Histopathology National Quality Improvement Programme
Information Governance Policy
Version 3.0

Developed by
The Working Group of the National Histopathology Quality Improvement Programme

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1. Executive Summary

The Faculty of Pathology, RCPI launched the National Quality Improvement Programme in Histopathology in January 2009 in collaboration with the National Cancer Control Programme (NCCP) and Directorate of Quality and Clinical Care (DQCC). This programme has been undertaken with funding support originally from the National Cancer Control Programme and since 2014, from HSE Quality Improvement Division (HSE QID). The fundamental aim of this QI Programme is to ensure patient safety and enhancement of patient care with timely, accurate and complete pathology diagnoses and reports.

As participating clinicians it is important to understand that this QI programme is not an exercise in individual performance management. Rather, its focus is on enabling local laboratory teams to monitor, review and improve the quality of their work in the context of national norms and intelligently set national targets and recommendations.

The IT system developed for use by all participants to store and analyse QI data allows individual laboratories to access their own data, generate and analyse reports using this data. It also allows individual laboratories to view national data with all hospitals summarised together and hospital ID’s anonymised.

The Faculty and SQI Programme Steering Committee have access to national data with all hospitals summarised together and hospital ID’s anonymised within the following groupings: All laboratories, Cancer Centres and General Centres. Consultant IDs are not recorded in the QI data and therefore are inaccessible. It is the responsibility of the Clinical Lead Pathologist and Clinical Director to drive continuous improvement locally based on QI data particularly in areas where results fall below the national average.

The Faculty of Pathology, RCPI recognises the importance of maintaining privacy and confidentiality at all times, and is committed to the highest standards with regard to the manner in which it collects, stores, accesses, shares and manages personal data.

There has been much discussion around the issue of monitoring individual Consultant ID as part of this programme and while there are benefits to adopting this approach, this data item will not be collated centrally at this time. The functionality to extract this data item will, however be built into the IT solution development to avoid incurring unnecessary costs should this become a requirement in the future. Such a change would require an amendment to this Information Governance Policy.

The Working Group and Steering Committee of the Histopathology QI Programme will review this Information Governance Policy every three years.

Amendments to this policy can only be approved with the agreement of all parties involved: Faculty of Pathology, RCPI, SQI Programme Steering Committee and a majority of Programme Participating Hospitals.

2. Introduction

A clinical audit is a quality improvement process within the clinical environment. Clinical audit is arguably the single most important method that any healthcare organisation can use to understand and assure the quality of the service that it provides (1). Clinical audit is the central component of the National QI Programme in Histopathology. To drive this QI Programme the Faculty of Pathology has developed guidelines of Quality Improvement in a number of key performance areas of Histopathology (2). These guidelines are implemented in public and private hospitals in Ireland with Histopathology laboratories. Participating laboratories are expected to collect key performance data locally for ongoing review and improvement, as outlined in the Participation Memorandum of Understanding (MOU).
Key quality data is recorded on the local Laboratory Information System (LIS) at participating sites as part of normal laboratory workflow, and will be routinely exported, encrypted and securely transmitted to a central data repository. A local authorisation step is required before data is accessible to Faculty ensuring that local laboratories maintain ownership of data after it is transferred. The repository will primarily be used locally to facilitate local review and reporting of key quality data and will be used nationally for national reporting and target setting and validation.

This key quality data consists of essential data items associated with each case and includes general case details like case ID, case age, receipt date and details of case procedures and tissue types and details of quality activities applied to the case. Please see Appendix II for more details.

A Histopathology module within Health Atlas Ireland was configured to facilitate Histopathology key quality data collection—this module is referred to as the “National QA Intelligence System (NQAIS) - Histopathology” within the broader context of the Histopathology National QI Programme.

3. **Document Purpose**

It is recognised that to encourage participation in clinical audit and quality improvement activities, clinicians need to feel safe with the process and to be assured that it will not be used against them in a punitive manner (2). This Information Governance Policy has been developed in order to manage the confidential processing and communication of quality data pertaining to individual Histopathology departments. This document is not intended to constitute a legal document. It has been prepared to define how data collected for the National Histopathology QI Programme will be governed, processed, stored, accessed and reported on. The existing legislation relevant to the QI Programme comprises:

- Freedom of Information Act 1997 and 2003
- Data Protection Act 1988 and 2003
- Medical Practitioners Act 2007

The Health Information and Patient Safety Bill will address audit and the QI Programme is engaged with securing full protection under this legislation with the Department of Health’s National Clinical Effectiveness Committee. The Faculty of Pathology recognises the value of the programme to patient safety and encourages histopathology departments to balance any risk perceived from the FOI Act against the risks of not being involved in this programme. The Data Protection Acts will be mentioned when appropriate in this document.
4. Information Flow

Data required for the Histopathology National QI programme is coded into local Laboratory Information Systems (LIS) at each participating site. Data is extracted and encrypted at each site before it is securely transferred to NQAIS-Histopathology. Each site maintains ownership of its own data at all times. Each site has access to its data on NQAIS in order to review it using the reporting functionality provided and sign the data off as being complete and accurate within the agreed time limits. The data then becomes accessible nationally for inclusion in national summary reports.

