IBMS Institute of Biomedical Science

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Communication of Pathology Diagnostic Results and Clinical Reports

Institute of Biomedical Science Policy

on

Communication of Pathology Diagnostic Results and Clinical Reports

As the UK professional body for biomedical science the Institute of Biomedical Science (IBMS) has established the following policy for those communicating pathology diagnostic results and clinical reports for those responsible for the delivery of clinical laboratory services. It is expected that all pathology providers will have systems in place and standard operating procedures to both identify and communicate diagnostic results and clinical reports, across all healthcare settings, which is an explicit requirement of ISO 15189:2012, clause 5.9.1.

The UK health departments have put patient care and safety at the heart of healthcare provision. It is the responsibility of the respective providers and all those involved in the delivery of service and care to deliver safe and high-quality patient care. It is the responsibility of the professions themselves to establish those standards of best practice relative to their own professions.

What this policy does

This policy provides guidance on the communication of patient pathology diagnostic results and clinical reports, by electronic methods of reporting and verbally via telephone or in person, to help ensure accuracy of transmission and receipt, whilst maintaining patient confidentiality.

What this policy does not

This policy does not attempt to be prescriptive for every situation. Where there are specific requirements these should be referred to in local policy and procedure documents.

Background

The IBMS has produced this professional guidance document to help biomedical scientists, clinical scientists, medical staff and support staff maintain high standards of practice and patient safety by ensuring that stringent minimum criteria are in place for the communication of pathology results and clinical reports.

It is the responsibility of each pathology departmental service manager to ensure that their staff are suitably trained, competent and authorised in communicating diagnostic results and/or clinical reports within their scope of practice. A record of their training and competency should be maintained.

Definition of pathology diagnostic result status

In the context of this document the use of the terms non-validated, validated and authorised diagnostic results and clinical reports are applied as follows:

- Non-validated - raw test result/ data

- Validated - manual or automated validation of results where quality control and assay performance is acceptable

- Authorised - where results have been reviewed and reported automatically using diagnostic algorithms or manually interpreted and authorised within the clinical context and a clinical comment/advice made were appropriate (clinical report).

Pathology staff eligibility for communication of diagnostic results and clinic reports

The IBMS views that it is essential for patient safety and appropriate clinical care that:

- Only authorised results can be communicated to an appropriate healthcare professional directly involved in the patients care by trained and competent specifically designated associate healthcare scientists, laboratory support, secretarial and administrative staff.
- HCPC registered biomedical and clinical scientists who are autonomous practitioners can communicate validated and authorised results.
- Appropriately trained and competent HCPC biomedical and clinical scientists or medical staff can provide clinical result interpretation and advice. This should be included in the clinical report if appropriate or to the audit trail.
- Non-validated results should not be issued. If required queries on non-validated results should be referred to a biomedical or clinical scientist for information on completion status.

Local polices should detail any communication requirements or procedures for specific type of results or clinical reports, including suitability for each type of communication option, particularly SMS messaging and verbal communications.

Communication options

The IBMS views that use of secure networks are the most secure method for the transmission of patient results, to ensure the correct results on the correct patient goes to the correct clinician. A secure network is configured to follow a set of rules and is designed to protect the integrity, confidentiality and accessibility of the computer network and data using both software and hardware technologies. This technology being essential in minimising a potential risk to breach of data protection.

The IBMS views alternative means to secure networks for transmission of results as presenting a potential increased risk to breach of data protection but practically and clinically an alternative means may be the only or appropriate option available in certain situations.

All communication methods require careful local risk management, controls, maintenance and monitoring to ensure data security.

Electronic

Secure Electronic Networks

The preferred method for issuing or giving pathology diagnostic results and clinical reports is via secure electronic IT networks such as internal laboratory to hospital and external laboratory to GP or laboratory to laboratory (e.g pathology diagnostic networks/hubs and spokes), where identified patient and associated results transfer seamlessly between data systems.

Maintenance of patient confidentially is always essential, ensuring results are only electronically communicated to appropriate healthcare professionals. The Data Security and Protection Toolkit (DSPT) is a compliance framework that covers all aspects of security and confidentiality with a focus is on building trust in health and care IT systems. All organisations processing patient and service user data must meet the DSPT requirements.

