



FACULTY OF PATHOLOGY
ROYAL COLLEGE OF PHYSICIANS OF IRELAND

National Histopathology QA Programme Implementation Report 2014

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National
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Programme

 Feidhmeannacht na Seirbhíse Sláinte
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Contents

Authors	1
Contributors	1
Foreword	4
Acknowledgements	4
Executive Summary	4
Introduction.....	5
Background.....	7
Surgical Pathology Workflow	7
National Cancer Forum Report 2006	8
Report of the Commission on Patient Safety and Quality Assurance.....	8
Misdiagnosis cases.....	9
Survey of Pathology Departments 2009	10
Strategy	11
Strategy	11
Vision.....	11
Approach.....	12
Scope & participation	13
Governance.....	14
Model.....	15
The Programme today.....	16
Overview	16
QA Guidelines	17
Monitoring and review of QA activities and outcomes	18
Survey of Pathology Departments 2011	19
Development	21
Guidelines	21
ICT Requirements & Strategy.....	22
Information Governance.....	23
Review of QA reports.....	24
Implementation.....	25
Phased implementation of Guidelines.....	25
The role of the Laboratory Information System	25
ICT Solutions	25
Challenges	27
Time & resources	27
Concerns regarding monitoring	27
Range & diversity of local practices & coding systems.....	27
Range & diversity of local IT support systems	27
Key to Success	29
Clinical leadership & participation	29
Collaboration	29
Communication.....	29
Project management approach	30
Next steps.....	31

National Histopathology QA Programme Implementation Report 2014

Data quality.....	31
Setting National Targets	32
Gather & share best practice	32
Communication on a national and international stage	32
National QA Programmes in Radiology and GI Endoscopy.....	33
References.....	34

Foreword

Within the National Cancer Control Programme there is a strong focus on quality and the development of a culture of measurement and quality assurance in cancer control. Patients with cancer should experience the highest possible standard of care irrespective of where they live. Timely access to high quality pathology reports is a key requirement for the diagnosis and management of cancer.

Pathology, like other diagnostic services, involves decision-making with a degree of uncertainty and a level of error is unavoidable. The National Histopathology Quality Assurance Programme evolved in response to misdiagnoses in breast cancer in Ireland and subsequent investigations by the Health Information and Quality Authority. The Programme identifies opportunities to make improvements in services as required and to share good practice. Successful implementation of the Programme has the potential to improve quality and patient safety and to build the trust and confidence of patients in the service.

The Programme is the result of a collaborative process between representatives of the Faculty of Pathology, RCPI, Faculty of Pathology, RCPI, the NCCP, HSE ICT, Directorate of Quality and Patient Safety, relevant HSE departments, Department of Health, Independent Hospitals Association of Ireland, and the Health Information and Quality Authority (as an observer). The quality assurance guidelines were developed using robust methodology and are unique in their national implementation.

Acknowledgements

Participating Pathologists & Medical Scientists, Faculty of Pathology, HSE ICT, Health Intelligence H&W Directorate, Open App development team, QA Programme Steering Committee, Professor Leslie Daly, HSE Patient Forum

Executive Summary

The National Quality Assurance (QA) Programme in Histopathology commenced in January 2009 and is led by the Faculty of Pathology Royal College of Physicians of Ireland (RCPI) and sponsored by the National Cancer Control Programme (NCCP).

The aim of the Programme is to provide a framework that ensures patient safety and enhancement of patient care with timely, accurate and complete diagnoses, reporting and service.

Overall governance of the programme is provided by a Steering Committee consisting of representatives from HSE ICT, Quality and Patient Safety Directorate (QPS), Relevant HSE departments, Department of Health, RCPI and RCSI. Programme management is provided by RCPI and ICT support is provided by HSE ICT.

Specialist support is provided through the established working group consisting of consultant Histopathologists. Together with the Steering Committee, they have developed and fully implemented the QA guidelines. The guidelines set out 11 key quality areas and 22 Key Quality Indicators (KQI) that will facilitate laboratories to monitor and evaluate their own performance against the national aggregate performance and intelligent targets. Examples of the quality areas include the timeliness of

processing and reporting of histopathology cases, accuracy and completeness of this reporting and peer review.

As part of the Programme, QA data is required to be extracted and encrypted from the hospitals' Laboratory Information Systems (LIS) and submitted to a central database on a regular basis. This central database, NQAIS (National Quality Assurance Intelligence System), has been developed and validated for QA storage, analysis and report generation.

The programme is clinician led and supported by all staff in laboratories including medical scientists and quality managers. Participants have been kept up to date with regular communications and workshops. Data from all 33 laboratories is collected on a monthly basis and an extract from the individual LIS is exported to NQAIS for collation of the Key Quality Indicators (KQIs). The Programme has developed an Information Governance Policy which sets out how data collected is governed, processed, stored, accessed and reported on. It is important to note that NQAIS transfers information in relation to the laboratory as a whole and that there is confidentiality in relation to individual practitioner data. Aggregate data displayed has anonymity of hospitals.

Since January 2013, all 33 public and private laboratories have been reporting and viewing their own real time data on NQAIS. The programme has been working to embed the programme, ensuring and maintaining the high quality data collection by participants on a monthly basis. The data uploads and data quality has steadily improved since Go Live.

The Faculty has developed, consulted and presented the methodology to participants for the setting of intelligent quality targets appropriate for the programme. Targets have been set for the initial QA activities of Intradepartmental Consultation, Frozen Section Correlation and Turnaround Time.

Introduction

In 2008 the Faculty of Pathology, RCPI undertook the development and implementation of a National Quality Assurance (QA) Programme in Histopathology motivated by a desire to minimise diagnostic error and ensure timely, accurate and complete pathology diagnosis and reports.

In early 2009, the Faculty submitted a proposal for this initiative to the National Cancer Control Programme (NCCP) and with the support and sponsorship of the NCCP the programme was formally launched in June 2009. The programme has enjoyed wide support and is governed by a Steering Committee with representation from the Faculty of Pathology, RCPI, the NCCP, Directorate of Quality and Clinical Care (DQCC), Department of Health (DOH), Relevant HSE departments, Independent Hospitals Association of Ireland (IHAI), HSE ICT and the Health Information and Quality Authority (as an observer).

High profile cases of breast cancer misdiagnoses and the subsequent investigations conducted by HIQA into these cases reaffirmed the critical need for such a programme.

