

Policy for the Management of Clinical Diagnostic Tests

Department / Service:	Trust-wide
Originator:	Heather Warner
Accountable Director:	Chief Medical Officer
Approved by:	Trust Management Committee
Date of Approval:	10 th May 2021
Review Date:	10 th May 2024
This is the most current document and is to be used until a revised version is in place	
Target Organisation(s)	Worcestershire Acute Hospitals NHS Trust
Target Departments:	Divisions & Clinical Directorates
Target staff categories:	Medical, nursing, Allied Health Professionals, Administrative

Policy Overview:

The purpose of this policy is to provide a framework for the development of detailed local Standard Operating Procedures, guidelines or protocols to support robust verification and communication of all diagnostic test results. The main objectives are to minimise the risk of misdiagnosis or failure/delay in diagnosis, to improve patient outcomes and quality of care.

Key amendments to this Document:

Date	Amendment	By:
Sep 11	Policy drafted	H. Warner
Aug 12	Policy revised following NHSLA / DNV briefing	C. Rawlings
Mar 15	Revision following clinical audit – generic process now described to move on from providing a template for local SOPs	C. Rawlings C. Catchpole
Jan 2017	Review and updates and to incorporate standards for the communication of patient diagnostic test results on discharge from hospital	S. Graystone
April 2017	Document approved at the Key Document Approval Group	KDAG
March 2019	Document extended for 3 months whilst review is carried out and approved	Suneil Kapadia
Jan 2021	Document extended until June to allow for thorough review and update	M. Hallissey
May 2021	Review of Key Document.	M. Hallissey

Contents page:

1. Introduction
2. Scope of this document
3. Definitions
4. Responsibility and Duties
5. The Diagnostic Test Process - Overview
6. Implementation of key document
 - 6.1 Plan for implementation
 - 6.2 Dissemination
 - 6.3 Training and awareness
7. Monitoring and compliance
8. Policy review
9. References
10. Background
 - 10.1 Equality requirements
 - 10.2 Financial Risk Assessment
 - 10.3 Consultation Process
 - 10.4 Approval Process

Appendices

Appendix 1 List of Diagnostic Tests

Supporting Documents

Supporting Document 1	Checklist for review & approval of a key document
Supporting Document 2	Equality Impact Assessment
Supporting Document 3	Financial Risk Assessment

1. Introduction

1.1 There are screening and diagnostic tests performed in healthcare every day on both inpatients and outpatients. As healthcare providers we must ensure that these tests are required for patient management, and the results are accessed, reviewed and acted upon in a timely way for optimal patient care.

1.2 Criterion 5.7 in the NHSLA Risk Management Standards for Acute Trusts (2012) included this rationale:

“The failure to access, acknowledge and act upon the results of diagnostic tests may result in an inappropriate delay and lack of timely treatment resulting in harm to patients. Organisations should have in place clear clinical risk management systems that identify guidance to reduce this risk.”

These should include the ability to record timely and accurate data; ensure that staff are trained in the use of software systems that support diagnostic functions; enable communication channels that are consistent across the organisation; provide known pathways that assist in the tracking of patients; and advise patients on how their test results will be communicated to them.”

Analysis of claims on the NHSLA database shows that a failure or delay in interpreting or acting on test results is one of the most common factors in relation to claims.”

1.3 The purpose of this policy is to provide a standard framework that describes responsibilities and the requesting process as well as setting standards for review and action regarding results. This will minimize the risks associated with failure/delay in accessing, reviewing and acting upon test results

1.4 For the purpose of this policy ‘timely’ is defined as:

- For inpatients no longer than 24 hours after the result is available
- For patients transferred to other providers or the care of their general practitioner a list of outstanding investigation results must be included in the transfer/discharge summary
- For outpatients, before the patients next planned outpatient/inpatient episode.

2. Scope of this document

2.1 This policy applies to all diagnostic testing processes undertaken within the Trust. Appendix 1 provides a list of some of the principal diagnostic tests, investigations and procedures available to clinicians to support diagnosis and clinical care

2.2 Any local policies, guidelines or SOPs should reference and follow the principles set out in this policy

3. Definitions

3.1 **Verification** - for the purpose of this policy, the term verification refers to acquisition, interpretation, communication and action.

3.2 **Skilled** – for the purpose of this policy, the term interpretation refers to trained or experienced practitioners/professionals.