5. Roles & Responsibilities

The appropriate, effective and efficient access to information within NQAIS- Histopathology requires a clear definition of the roles and responsibilities of the different parties involved in the programme and a definition of access rights based on those roles.

Representatives of each organisation involved in this programme (e.g. stakeholders, participants, contractors), and staff members likely to access QI data, analyses or reports, will be asked to read, agree and observe the rules set out in this Information Governance Policy.

Before such access is permitted, hospitals must ensure that these individuals agree to and comply with this Information Governance policy. Key members of the participant hospital must sign the Histopathology QI Memorandum of Understanding which states agreement & compliance with this Information Governance Policy, and which will remain applicable even after cessation of involvement in the Histopathology National QI Programme.

There are four parties to the National Histopathology QI Programme as per the QI Programme Memorandum of Understanding:

a) Participating hospital in the National Histopathology QI Programme

b) Faculty of Pathology, Royal College of Physicians of Ireland (19 South Frederick Street, Dublin 2)
c) Steering Committee of the National Histopathology QI Programme
d) Programme Management, RCPI, (19 South Frederick Street, Dublin 2)

Other parties with responsibilities in the programme.
e) Office of the Chief Information Officer (OCIO), HSE (represented on the QI Steering Committee)
f) Health Intelligence Team, HSE
g) ICT service providers

Roles & responsibilities for each of the above parties are defined as follows:

5.1. Participating Hospital

Participating Hospitals are the owners and controllers of the quality improvement data stored within NQAIS-Histopathology. As such, they should ensure that their histopathology department staff are trained in the use of the system as well as the local policies that govern data usage.

Responsibilities of all members of the Participating Hospital

- Develop and implement local protocol(s) regarding data access and reporting, report circulation and storage.
- Report and manage patterns of practice with the potential to affect patient safety, as part of National Histopathology QI Programme activities, in compliance with local policy and governance structures.
- Process data according to local protocol and in compliance with this Information Governance Policy
- Report on breaches of this Information Governance Policy, through the locally established clinical governance structures level and to the Steering Committee for the Programme.
- Note: The Data Controller is responsible for the integrity of data and can authorise or deny access to data. The Data Controller determines the purposes for which and the manner in which data pertaining to the National QI Programme are to be processed. As Data Controllers, participating hospitals should take steps to ensure that they are in compliance with the Data Protection Acts and that all system users are aware of the data collected and the uses to which this data will be put. No personally identifiable information is collected in NQAIS-Histopathology.

Responsibilities of the Hospital CEO or General Manager

- Identify a Histopathology Department Clinical Lead locally with overall responsibility for the QI Programme (allowing dedicated time for QI activity).
- Establish a Quality Committee / structure within each department to review data and take action as required, linking with relevant hospital governance structures and structures set out in the Programme Guidelines.
- Ensure that all users of NQAIS-Histopathology have read and understood this Information Governance Policy.
- Overall responsibility rests with the local hospital management / governance for quality and safety, to ensure resources to participate in the Programme and to review local QI reports and drive continuous improvement. Formalise the reporting of QI data locally ensuring the review cycle is adhered to.
- The Histopathology Department sits within the local governance of the hospital and the overall responsibility for the programme rests with the local governance of the hospital and the respective regional and national structure for that hospital. The department and the hospital governance have the responsibility to review the QI data and to drive continuous improvement within the hospital.

Responsibilities of the Histopathology Clinical Lead
• The Histopathology Clinical Lead has overall responsibility for the programme within their local site.
• Identify a designated person or two persons locally with responsibility for the operational support of NQAIS-Histopathology and other administrative tasks on an ongoing basis (Local Operational Manager).
• Develop local policies which will outline how NQAIS-Histopathology access permissions will be determined.
• Support department in driving continuous improvement in the department (allowing for dedicated time/resources for QI activities) in conjunction with the Clinical Director.
• Report and manage patterns of practice with the potential to affect patient safety, as part of Histopathology National QI Programme activities, in compliance with local policy in conjunction with the Clinical Director.
• In instances of staff change, ensure that incoming staff members receive proper training prior to using NQAIS-Histopathology.
• Review statistics and reports in NQAIS-Histopathology on a monthly basis as per the Histopathology QI Programme MOU. This review should be done relative to National Targets and Recommendations.
• Notify the hospital management structure / discuss with clinical director of the departmental QI performance on a quarterly basis at a minimum.
• Authorise local user access rights and access levels to NQAIS-Histopathology for this programme in accordance with local policies.
• Co-ordinate the ongoing setup and removal of authorised local users for NQAIS-Histopathology this programme in conjunction with the Local Operational Manager.
• Identify centrally generated report recipients e.g. all consultants within department, Hospital management, quality and safety committees, etc.
• Review and verify the accuracy and completeness of local QI data by utilising local report and analysis tools provided.
• Attend (or nominate deputy) all workshops provided by the National QI Programme.