The Faculty of Pathology, RCPI assisted in these look backs and HIQA investigations.

Such look back investigations are costly in financial terms and in the time and expertise that needs to be set aside to produce an in depth and accurate report.

The introduction of this programme will have a number of economic impacts.

- Accurate patient diagnoses will minimise morbidity and mortality and with this the economic burden that accompanies delayed diagnoses for the patient and the health service. This

burden can include inability to work, inability to care for loved ones, emotional distress, repeating unnecessary tests, misdirection of further investigations and duplication of work.

- While such a QA Programme will not stop necessary —look backs as they become apparent, it offers a confident streamlined approach to dealing with QA issues and allows for a timely conclusion of such investigations. This will ultimately impact on the time spent and the financial costs associated with such procedures.
- The QA Programme will reduce errors and therefore reduce any legal costs of potential law suits.
- Where histopathologists see discrepancies then it is an important prelude to standardising histopathology protocols and may prevent the performing of tests which may not be appropriate or necessary.

Pathology, like many diagnostic services involves decision making under conditions of uncertainty and a certain degree of error is inevitable. Effective quality assurance programmes can track error rates and provide opportunities for error reduction [1].

Participation in the programme was not mandatory but all Histopathology laboratories in Ireland, from both private and public hospitals, have elected to take part.

Histopathology is a diagnostic service and as such all patients and therefore the public interacting with the health service will benefit from the implementation of the QA Programme in Histopathology. In order to engage with patients and gain feedback from members of the public, presentations followed by questions and answers on the QA Programmes, were given at both the Royal College of Physicians of Ireland St Luke’s Symposium Public Meeting “Error in Medicine” understanding uncertainty and the Health Services Executive Patient Forum in November and December 2011.

This report aims to provide an overview of the National QA Programme in Histopathology. We will look at the background to the programme, detail the achievements and current status of the programme and present an aggregated summary of national QA activities and outcomes. For the benefit of others embarking on similar initiatives in the future, the programme strategy, development and implementation will be described. We will also look at challenges and key success factors.

Background

Surgical Pathology Workflow

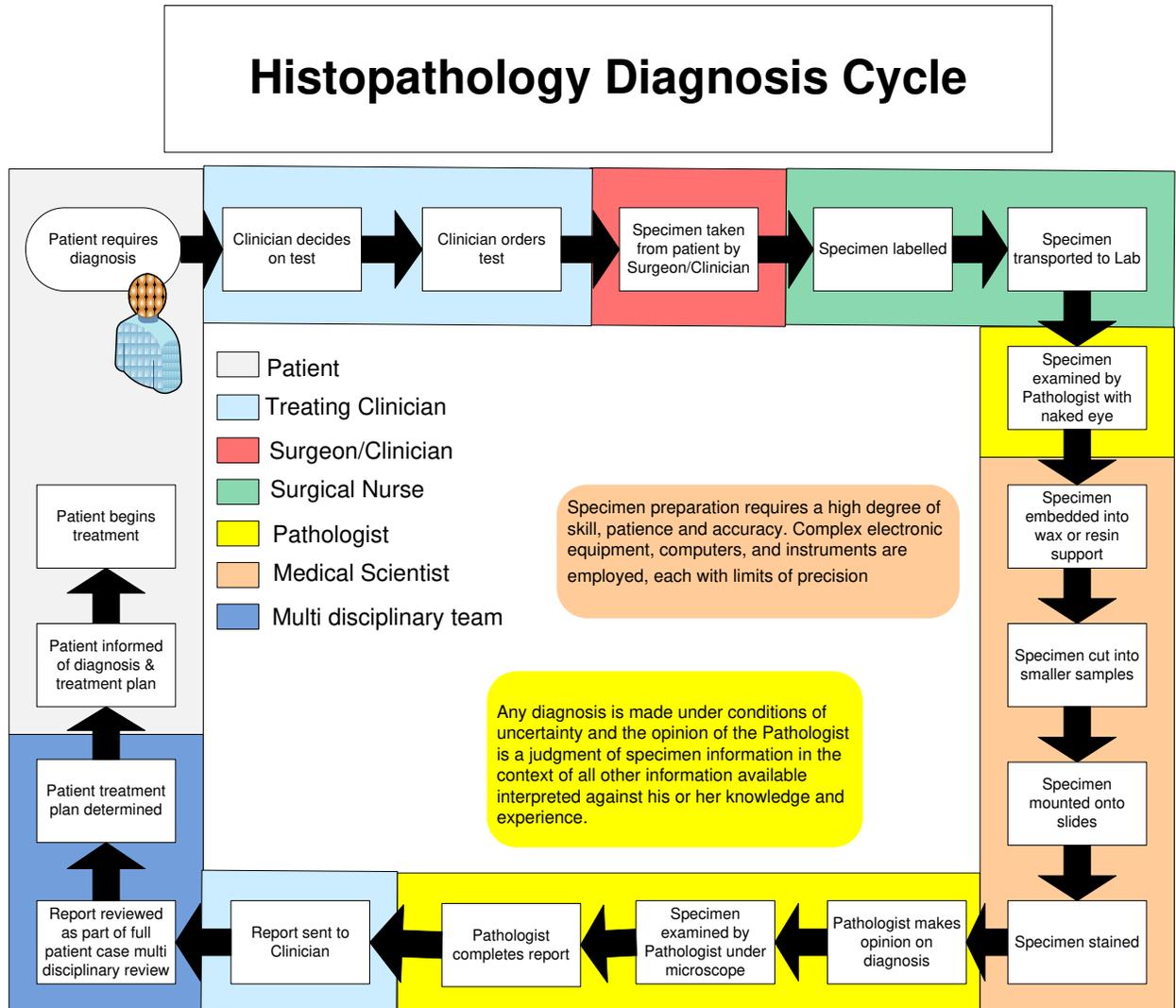


Figure 1 Histopathology Diagnosis Cycle

Surgical pathology is the study of tissues removed from living patients during surgery to help diagnose a disease and determine a treatment plan. Often, the surgical pathologist provides immediate consultation to the surgeon during surgery to help determine the best surgical process. For example, when performing breast cancer surgery, a surgical pathologist's examination of tissues removed during surgery can help determine whether to remove lymph nodes under the arm as well.

Surgical pathology includes both the physical examination of the tissue with the naked eye, as well as examining processed tissue under a microscope.