- 3.3 **Interpretation** – for the purpose of this policy, the term interpretation refers to the explanation provided by the performer of the test and the understanding of the individual reviewing a test result.
- 3.4 **Diagnostic Tests** – These are performed on patients with specific complaints or signs or symptoms of a disease/condition – these include procedures such as laboratory tests and other pathology investigations, endoscopy, physiological measurements, and imaging procedures (a list of diagnostic tests will be developed refer to Appendix 1)
- 3.5 **Standard Operating Procedure (SOP)** – For the purpose of this policy all local documents will be described as SOPs e.g. a policy, guideline, protocol or Standard Operating Procedure
- 3.6 **ICE** – The ‘ICE Order Communications’ system. This system is used to electronically request and report all pathology (except blood transfusions and histopathology) and radiology diagnostic tests
- 3.7 **CRIS** – Clinical Radiology Information System
- 3.8 **Suitably trained health care professional** – Health care professionals, including medical practitioners and other staff groups who are competent to undertake the required actions (e.g. requesting investigations or receiving and taking appropriate action).

4. Responsibility and Duties

4.1 **Divisional Management Teams:**

Must ensure that all relevant staff are aware of and adhere to this policy. They are also responsible for ensuring that monitoring of diagnostic tests requested by their clinical teams takes place and provide assurance that results are viewed by suitable trained health care professional and acted upon appropriately: and where there is a shortfall in compliance action is taken to improve.

4.2 **All Staff employed by Worcestershire Acute Hospitals NHS Trust**

- All staff are responsible for:
 - carrying out the designated duties as outlined in this policy and within their local guidelines or equivalent protocols/Standard Operating Procedures (SOPs) where present.
 - requesting a clinical diagnostic test, investigation or screening procedure only when the result is likely to influence diagnosis or patient management.
- All clinical diagnostic tests must be undertaken by authorised healthcare staff following appropriate training where necessary.
- When diagnostic tests are requested healthcare staff must ensure that information provided includes:
 - The correct patient/service user details.
 - The appropriate clinical diagnostic test, investigation or screening procedure required.
 - The details of the appropriate healthcare worker for return of the clinical diagnostic test or screening result for viewing and subsequent action.
- The requesting of the diagnostic test must be clearly documented in the medical record

- Timely viewing and recording the receipt of the clinical diagnostic test, investigation or screening result is required; the interpretation and the consequent management plan must also be recorded in the clinical record;
- Information regarding any urgent requests with pending results should be formally handed over to the relevant clinical team looking after the patient if there is a transfer of care e.g. out of hours or in-patient transfer between teams.
- The process for how results are communicated to the patient/service user and other appropriate healthcare staff as appropriate is also required.
- Ensure that appropriate actions on results are taken and documented, and that the method of communication is recorded, i.e. face to face contact, phone call, letter, email, fax, etc.
- Where electronic requesting is available e.g. ICE, this must be used as the primary requesting method.

4.3 **Administrative Staff**

The role of administration staff may include acquiring or the recording of the receipt of clinical diagnostic test or screening results.

4.4 **Locum staff requesting investigations**

Where locum staff request investigations that will not be reported before the end of their period of employment specialities/divisions must have a robust system for handing over the responsibility for care of patients managed by the locum to a named clinician, together with any outstanding investigations for that patient. The responsibility for ensuring investigation results are reviewed will then pass to that named individual.

4.5 **Divisional Governance Groups**

Divisional governance processes must ensure that monitoring of the timely review of investigation results is happening and where necessary improvement action is occurring to ensure practice is in line with the standards outlined within this policy. Divisions will report performance to the Clinical Governance Group with a frequency determined by that group but no less than every 6 months.

4.6 **Clinical Governance Group (CGG)**

Chaired by the Chief Medical Officer, the CGG will review the effectiveness of this policy and request for improvement actions if appropriate.

