



FACULTY OF PATHOLOGY
ROYAL COLLEGE OF PHYSICIANS OF IRELAND

National Quality Assurance Programme in Histopathology Information Governance Policy

Developed by
The Steering Group of the National QA Programme in
Histopathology

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1. Executive Summary

The Faculty of Pathology, RCPI launched the National Quality Assurance Programme in Histopathology in Jan 2009 in collaboration with the National Cancer Control Programme (NCCP) and Directorate of Quality and Clinical Care (DQCC). The fundamental aim of this QA 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 QA programme is not an exercise in individual performance management, its focus being, rather 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 benchmarks (Q marks).

The IT system developed for use by all participants to store and analyse QA data will allow individual laboratories to access their own data, analyse and generate reports using this data. It will also allow individual laboratories to view national data with all hospitals summarised together and hospital ID's anonymised. The Faculty and Programme Steering Group will have access to national data with all hospitals summarised together and hospital ID's anonymised within the following groupings: All laboratories, Cancer Centres and Non Cancer Centres. The Faculty, Programme Steering Group and NCCP will have access to Cancer Centre data with Cancer Centres individually represented but with hospital ID's anonymised i.e. Cancer Centre A, Cancer Centre B, Cancer Centre C. Consultant ID will not be accessible. There will be an opportunity for Non Cancer Centres to opt into the NCCP review. It will be the responsibility of the lead Pathologist and Clinical Director to drive continuous improvement locally based on QA data particularly in areas where results fall below the national average.

While improvements can and will inevitably be made almost immediately, it is acknowledged that a considerable period of time will be required before this system is validated, QA data has stabilised and intelligent, evidence-based national benchmarks (Q marks) can be set.

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.

It is envisaged that day to day central management of the QA programme will be redefined once the initial programme implementation phase is completed. This will trigger a review of this Information Governance Policy.

Amendments to this policy can only be approved with the agreement of all parties involved: Faculty, Steering Group and a majority of Programme Participants.

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 QA programme in Histopathology. To drive this QA programme the Faculty of Pathology has developed guidelines of Quality Assurance in a number of key performance areas of Histopathology (2). These guidelines are currently being implemented in all public, private and voluntary hospitals in Ireland with Histopathology laboratories. Once implemented, participating laboratories will be expected to collect key performance data locally for ongoing review and improvement.

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 to facilitate local review and reporting of key quality data.

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.