Responsibilities of the Local Operational Manager:
• Review and verify the accuracy and completeness of local QI data utilising local report and analysis tools
• Maintain local code mapping tables and clinicians tables on NQAIS-Histopathology.
• Supply and maintain up to date mailing list for the receipt of National reports and communications.
• Co-ordinate the ongoing setup and removal of authorised local users for NQAIS-Histopathology in conjunction with Histopathology Clinical Lead.

Responsibilities of all members of Histopathology Department:
• Ensure that all QI activity is accurately recorded on the Laboratory Information System.
• Follow local policies regarding use of data accessed through hospital systems.
• Data available to histopathology department staff should not be shared with any third party without the consent of the hospital.

5.2. Faculty of Pathology, RCPI

The Faculty of Pathology, RCPI has access to aggregate national data only. The Faculty of Pathology, RCPI has convened and refers to the Steering Committee for all of their data processing roles and responsibilities.

Responsibilities of the Faculty of Pathology, RCPI:
• Develop and maintain standards of practice and safety in the Histopathology QI Programme.
• Develop and continuously review the national targets using the data provided.
• Provide professional and educational support to the participating hospitals in achieving the proposed targets.
• Provide the specialist support to the programme through an appointed working group and members on the Steering Committee.
• Appoint and support members to the working group as required.

5.3. Steering Committee of the Histopathology National QI Programme

The Steering Committee of the National QI Programme has access to anonymised national aggregated data only. The participating hospital is the data owner and therefore responsibility for uploading the summary data, review of all data and performance and subsequent quality improvement rests with the hospital/department via their governance structures.

Responsibilities of the Steering Committee of the Histopathology National QI Programme:
• Define the Information Governance Policy for this programme.
• Oversee the development and implementation of the ICT solutions necessary to support the needs of this programme, in collaboration with the HSE Office of the CIO and Health Intelligence Ireland (HII).
• Ensure that adequate technical & organisational security measures are put in place to safeguard against unauthorised access, alteration, disclosure and destruction of data, in collaboration with the HSE Office of the CIO and Health Intelligence Ireland (HII).
• Ensure that upon initial rollout of NQAIS-Histopathology, all of the system’s users receive appropriate training prior to using the system.
• Identify a designated National Operational Manager (QI Programme Manager) with responsibility for the operational management of the National Histopathology QI Programme on an ongoing basis.
• Authorise national users’ access to NQAIS-Histopathology for this programme.
• Use data in the setting of National Targets in response to requests through the Faculty of Pathology, RCPI.
• Ensure data is not disclosed to any third party without consent of the Data Controller. Only use data for the purpose intended: to facilitate the enhancement of patient care with timely, accurate and complete Histopathology diagnoses and reports.
• The Data Processor, with respect to data in NQAIS-Histopathology, for the Histopathology National QI Programme is the Programme Steering Committee and Faculty of Pathology, RCPI. The Data Processor is the entity that holds or processes QI data, but does not exercise responsibility for or control over the QI data. This responsibility remains with participating hospitals as Data Controllers.

5.4. Programme Management, RCPI

RCPI Programme Management works with an established working group of clinicians appointed by the Faculty of Pathology, RCPI and Steering Committee and provides programme management services to the programme. The QI Programme Manager (National Administrator), has access to all data in an administrative capacity only, as set out in this Information Governance Policy.

Responsibilities of designated QI Programme Manager:
• Support the ongoing development and use of NQAIS-Histopathology (e.g. additional analyses/reports & departments), along with the Health Intelligence System Manager and HSE OCIO.
• Ensure that all stakeholders and participants receive and understand the Information Governance Policy for this programme.
• Liaise with local Histopathology departments to ensure that QI data is recorded and reviewed as scheduled, in a timely manner.
• Develop and distribute standard operation procedures (SOPs) for NQAIS-Histopathology user setup and support related processes to ensure a consistent approach and national user training carried out by participating hospitals.
• Co-ordinate the ongoing setup and removal of authorised national users for this programme.
• Handle QI Programme related calls/queries on an ongoing basis.
• Review national QI data and agreed metrics annually/on a regular basis, as agreed to with the Steering Committee
• Generate and circulate national, anonymised QI reports to the list of recipients agreed to by the Faculty of Pathology
• Ensure data is not disclosed to any third party without consent of the QI Programme Steering Committee.
• Use data for the purpose intended e.g. to facilitate the enhancement of patient care with timely, accurate and complete Histopathology diagnoses and reports

5.5. **HSE Office of the Chief Information Officer (OCIO)**

The HSE OCIO has overall responsibility for the successful delivery of the necessary ICT solution(s) to support the needs of this programme, in connection with public and voluntary hospitals, and is accountable for the approved ICT capital budget.