Secure email

For communication of diagnostic results where it is not currently feasible for use of secure electronic networks then secure email, may provide an alternative for secure reporting, particularly with centralised diagnostic services, i.e. nhs.net to nhs.net, which allow secure reporting.

1. There should be a policy relating to the use of email to communicate with service users and if appropriate patients which is regularly reviewed.

2. When using secure email, there is still a potential patient safety and governance issue due to the possibility of sensitive patient information being emailed to the incorrect individual, particularly when similar names exist.

3. Where possible a dedicated shared mailbox should be set up, rather than an individual's account.

4. Mailbox access should only be granted to persons within each organisation that meet the organisations required governance standards and should be monitored by IT services to ensure that they are not infected with malware or viruses.

5. To minimise the potential for errors, particular attention must be given to the use of a suitably encrypted and secure end-to-end transmission of the report, with sender and recipient using the same email system. Examples include:

- NHS Mail (nhs.net to nhs.net). This is the only system that should be used for sending person identifiable data to other NHS organisations.
- Local email systems within an organisation. These should typically only be used for transferring person identifiable data within the same organisation if deemed suitably secure by the host organisations IT department
- Central and Local Government e-mail. To provide integrated safe care for patients, it may be required to share data with other organisations such as social care, MoD etc. NHS mail is securely routed over the Government Secure Intranet Convergence Framework to allow transmission of person identifiable data to the following email domains:

  @cjsm.net (Criminal and Justice)
  @gcsx.gov.uk (Local Government/Social Services)
  @gse.gov.uk (Central Government)
  @gsi.gov.uk (Central Government including Department of Health)
  @gsx.gov.uk (Central Government)
  @hscic.gov.uk (The Health and Social Care Information Centre)
  @mod.uk (Military)
  @nhs.net (NHS email)
  @pnn.police.uk (Police)
  @scn.gov.uk (Criminal and Justice)

6. Whilst confidential information can be sent to these addresses from nhs.net addresses, they need to be tested first and verified with the recipient.

7. Ideally results should be sent as an electronic copy of the report from the laboratory information management system (or other such system) to ensure inclusion of all necessary patient details, reference ranges, and interpretive comments and to remove the risk of a result transcription error.

8. Where results are typed there should be sufficient patient details (e.g. minimum 3 points of ID) provided to allow for accurate identification of the patient by the receipting party. There should also be the inclusion of any reference ranges and appropriate interpretive clinical comments where applicable. Care should be taken to check for transcription errors.

SMS messaging

SMS messaging is increasing being used across healthcare settings as brings benefits both to healthcare professionals and patients. SMS stands for Short Message Service, and it's the most common form of text messaging used today. A single text message is limited to 160 characters including spaces.

Where biomedical and clinical scientists are using SMS messaging to notify patients or service users of results there should be:

1. A policy relating to clinical application and the use of text messages to communicate with patients and service users which is regularly reviewed

2. Use an established text message service for communications, rather than a personal phone.

3. Undertake a Data Protection Impact Assessment (DPIA) for text message service offered to patients/service users by your organisation and take reasonable steps to ensure the communication methods used are secure.

4. Be transparent with patients/service users about how information is being used including:
    a. It is appropriate to rely on implied consent for confidentiality purposes when contacting individual patients and service users about their individual care.
    b. Respect patients' objections/preferences to receiving or not communications in this way
    c. Have processes in place to remind patients and service users to update their mobile number when needed.
    d. Explain to the patient or service user that it is their responsibility to keep and provide an up-to-date email address and/or mobile phone number.
    e. Be clear that the service is not responsible for onwards use or transmission of text message once it has been received by the patient /service user.