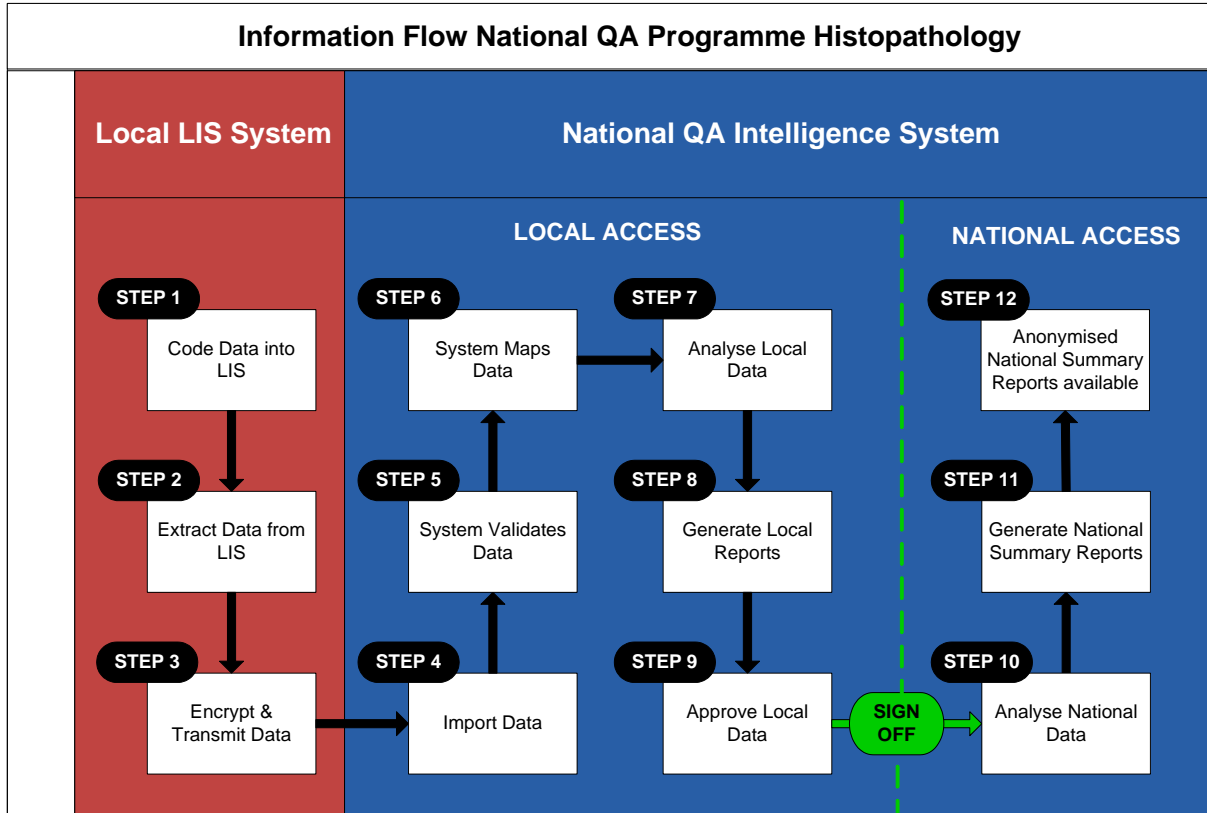
An existing HSE IT application, Health Atlas Ireland (HAI), developed by the Health Information Unit of the DQCC, will be enhanced to store, analyse, access and report on key quality data locally and nationally. Essentially a Histopathology module within HAI will be configured to facilitate Histopathology key quality data – this module will be referred to as the “National QA Intelligence System (NQAIS) for Histopathology” within the broader context of the National Histopathology QA Programme.

3. Document Purpose

The data collected centrally for this National QA programme does not contain any personally identifiable information, as defined in the Data Protection Act 1988 (7) and subsequent Data Protection (Amendment) Act 2003 (8), as Medical Record Numbers (MRNs) will be encrypted before leaving the hospital site. However, it is recognised that to encourage participation in clinical audit, 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). As such, 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 QA programme in Histopathology will be governed, processed, stored, accessed and reported on. This document includes a statement of agreement to be signed by all parties involved in the programme certifying that they have read, understood and agree with the principles set out in this information governance policy.

4. Information Flow

Data required for the National QA programme in Histopathology 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 the National QA Intelligence System (NQAIS) for Histopathology. Each site maintains ownership of its own data at all times. Each site has access to its data on the NQAIS in order to review it using the reporting functionality provided and sign it off as being complete and accurate within the agreed time limits. Only then does data become accessible nationally for inclusion in national summary reports.



5. Roles & Responsibilities

The appropriate, effective and efficient access to information within the Histopathology module of the HAI system requires a clear definition of the roles and responsibilities of the different parties involved in the National QA 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 QA 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, these individuals must sign a statement of agreement & compliance with this Information Governance Policy, which will remain applicable even after cessation of involvement in National Histopathology QA Programme.

Roles & responsibilities are defined as follows:

5.1. Data Originator

Data Originator = Entity from which data pertaining to National QA programme originates. The Data Originator is responsible for the integrity of data and can authorise or deny access to data.

The Data Originators for the National QA Programme in Histopathology are the participating Histopathology departments.