“histopathology is currently practiced in an environment where there is an expectation that its results consistently and invariably are the absolute truth.”

Diagnostic error in anatomical pathology: the uncertainty of its measurement?

Bryant, S. J.1; Davies, D. J.2†

“the opinion is a judgment of that information in the context of all other information available to the pathologist interpreted against his or her knowledge and experience.” Bryant, S. J.1; Davies, D. J.2†

There must be an increased understanding of ‘uncertainty measurement’ in histopathology to diminish unrealistic expectations Diagnostic error in anatomical pathology: the uncertainty of its measurement?

National Cancer Forum Report 2006

In September 2006 the National Cancer Forum launched the second Strategy for Cancer Control in Ireland. This strategy makes recommendations in relation to the organisation, governance, quality assurance and accreditation of all aspects of cancer care. The report highlights key trends in instances of cancer in the Irish population. In a population of approximately 4 million the average annual number of new cancer cases from 1994 to 2001 was 20,000. There were 7,500 cancer-related deaths per annum over the same period. As Ireland has an ageing population, an approximate doubling in the number of people who will develop cancer in Ireland by 2020 is predicted.

Part of the vision stated by the National Cancer Forum in their 2006 strategy is as follows:

‘Ireland will have a system of cancer control which will reduce our cancer incidence, morbidity and mortality rates relative to other EU15 countries by 2015.’

The strategy calls for a cancer experience in all parts of the country that is comparable and of the highest possible standard and advocates an approach which has emerged internationally in cancer policy and is promoted and supported by the World Health Organisation (WHO). One of the strands of this approach is a strong focus on quality and the development of a culture of measurement and quality assurance in cancer control.

Report of the Commission on Patient Safety and Quality Assurance

In July 2008 a report was released by the Commission of Patient Safety and Quality Assurance which provides clear and practical recommendations to ensure patient safety and the delivery of high quality health and personal social services.

In the report an emphasis is placed on enabling healthcare professionals to use information to monitor the safety and quality of the services that are being provided so as to enable the sharing of good practice, make improvements as required and inform the planning of services. The requirements for good clinical effectiveness include access for healthcare professionals to the most up-to-date information and evidence-based practice relating to the condition or specialty area, and the undertaking of effective clinical audit by individuals, teams, organisations and the wider health system in a well led, organised and effectively managed manner, with strong clinical leadership to

support and drive the activity. Clinical effectiveness also includes establishing clinical standards, guidelines and indicators that enable healthcare professionals to monitor their individual, team and organisation's performance against nationally, and where possible, internationally recognised comparative parameters.

The commission identify clinical audit as the single most important method that any healthcare organisation can use to understand and assure the quality of the service that it provides and recognise that clinical audit needs to be at the heart of clinical practice.

As part of the implementation of this Report, the development of national programmes and standards for clinical audit which support the safety and quality of health services was recommended.

Misdiagnosis cases

Previous misdiagnosis cases have led to painful large scale investigations or look backs with associated cost and negative impact to the trust of patient and the reputation of the entire Pathology community. Part of the reason the Faculty have taken the initiative to launch this national programme is to enhance the quality of pathology services, to assure the public of the quality of pathology services and to greatly reduce the need for look back investigations.

Survey of Pathology Departments 2009

Prior to guideline rollout the lead Histopathologist, medical scientist, laboratory manager and CEO were identified for each hospital. A questionnaire was circulated to the lead pathologist at each hospital to ascertain the current QA activities being conducted at each hospital and information regarding their current local laboratory information system. This survey provided baseline data to inform and facilitate the implementation phase of the guidelines.

Out of 35 respondents, this survey showed that all labs were aware of the roll-out of the QA Programme and the development of QA guidelines.

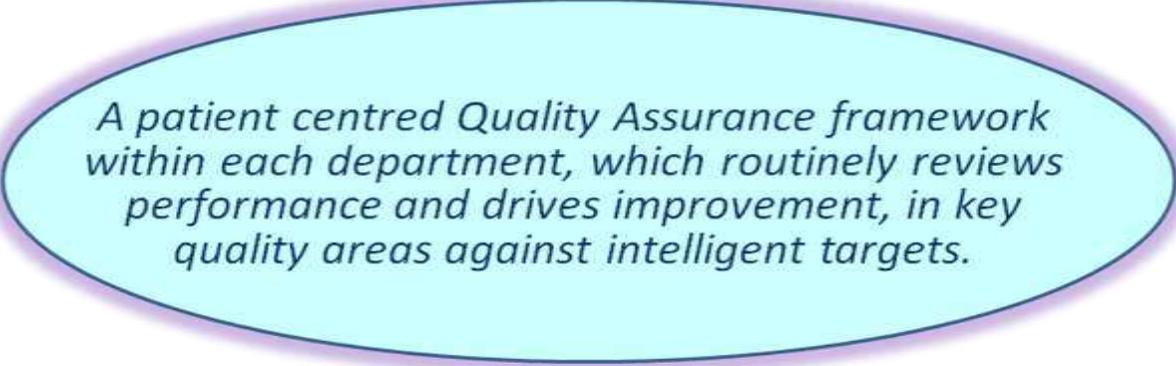
The range of histopathology staff varied across all hospitals with the number of consultant histopathologists ranging from 1 to 9 and medical scientists from 1 to 28.

It also showed the wide range of different Laboratory Information Systems and coding structures in use.

In summary, it supported the need for a National QA programme in Histopathology.

Strategy

Vision



A patient centred Quality Assurance framework within each department, which routinely reviews performance and drives improvement, in key quality areas against intelligent targets.

