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

Out-of-hours reporting of laboratory results requiring urgent clinical action to primary care: Advice to pathologists and those that work in laboratory medicine

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The Royal College of Pathologists
2 Carlton House Terrace, London, SW1Y 5AF
Tel: 020 7451 6700
Fax: 020 7451 6701
Web: www.rcpath.org

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1 Introduction

This document is the result of work initiated by the College's Specialty Advisory Committees (SACs) and Regional Councils in 2005, led by Dr Graham Beastall and Dr Danielle Freedman (2007) and with the involvement of The Royal College of General Practitioners (RCGP). It was revised in 2010 by College SACs and Lay Advisory Committee, in consultation with the RCGP and reference to the document, *Reporting Abnormal Pathology Results to Out of Hours Providers*, produced by the Department of Health Pathology Futures Group (2010).

The document is published as 'advice to pathologists' and is offered as a basis on which pathologists can construct local guidelines.

'Out of hours' refers to the period of the working week when GP surgeries are unstaffed (often 18:30–08:00 hours every weekday and all day at weekends and bank holidays, though some surgeries and walk-in centres/urgent care centres are now open 08:00–20:00, either weekdays or every day) and/or responsibility for patient care has been passed from the normal GP to an out-of-hours provider.

It is the responsibility of pathology services to work with out-of-hours providers and Primary Care Trusts (PCTs) (or their successor bodies) to ensure that adequate local arrangements are in place to deal with the reporting of abnormal test results out of hours. It is normally outside the remit of the professional role of clinical laboratory staff to contact patients directly with abnormal results.

2 Stakeholders

The following are stakeholders in facilitating the effective communication of markedly abnormal laboratory test results out of hours:

- laboratory staff
- pathologists (medical staff and clinical scientists)
- general practitioners (GPs)
- Primary Care Trusts (PCTs) or successor commissioning bodies
- GP cooperatives
- out-of-hours providers of primary care
- patients' representatives.

3 Background

The Royal College of Pathologists became aware of several serious untoward incidents relating to the inability of laboratory staff to find an appropriate primary care physician to act on a life-threatening or markedly abnormal test result. The Regional Councils have provided examples of such incidents or 'near misses' and these have been collated to identify important themes. A 2010 survey by the Yorkshire Centre for Health Informatics on behalf of the National Patient Safety Agency received responses from 74 laboratories in England, of whom more than 40% indicated they had experienced difficulties in reporting potentially critical results to out-of-hours providers.

The problems in reporting and acting on markedly abnormal laboratory test results fall into three main areas:

- laboratory staff not knowing whom to contact when a GP surgery is closed and not knowing how to make that contact

- staff at the out-of-hours provider not appreciating the importance of the abnormal result and being unwilling to accept responsibility for the result
- staff at the out-of-hours provider being unable to contact the patient and/or unable to access patient records as part of the corrective action.

The out-of-hours provider will usually have no previous knowledge of the patient and limited access to patient records. The abnormalities being communicated are, by their very nature, acute and potentially life-threatening. Appropriately qualified laboratory staff will therefore play a key role in interpreting the results in the context of other information available in the laboratory, and in guiding the out-of-hours doctor receiving the result.

4 General principle

The responsibility of the laboratory staff is to communicate the markedly abnormal test result to the clinical team – either to the GP who made the request or to the out-of-hours provider. It is the responsibility of the requesting clinical team to review results of tests that they have requested and have proper handover arrangements in place to review and act on abnormal results after hours, in the best interests of the patient. The PCT or commissioning body has a responsibility to ensure that adequate out-of-hours cover arrangements are available, and that details of these arrangements are communicated to the laboratory.

5 Identifying a markedly abnormal laboratory test result

A markedly abnormal laboratory test result is a result that may signify a pathophysiological state that may be life-threatening or of immediate clinical significance and that requires urgent action. A list of such markedly abnormal laboratory test results needs to be agreed between stakeholders at a local level. It is important to emphasise that the list is not restrictive, and that senior laboratory staff may decide to communicate other test results at their discretion. This may apply at weekends, where milder abnormalities may require urgent notification if it is felt that action is required before Monday (or the first working day after a public holiday).