Responsibilities of all members of the Data Originator:

- Identify a designated Clinical Lead locally with overall responsibility for the programme, e.g. Lead Pathologist, Clinical Director
- Develop local protocol regarding data access and reporting, report circulation and storage
- Report and manage patterns of practice with the potential to affect patient safety, uncovered as part of National Histopathology QA Programme activities, in compliance with local policy
- Process data according to local protocol and in compliance with this information Governance Policy

Responsibilities of the designated **Clinical Lead**:

- Identify a designated person locally with responsibility for the operational management of the programme on an ongoing basis
- Authorise local user access rights and access levels to the NQAIS for this programme
- Identify centrally generated report recipients e.g. all Pathologists within department
- Review and verify the accuracy and completeness of local QA data by utilising local report and analysis tools provided
- Approve and sign-off QA data for each relevant period, allowing status of data to change from local to national
- Review local performance relative to National Benchmarks provided
- Report and manage patterns of practice with the potential to affect patient safety, uncovered as part of National Histopathology QA Programme activities, in compliance with local policy

Responsibilities of the Local Operational Manager:

- Ensure all QA activity is accurately recorded on the Laboratory Information System (LIS)
- Provide accurate list(s) of locally implemented codes to Data Controller to facilitate mapping to agreed national codes
- Maintain local code mapping tables on the NQAIS
- Ensure data extracted from the LIS is accurate and complete
- Encrypt sensitive data (i.e. Medical Record Number, Consultant ID) before QA data leaves the laboratory using encryption facilities provided
- Routinely transmit QA data to the NQAIS using secure data transfer facilities provided, ensuring that it is imported and updated successfully
- Develop standard operation procedures (SOPs) for all QA programme related processes to ensure a consistent approach and facilitate local user training
- Supply and maintain up to date mailing list for the receipt of National reports and communications

5.2. Data Controller

Data Controller = Entity that determines the purposes for which and the manner in which data pertaining to the National QA programme are to be processed.

The Data Controller for the National QA Programme in Histopathology is the Faculty of Pathology, RCPI under the direction of the Programme Steering Group.

In the context of this programme the Faculty of Pathology, RCPI is defined as the Dean of the Faculty with advisory Faculty members as follows: the Chair of the Histopathology Subgroup and members of the National QA Programme in Histopathology Working Group. The Dean of the Faculty is responsible for final decisions.

Responsibilities of Data Controller:

- 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 ICT Directorate and HSE Health Information Unit
- Ensure that adequate technical & organisational security measures are put in place to safeguard against unauthorised access, alteration, disclosure and destruction of data
- Ensure that all NQAIS users receive appropriate training prior to using the system
- Identify a designated National Operational Manager with responsibility for the operational management of the National Histopathology QA programme on an ongoing basis
- Authorise national user access to the NQAIS for this programme
- Use data in the setting of National Benchmarks
- Ensure data is not disclosed to any third party without consent of the Data Originator
- Ensure data is used only for the purpose intended i.e. to facilitate the enhancement of patient care with timely, accurate and complete pathology diagnoses and reports

Responsibilities of designated National Operational Manager:

- Support the ongoing development and use of the NQAIS (e.g. additional analyses/reports & laboratories), liaising with the System Manager and HSE ICT Directorate as necessary
- Ensure that all stakeholders and participants comply with the Information Governance Policy for this programme
- Maintain list of national codes (e.g. quality, procedure, tissue codes)
- Assist Data Originators with the mapping of local / national codes

- Liaise with local laboratories to ensure that QA data is uploaded as scheduled, in a timely manner
- Develop standard operation procedures (SOPs) for all QA, user setup and ICT support related processes to ensure a consistent approach and facilitate national user training
- Co-ordinate the ongoing setup and removal of authorised national and local NQAIS users for this programme (e.g. review authorised access forms from participant laboratories)
- Handle QA programme related calls/queries on an ongoing basis
- Review national QA data and agreed metrics
- Generate and circulate national QA reports to the agreed list of recipients

5.3. HSE ICT Directorate

The HSE ICT Directorate has overall responsibility for the successful delivery of the necessary ICT solution(s) to support the needs of this programme, and is accountable for the approved ICT capital budget.