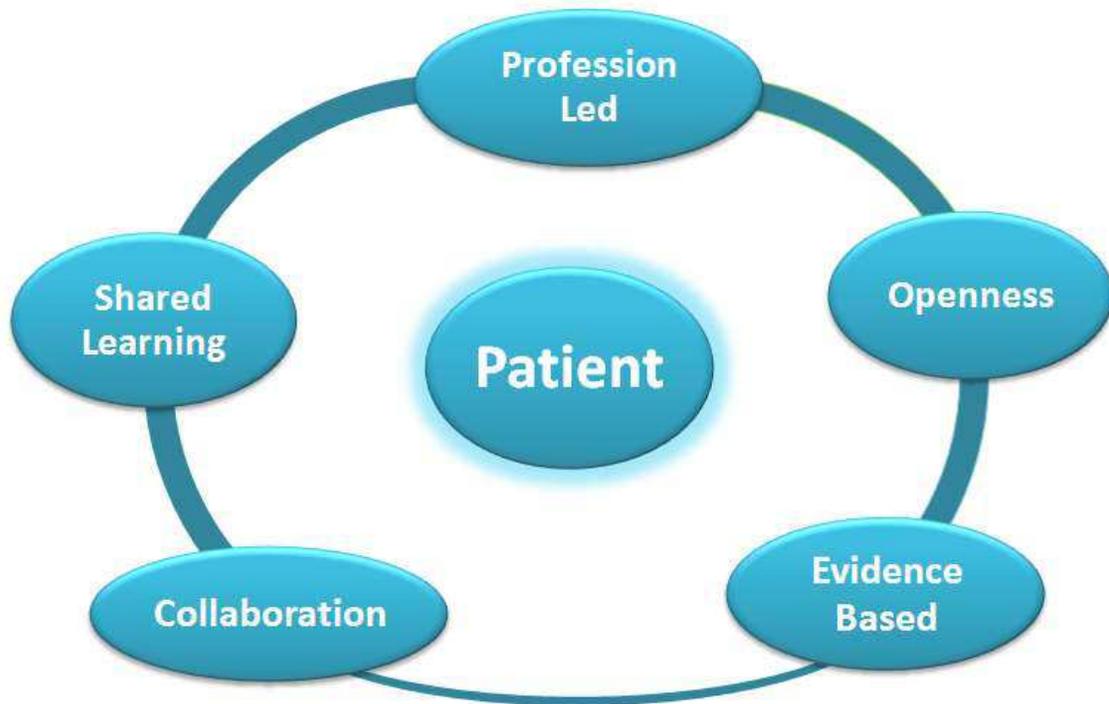
Figure 2 Vision

Approach

The National QA Programme in Histopathology supports the implementation of the programme through project management and governance structures of the QA Programme, focused workshops and stakeholder involvement. This provides advice and support to conduct the QA activities of the guidelines, provides ICT supported solutions on a national basis to collect data and provides an ICT central repository (NQAIS). This will provide at a glance reports to each histopathology department in a timely fashion.

The implementation of the QA Programme in addition to the publication of the guidelines ensures dissemination of the guidelines to all public and private hospitals in Ireland.

Figure 3 Approach



Scope & participation

The scope of this programme includes Histopathology, Cytopathology, Neuropathology and Autopsy including recognised sub speciality Paediatric & Perinatal Pathology.

This Quality Assurance programme is inclusive of all national private, public and voluntary hospitals with histopathology laboratories.

Figure 4 Scope



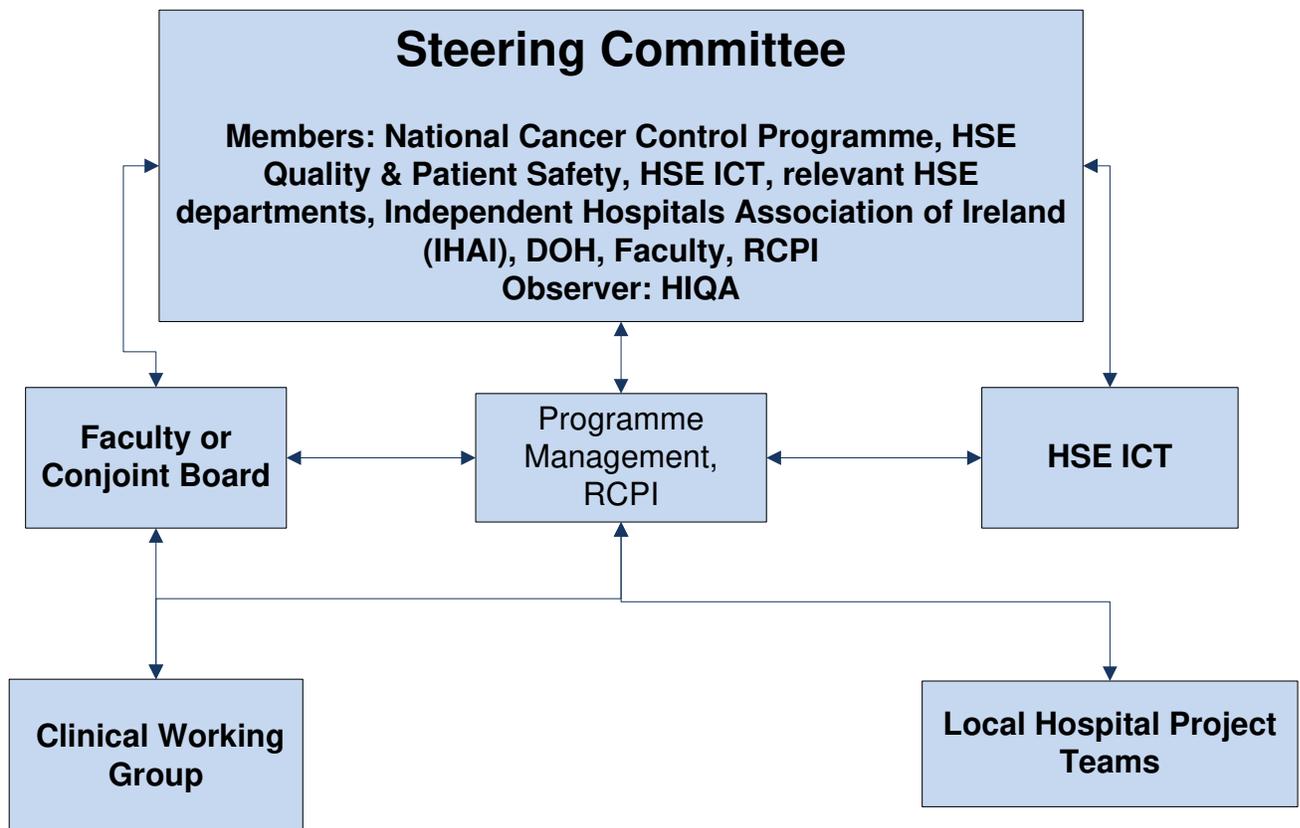
Governance

The Steering Committee was established to govern the National QA Programme in Histopathology and consists of representatives from key stakeholders of the healthcare system in Ireland.

The role of the Steering Committee is to provide overall governance of the rollout of the National Quality Assurance Programmes.