Responsibilities of HSE OCIO:
• Identify a designated ICT Project Manager to assume overall responsibility for the delivery of the necessary ICT solution(s), and for the approved ICT capital funding
• Procure software development services (as necessary) to facilitate the development of NQAIS-Histopathology and interfaces, and QI web interface applications to meet the needs of this programme, and to facilitate the ongoing maintenance, support and development of these systems to meet ongoing and evolving needs
• Assist with the detailed design, development, testing and implementation of the central reporting system on an ongoing basis
• Lead the detailed design, development, testing and implementation of all necessary Histopathology Reporting System (ERS) extracts and interfaces in collaboration with the QI Programme Manager and participating-Histopathology departments.
• Manage the ongoing relationships and contracts with the web-interfaces vendors for the provision of essential ICT services to public and voluntary hospitals (e.g. software development, maintenance & support, database/systems administration)
• Advise the Data Controller and QI Programme Manager on appropriate technical & organisational security measures to safeguard against unauthorised access, alteration, disclosure and destruction of data
• Identify a designated person with responsibility for liaison with Health Intelligence Ireland and the Programme Manager on an ongoing basis
• Process data only on and subject to the instructions and agreement of the Data Controller (i.e. potential data processor role)

5.6. **Health Information, Health Intelligence Ireland (HII), HSE**

The Health Information Unit, HSE, in collaboration with the QI Programme Manager, HSE OCIO, and other stakeholders will manage the ongoing relationship and vendor contract for the provision of essential ICT services (e.g. software development, maintenance & support service levels, database/systems administration) in relation to NQAIS-Histopathology.

Responsibilities of all members of HII:
• Identify a designated HSE System Manager with overall responsibility for NQAIS-Histopathology related issues requiring Health Intelligence involvement.
• Manage the ongoing relationship and contract with HEAnet for hosting the NQAIS (e.g. access/security, disaster recovery, network management)

Responsibilities of designated System Manager:
• Support the ongoing management and security of NQAIS-Histopathology, liaising as necessary with the approved vendor(s) of the various QI ICT systems described in this document, HII, the National
Operational Manager and the HSE OCIO (e.g. system configuration, user setup, issuing of security certificates)

- Set up and maintain authorised national users on the NQAIS-Histopathology. As the Health Atlas is the platform for hosting NQAIS-Histopathology, Health Intelligence has to be involved in the initial setup of the Programme in the live Atlas and the initiation of the User Management function. Once the initial Programme Controllers from the HSE or RCPI / RCSI Colleges are assigned, Health Intelligence has no further role in User Management.
- Support the ongoing development of NQAIS-Histopathology (e.g. additional reports and analyses)

5.7. ICT system & service providers

ICT system and service providers and NQAIS-Histopathology, will be contracted by the HSE OCIO to develop and maintain the necessary ICT solutions and infrastructures to support this programme. These providers will work in collaboration with the QI Programme Manager, HSE OCIO Project Manager, HSE Health Intelligence Unit and participant Histopathology Departments.

Responsibilities of each provider:

- Identify a designated person to lead and co-ordinate all necessary development work, within their own organisation
- Enhance their existing solution/infrastructure(s) to meet the needs of this programme
- Maintain, support and develop the enhanced solution/infrastructure(s) to meet ongoing and evolving needs
- Assist with the design and implementation of appropriate technical security measures to safeguard against unauthorised access, alteration, disclosure and destruction of data
- Process data only on and subject to the instructions and agreement of the QI Programme (i.e. potential data processor role)
- Ensure data is not disclosed to any third party without consent of the QI Programme Steering Committee.

6. Access

It has been agreed that the existing Health Atlas Ireland application and supporting infrastructure will be enhanced to facilitate the NQAIS for this programme. Existing information security mechanisms to safeguard data confidentiality, integrity and access will be modified as necessary to meet the needs of this programme.

Access to data in the NQAIS will be restricted to authorised local and national users who must be members of the defined Data Originator, Data Controller, HSE OCIO Directorate and HSE Information Unit entities. Authorised users will be granted appropriate access to specific functionality, and will be appropriately restricted to local or national views of the data on the NQAIS. Authorisation for the granting of user access accounts and for the associated data access rights is required from the specified Access Controller (see table 1 below).