The Specialty Advisory Committees have drafted lists of suggested triggers for contacting primary care out of hours (see Appendix 1) and pathologists should use these lists as a guide.

A fail-safe method is required within the laboratory to help biomedical scientist (BMS) staff to identify results that fall within the agreed abnormal category. Junior BMS staff must be able to contact senior members of the department (medical staff or clinical scientists) for support and advice out of hours and pass to them the responsibility for communicating a markedly abnormal result to the out-of-hours provider when appropriate.

6 Communicating an abnormal laboratory test result

Primary Care Trusts or GP commissioning bodies should be asked to inform the laboratory of specific arrangements for making telephone contact with a GP out of hours. Laboratories should collate this information into a formal document and display it in a prominent place. Senior members of the laboratory department should be able to access this information at all times.

When reporting a markedly abnormal result out of hours, laboratory staff are required to give the following information:

- the name and date of birth of the patient, together with any unique patient identifier

- the abnormal test result (and reference range if requested)
- the date and time of the request
- the name of the requesting physician 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.

Laboratories should have procedures in place to ensure that interpretation and clinical advice are available from a consultant pathologist or clinical scientist where appropriate, and should maintain records of all abnormal results communicated out of hours.

The record should include the information specified above, together with the name of the person to whom the result was communicated and the date and time of the communication.

All abnormal results telephoned to the deputising service should also be telephoned to the requesting GP at the first opportunity within normal working hours.

7 Providing adequate patient information with the request

GPs 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 out of hours to another doctor.

GP request forms should be designed to accommodate the information specified above, including a section for the patient's telephone number, and GPs should be requested to provide all the necessary details in a legible fashion or accurately for electronic pathology requests where this is available.

Laboratory services need to liaise with the PCTs or commissioning bodies in their area to promote accurate, explicit and consistent information on pathology request forms and to ensure accurate information is available as to which out-of-hours providers cover the patients of all practices served by the laboratory.

It is the responsibility of the requesting GP to complete the request form with sufficient patient details and clinical information to permit effective out-of-hours communication between the laboratory and any out-of-hours provider. Consideration needs to be given to confidentiality and data protection issues relating to the inclusion of the patient's telephone number on the request form.

Wherever possible, the laboratory service should aim to identify abnormal results and communicate them directly to the patient's own GP between 08:00 and 18:30 hours on weekdays. At all other times, including bank holidays, an out-of-hours provider who will not know the patient nor have access to their records will need to be contacted with abnormal results.

8 Taking action on an abnormal laboratory result

The doctor receiving the markedly abnormal laboratory test result must decide how to act in the best interests of the patient. Each case should be treated on its individual circumstances. However, it is recognised that this doctor will often have limited access to information about the patient, while the laboratory consultant will have access to the patient's long-term laboratory record, and may also have access to further clinical information via the electronic patient record. The laboratory consultant can integrate this information with his or her specialist expertise in order to provide valuable advice to the out-of-hours doctor.

9 Developing active local relationships

Out-of-hours providers may cover patient populations across a number of different laboratories. Laboratory services will benefit from developing and nurturing local relationships. Invariably there will be an out-of-hours or urgent care lead at the PCTs or commissioners covered and a medical director for out-of-hours providers. There are also local Urgent and Emergency Care Networks that involve a number of different providers, e.g. walk-in centre, minor injuries units and local hospitals. Many healthcare professionals other than GPs complete request forms in primary care, and the importance of providing all relevant details, including the patient's telephone number, should be emphasised to everyone involved. There should be active engagement of local stakeholders to promote a consistent message across the local Urgent Care Network.

There needs to be a designated protocol for the laboratory to report lack of response from out-of-hours providers back to PCTs or commissioners. There needs to be a relationship and dialogue between laboratories and out-of-hours providers to ensure consistency of reporting of those results that are required to be conveyed urgently out of hours, together with ongoing monitoring or audit of the laboratory's performance in communicating agreed parameters consistently.

10 Conclusion

Both Royal Colleges strongly advise members affected by these issues to enter into local negotiation with relevant stakeholders to address any problems and promote the development of good relationships.