Their responsibilities include the review and approval of the programme strategy, to assist in the resolution of strategic level issues and risks and to ensure that the programme is aligned with organisational strategy.

Figure 5 Governance



Model

The QA Programme in Histopathology comprises the guidelines and the implementation of the guidelines. A detailed strategy for the Implementation of a National QA Programme in Histopathology was developed by the Steering Committee at the beginning of the programme.

Figure 6 shows the stages of the QA Programme. Phase 1 of this strategy focused on the development, approval and roll out of the Histopathology QA guidelines. Initiation of this programme involved the engagement of key stakeholders, the design stage focused on the development and approval of the guidelines, gap analysis to assess hospitals’ readiness for guideline implementation, conducting of a series of educational and consultation workshops, identifying key contacts at each laboratory for future assistance in guideline rollout, overall project scheduling and the design of the supporting ICT implementation.

The roll-out stage involved local histopathology departments conducting activities and recording data. The measuring and control stages will involve the collation of data for histopathology departments relative to the national aggregate and then initiating quality improvement based on results. A full time project manager was assigned by the RCPI to assist with the implementation of the strategic implementation plan and work directly with hospitals to implement the guidelines.

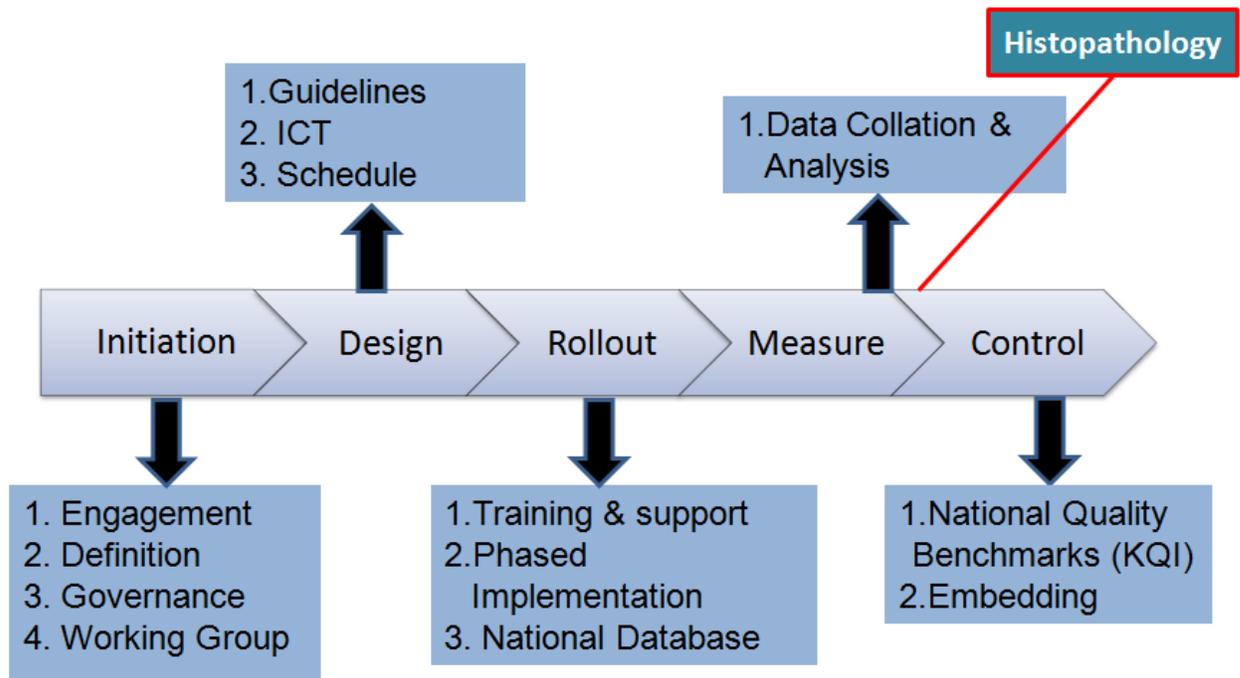


Figure 6 Programme Model

The Programme today

Overview

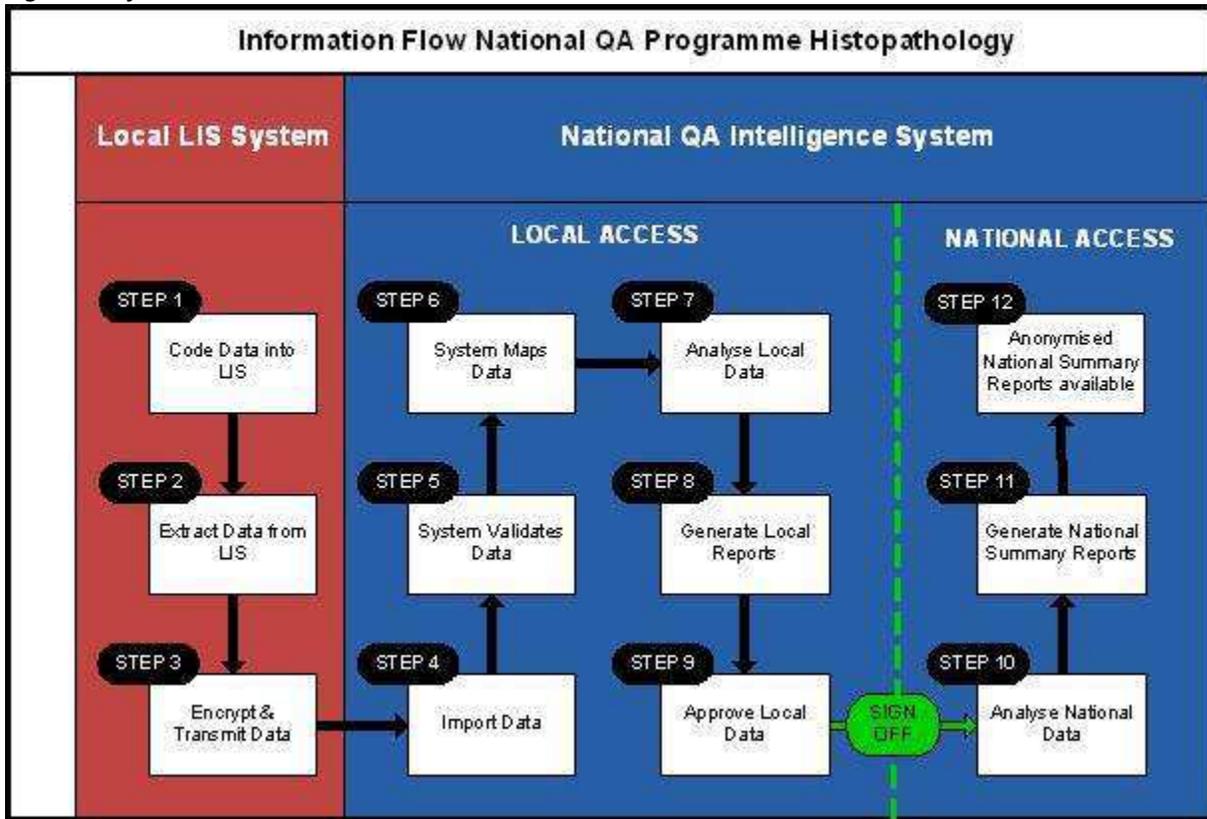
Guidelines for the National QA Programme in Histopathology were developed and issued in 2009. As part of the Programme, QA data is required to be extracted and encrypted from the hospitals' LIS and submitted to a central database on a regular basis.