Verbal

The verbal transmission of results is a significant patient safety issue, due to the possibility of misinterpretation, transcription errors and the potential that verbal reports are not further communicated within clinical team, read, or recorded/filed in the relevant patient's record. However, it is recognised that there are instances when verbal transmission of results is either desirable or the only possible option available. These include:

- frozen section results
- unexpected diagnostic results indicative of the presence of serious disease or acute event that require urgent medical or therapeutic intervention
- results of self-managed chronic disease monitoring
- results of pregnancy tests

Particular attention must be given to the following:

- the identification of the individual receiving the results and that of the patient
- confirmation that results have been transcribed accurately by repeating back and action required
- follow-up reports

Telephone communications or face-to-face enquiry

Most verbal communications of results is conducted via telephone but occasionally it is a face-to-face enquiry and following the same considerations and procedures:

1. Verbal results may only be communicated by those individuals trained, competent and authorised in this procedure.

2. Staff should be courteous and professional in handling queries, while ensuring that any telephone enquiry is from a legitimate source and may refuse to communicate results if there are doubts over the competency shown by the individual receiving them and ask to be referred to a more senior Healthcare professional.

3. The individual relaying the result first needs to assess the seriousness and urgency of the results findings and ensure they speak directly to a member of the patient's clinical team or for centralised diagnostic services communication with the referring sample pathology department. If there is any doubt about the caller's reasons for requesting results, the call should be passed to a senior member of staff to discuss and advise.

4. Maintenance of patient confidentially is always essential, ensuring results are only verbally communicated to appropriate healthcare professionals. For face-to-face enquiries if feasible provide a paper printout of the patients results.

5. Patients must be accurately identified using agreed local procedures, including any anonymity codes as appropriate and the individual receiving the result must be authorised to do so and must understand medical and scientific terminology.

6. A system of passwords or identity codes for wards, clinics, GP surgeries (e.g. NHS surgery numbers) or clinicians should be considered and results only provided if the correct code is given.

7. It is the responsibility of the requesting clinician, in charge of the care of the patient, to review their pathology results. However, reasonable attempts should be made to communicate results verbally to appropriate clinical team where it is clinically important for patient care and safety. A record should be retained electronically or manually for audit purposes against appropriate results where verbal communication attempts failed and a full or interim electronic report issued urgently.

8. There should be a local standard operating procedure that should include handling of verbal requests and transmission of results, either in response to a query or for reporting a result of clinical concern, a guidance list of the types of results that may be released ahead of or in addition to the standard secure electronic result system and specify the circumstances and staff that may give each type of result.

9. Except for biomedical or clinical scientists working in direct patient care roles, results should not be given to patients or their relatives or any other unauthorised person.

10. All identification data should be checked against the information held on the laboratory information system (LIMS) or against the electronic patient record (EPR). If necessary, additional supporting information should be requested from the enquirer, i.e. name, date of birth and/or address.

11. If supporting information is incorrect, results should not be communicated verbally and if appropriate local procedures followed for addressing patient/sample identification issues.

12. A record of results given should be retained electronically or manually for audit purposes. The recorded data should include:

    - nature of the communication – e.g. email, phone
    - name and status of the person giving the result
    - name and status of the person to whom the results were given
    - date and time of the communication
    - patient's name and identity number or date of birth
    - an indication of the result given
    - an indication of the clinical reason for the call

13. It is the responsibility of the pathology service provider to ensure adequate local arrangements of communication 24/7 of clinically important diagnostic results

14. Care should be taken to ensure that results of a sensitive clinical nature or that have medico-legal implications, are only given to the requesting clinical team.

15. With results of a sensitive clinical nature or medico-legal implications the use of a call back system to a recognised location is essential to ensure verbal results are given to the appropriate person.

Follow-up reports

All verbal results must be supplemented by a follow-up report that acknowledges and confirms the results communicated verbally, which must then become part of the patient record. This follow-up report must include the identity of the person who transmitted the result and the identity of the person who received the result, together with the date and time of the conversation. Where this capability is not available within the primary record (i.e. the LIMS or EPR) an alternative electronic auditable system should be used.

Direct communications face to face or virtual

Clinic settings

Biomedical and clinical scientists with direct patient care roles if within their scope of practice may provide results directly to patients or carers e.g.

- Biomedical and clinical scientists providing point of care testing services may relay result to patient and/or provide with result report to take to another clinician for treatment. It is essential that local clinical governance arrangements define clinical follow up of these results.