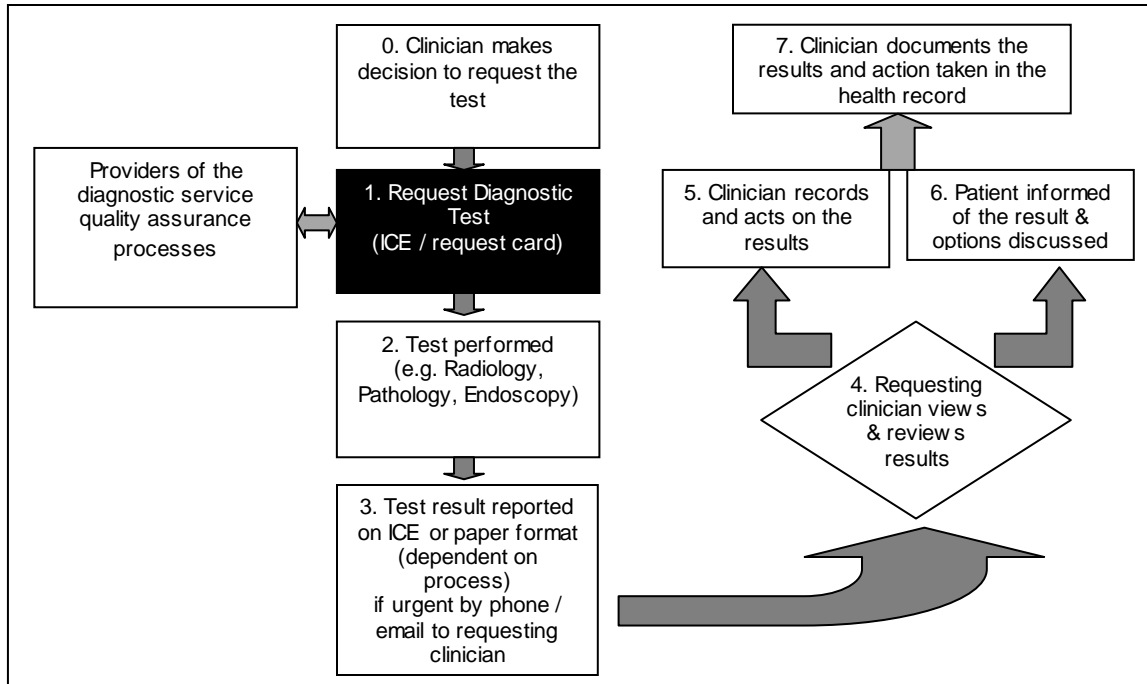
5. The Diagnostic Test Process - overview

5.1 General Principles: The elements of the diagnostic test process include the following: the decision to test, making a request, the processing/undertaking of the investigation, reporting of the results, acting upon the results, and communicating the outcome and implications of the test results to patients are set out below.

5.2 Accessing ICE requires a password. It is the responsibility of individual directorates/divisions to ensure that all clinicians have a log in /access to the system including short term locums. Where appropriate an understanding of the alternative method of requesting a test, investigation or procedure may also be required.

5.3 It is the responsibility of the clinician or the clinical team requesting the diagnostic test to view and act upon the findings of the results and communicate the impact or resulting treatment options to the patient, with advice where necessary

Diagram 1 – The Diagnostic Test Process:



Element	Guidance
0. Decision made by clinician to request the diagnostic test	<ul style="list-style-type: none"> Following national/local best practice guidance relevant to the patient's clinical need
1. Request the test	<ul style="list-style-type: none"> The request must provide full details of the requesting clinician and the patient demographic details along with the relevant clinical details. Include who requests the test and their authority to do so (see below). The request will be made electronically through ICE when it is possible to do so, or via a paper using the request form appropriate to the test required. A decision may be made by the diagnostic service not to perform the test/investigation (e.g. inappropriate test, lack of clinical information, test contraindicated) – this will be communicated back to the referring clinician.
2. Test performed by the diagnostic service	<p>The departments undertaking (or outsourcing) the diagnostic test are responsible for:</p> <ul style="list-style-type: none"> The quality control and quality assurance of those tests. Performance of the test within agreed timescales
3. Test result reported	<p>The departments undertaking (or outsourcing) the diagnostic test are responsible for:</p> <ul style="list-style-type: none"> Issuing the results (and providing interpretation when required) within agreed timescales on ICE or other agreed means Contacting the requesting clinician via phone, email or in person if the results need to be urgently communicated
4. Requesting clinician (or clinical team) views and reviews the results	<p>The clinical team that initiated the original investigation is responsible and accountable for:</p> <ul style="list-style-type: none"> Reviewing the investigation result in a time frame that fits with the patients' clinical condition and does not compromise their safety. Validating the result with respect to the clinical context (and requesting further investigation where necessary) Documenting that the results have been reviewed and the impact on patient care in the clinical record, Acting upon the result Giving sufficient, clear and timely information to all patients (and where appropriate their families, carers, care coordinators and key-workers) about diagnostic tests and test results at discharge. This should include details of any follow-up arrangements and contact details for assistance if there are any concerns or delays. Tracing / retrieving / following up non-receipt of results Filing the results on ICE or other agreed systems When a patient is discharged, hospital clinical teams should have a process in place to ensure that test results are seen, acted on and communicated to general practitioners and patients in a timely and responsive manner. Responsible consultants leading clinical teams

