

# The communication of critical and unexpected pathology results

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# Author: Dr Bernie Croal, Aberdeen Royal Infirmary

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The Royal College of Pathologists Fourth Floor, 21 Prescot Street, London, E1 8BB Tel: 020 7451 6700 Fax: 020 7451 6701 Web: www.rcpath.org

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# 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 an expansion of previous RCPath documents published in 2005 and 2010 relating to the outof-hours reporting of laboratory results requiring urgent clinical action to primary care. 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.

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 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 H.M. 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
- out-of-hours 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. As a consequence, 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 15189:2012, clause 5.9.1.

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 communicate critical or unexpected results to the clinical teams responsible.

## 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.

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 Methods for rapid communication

In the future, if available, pathology providers should seek to use automated electronic systems that provide real-time rapid alerts for critical or unexpected laboratory test results. Ideally, such electronic alerts directly to clinical teams should also have a feedback mechanism to allow the laboratory to ascertain whether any such alert has been received, read, understood and even actioned.

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 so as to avoid saturation of the system and put unnecessary demands upon both the laboratory service having to make the calls and the clinical units having to receive them and take action.

# 5 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

- any relevant clinical history that may be available or relevant past laboratory test results
- a contact address for the patient and any telephone number if known (this may be more relevant for primary care locations).

This should ideally be transmitted via electronic means, with read receipts if available, to avoid verbal transcription errors. Unnecessary verbal transmission of results should be avoided if access electronically is possible.

The circumstances and setting of the clinical team receiving the communication needs to be taken into account; the type of information required by an out-of-hours provider of primary care will be very different to that required by an intensive care department with live electronic availability of laboratory results.

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, and where this has been made available, either within or outwith the 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.

# 6 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 out-of-hours 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.

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.

# 7 Reporting of results directly to patients

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.

# 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. Deviation may of course be justified – discussion with clinical services locally is encouraged.

Local decisions also need to be made as to the circumstances whereby rapid communication is made out of hours to GP services or as a result of a sample from outpatient departments. This will depend on the nature of the out-of-hours 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, out of hours only, otherwise more immediate communication may be justified. Communication type B in the table suggests communication within 24 hours to a GP or GPs' out-of-hours service.

Laboratories may also consider, following local consultation, less stringent thresholds for out-of-hours communication for some of the analytes.

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  $\leq$  or  $\geq$  respectively.
- **b** Communication type:
  - **A** = rapid communication within 2 hours, usually by telephone
  - **B** = out of hours (OOHs) then communication within 24 hours to GP/GP OOHs service.
- **c** 354 umol/L cut point aligned with *KDIGO Clinical Practice Guideline for Acute Kidney Injury* and National AKI Algorithm:

www.kdigo.org/clinical\_practice\_guidelines/pdf/KDIGO%20AKI%20Guideline.pdf www.england.nhs.uk/wp-content/uploads/2014/06/psa-aki-alg.pdf

- **d** Please see 'Comments' column of the table for explanation.
- e Please see 'Comments' column of the table for explanation.