This central database, National Quality Assurance Intelligence System (NQAIS), has been developed and validated for QA storage, analysis and report generation. To date, thirty three public and private laboratories are now live on this system and generating local QA reports.

Initial national targets have been developed and will continue to be progressed together with ongoing validation of national data.

This quality assurance programme is a component in maintaining a quality laboratory. Quality in a laboratory is dependent on a host of structural and personnel factors. Quality assurance and improvements must be weaved into all systems of the laboratory to achieve the best possible outcome. Local quality management systems should be in place to direct, control and coordinate quality.

Figure 7 Information Flow



QA Guidelines

The QA Guidelines were developed to provide guidance to pathologists on the implementation of a QA programme in Histopathology, Cytopathology, Neuropathology and Autopsy including recognised sub speciality Paediatric & Perinatal Pathology. Local protocol has determined how these guidelines are adapted but it was recommended that systems are developed to collate the required data for each monitor outlined in the document.

The guidelines outline:

- The key quality monitors with associated indicators by which individual histopathology laboratories will monitor their activities.
- Recommendations for the measurement of each key quality monitor.
- Existing National and International Benchmarks (where available) for each key monitor.

Figure 8 QA Monitors

	Monitor	Key Quality Indicators
1	Inter Institutional Consultation	% agreement
2	Intradepartmental Consultation	% cases
3	Correlation of frozen section diagnosis with final diagnosis	% concordance, % discordant, TAT
4	Cytology Quality Assurance	% discordant, % false positive, % false negative
5	Retrospective Review (focused real time/report completeness)	% agreement, % completeness
6	Multidisciplinary Team Meetings	% of total cases discussed, % agreement
7	Laboratory based non-conformances	No. of non-conformances, Clinical impact
8	Laboratory based External Quality Assessment	List of schemes, results
9	Turnaround Time	TAT by case type
10	Addendum reports	Qty, error classification, clinical impact
11	Reports communicated directly to clinician by pathologist	No. of cases communicated

Monitoring and review of QA activities and outcomes

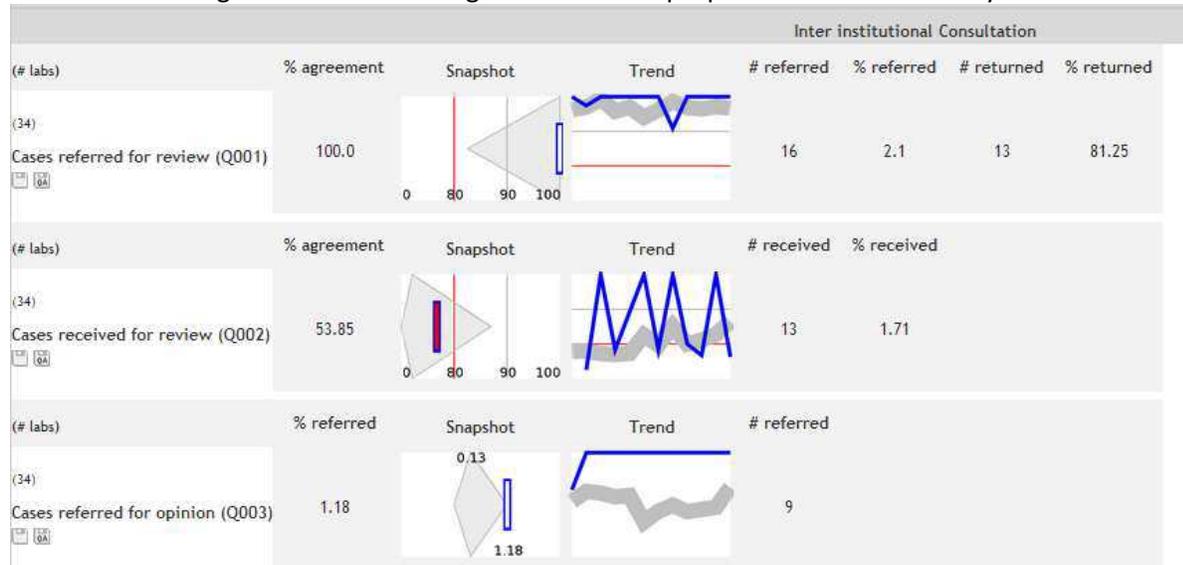
The fundamental aim of the QA programme is to improve quality and enhance patient care. An essential component of this QA Programme is the development of web-enabled health intelligence systems to store, analyse, provide access and report on key quality data locally and nationally.

To support this aim, QA reports generated by NQAIS should regularly be reviewed at Quality Committee Meetings. Opportunities for improving quality should be identified and quality improvement initiatives developed and implemented accordingly.

Data should be uploaded and analysed for accuracy on a monthly basis and formally reviewed by the clinical lead and Quality Committee on at least a quarterly basis to identify areas where targets are being met but also areas of underperformance.

Figure 9 Example of a section of a NQAIS Histopathology report

Please note the figures used in this diagram are for the purposes of illustration only



Survey of Pathology Departments 2011

In 2011, a second questionnaire was circulated to the lead pathologist at each hospital to ascertain the level of progress made in regard to the implementation of the programme.

This survey provided data to inform and facilitate next steps for the programme.