	<p>must ensure their team members understand and comply with this local process.</p> <ul style="list-style-type: none"> When a patient is discharged there should be a mutually agreed standardised system between primary care and secondary care to support the safe and effective hand-over of diagnostic tests and test results, including any outstanding actions where appropriate. Essential information about diagnostic tests and test results should be clearly identifiable and highlighted to avoid important information being overlooked. Any diagnostic tests that are processed by the Worcestershire Acute Trust Pathology or Radiology Services regardless of whether ICE was used to request the test will be viewable using the ICE system. Other diagnostic test results not processed by the Worcestershire Acute Trust Pathology or Radiology Services will be reported to the requesting clinician via the agreed method for that test, usually in writing / paper report. It is the responsibility of the clinician to ensure the test result is entered into the patients' medical record.
5. Requesting clinician acts upon the test results	<ul style="list-style-type: none"> The clinician documents the impact of the results in the patient's health record, determines the actions required and informs the relevant health care professionals responsible for on-going care.
6. The clinician informs the patient of the results	<ul style="list-style-type: none"> The patients will be informed of the results within an appropriate timescale and their management plan and options will be discussed.
7. Recording the test results	<ul style="list-style-type: none"> Documentation of the results and logging the actions taken in the patient's record is undertaken by a member of the clinical team reviewing the results – this will normally be the requesting clinician but may be a delegated function.

6. Implementation

6.1 Plan for implementation

Following approval the policy will be implemented through the following actions:

- Publication on the Trust's intranet
- Dissemination of information regarding the policy through the Trust Communications department
- Provision of the policy to Divisions for local implementation

6.2 Dissemination

This policy will be disseminated to all staff through publication on the Trust's intranet and to the Divisional Management Teams

6.3 Training and awareness

The training required for requesting, validation and communication of results to clinical teams will be covered in the ICE training programme (new staff receive this at

induction). There must be staff training about the verification of results process so that each staff member understands how his or her role contributes to the overall process. Training must also include locum staff having access to ICE who will receive training in requesting and accessing results in ICE using a personalised temporary account.

Any policy update will be re-launched with appropriate Trust-wide publicity

7. Monitoring and compliance

A range of methods will be used to monitor the effectiveness of this policy:

- ICE viewing Audit with feedback to Divisional management teams
- Diagnostic services monitoring of turnaround times against agreed standards.
- Clinical audit of paper results – to be included in clinical service audit forward plans.
- Clinical Audit of results and appropriateness of actions taken
- Audit of discharge communication to ensure test results and outstanding investigations are include in documentation and that this information has been communicated to patients and/or carers.
- Report on policy compliance by divisions every 6 months to CGG with actions to improve when standards are not met.

8. Policy Review

This policy will be reviewed no later than two years from its approval date.

9. References

Early identification of failure to act on radiological imaging reports, NPSA Safer Practice Notice 16, February 2007
CRIS – Radiology Information System
ICE Order Communications – Results reporting (Trust) guide
WAHT-CG-564 - Early Identification of failure to act on Radiological Imaging Reports
ICE Requesting Handout – Web Access – Quick Guide V2
ICE Requesting – Inpatient Phlebotomists Ward Round - Handout
ICE Requesting – Inpatient requesting Radiology and Pathology Tests - handout
Pathology Handbook
NHSLA Risk Management Standards for NHS Trusts providing Acute, Community or Mental Health & Learning Disability Services and Independent Sector Providers of NHS Care (2011/12)
Policy for the development, management and approval of key documents – WAHT-CG-001
Policy to identify all patients – WAHT-CG-019
Standards for the communication of patients’ diagnostic test results on discharge from hospital. NHSE Patient Safety Domain. March 2016

10. Background

10.1 Consultation

The following have been consulted in the development of this policy:

- Task & Finish Group
- Divisional Management Teams
- Pathology Directorate
- Radiology Directorate

Endoscopy Directorate
ICE Project Manager
MD for Patient Safety
Heads of Nursing / Midwifery
Matrons

10.2 Approval process

This policy will be approved by the Key Documents Approval Group following the consultation process described above.

10.3 Equality requirements

This policy does not have equality impacts.

10.4 Financial risk assessment

There is no specific financial risk associated with the implementation of this policy. The systems for requesting and reporting the results of diagnostic tests are in place.

The implementation of this policy should lead to improved reliability, reduce delays, reduce the harm caused to patients and over time reduce claims related to missed or delayed diagnosis.