Analyte		Action	Limits <sup>a</sup>	Communic	cation Type <sup>b</sup>	
(serum/plasma)	Units	Lower	Upper	Primary Care	Secondary Care	Comments
Na	mmol/L	120 (130 if < 16 yrs)	160	A	A	Note particular concern of risk of death in children with hyponatraemia.
к	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)	А	А	Agree, by local consensus, higher thresholds for phoning results in patients with known kidney disease including
creat	umol/L		354 <sup>c</sup> (≥ 200 if < 16 yrs)	А	А	those on dialysis. Specific local cut points likely to be required for babies and neonates.
glucose	mmol/L	2.5 <sup>d</sup>	25 (≥ 15 if < 16 yrs)	A	A	Exact cut points and response should be determined locally. <sup>d</sup> Glucose results < 2.5 mmol/L from primary care may be less crucial to phone immediately. For GPs and OPD, upper cut point of 30 mmol/L in known type 2 DM may be more appropriate.
Calcium (adj)	mmol/L	1.8	3.5	B <sup>e</sup>	А	<sup>e</sup> Primary Care: If out of hours (OOHs) then communication next day to GP or GP OOHs service. Calcium levels $\geq$ 3.5
Mg	mmol/L	0.4		A	A	mmol/L may warrant more immediate communication with
PO4	mmol/L	0.3		В	A	Primary Care as agreed by local consensus.
AST	U/L		15 x ULN	A	A	
ALT	U/L		15 x ULN	A	A	Agree specific cut points with key users locally (A&E, Liver
Total CK	U/L		≥ 5000	Α	A	Unit/Medical Admissions, Gl Medicine).
Amylase/Lipase	U/L		5 x ULN	А	А	
Digoxin	ug/L		2.5	В	A	Check timing >6hrs from last dose. More urgent if K+ < 3.0 mmol/L. Phone immediately to primary care if overdose suspected or K+ low.
Theophylline	mg/L		25	В	A	
Phenytoin	mg/L		25	В	A	
Lithium	mmol/L		1.5	В	A	
CRP	mg/L		300	А	-	
Troponin (I or T)			Local cut off for MI	А	-	Exact cut point should be discussed with local clinicians in cardiology and Primary Care.
AKI			AKI-3	А	А	All new occurrences
ΑΚΙ			AKI-2	А	А	All new occurrences
AKI			AKI-1	В	А	Only if K > 6.0 mmol/L. Primary Care: If out of hours (OOHs) then communication next day to GP or GP OOHs service.
Ammonia	umol/L		100	-	А	
Bicarbonate	mmol/L	10		-	А	
Cortisol	nmol/L	50		В	А	Unless part of overnight dexamethasone suppression test
Cortisol (SST 30min)	nmol/L	250		В	A	As part of short synacthen test. Cut point used may need to be specific to assay being used.
Ethanol	mg/L		4000	-	А	or 400 mg/dL - consider much lower threshold in paediatrics.
Paracetamol	mg/L		f	А	А	f - All detectable levels - Agree specific thresholds locally with acute admissions/A&E - especially for paediatric samples.
Salicylate	mg/L		300	А	А	
Bilirubin (conj)			25	В	A	Neonates only

# 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 seven 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.

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 <sup>9</sup> /L	<0.5	
	x10 <sup>9</sup> /L	>50	
Lymphocytes	x10 <sup>9</sup> /L	>50	Requires urgent but not immediate referral
Platelets	x10 <sup>9</sup> /L	<30	
Platelets	x10 <sup>9</sup> /L	>600	Requires assessment and referral
Platelets	x10 <sup>9</sup> /L	>1000	Requires urgent referral for assessment

## Full blood count parameters

## Blood film

Presence of blasts or diagnosis sug myeloid lukaemia		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.

In the following situations (shown in the table), contact with primary care should be additional to attempts to communicate results to the requesting secondary care team.

<u>Analyte serum/plasma</u>	<u>Units</u>	-	<u>n Limits</u> <u>Above</u>	Additional Comments	How was this derived.
Autoimmunity					
ANCA new ANCA anti-PR3 Ab patient	IU/ml		*	Only a clearly positive result in a clinical context suggestive of small vessel vasculitis should be telephoned - decision threshold for telephoning to be determined by local agreement with major users.	Manufacturer reference range and discussion with local clincal team
new ANCA anti-MPO Ab patient	IU/ml		*		Manufacturer reference range and discussion with local clincal team
new anti-GBM Ab patient	IU/ml		*		Manufacturer reference range and discussion with local clincal team

\* cut point should be derived according to local situation and manufacturer guidance related to assay used.

#### **Liver Antibodies**

Positive LKM/SMA/SLA/LC-1		Children with very high ALT and	
POSITIVE ERIVIJ SIVIAJ SLAJ EC-1		positive LKM/SMA/SLA/LC-1	

**Laboratory Myeloma Investigation** - detection of new monoclonal bands exceeding defined quantitative levels (by densitometry) and/or abnormal free light chain ratios with accompanying features suggestive of a new diagnosis of myeloma e.g background immunosuppression, impaired renal function

New monoclonal band - any isotype	g/L	>30	BSCH
IgG	g/L	>15	BSCH
IgA & IgM	g/L	>10	BSCH

\*\*NB a lack of consensus between the Clinical Biochemistry and Immunology SACs emerged regarding the inclusion of immunoglobulin results as part of the defined "critical results" list - hence the omission from the Biochemistry appendix. Pathology services should make the decision on whether to include such guidance based on local circumstances and opinion.