6.1. Encryption

Once data is extracted from the local LIS, it is encrypted locally and all data for that period is saved and transferred securely to NQAIS Histopathology. Access to this information locally must be controlled according to local procedure.
6.2. Local Access levels

The NQAIS central repository of data has controlled access levels at local level:

<table>
<thead>
<tr>
<th>Role</th>
<th>Access</th>
<th>Expected Users</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Manager</strong></td>
<td>Create, modify or delete NQAIS-Histopathology system user. Manage Mapping Tables for the hospital accounts, including assigning user roles, for the hospital</td>
<td>Clinical Lead, Local Operational Manager</td>
</tr>
<tr>
<td><strong>Analyst</strong></td>
<td>View all QI statistics and reports for the hospital</td>
<td>Clinical Lead, Local Operational Manager</td>
</tr>
<tr>
<td><strong>Sign Off Manager</strong></td>
<td>Sign off data, after review.</td>
<td>Clinical Lead</td>
</tr>
<tr>
<td><strong>Upload</strong></td>
<td>Upload and Encrypt data extract files to NQAIS-Histopathology</td>
<td>Local Operational Manager</td>
</tr>
<tr>
<td><strong>Export</strong></td>
<td>Export QI statistics reports as PDFs or Excel files.</td>
<td>Clinical Lead, Local Operational Manager</td>
</tr>
</tbody>
</table>

6.2.1 National Access levels

<table>
<thead>
<tr>
<th>Role</th>
<th>Access</th>
<th>Expected User</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>National Analyst</strong></td>
<td>Execute quality reports on aggregated anonymised quality data</td>
<td>Members of the Working Group and Steering Committee</td>
</tr>
<tr>
<td><strong>National Administrator/Manager</strong></td>
<td>Access to data from all participating hospitals including hospital IDs. The purpose of this access is programme administration (trouble shooting, participant queries etc).</td>
<td>QI Programme Management Team</td>
</tr>
</tbody>
</table>

7. Reporting

NQAIS Histopathology provides functionality for the development of standard and ad hoc reports using National Histopathology QI data. Additional functionality can be added as data matures and clearer definition of relationships between sites is developed.

7.1. Locally generated reports

Participants will have the facility to access and analyse their own local data at all times in order to facilitate local review and quality improvement. Information governance around the generation, storage and circulation of reports produced using local Histopathology performance data should be consistent with this national policy but governed according to local protocol.
7.2. Centrally generated reports

Centrally generated reports from NQAIS-Histopathology will be made available to participants, the Faculty and the Programme Steering Group only. Reports will be made available to each hospital department and will identify receiving hospital only. Reports made available to the Faculty and Programme Steering Group will contain national data with all hospitals summarised together and hospital ID’s anonymised within the following groupings:

A) All Participants
B) Cancer Centres
C) General Centres

Reports made available to the Faculty and SQI Programme Steering Group.

Reports generated or received by participants containing any reference to other participants, albeit anonymous, must not be published outside of the hospital. This includes reference to position on any scale of measure with inferred reference to other participants (e.g. Hospital X has the shortest turnaround time).

The QI Programme aims to publish an Annual National Data Report which will be made publically available. This report will anonymise hospital IDs, but will identify hospitals as Cancer Centres or General Centres.

8. Issue Resolution Pathway

It is important that there is a route for the resolution of issues, discovered through participation in the QI Programme. The pathway for resolution of issues relates only to those issues that are brought to the attention of the QI Programme.

The Faculty of Pathology, Steering Committee and RCPI Programme Management do not monitor the performance of any individual hospital.

In the event that a hospital brings an issue of clinical relevance to the attention of the QI Programme, the RCPI and Faculty of Pathology Working Group will assist the participant hospital in resolving the issue. If the issue cannot be resolved, the Working Group and RCPI will bring the issue to the attention of the Steering Committee who will communicate with the appropriate relative body.

Please see the pathways (Public and Private) outlined in Appendix 1 for full details on this process.

9. Secondary use of Data

Access to data in the NQAIS can be granted by the participant hospitals for approved research purposes. Clinicians wishing to apply for access must follow the ‘Research Access Application Procedure’

Access will be granted based on the criteria set out in this procedure. In the cases where access is granted, hospital identities will remain anonymous.
10. References


2) Guidelines for the Implementation of a National Quality Assurance Programme in Histopathology. Faculty of Pathology, RCPI


12) Health Intelligence Unit, HSE. Health Intelligence Initiatives - Population Health, Knowledge Management and Health Informatics. 2009.


14) HSE Incident Management Policy and Procedure 2008. Health Service Executive


18) Data Processing Agreement between Caredoc Limited and the Health Service Executive, 2005
11. Appendix 1 – Issue Resolution Pathway

Issue Resolution Pathway – Histopathology QI Programme in Public and Voluntary Hospitals

Note: All existing hospital procedures must be followed e.g. Open Disclosure, Patient Safety Incident, Serious Reportable Events (SRE), etc. This Pathway is in addition to these procedures. In alignment with the HSE SRE Policy, 4 months after the Issue Resolution Pathway has begun, the SCI Programme will enter HSE Escalation Process Phase. Efforts to resolve issue will continue.