Appendix A Triggers for contacting out-of-hours providers of primary care

A1 Clinical biochemistry

Below are illustrative action limits for contacting GPs out of hours. These limits are based on the first abnormal set of results or repeat results that have shown a markedly significant change for an individual patient. Each laboratory is advised to agree its own repertoire of analytes and specific action limits and reporting procedures with local primary care services.

Analyte (serum/plasma)		Action limits	
		Below	**Above**
Sodium	mmol/L	120	150
Potassium	mmol/L	2.5	6.5
Urea	mmol/L		30 (>10 if <16yr)
Creatinine	µmol/L		400 (>200 if < 16yr)
Glucose	mmol/L	2.5	25
Calcium adj	mmol/L	1.8	3.5
Magnesium	mmol/L	0.4	
Phosphate	mmol/L	0.3	
AST	U/L		15 x upper limit of normal (ULN)
ALT	U/L		15 x ULN
Total CK	U/L		>5000 unless ? MI
Amylase	U/L		5 x ULN
Carbamazepine	mg/L		25
Digoxin	µg/L		2.5
Theophylline	mg/L		25
Phenytoin	mg/L		25
Phenobarbitone	mg/L		70
Lithium	mmol/L		1.5
Triglyceride	mmol/L		>20
CRP	mg/L		>300
Troponin (I or T)			>local cut-off for MI

A2 Haematology

The focus of these guidelines is those few tests where urgent contact with GPs is required. Action required may include:

i) immediate medical intervention, including admission to hospital or change in the patient's treatment

ii) urgent referral for assessment during the next working day

iii) urgent referral to an out-patient clinic.

While the decision to contact the out-of-hours provider will be based solely on the numerical values obtained, the assessment and clinical decision will depend on the clinical context and the input of the consultant haematologist with whom the results should be discussed.

Contact outside normal working hours often involves an out-of-hours provider when access to the patient can be difficult. However, this should not influence the decision to contact the out-of-hours provider, which should be based on the need for urgent (i.e. immediate) or next-day medical intervention.

The clinical context is crucial in making the ultimate decision and will not always be known to the laboratory. In these circumstances, it is best to contact the out-of-hours provider.

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.

If there is no electronic link to the requesting clinician, there should be a set of triggers for contact with the practice during the next working day.

A2.1 The following table shows suggested minimum criteria that haematology laboratories should include in their own local standard operating procedure. These will also be influenced by the availability of previous results, together with the findings on 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	>1000	Requires urgent but not immediate referral
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		>6.5	For patients on warfarin

A3 Immunology

Diagnostic immunology laboratories do not, in general, offer routine sample testing or reporting on a 24/7 basis in the UK. Most units operate routinely within ‘normal’ working hours similar to those in primary care (approximately 08:00–18:00), with a small number also operating routine extended arrangements into the later evening. Many will also offer an *ad*

hoc facility for processing, or completing analysis, of clinically urgent samples within a limited period of extension to the working day as necessary. *Ad hoc* arrangements may also be in place for the continuous availability of urgent testing and interpretation by local agreement in clearly defined circumstances (such as renal or pulmonary vasculitis or severe primary immunodeficiencies).

Such arrangements are usually only applicable to acute care of patients in a secondary care environment. In these circumstances, and taking into account that much immunology testing is required and performed 'cold', it is rarely necessary to communicate test results urgently to primary care out of hours.

One possible exception to this is the finding of a new, high titre anti-neutrophil cytoplasmic antibody (ANCA, anti-PR3, anti-MPO) result in a patient undergoing testing from primary care or who is in the process of current outpatient investigation by secondary care or who has been recently discharged from inpatient care before the results of tests are known. In the latter two situations, contact with primary care should be additional to attempts to communicate results to the requesting secondary care team.

A4 Microbiology and virology

Some microbiology and virology results may need to be reported urgently, particularly over a weekend or bank holiday, but also when GP surgeries are closed during the working week.

Microbiology or virology results may have additional implications for the public health of a community, as well as the individual patient, and would then need to be communicated to the local Health Protection Team, as well as the out-of-hours provider. Results may be of particular significance if they relate to an outbreak of infection, a possible deliberate release or have been obtained from the investigation of patients from an institutional setting, such as a school, prison or care home, where there is a significant risk of infection.