- Biomedical and clinical scientist who within their scope of practice are providing direct clinical patient services will have requested pathology investigations and then will discuss results and their meaning to their patients.

Multi-discipline team meeting (MDT)

MDTs are integral part of the patient care pathway to ensure best outcomes for patients. The format can be face-2-face and/or virtual. Biomedical and clinical scientists participating in MDT's should ensure virtual connectivity is compliant with local IT security. Identifying patient information should be kept to a minimum. Biomedical and clinical scientist have a duty of care to ensure advice given, results and clinical reports presented are accurate for each individual patient particularly if transcribed.

Ward rounds

Biomedical and clinical scientists as part of the clinical team on ward rounds which can also occur in a virtual setting would be expected to provide and discuss patients results, clinical reports and contribute to ongoing treatment plans.

Discipline Specific Guidance

The presence of certain clinical symptoms or results may be regarded as critical and/or important for clinical management of the patient and therefore may require urgent verbal transmission by an appropriately trained and competent biomedical or clinical scientist or medical staff, as previously detailed or as outlined below. The following information is intended primarily as guidance for biomedical and clinical scientists in the development of local protocols for communication of discipline specific results, which may vary according to clinical services supported.

All disciplines

Critical and/or important results for clinical management of the patient that and therefore require urgent communication:

- An amended report which is different from the initial findings and may impact on patient management

Andrology

Critical and/or important results for clinical management of the patient that may require urgent verbal communication:

Include:

- urgent semen analysis (morphology, motility, count and vitality)
- screening of post vasectomies

Blood Transfusion

Critical and/or important results for clinical management of the patient that require urgent communication:

Include:

- results that may lead to a delay in the provision in blood components
- results where follow up samples are required urgently
- results that will prevent a possible transfusion reaction
- results where clinical intervention is required urgently
- results of direct antiglobulin tests where clinically relevant
- results influencing the need for anti-D immunoglobulin
- specified locally defined and documented results

Cellular Pathology

Critical and/or important results for clinical management of the patient that may require urgent verbal communication:
The following results should only be given by medical staff and appropriately qualified biomedical scientists and clinical scientists.

- unauthorised, unsigned or interim reports
- frozen section reports
- any result that requires a clinical opinion.

The following results may be given by appropriately trained and competent biomedical scientists

- Rapid On-Site Evaluation (ROSE) adequacy or triage.

The following results may be given by appropriately trained and competent biomedical scientists or nominated authorised clerical staff:

- all authorised reports, i.e. signed reports

Clinical Chemistry

Critical and/or important results for clinical management of the patient that may require urgent communication:

Include:
- validated or authorised
- tests as listed in Royal College Pathology criterial results guidelines

Cytopathology

Critical and/or important results for clinical management of the patient that may require urgent communication:

Results below should be given by appropriately trained and competent medical staff or, when in relation to cervical cytology, by an appropriately qualified and competent biomedical scientist:

Include:

- rapid FNA results, e.g. breast clinic;
- any results that may require a clinical opinion.
- results on synovial fluids where the presence of crystals is important

- assessments of the amount and quality of material from FNAs so that repeat samples may be obtained
- signed reports or cervical screening tests that have passed quality control checks.

The results below should be given by appropriately trained and competent medical staff or by an appropriately qualified and competent biomedical scientist:

- unsigned or interim reports

The following may be given by appropriately trained and competent staff:

- all clinically authorised results

Haematology

Critical and/or important results for clinical management of the patient that may require urgent verbal communication. This can apply to authorised and validated results, which have been assessed by an appropriately competent and qualified member of staff.