Figure 10 The below pie chart details who is primarily responsible for managing and monitoring the coding in the laboratory. (n=24)

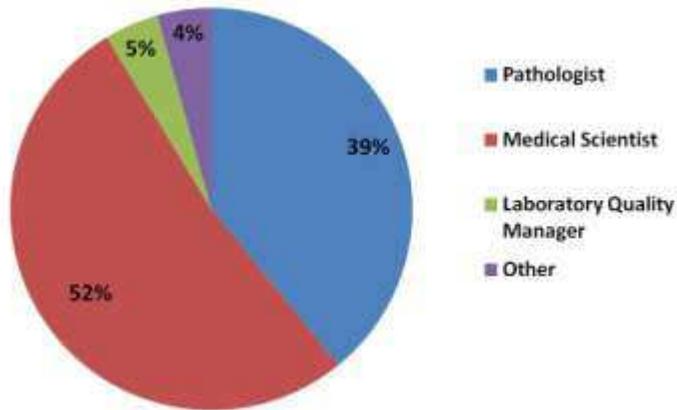
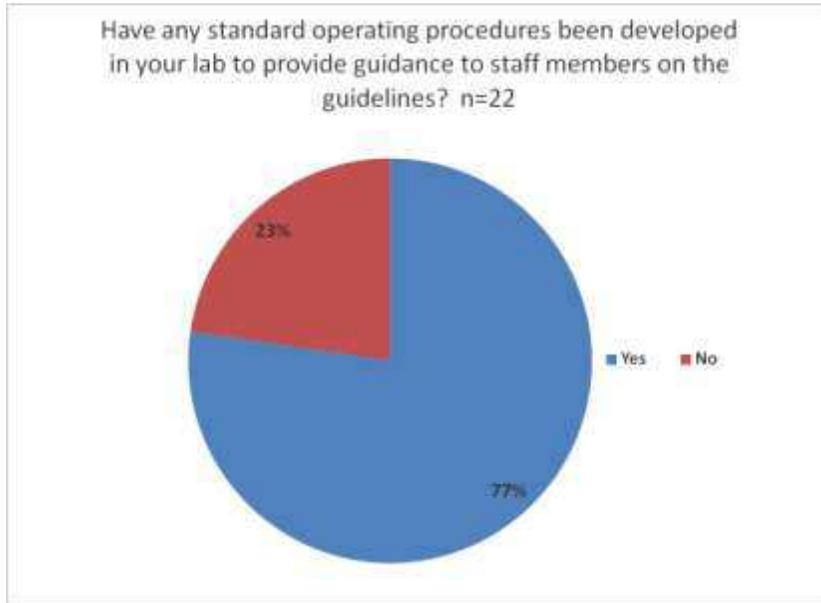


Figure 11 The below pie chart details whether or not laboratories have developed Standard Operating Procedures (SOP) to support the implementation of the QA guidelines.



Development

Guidelines

The national QA guidelines in Histopathology provide guidance to pathologists on the implementation of a QA programme in Histopathology by defining the key quality activities and associated key quality indicator parameters that should be monitored by histopathology departments in the laboratory diagnostic and autopsy services that they provide.

Subspecialties of Histopathology including Cytopathology, Neuropathology, Paediatric and Perinatal pathology are also covered by these guidelines.

The guidelines are intended for use primarily by consultant pathologists and focus mainly on the clinical interpretation and reporting of histopathology within the hospital setting and also autopsy practice. However, they are also used by other members of the multidisciplinary team working in the laboratory including medical scientists and quality managers.

Recognising that the successful introduction of a QA Programme requires common purpose and collaboration between pathologists, laboratory scientists and hospital management, regular forums and workshops were used to consult with representatives from these areas to further inform the development of the guidelines.

Presentations were also made at the annual meetings of the Irish Society of Surgical Pathology in 2009, 2010 and 2013 with the majority of consultant histopathologists in attendance at both meetings together with trainee pathologists and consultant pathologists from abroad.

The methodology utilised to develop the guidelines involved the systematic review and adaptation of aspects of existing guidelines in other jurisdictions and a consensus approach to identify the application of requirements for a QA Programme in Histopathology in Ireland.

ICT Requirements & Strategy

The Histopathology QA ICT System was developed to support the QA programme and has now been implemented in all 33 public and private laboratories participating in the QA programme. Information on quality activities is recorded by laboratory staff on their existing Laboratory Information Systems (LIS). The project worked with each of the LIS vendors to develop extract tools that take information from each LIS and store it in a QA data file using a standard format specified by the project.

During the development stage of the programme, a number of workshops were held with all participating laboratories invited to attend. Key items of interest were discussed during these collaborative workshops. It was during one of these workshops that a summary versus raw data approach was discussed. The pros and cons for both approaches are detailed below.

Figure 12

	Raw	Raw	
Pros	A new data analysis resource for all quality indicators available to hospitals	More time required to implement	Cons
	Less human intervention	Extra man power required	
	Less workload at local level when programme is established	High dependency on Laboratory system vendors	
	Summary	Summary	
	Clearly within scope of the project	Limited potential for data analysis and interpretation at National level	
	Within timeframe of the project	More complicated audit required at hospital site	
	Simple solution at Faculty level	Greater risk of human error	
		Greater increase in workload for local lab/IT teams	

At the 2010 workshop, it was decided that an automatic extraction of raw data would minimise local workload, ensure accuracy of data and allow for a standardised approach to QA data review and improvement.

The Faculty, supported by HSE ICT, committed to the development and rollout of an IT solution which assists in the recording, collation, analysis and reporting of data pertaining to these guidelines in a manner which minimises the impact on service delivery. This IT solution has been designed to integrate fully with existing and emerging IT systems in Histopathology.

The project team and QA Programme Working Group collaborated with HSE ICT and the Health Intelligence H&W Directorate HSE to develop and validate a user-friendly central database for QA storage, analysis and report generation called the National Quality Assurance Intelligence System (NQAIS).

NQAIS is web-enabled, built using open source technologies and enables each laboratory to review its clinical quality in both a local and national context at a glance.

To ensure the accuracy and consistency of data reported it was recommended to standardise the coding of medical terms across all histopathology laboratories. The current variability in the version and use of the coding system across all histopathology laboratories limits the degree of standardisation attainable. Therefore, a coding system and document recommends a set of QA Programme specific codes to capture the data as recommended in the guidelines. This document also proposes a minimal set of standard Procedure codes to ensure meaningful reporting of TAT.