Increasing diversity of healthcare provision and patterns of care will require inclusion of clear arrangements within service specifications.

It is the responsibility of the biomedical scientist who becomes aware of new results for primary care patients out of hours in the following categories to inform the senior virologist or microbiologist on call.

The acute infections with outbreak potential (see section 1.1) and acute hepatitis A or B (see section 1.3) would also be notifiable to the local Health Protection Team out of hours, depending on local arrangements with Health Protection Units. This would be the responsibility of the senior virologist or microbiologist on call.

The following list is not exhaustive, but includes the most frequent or important infections requiring urgent contact with the out-of-hours provider.

A4.1 Acute infections with outbreak potential known to be in close community or residential setting, e.g. boarding school, nursing home:

- influenza
- measles
- mumps
- transmissible enteric pathogens, e.g. norovirus, salmonella, Ecoli 0157, and including those requiring notification to the Accountable Officer
- transmissible respiratory pathogens with serious implications for the patient's

immediate care and/or contacts, e.g. RSV, legionella infection, TB, invasive Lancefield group A streptococcus infection

- other serious infections such as diphtheria, SARS.

A4.2 Acute infections in pregnancy that pose risk to pregnant/neonatal contacts:

- parvovirus B 19
- rubella
- varicella-zoster virus
- acute bacterial infections in pregnancy and the post-partum period, for example Group A streptococcus in a high vaginal swab.

A4.3 Acute viral hepatitis (A or B) and any newly diagnosed hepatitis B for prophylaxis *(HNIGI* vaccine or HBIG) in some contacts.

A4.4 Susceptibility to varicella in pregnant or immunocompromised contact for prophylaxis with VZIG for significant exposure.

A4.5 Any other infection that is required to be notified to the Health Protection Agency (or its successor) by laboratories under the Health Protection (Notification) Regulations 2010, when the notification is considered urgent based on the the likelihood that an intervention is needed to protect human health and the urgency of such an intervention (see Table 2 in Health Protection Legislation (England) Guidance 2010 for guidance as to when this is likely to be the case.
www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_114589.pdf

A4.6 Significant positive blood culture results from patients who have been sent home, for example from A&E or the medical assessment unit.

A4.7 Antibiotic assay results from patients who are self-administering in the community.

Appendix B Out-of-hours protocol for the reporting of markedly abnormal laboratory test results: advice for out-of-hours service

A markedly abnormal laboratory result may indicate that the patient needs urgent treatment. The communication of such important results should be a priority, and in certain circumstances it could be life-saving. To enable the doctor to assess the urgency of the situation, full and accurate information is crucial. This approach will save time and help with the decisions to be made. In the interest of the patient's well being, it is the responsibility of an out-of-hours clinician to act upon abnormal results.

When contacted by the laboratory with an abnormal result in the out-of-hours period, the call handler will obtain all the patient's demographics and enter the information on the computer in the normal way, making sure the telephone number of the pathology laboratory is always inserted in the 'Remarks' box. The call handler will also take details of the pathologist and the bleep or contact details.

All the results are to be listed carefully in the 'Symptoms' box. Accuracy is crucial and each recorded result should be read back to the pathology laboratory caller for verification. The call handler should always ask for unfamiliar words to be spelled out, and not to be afraid to ask this more than once. When the results are to be faxed to the out-of-hours service, the call handler should make a note of this in the 'Remarks' box.

If the patient's details are incomplete, i.e. there is no contact number for the patient and no trace of a telephone number via directory enquiries, the outcome of the triage would be a home visit, with a note on the patient's details that the patient has not been contacted.

The outcome of the triage/home visit may require the results to be passed via fax to the patient's own GP, along with the triage/face-to-face consultation.

If the out-of-hours provider has insufficient patient contact details to carry out a visit and the hospital laboratory is unable to supply these details, it is the responsibility of the out-of-hours provider to ensure that the GP practices are aware of this the next working morning.

It is the responsibility of the PCT to have mechanisms in place to communicate results to the relevant GP practice or out-of-hours service. Also, for governance purposes, there must be an audit process for adverse incident reporting.

Adapted from 'Croydon Doctors On Call Out of Hours Service'