### Start
- **START:** Hospital Unit requests assistance after internal review of data reveals potential quality issue

### QI Data Analysis
- SQI programme performs QI Data Analysis to confirm data variation from target is within expected normal variation

### Investigation
- Patient Safety Issue or Non-Patient Safety Issue?
  - Normal or Abnormal Variation?
    - **ABNORMAL**
      - SQI Programme refers back to unit for resolution with assistance as required.
    - **NORMAL**
      - SQI Programme refers back to unit for resolution with assistance as required.

### Corrective Action
- HQI Resolution Group sends letter to Hospital/CIO, cc Clinical Lead, requesting appointment of Senior Accountable Person

### Escalation
- **START:** SCI Programme identifies unit has not uploaded within timeframe (MCU)
  - Hospital CEO replies with appointment
  - HQI Resolution Group reviews issue

### HSE Escalation Process
- **START:** SCI Programme notifies appropriate Hospital Group CIO, cc Hospital CEO
  - Hospital Group CIO notifies Nat’l Director HSE Acute Hospitals Division, cc to Nat’l Director HSE QID, Nat’l Director GAV and SCI Programme Steering Committee Chair
  - Hospital Group CIO notifies SQI Steering Committee in writing upon resolution

**Legend**
- Hospital Department Action
- SQI Programme Action
- HQI Resolution Group Action (2 members QI Working Group + 2 members FRATH Histopathology Working Group + 1 Senior Accountable Person from referring Hospital)
- Specialty QI Programmes Steering Committee Action
- HSE Hospital Group C.O.O. Action

Share learning with all SCI Programme participants and HSE National Director via Annual Report

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Issue Resolution Pathway – Histopathology QI Programme in Private Hospitals

Note: All existing hospital procedures must be followed. This Pathway is in addition to these procedures.

Four months after the Issue Resolution Pathway has begun, the SQI Programme will notify the appropriate Hospital CEO. Efforts to resolve issue will continue.

<table>
<thead>
<tr>
<th>Start</th>
<th>QI Data Analysis</th>
<th>Investigation</th>
<th>Corrective Action</th>
<th>Escalation</th>
<th>End</th>
</tr>
</thead>
<tbody>
<tr>
<td>START: Hospital Unit requests assistance after internal review of data reveals potential quality issue</td>
<td>SQI programme performs QI Data Analysis to confirm data variation from target is within expected normal variation</td>
<td>HGI Resolution Group reviews Potential Clinical Issue</td>
<td>HGI Resolution Group sends letter to Hospital CEO, requesting appointment of Senior Accountable Person</td>
<td>START: SQI Programme identifies unit has not uploaded within timeframe (see MOU)</td>
<td></td>
</tr>
<tr>
<td>Is issue data or clinical?</td>
<td>Normal or Abnormal Variation?</td>
<td>POSSIBLE CLINICAL PATIENT SAFETY ISSUE</td>
<td>Hospital CEO replies with appointment</td>
<td>HGI Resolution Group confirms clinical issue – Letter to Unit QI Clinical Lead and Senior Accountable Person, cc Hospital CEO</td>
<td></td>
</tr>
<tr>
<td>Is Issue Data or Clinical?</td>
<td>Normal</td>
<td>NON-PATIENT SAFETY ISSUE</td>
<td>HGI Resolution Group reviews issue</td>
<td>HGI Resolution Group notifies Unit Clinical Lead and Senior Accountable Person</td>
<td></td>
</tr>
<tr>
<td>SQI Programme refers back to unit for resolution with assistance as required.</td>
<td>Unit QI Clinical Lead notifies SQI Programme in writing when the issue is resolved.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POSSIBLE CLINICAL PATIENT SAFETY ISSUE</td>
<td>Patient Safety Issue or Non-Patient Safety Issue?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abnormal</td>
<td>HGI Resolution Group refers back to unit for resolution with assistance as required.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SQI Programme refers back to unit for resolution with assistance as required.</td>
<td>Unit QI Clinical Lead notifies SQI Programme in writing when the issue is resolved.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Legend:
- Hospital Department Action
- SQI Programme Action
- HGI Resolution Group Action (2 members QI Working Group + 2 members PATH Histopathology Working Group + Senior Accountable Person from referring Hospital)
- Specialty QI Programme Steering Committee Action

Share learning with all SQI Programme participants.
### 12. Appendix II – Key Quality Data Collected