Include:
- unexpected haemoglobins of less than 70g/L
- unexpected platelet counts of less than 30 x10^9L or greater than 1000 x10^9L
- unexpected neutropenia <0.5x109/L or neutrophilia >50x109/L
- newly presented leukaemia's
- newly presented *Plasmodium falciparum* and *Plasmodium knowlesi* infection
- newly positive sickle haemoglobin screen in patients about to undergo anaesthesia
- newly presented sickle cell disease
- newly presented severe haemophilia A or B, or acquired haemophilia
- Suspected DIC/TTP/HELLP/MAHA
- INR >5.0 for patient on warfarin
- D-dimer results for exclusion of VTE
- unexpected isolated prolonged PT or APTT or reduced Fibrinogen with bruising/bleeding symptoms and/or requires urgent invasive procedure

Immunology

Critical and/or important results for clinical management of the patient that may require urgent verbal communication:
Include:

- new ANCA MPO/PR3 & GBM results.
- some cellular immunology tests or CSF oligoclonal bands.

Medical microbiology including virology

Critical and/or important results for clinical management of the patient that may require urgent verbal communication:

- presence of bacteria, fungi, parasites or viruses causing meningitis or encephalitis in CSF of patients, detected through microscopy, culture or molecular methods
- presence of bacteria or fungi in a blood culture of a patient presenting with sepsis or severe infection, detected through microscopy, culture or molecular methods
- detection of Clostridium difficile toxin in the stool of a patient with pseudomembraneous colitis or toxic megacolon
- new diagnosis of HIV
- new diagnosis of Hepatitis in a patient with fulminant liver failure
- invasive Group A Streptococcal infections (IGAS)
- AFB seen on microscopy
- Rifampicin resistant Mycobacterium tuberculosis
- Pneumocystis jiroveci detected by molecular methods
- VZV status in pregnancy
- BBV results following needlestick injury
- all notifiable organisms or diseases

The following results may be given by biomedical and clinical scientists in accordance with local policies and procedures:

- all clinically authorised results
- all validated results awaiting a clinical decision or review (a note should be made to the clinician that the result is pending clinical review).

Queries on non-validated results must be referred to a biomedical or clinically authorised member of staff and in accordance with local reporting policies and procedures.

The following results may be given by other appropriately trained and competent staff in accordance with local policies and procedures:

- all clinically authorised results

Legal framework

The verbal and email transmission of patient results is governed by a legal framework that includes:

- EU General Data Protection Regulation [GDPR], and the 2018 Data Protection Act
- The Caldicott Principles - in particular Principle 4;
- Guidance on the use of facsimile transmissions for the transmissions of personal health information within the NHS in Scotland; the Scottish Office NHS MEL (1997) 45 http://www.sehd.scot.nhs.uk/mels/97_45.html

References and Documents

ISO 15189: 2012. Medical laboratories - Requirements for quality and competence.
https://www.ukas.com/services/accreditation-services/medical-laboratory-accreditation-iso-15189/

Caldicott Report on the Review of Patient-Identifiable information
https://www.igt.hscic.gov.uk/Caldicott2Principles.aspx

Data Protection Act 2018
http://www.legislation.gov.uk/ukpga/2018/12/contents/enacted

EU General Data Protection Regulation (GDPR) enforceable from 25th May 2018
https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/

Human Rights Act 1998
http://www.opsi.gov.uk/acts/acts1998/ukpga_19980042_en_1

The communication of critical and unexpected pathology results 2017, Royal College of Pathologists https://www.rcpath.org/resourceLibrary/the-communication-of-critical-and-unexpected-pathology-results-pdf.html

Email and text message communications – NHS Transformation Directive 2022
https://www.nhsx.nhs.uk/information-governance/guidance/email-and-text-message-communications/

NHS Digital - DAPB4017 Pathology Test and Results Standard Specification – V.1 2021
https://digital.nhs.uk/

NHS - Information Governance Framework for Integrated Health and Care: Shared Care Records – September 2021 - https://transform.england.nhs.uk/

Further information

IBMS guidance and standards publications

The IBMS's BenchMark series of professional policies and guidance are available to download at www.ibms.org/resources/professional-guidance/

Articles, resources and further information on the biomedical science profession and getting involved in promoting the profession are available at www.ibms.org

Information on the IBMS's Continuing Professional Scheme is available at www.ibms.org/cpd/

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Produced by: Education and Professional Standards Committee

Contact: Education Department

T: + 44 (0)20 7713 0214, **E: education@ibms.org**

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