national guidance if available.

Recommendations for microbiology and virology departments

1 Departmental policy

a) **Each department should create its own policy for communication of critical and unexpected results** felt to be critical for optimal patient management, and within the capabilities of the systems locally. These may be time critical and suspected e.g.

meningococcus, or unexpected by felt to be critical because of e.g. infection control and treatment implications e.g. finding a carbapenemase producing organism upon culturing a sample.

b) **The departmental policy should reflect local clinicians' needs**, be workable and agreed by clinicians and microbiologists. Centralisation and automation of laboratories may affect turnaround time and reporting to the local site; this must be communicated in the pathology handbook so clinicians are aware.

c) **The policy should reflect local laboratory information management system (LIMS) and the availability of human resources,** e.g. automatic comments and interim reports may suffice for some conditions, whereas life-threatening sepsis warrants immediate communication (usually by telephone) to the clinician, e.g. positive blood cultures with likely significant pathogens, CSFs. In addition, viral RNA or DNA detected in CSF samples, new HIV positive and other blood-borne virus results, viral DNA detected in whole blood samples, respiratory and gastroenteritis virus positive results impacting immediately on the management of the patient as well as infection control issues may require urgent communication. Departments should decide which results will immediately impact on patient management and require immediate telephoning rather than just reporting via LIMS. This should include urgent results that need to be reported to the local health protection team in accordance with their policies.

d) **The critical and unexpected results should be communicated, in accordance with local agreement, to the requesting clinical team or clinician on call** – never to the patient directly. Ideally the result should be communicated to the clinician best placed to make a management decision based on the results. For example, positive MRSA screens may be telephoned to the nurse who can institute infection prevention and control measures in line with local policy. However, a positive blood culture or CSF requires a prescribing clinician to be informed of the result, and a prescriber who can clinically review the patient if required. Result communication should the most appropriate individual health care team member to enable robust documentation, immediate actions and avoid transcription errors. The use of the optimal methods of communication with up to date contact details of clinical team members is desirable and if possible, should be part of the departmental communication of results policy. **Critical results such as positive blood cultures/csfs must not routinely be emailed to a consultant if not also telephoned to the parent team** (unless by prior

arrangement, e.g., to a manned 24/7 inbox). Clinicians are not at their computers 24/7 and so the result may not be seen within the appropriate time frame. Blood cultures which become positive after a patient has been discharged must be telephoned to the last team to care for that patient. For example, if a patient was discharged from a medical ward, then that team must be notified of the blood culture. If the patient had a blood culture taken in the emergency department (ED) and subsequently discharged without admission, then a clinician in ED must be telephoned of the result. If a patient has been transferred to another hospital, then the microbiology team for that hospital must be notified of the positive blood culture. Departments must agree on a local policy for blood cultures that look like potential skin contaminants in patients who have been discharged home and if these need to be called out urgently. This may need to be decided on a case-by-case basis i.e. based on the patient's clinical condition.

e) **Communication of results, specifying to whom the result was communicated and when, should be documented where most appropriate,** usually on the LIMS system directly and/or in the workbooks or working diaries/systems held by clinical staff, the latter only being used where the LIMS/EPR does not allow for the transcribing of pertinent detailed information.

2 Interim reports

For those interim results that need to be reported to clinicians urgently, they should be issued electronically, clearly marked as interim, via LIMS and wherever possible telephoned. Reporting conversations and advice via LIMS helps to avoid transcription errors or misunderstandings.

For results that are felt to be urgent but not critical, such as interim results for presence of significant Group A streptococci but before sensitivity are ready, the interim result may be issued to help the clinician expedite treatment. The need to make a result critical is very contextual; for example, Group A streptococci in a GP patient may be authorised as an interim report but need not be telephoned. In contrast, the same result in an inpatient has the potential for ongoing transmission in secondary care and therefore needs to be telephoned to the team, either by the clinical team (especially if there is concern regarding a deeper/disseminated infection such as necrotising fasciitis), or by the infection prevention and control team.