<table>
<thead>
<tr>
<th>ID</th>
<th>Field Name</th>
<th>Description</th>
<th>Field Format</th>
<th>Req’d</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Hospital Patient Identifier</td>
<td>Unique number assigned within the LIS to identify the patient; also known as the Patient’s Medical Record Number</td>
<td>Any character sequence, including punctuation and spaces, but excluding commas</td>
<td>Mandatory</td>
</tr>
<tr>
<td>B</td>
<td>National Patient Identifier</td>
<td>Unique national identifier assigned to patient within the LIS to identify a patient</td>
<td>Any character sequence, including punctuation and spaces, but excluding commas</td>
<td>Blank expected</td>
</tr>
<tr>
<td>C</td>
<td>Patient Sex</td>
<td>Indicator to denote the sex of the Patient</td>
<td>Code values from local mapping table only</td>
<td>Optional</td>
</tr>
<tr>
<td>D</td>
<td>Case ID</td>
<td>Unique number generated within the LIS to identify an individual case; can include multiple parts, such as “HH123456/10”</td>
<td>Character sequence, including punctuation and spaces, but excluding commas. Format is welldefined and specific to each lab.</td>
<td>Mandatory</td>
</tr>
<tr>
<td>E</td>
<td>Case Age</td>
<td>Age of patient on the date that the case was initially entered onto</td>
<td>Integer or floating point number (for example 45 or 0.25)</td>
<td>Varies</td>
</tr>
<tr>
<td>ID</td>
<td>Field Name</td>
<td>Description</td>
<td>Field Format</td>
<td>Req’d</td>
</tr>
<tr>
<td>----</td>
<td>----------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------</td>
<td>-------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>the LIS</td>
<td>Where age is unavailable, use the value 0</td>
<td></td>
</tr>
<tr>
<td>F</td>
<td>Case Received Date/Time</td>
<td>Date/time the case was physically received by the laboratory assuming this date can be recorded (or logged on the LIS assuming that this was done in a timely fashion).</td>
<td>Date/time using one of the following formats: YYYY-MM-DD hh:mm:ss YYYY/MM/DD:hh:mm YYYY/MM/DD/hhmm DD/MM-YY hh:mm:ss[ttt] DD/MM/YYYY:hh:hh</td>
<td>Mandatory</td>
</tr>
<tr>
<td>G</td>
<td>Case Reporting Pathologist ID</td>
<td>Consultant ID of the consultant/pathologist responsible for reporting this case.</td>
<td>Any character sequence, including punctuation and spaces, but excluding commas</td>
<td>Blank Expected</td>
</tr>
<tr>
<td>H</td>
<td>Case Report Authorised Date/Time</td>
<td>Date/time the case report was authorised by the reporting pathologist.</td>
<td>Formats as listed for Case Received Date/Time</td>
<td>Mandatory</td>
</tr>
<tr>
<td>I</td>
<td>Case Procedure Code</td>
<td>Code recorded within LIS for a clinical procedure completed, such as “P01” to indicate a small biopsy</td>
<td>Code values from local mapping table only</td>
<td>Mandatory for P records</td>
</tr>
<tr>
<td>J</td>
<td>Case Procedure Completed Date/Time</td>
<td>Date/time the case procedure was actually completed (or logged on the LIS assuming that this was done in a timely fashion).</td>
<td>Formats as listed for Case Received Date/Time</td>
<td>Optional</td>
</tr>
<tr>
<td>K</td>
<td>Case Quality Code</td>
<td>Code recorded within LIS for quality procedure completed, such as “Q001” to indicate a case referred externally for review.</td>
<td>Code values from local mapping table only</td>
<td>Mandatory for Q records</td>
</tr>
<tr>
<td>L</td>
<td>Quality Procedure Completed Date/Time</td>
<td>Date/time the case quality procedure was actually completed (or logged on the LIS assuming that this was done in a timely manner).</td>
<td>Formats as listed for Case Received Date/Time</td>
<td>Optional</td>
</tr>
<tr>
<td>ID</td>
<td>Field Name</td>
<td>Description</td>
<td>Field Format</td>
<td>Req’d</td>
</tr>
<tr>
<td>----</td>
<td>---------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>M</td>
<td>Case Morphology Code</td>
<td>Code recorded within LIS for morphology, such as the SNOMED diagnosis code.</td>
<td>Code values from local mapping table only</td>
<td>Mandatory for M records</td>
</tr>
<tr>
<td>N</td>
<td>Morphology Code Authorised Date/Time</td>
<td>Date/time the case morphology code was actually authorised (or logged) on the LIS.</td>
<td>Formats as listed for Case Received Date/Time</td>
<td>Optional</td>
</tr>
<tr>
<td>O</td>
<td>Specimen ID</td>
<td>Unique number generated within the lab Information System to identify a specimen; this is often a suffix like “/A” or “/B” and it may include multiple parts.</td>
<td>Character sequence, including punctuation and spaces, but excluding commas. Format is well defined and specific to each lab.</td>
<td>Mandatory for S records</td>
</tr>
<tr>
<td>P</td>
<td>Specimen Tissue Code</td>
<td>Code identifying the type of tissue processed, such as “THYR” to indicate thyroid</td>
<td>Code values from local mapping table only</td>
<td>Mandatory for S records</td>
</tr>
<tr>
<td>Q</td>
<td>Specimen Received Date/Time</td>
<td>Date/time specimen was received by the local laboratory. In some laboratories this may be the same as the Case Received Date/Time. If it is not possible to record this on the LIS, it may be acceptable to use the Specimen Logged Date/Time, assuming that logging of specimens on the LIS is completed on a timely basis.</td>
<td>Formats as listed for Case Received Date/Time</td>
<td>Optional</td>
</tr>
<tr>
<td>R</td>
<td>Specimen Priority</td>
<td>Indicator to denote the relative priority of this Specimen, such as “U” to indicate Urgent</td>
<td>Code values from local mapping table only</td>
<td>Optional</td>
</tr>
<tr>
<td>S</td>
<td>Block ID</td>
<td>Unique number generated within the lab Information System to</td>
<td>Character sequence, including punctuation and spaces, but excluding</td>
<td>Mandatory for S records</td>
</tr>
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13. Revision History