Responsibilities:

- 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
- Lead the initial specification and design of the NQAIS, and standardised LIS interfaces, in collaboration with the National Programme Manager and HSE Health Intelligence Unit
- Procure software development services (as necessary) to facilitate the enhancement of the HAI and LIS 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 NQAIS
- Lead the detailed design, development, testing and implementation of all necessary LIS interfaces to facilitate the routine export of detailed QA data, in collaboration with the National Programme Manager and participating laboratories
- Manage the ongoing relationships and contracts with LIS vendors for the provision of essential ICT services (e.g. software development, maintenance & support, database/systems administration)
- Advise the Data Controller and National 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 the Health Information Unit and the Operational Manager on an ongoing basis
- Process data only on and subject to the instructions of the Data Controller (i.e. potential data processor role)

5.4. Health Information, Health Intelligence Unit, HSE

The Health Information Unit, HSE, in collaboration with the National Programme Manager, HSE ICT Directorate, OpenAPP and other stakeholders will lead the development of the NQAIS, which builds upon the existing Health Atlas Ireland functionality and infrastructural design.

Responsibilities:

- Identify a designated System Manager with overall responsibility for the ongoing management of the HAI system, enhanced to include the NQAIS
- Lead the detailed design, development, testing and implementation of the NQAIS (e.g. user interfaces, analyses, displays and report formats) based on the existing HAI system and supporting infrastructures, in light of the specified QA requirements and in collaboration with the National Programme Manager and HSE ICT Directorate

- Manage the ongoing relationship and contract with OpenAPP for the provision of essential ICT services (e.g. software development, maintenance & support service levels, database/systems administration)
- Manage the ongoing relationship and contract with HEAnet for hosting the NQAIS (e.g. access/security, disaster recovery, network management)
- Process data only on and subject to the instructions of the Data Controller (i.e. potential data processor role)

Responsibilities of designated **System Manager**:

- Support the ongoing management and security of the NQAIS, liaising as necessary with OpenAPP, HEAnet, the National Operational Manager and the HSE ICT Directorate (e.g. system configuration, user setup, issuing of security certificates)
- Set up and maintain authorised users on the NQAIS in collaboration with the Data Originators
- Handle technical calls/queries relating to the NQAIS on an ongoing basis
- Support the ongoing development of the NQAIS (e.g. additional reports and analyses)

5.5. ICT system & service providers

Existing ICT system and service providers (i.e. LIS/HAI system vendors, HEAnet) will be contracted by the HSE to develop and maintain the necessary ICT solutions and infrastructures to support this programme. These providers will work in collaboration with the National Programme Manager, ICT Project Manager, HSE Health Information Unit and participant Laboratories.

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 of the Data Controller (i.e. potential data processor role)

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 ICT 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, sensitive data (i.e. MRN) will be encrypted locally and all data for that period will be saved and transferred securely to the NQAIS. The Lab no. can be used to identify the patient locally on the LIS if required. Access to this information locally must be controlled according to local procedure. In the event that a Unique Health Identifier is introduced the encryption process will ensure that records for the same patient in different laboratories are not linked together (i.e. they will not result in the same identifier following encryption).

6.2. Local Access levels

- **Local ‘Standard Access’** = A person or persons designated by the Data Originator with responsibility for local report generation will have access to local data and analysis/reporting functionality.
- **Local ‘Update Access’** = A person or persons designated by the Data Originator with responsibility for uploading QA data to the NQAIS will have permission to upload and replace their own local QA data files to the NQAIS.
- **Local ‘Approval Access’** = A person or persons designated by the Data Originator with responsibility for review and approval of QA data for a given period will have permission to sign off on local QA data.

6.3. National Access levels

- **National ‘Standard Access’** = Members of the Data Controller will have access to anonymised data and reports only.
- **National ‘Administrator Access’** = The National Operational Manager designated by the Data Controller will have access to data from all participating Hospitals including Hospital IDs, but MRN will remain encrypted. This access is for the purposes of programme administration only (e.g. troubleshooting, addressing participant queries).