3 GP patients

3.1 GP patients within normal working hours

Time critical or unexpected results that require urgent attention e.g. a toxin positive *Clostridioides difficile* result, anything listed as urgent on the Notification of Infectious Diseases Poster should be telephoned to the GP practice as soon as possible.[2] A local decision must be made as to whether reception staff can take the call or if there is a need to speak to a practising clinician (e.g. with positive *C. difficile* results). For less urgent/critical results, some integrated care boards (ICBs) provide primary care with generic email addresses. Discussion with ICBs could help to streamline workload by allowing for emailing of certain urgent results, provided there is a dedicated person to review those results in a timely manner.

3.2 Critical or unexpected results on GP patients out-of-hours

Laboratories should telephone significant results from GP patients when OOHs to the local OOHs doctors' service, including at weekends. In many cases this OOHs service is provided by the ICB and local Health Protection Unit (HPU), which includes urgent notifications to UKHSA as per the Notification of Infectious Diseases (NOIDS) statutory notifications. It is preferable for services to be run via ICBs rather than 111 as the former have dedicated staff with experience in infection. However, not all ICBs will have this resource and local agreement must be made as to the best way to communicate critical and urgent results.

Examples of results that should be telephoned OOHs include:

- *C. difficile* toxin positives (GP service to review patient)
- PVL positive MRSA isolates (for notification [HPU] and management [GP])
- Significant Group A streptococcal isolates, i.e. in maternity patients, necrotising fasciitis and invasive Group A Streptococcus (notification [HPU] and management [GP])
- Significant salmonellae, e.g. *Salmonella typhi*, *Salmonella paratype* and any isolate associated with a potential outbreak (for notification [HPU] and management [GP])
- acute viral hepatitis A or B (to the OOH HPT)
- VZV IgG negative results for those exposed to -VZV and at risk (e.g. immunocompromised, pregnant women, neonates) to the OOH GP service

- Measles RNA or IgM positive or measles IgG negative results in at risk patients exposed to measles (to the OOH HPT).

4 Reporting to UK Health Security Agency or equivalent bodies in the devolved nations

Microbiologists/Virologists may telephone any urgently notifiable infections to the clinical teams as well as the UK Health Security Agency (UKHSA) Health Protection Team. Non-urgent notifiable diseases should be communicated to the local health protection team (HPT) by the direct care clinician. Results related to enteric or respiratory outbreaks and notifiable diseases that require urgent notification may be telephoned to the local HPT by the microbiologist/virologists or the clinician looking after the patient, depending on who is best placed to provide the relevant information. (See *Reporting to UKHSA: a guide for diagnostic laboratories* for more information). Non urgent notification may be communicated electronically, e.g. by email.

4.1 What type of results should be telephoned in secondary care?

There are variations in practice around the country according to:

- local needs
- the types of specimens processed by individual laboratories
- who actually telephones, e.g. consultant/specialty trainee microbiologist/virologist, biomedical scientist or clinical scientist
- the degree of importance microbiologists and virologists place on certain results.

British Infection Association (BIA) and RCPath have published *Best practice standards for the delivery of NHS infection services in the United Kingdom* which includes results which are deemed to need urgent processing.[3] These would therefore also yield results that require urgent communication to the requesting clinician and are listed below:

- new positive microscopy or significant culture normally sterile sites, e.g. blood, cerebrospinal fluid (CSF), tissue, biopsies, unless there is reasonable evidence of contamination, or the nature of the infection is already known and the patient is on appropriate treatment. Joint fluid results according to local agreement only.
- new isolates from tissue or bone may need to be telephoned (unless the details indicate a chronic infection, such as infected ulcers or diabetic feet)

- new results that indicate an urgent need to isolate the patient or initiate other infection control measures. This depends not only on the result, but the location of the patient. For example,:
  - one would urgently telephone a new smear positive TB in an inpatient but could either email a chest clinic TB result or make a non-urgent call the next working day.
  - unexpected results with significant clinical/infection control/public health impact (e.g. *S. typhi*, *Escherichia coli* O157, *Salmonella dysenteriae*, *Campylobacter*), salmonella or norovirus must be telephoned if inpatients or nursing home residents.
  - respiratory virus and gastroenteritis viral infections (depending on local capacity and agreement) measles results – IgM or RNA positive should be telephoned to ICP.