<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Editor(s)</th>
<th>Changes</th>
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<tbody>
<tr>
<td>Draft 1.0</td>
<td>17/06/10</td>
<td>Gillian Walsh &amp; Fergus Murray</td>
<td>Original Draft</td>
</tr>
<tr>
<td>Draft 1.1</td>
<td>30/06/10</td>
<td>Gillian Walsh</td>
<td>First review with Programme Steering Group</td>
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<tr>
<td>Draft 1.2</td>
<td>23/07/10</td>
<td>Gillian Walsh</td>
<td>Reviewed with Health Information/Intelligence Unit</td>
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<tr>
<td>Draft 1.3</td>
<td>23/08/10</td>
<td>Fergus Murray</td>
<td>Include changes agreed at meeting of RCPI, HSE ICT, HSE HIU and OpenAPP on 4th August</td>
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<td>Draft 1.4</td>
<td>06/09/10</td>
<td>Gillian Walsh</td>
<td>Reviewed with QA Programme Working Group</td>
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<tr>
<td>Draft 1.5</td>
<td>10/09/10</td>
<td>Gillian Walsh</td>
<td>Second review with Programme Steering Group</td>
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<tr>
<td>Draft 1.6</td>
<td>13/10/10</td>
<td>Gillian Walsh</td>
<td>Comments received at Programme Update day</td>
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<tr>
<td>Draft 1.7</td>
<td>05/11/10</td>
<td>Gillian Walsh</td>
<td>Input from Faculty of Pathology Executive &amp; Programme Steering Group</td>
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<tr>
<td>Draft 1.8</td>
<td>16/11/10</td>
<td>Gillian Walsh</td>
<td>Reviewed with Working Group &amp; Steering Group</td>
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<td>Draft 1.9</td>
<td>21/11/10</td>
<td>Gillian Walsh</td>
<td>Second review at Faculty of Pathology Executive</td>
</tr>
<tr>
<td>Draft 2.0</td>
<td>14/12/10</td>
<td>Gillian Walsh</td>
<td>Approved by Histopathology Working Group and Programme Steering Group</td>
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<tr>
<td>1.0</td>
<td>11/02/11</td>
<td>Gillian Walsh</td>
<td>1st formal release following 30 day consultation period with Faculty Fellows</td>
</tr>
<tr>
<td>Draft 2.1</td>
<td>20/11/15</td>
<td>Sarah Treleaven</td>
<td>Change Quality Assurance to Quality Improvement, other revisions in line with HSE QID input.</td>
</tr>
<tr>
<td></td>
<td>3/2/16</td>
<td>Mairead Guinan</td>
<td>Include oversight model (Appendix 1) agreed in 2015</td>
</tr>
<tr>
<td>Draft 2.2</td>
<td>20/04/16</td>
<td>Mairead Guinan</td>
<td>Update per Data Protection Commissioner advice – for consultation and completion after annual workshop on 10th May</td>
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<tr>
<td>Draft 3.0</td>
<td>28/11/16</td>
<td>Sarah Treleaven</td>
<td>Updated Issue Resolution Pathways included post Steering</td>
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<td>Version</td>
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<td>Editor(s)</td>
<td>Changes</td>
</tr>
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<td></td>
<td>Committee Approval</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Update Roles and Responsibilities to reflect stakeholders rather than Data Protection Acts groupings</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Standardisation with EQI and RQI Information Governance Policies</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Add small references to Clinical Director in Section 5</td>
</tr>
</tbody>
</table>