#### Suspected Immunodeficiency

SCID/ new severe lymphopenia	T cell (absolute numbers)	Any new lymphopenia reviewed in the context of clinical details and actioned as appropriate	ESID criteria
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# 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 tests may be required involving blood-borne virus exposure incidents, unbooked pregnancies, VZV IgG testing in those at risk whom have been exposed, HIV and other blood-borne virus infections in a critical care setting, respiratory and gastroenteritis virus infections, donor organ transplant screens, viral haemorrhagic fever tests and involve assays that can take 1–2 hours for serology tests and some point-of-care molecular tests, up to 3 hours for a range of molecular based tests.

Evolution of the medical microbiologist's clinical role – more pressure on time, more emphasis on ward rounds, bedside consults, infection control, OPAT, etc – necessarily means less time in the laboratory and to phone 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 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 unexpected results felt to be critical for optimal patient management, and within the exigencies of the systems locally.
- 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.
- 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.
- 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.

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.

#### 2 Interim reports

For those results not phoned that need to be reported to clinicians urgently, they should be issued electronically/in writing (whenever possible), e.g. interim results, to consolidate the phone call and 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.

## **3** Outpatients/GP patients

Depending on local arrangements, some laboratories phone significant results from GP patients when out of hours to the local out-of-hours doctors' service, including weekends.

Examples of results that could be phoned include:

- *C difficile* toxin positives
- significant Group A streptococcal isolates
- MRSA (if the clinical details justify it)
- significant salmonellae
- significant positive blood cultures for patients discharged from emergency departments, the principle of the result being the responsibility of the requestor still holds, we are not convinced it is fair to expect an out-of-hours GP to follow it up in the first instance
- HIV and other blood-borne virus positive results
- acute hepatitis A, B, C (if interpreted as acute), E
- HSV and VZV DNA detected in lesion fluid
- VZV IgG negative results for those exposed to chickenpox and at risk.

## 4 Reporting to Public Health England (PHE) or equivalent bodies in the devolved nations

Notifiable diseases should be communicated to PHE by the clinician. However, significant enteric pathogens/notifiable diseases with potential outbreaks may be communicated directly under local agreements with PHE. They may take the form of routine (by mail/electronic), rapid (daytime phone call) or urgent (phone 24/7) communications. Virologists will phone any notifiable viral infections to both the clinical teams as well as the PHE Health Protection Team.

#### 5 What type of results should be phoned?

There are variations in practice around the country according to:

local needs

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

Hence, the following may be helpful principles in considering what may be urgently phoned; they are merely examples to consider when formulating the local policy:

- new positive microscopy or significant culture or viral DNA or RNA detection from normally sterile sites, e.g. blood, CSF, joint fluid, unless there is reasonable evidence of contamination or the nature of the infection is already known
- **new isolates from tissue or bone may need to be phoned** (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:
  - a) one would urgently phone 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
  - b) unexpected results with significant clinical/infection control/public health impact, e.g. S. typhi, E. coli O157, S. dysenteriae, Campylobacter, salmonella or norovirus must be phoned if inpatients or nursing home residents
  - c) respiratory virus and gastroenteritis viral infections.
- potentially toxic or subtherapeutic antimicrobial serum levels
- **some molecular and antigen tests** blood PCR for Aspergillus, galactomannan, viral DNA or RNA detection including quantification
- **specific serological assays** new HIV positive, HAV IgM positive, HBsAg positive and HBcIgM positive, HEV IgM positive, VZV IgG negative (in at risk and exposed patients/staff).

#### 6 Who should phone results?

Again this is a local decision; may be junior F2/non-clinical staff, but only if no guidance or discussion is required.

#### 7 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 out of hours.

# 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

This 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 multidisciplinary 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.

## **Recommendations for cellular pathology departments:**

- 1. Each department should create its own policy for urgent diagnoses and should define criteria for significant unexpected diagnoses.
- 2. 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.
- 3. 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.
- 4. The 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 multidisciplinary team.
- 5. 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.
- 6. 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.
- 7. 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-BT 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 NHS-BT 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 NHS-BT 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.

Please note the Histocompatibility and Immunogenetics appendix did not feature as part of the initial consultation. It was submitted via the RCPath Histocompatibility and Immunogenetics SAC and will undergo more formal consultation in the next major review.

# Appendix G Transfusion Medicine

Transfusion results should be phoned 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'. 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 DH 'never event' and WBIT is SHOT-reportable as a 'near miss' transfusion adverse event.

Please note the Transfusion Medicine appendix did not feature as part of the initial consultation. It was submitted via the RCPath Transfusion Medicine SAC and will undergo more formal consultation in the next major review.