Other examples of results that require urgent communication:

- corneal scrapes, vitreous taps, aqueous taps, who communicates these results depends on local agreement and organism identified
- cerebral and hepatic abscesses
- potentially toxic or subtherapeutic antimicrobial serum levels. This may be communicated by a blood sciences biomedical scientist or clinician if they process the samples as per local agreements.
- measles IgM or PCR positive
- herpes simplex virus (HSV) or VZV PCR positive results in eye swabs, immunocompromised patients, neonates, antenatal and immediately postnatal patients. Communication of these results will depend on clinical scenario.
- aspergillus or galactomannan PCR positive blood
- emerging pathogens and uncommon pathogens that can cause significant mortality and/or morbidity e.g. viral haemorrhagic fever viruses, MERS-CoV, avian influenza
- HAV IgM positive
- HBc IgM positive (if HBsAg positive)
- VZV IgG negative in at risk patients and staff exposed to VZV

- measles IgG negative in at risk patients and staff exposed to measles.

NB: This list is not exhaustive and other results may need to be communicated urgently based on clinical scenario of the patient and/or situation within the Trust, hospital or ward, e.g. outbreak scenarios.

4.2 Who should telephone results?

Again this is a local decision; may be junior F2/non-clinical staff but only under the direct supervision of a senior member of the team.

4.3 Who should receive results?

The departmental policy should state explicitly a list of the types of qualified staff who would be felt appropriate recipients to receive results.

Preferably – and this is not the responsibility of microbiology – there should be a documented and agreed procedure for recording and disseminating the results at the clinical end, e.g. which results can be given to GP receptionists, or who should receive the final result OOHs.

Appendix E Cellular pathology

Cellular pathology differs from other pathology disciplines in that the processing of the specimen usually takes from several hours to a day or more, the exceptions being frozen sections and some cytology samples. The concept of 'critical' results is therefore less applicable but is interpreted as those results which would be likely to affect patient management within 24 hours of the specimen being taken or those situations where further prompt action by the clinical team is likely to be helpful. In cellular pathology, effective and timely communication of results is important for safe patient care.

Most cellular pathology samples result from invasive procedures and are needed for diagnosis, prognosis or monitoring. As such, the referring clinician is responsible for ensuring both that they have indicated any degree of clinical urgency to the laboratory, and that they have received and acted upon the report. This primary responsibility is not dependent on any communication from the laboratory.

Pathologists should consider the following examples of situations in which results might need to be communicated urgently to clinicians, outside the normal parameters for the electronic delivery of laboratory results.

1 Cases where there is a predictable degree of urgency

Such cases would include intraoperative frozen sections, some medical renal biopsies and some biopsies from organ transplant patients where prompt assessment according to local protocols will determine the management of the patients.

2 Cases unexpectedly found to be infectious

The clinical implications and severity of the infection, risk of transmission of infection to staff, other patients and the public, and the need for immediate contact tracing should be considered by the reporting histopathologist. Consideration should also be given as to whether or not the condition is a notifiable disease.

3 Expected malignancy case where no malignancy is found in the specimen

Frequently this will result in extra sections and/or levels being examined by the reporting pathologist. The requesting clinician may benefit from a warning that further laboratory work is underway and may be able to provide additional relevant clinical history. If no malignancy is found at the end of a thorough histopathology search, there may be

cases where the possibility of a wrong site surgery never event should be considered. Such cases should be discussed with the requesting clinician in the first instance.

4 Biopsy or removal of an unexpected organ

While acknowledging this an extremely rare occurrence, it is important to communicate immediately to ensure clinical follow up for unexpected clinical complications and repeat biopsy of the correct organ. Please note, some organs are regularly biopsied en passant, e.g. rectal mucosa in transrectal ultrasound biopsies of the prostate; this does not constitute an unexpected finding as covered by this guidance.

5 Unexpected finding of malignancy

This is important where the case would not routinely be scheduled for MDT meeting discussion and there is a risk that the histopathology report may be missed by the requestor. An example of this would be a melanoma removed by a GP who anticipated that the lesion was a benign lesion.

6 Findings that trigger a particular referral pathway

An example of this would be molar pregnancy identified in products of conception.