APPENDIX 1**List of Clinical Diagnostic Tests Procedures**

Examples to be considered can be seen below (NB this list is not exhaustive):

Cardiac Investigations

ECG
Exercise testing/stress testing
Ultrasound
Angiography

Near Patient Testing

Blood glucose
Blood pressure
Body mass index
Urinalysis
Blood gas analysis

Pathology

Biochemistry
Haematology
Non-gynae Cytology
Histology
Microbiology
Andrology
Immunology

Radiology

Ultrasonography
X-Ray
CT
MRI
Dexa scan
Nuclear medicine
Fluoroscopy
Mammography

Respiratory Tests

Lung function
Sleep investigations

Other

Urodynamics
Vascular ultrasound
Endoscopy
Colposcopy
Maternity ultrasound
Maternal Cardiotocography (CTG)
Neurophysiology

Supporting Document 1 – Checklist for review and approval of key document

This checklist is designed to be completed whilst a key document is being developed / reviewed.

A completed checklist will need to be returned with the document before it can be published on the intranet.

For documents that are being reviewed and reissued without change, this checklist will still need to be completed, to ensure that the document is in the correct format, has any new documentation included.

1	Type of document	Policy
2	Title of document	Policy for the management of clinical diagnostic tests
3	Is this a new document?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> If no, what is the reference number WAHT-CG-746
4	For existing documents, have you included and completed the key amendments box?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
5	Owning department	Corporate Clinical Governance
6	Clinical lead/s	AMD Patient Safety & Clinical Effectiveness
7	Pharmacist name (required if medication is involved)	n/a
8	Has all mandatory content been included (see relevant document template)	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
9	For policies and strategies, does the document have a completed Equality Impact Assessment included?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
10	For patient information, have you piloted the leaflet? If yes, please give details.	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input checked="" type="checkbox"/>
11	Please describe the consultation that has been carried out for this document	Review with the Divisional Management Teams and diagnostic test providers.

Once the document has been developed and is ready for approval, send to the Systems and Standards department, along with this partially completed checklist, for them to check format, mandatory content etc. Once checked, the document and checklist will be returned to yourself, to submit to relevant committee for approval.

12	Step 12 To be completed by Systems and Standards Department	
	Is the document in the correct format?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	Has all mandatory content been included?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	Date form returned ____/____/____	
13	Please state the name of the approving	

	body (person or committee/s)	
14	Approval date	____/____/____
15	Please state how you want the title of this document to appear on the intranet, for search purposes and which specialty this should be saved under	

Implementation

Briefly describe the steps that will be taken to ensure that this key document is implemented

Action	Person responsible	Timescale
Implementation plan devised with DMT's to include monitoring of compliance	AMD Pt Safety	April 2017

Plan for dissemination

Disseminated to	Date
All staff via the Trust's intranet	
Divisional Management Teams	
Medical staff via clinical forums	

Please return an electronic version of the approved document and completed checklist to the Clinical Governance and Patient Safety Department

Please sign below

Name _____

Designation _____

Date _____

Office use only	Reference Number	Date form received	Date document published	Version No.

Supporting Document 2 - Equality Impact Assessment Tool

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

		Yes/No	Comments
1.	Does the policy/guidance affect one group less or more favourably than another on the basis of:		
	• Race	No	
	• Ethnic origins (including gypsies and travellers)	No	
	• Nationality	No	
	• Gender	No	
	• Culture	No	
	• Religion or belief	No	
	• Sexual orientation including lesbian, gay and bisexual people	No	
	• Age	No	
2.	Is there any evidence that some groups are affected differently?	No	
3.	If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?	N/A	
4.	Is the impact of the policy/guidance likely to be negative?	No	
5.	If so can the impact be avoided?	N/A	
6.	What alternatives are there to achieving the policy/guidance without the impact?	N/A	
7.	Can we reduce the impact by taking different action?	N/A	

If you have identified a potential discriminatory impact of this key document, please refer it to Assistant Manager of Human Resources, together with any suggestions as to the action required to avoid/reduce this impact.

For advice in respect of answering the above questions, please contact Assistant Manager of Human Resources.

Supporting Document 3 – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	No
2.	Does the implementation of this document require additional revenue	No
3.	Does the implementation of this document require additional manpower	No
4.	Does the implementation of this document release any manpower costs through a change in practice	No
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	No
	Other comments:	

If the response to any of the above is yes, please complete a business case which is signed by your Finance Manager and Directorate Manager for consideration by the Accountable Director before progressing to the relevant committee for approval