Table 1: Summary of user access levels

Access Level		Local			National	
		Standard	Update	Approval	Standard	Administrator
Permissions	Import & Delete	No	Yes	No	No	No
	Analyse & Report	Yes	Yes	Yes	Yes	Yes
	Sign off	No	No	Yes	No	No
Accessible Data	Local Encrypted	Yes	Yes	Yes	No	Yes
	National Encrypted	Yes	Yes	Yes	Yes	Yes
	Hospital ID's	No	No	No	No	Yes
Access Controller		Data Originator			Data Controller	

7. Reporting

The NQAIS will provide functionality for the development of standard and ad hoc reports using National Histopathology QA data.

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 will be made available to participants, the Faculty and the Programme Steering Group only. Reports will be made available to each Data Originator 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) Non Cancer Centres

Reports made available to the Faculty, Programme Steering Group and NCCP will also contain Centre data with Cancer Centres individually represented but with hospital ID's anonymised i.e. Cancer

Centre A, Cancer Centre B, Cancer Centre C. Reports cannot be published to or shared with any other party.

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).

8. Secondary use of Data

Access to data in the NQAIS can be granted by the Data Controller 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.

9. References

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- 2) Guidelines for the Implementation of a National Quality Assurance Programme in Histopathology. Faculty of Pathology, RCPI
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- 6) The Health Information and Quality Authority. International Review of Information Governance Structures. 2009.
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- 9) FOI Central Policy Unit, The Department of Finance. A Short Guide to the Freedom of Information Act 1997 and Freedom of Information (Amendment) Act 2003. 2004.
- 10) The Office of the Data Protection Commissioner. Data Protection Guidelines on Research in the Health Sector. 2007.
- 11) The National Cancer Registry, Ireland. Data Confidentiality in the National Cancer Registry - General policy, procedures for release of data and staff guidelines. 2007.
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- 13) The Office of the Data Protection Commissioner. Data Protection Acts 1988 and 2003 - A Guide for Data Controllers. 2008.
- 14) HSE Incident Management Policy and Procedure 2008. Health Service Executive
- 15) Flowers L, Riley T. State-based mandatory reporting of medical errors. An analysis of the legal and policy issues. Portland, ME, National Academy for State Health Policy, 2001.
- 16) World Alliance for Patient Safety, WHO Draft Guidelines for adverse event reporting and learning systems. World Health Organisation 2005
- 17) Implementation Steering Group for the Report of the Commission on Patient Safety and Quality Assurance First Quarterly Progress Report End September 2009. Department of Health and Children
- 18) Data Processing Agreement between Caredoc Limited and the Health Service Executive, 2005

Revision History

Version	Date	Editor(s)	Changes
Draft 1.0	17/06/10	Gillian Walsh & Fergus Murray	Original Draft
Draft 1.1	30/06/10	Gillian Walsh	First review with Programme Steering Group
Draft 1.2	23/07/10	Gillian Walsh	Reviewed with Health Information/Intelligence Unit
Draft 1.3	23/08/10	Fergus Murray	Include changes agreed at meeting of RCPI, HSE ICT, HSE HIU and OpenAPP on 4 th August
Draft 1.4	06/09/10	Gillian Walsh	Reviewed with QA Programme Working Group
Draft 1.5	10/09/10	Gillian Walsh	Second review with Programme Steering Group
Draft 1.6	13/10/10	Gillian Walsh	Comments received at Programme Update day
Draft 1.7	05/11/10	Gillian Walsh	Input from Faculty of Pathology Executive & Programme Steering Group
Draft 1.8	16/11/10	Gillian Walsh	Reviewed with Working Group & Steering Group
Draft 1.9	21/11/10	Gillian Walsh	Second review at Faculty of Pathology Executive
Draft 2.0	14/12/10	Gillian Walsh	Approved by Histopathology Working Group and Programme Steering Group
1.0	11/02/11	Gillian Walsh	1 st formal release following 30 day consultation period with Faculty Fellows