6.1 Recommendations for cellular pathology departments

- Each department should create its own policy for urgent diagnoses and should define criteria for significant unexpected diagnoses.
- Pathology departments should determine specific urgent diagnoses in collaboration with the referring clinicians. These diagnoses should include situations in which urgently conveying the information might directly affect patient care.
- Pathologists should use their clinical judgment to determine which results should be communicated urgently. This would include cases where a diagnosis is significantly modified after the initial report.
- Methods of communication should be established to suit each referring team. For example, the LIMS can generate automated electronic alerts for specific diagnoses. Malignant diagnoses, especially where unexpected, can be referred to the appropriate MDT.
- Where considered appropriate, direct verbal communication between the pathologist and the referring clinician/clinical team may be the most effective method.

Pathologists should document the communication, either within the original pathology report, as an addendum or in the LIMS. The documentation should include who spoke with whom, the date and the time.

- The departmental policy should include a procedure for the contact of clinical teams with urgent diagnostic information. This may include the referring clinician or other healthcare professionals, with details of how to contact them directly or through hospital switchboards. In some situations, a process may be required for escalating the results to others if the designated recipient is unavailable.
- If it is anticipated that there will be a significant delay in the preparation of a final written report (for example in waiting for additional investigations, referral to another colleague or referral to another centre), an interim report summarising the current position and differential diagnosis may be issued to the relevant clinical team so that the timing of clinical review, e.g. outpatient attendance, can be optimised. The decision when to issue an interim report is one of clinical judgment, based upon the context of the case. The case should be tracked in the laboratory to flag that a final report is still outstanding and a final written report should be issued as soon as possible.

Appendix F Histocompatibility and immunogenetics

The following situations are those in which test results must be communicated to clinical teams for urgent action.

Deceased donor HLA type

The timely reporting of deceased donor HLA types into NHS Blood and Transplant (NHSBT) Organ Donation and Transplantation (ODT) is critical to the minimisation of organ ischaemia time and outcomes of transplantation. A report meeting the minimum reporting requirements for allocation as defined by NHSBT ODT must be submitted as soon as typing is completed.

Deceased donor HLA type discrepancy

A difference in the donor HLA type between the donor and recipient centres may have implications for patient management resulting from a changed match grade, repeat mismatch and/or presence of donor HLA specific antibody against unsuspected mismatches. In all such circumstances the finding must at the earliest opportunity be communicated to the other centre involved in the discrepancy, to NHSBT to allow revision of match grades for other offers from the same donor and to the local centre Consultant with direct responsibility for patient care. The information must, as appropriate, include detail of the revised match grade, repeat mismatches and antibody conflicts.

Deceased donor crossmatch results

The expedient reporting of prospective crossmatch results for deceased donors is essential to minimisation of laboratory contribution to organ cold ischaemia time and efficiency of surgical flow. Results must be made directly available to the consultant with direct responsibility for patient care.

Donor HLA specific antibodies

In all circumstances where donor HLA specific antibodies are detected in submitted samples of patients undergoing antibody removal treatment or in the context of a clinical diagnosis of rejection the finding must be urgently communicated to the consultant with direct responsibility for patient care. Advice on follow-up monitoring should be offered.

Appendix G Transfusion medicine

Transfusion results should be telephoned for immediate/next day action (as appropriate) when the following is encountered:

1. a high post-delivery Kleihauer (FMH test) result which exceeds the standard dose of anti-D Ig to alert the clinical area of possible need to extra anti-D Ig, pending confirmation
2. a significant rise in the titre/quantitation of a red cell antibody in pregnancy that is capable of causing haemolytic disease of the fetus and newborn. These are usually known antibodies being monitored but might be new and therefore unexpected. This finding would require further action and timely assessment of the mother by the obstetric team and/or fetal medicine unit.
3. a new red cell antibody where transfusion is required urgently when there could be a delay in finding compatible blood. This might include patients for planned blood-requiring surgery or a patient with significant or symptomatic anaemia with no other treatment options.
4. an unexpected change in blood group compared to a historical blood sample. This most often represents a misidentified patient, also described as ‘wrong blood in tube’ (WBIT). In such situations urgent re-sampling is necessary to determine if the current or historical sample is correct and may lead to the timely identification of other patients that have been incorrectly identified. ABO incompatible transfusion is a Department of Health ‘never event’ and WBIT is Serious Hazards of Transfusion (SHOT)-reportable as a ‘near miss’ transfusion adverse event.