It is accepted that some laboratories, due to local practice, may utilise alternative codes or systems to collate some or all of the data. All local codes relating to the QA programme will be mapped to a set of national codes in the NQAIS reporting system.

An implementation plan and schedule was developed by HSE ICT in collaboration with the project team. Each laboratory was responsible for data quality, mapping tables from their local codes to national codes and the extraction, testing and verification of their own data on NQAIS.

Information Governance

Information Governance ensures necessary safeguards for, and appropriate use of, patient and personal information.

The Health Information and Quality Authority (HIQA) define Information governance as follows:

'Information governance provides a means of bringing together all the relevant legislation, guidance and evidence-based practice that apply to the handling of information and offers a consistent way for people working in health and social care to deal with the many different legal provisions, guidance, and professional codes of conduct that apply to handling personal health information'

The data collected centrally for this National QA programme does not contain any personally identifiable information on the patient, as defined in the Data Protection Act 1988 and subsequent Data Protection (Amendment) Act 2003, as patient information will not be uploaded and Medical Record Numbers (MRNs) will be removed before data is entered in the central NQAIS database.

This policy has been prepared to define how data collected for the National QA programme in Histopathology will be governed, processed, stored, accessed and reported on.

The purpose of the programme is to enable local Histopathology Laboratories to monitor, review and improve the quality of their work in the context of national norms and intelligently set national benchmarks (quality targets).

The QA Reports in the Histopathology QA Programme will provide a standardised method of processing and displaying QA data locally for each laboratory across the country.

The key points from the Information Governance Policy for this programme are outlined below.

- The Data Originator is the entity from which data pertaining to the National QA Programme originates. In this case, the participating laboratories.

- The Data Controller is the entity that determines the purposes for which and the manner in which data pertaining to the National QA Programme are to be processed. In this case, the Faculty of Pathology, under the direction of the Programme Steering Committee.
- Through NQAIS, participants have the facility to access and analyse their own local data at all times in order to facilitate local review and quality improvement.
- Centrally generated reports will be made available to participants, the Faculty and the Programme Steering Committee only. Reports made available to the Faculty and Programme Steering Committee will contain national data with all hospitals summarised together and hospital identifiers anonymised within the following groupings:
 - All Participants
 - Cancer Centres
 - Non Cancer Centres

A copy of the QA Programme Information Governance Policy can be found at the following RCPI link under Improving Patient Care.

<http://www.rcpi.ie/article.php?locID=1.10.274.277>

Review of QA reports

Data should be uploaded and analysed for accuracy on a monthly basis but formally reviewed by the clinical lead and Quality Committee on at least a quarterly basis to identify areas where targets are being met but also areas of underperformance.

Although it is likely to be a rare event, the QA reports generated locally through NQAIS have the potential to identify histopathology departments who are underperforming in relation to national targets. Such identified poor performance may have a variety of possible causes. However, it must be considered that it might reflect poor performance in clinical practice.

The ongoing regular review of QA data and subsequent management of poor performance identified by the QA programme sits firmly at a local hospital/department level. Clinical leads should be aware of and act on their responsibilities in relation to this.

Appropriate governance structures and processes should be developed and put in place locally to identify and manage poor performance. These governance structures and processes need to be cognisant of the fact that there may be performance issues that are not identified by the QA programme.

The Quality Committee should also review the quality of local QA data and develop means of improving this data quality. The quality of local QA data may be enhanced through the development and review of local SOPs for all QA programme activities and training of new staff.

Implementation

Phased implementation of Guidelines

The Faculty made a number of recommendations within the QA guidelines and assisted in their phased implementation and review. The guidelines set out the key quality indicators necessary to implement a QA programme within the Histopathology department.

The implementation phase facilitated the collection of the key quality indicators and each hospital is now able to monitor its own performance against the aggregate national performance intelligent targets to be set by the Faculty as the data matures. This data will highlight the quality of data collected and should provide evidence for the continuance of the QA activity.

The role of the Laboratory Information System

All of the data is recorded on the local LIS as part of the normal laboratory workflow, and is available for export and secure transmission to the central data repository.

A detailed requirements specification was drafted by HSE ICT and the working group which defined the raw data to be exported for this programme on a routine basis (e.g. monthly) by each participating laboratory from their existing LIS, based on an initial analysis of requirements and engagement with the LIS vendors, and describes the functionality needed to support this.

Each LIS vendor was asked to develop and submit a formal quotation and proposed schedule for the development, testing and implementation work involved.

The project worked with each of the LIS vendors to develop extract tools that take information from each LIS and store it in a QA data file using a standard format specified by the project.

ICT Solutions

The National Quality Assurance Intelligence System (NQAIS) for Histopathology was built upon the open-source Health Atlas Ireland security and technical infrastructure. Health Atlas Ireland enables role-based access for users within the HSE and collaborating agencies, in line with governance requirements, to a wide range of databases, statistical and mapping functionality. The Atlas was developed by Health Intelligence H&W Directorate HSE and it evolves in collaboration with many agencies both service and academic inside and outside the health sector. Seed funding for Atlas was provided by the Health Research Board. The Atlas Ireland supports the quest for better health for patients, their families and the population by exploiting the quality assurance, health mapping and research potential of available data. The central concept is to allow large and complex data sets to be easily analysed and the results displayed in simple and easy to understand displays. Innovative “pictograms” were evolved to communicate patterns of quality in health care in a very intuitive format. As a result of the successful rollout of NQAIS Histopathology, a number of NQAIS modules for other health care domains have been evolved or are under development.

The QA Histopathology application, as part of the QA Programme in Histopathology, is built on data provided from coding on the local laboratory information systems and provides secure code mapping for all laboratories to create local versus aggregate national (or selected groups of laboratories) views and

reports. There are no league tables and the only individual hospital data that can be seen is that of the user hospital.

This system was developed in collaboration with the QA Programme and Health Intelligence Ireland.

The system expanded rapidly in 2011 in the breadth and complexity of the analytic facilities delivered. The rapid expansion of the system and its uses will continue apace in 2013/2014 with the Endoscopy and Radiology QA Programmes developing their own NQAIS modules.

Challenges

Time & resources

The timescale for the project significantly exceeded expectations at the outset.

In the earlier stages of the project it was expected that the ICT solution could be developed and deployed more quickly than proved to be the case. Difficulties arose with getting some of the LIS vendors to prioritise the work concerned and commit the required resources. With most LISs it took several iterations of software testing and correction before the software enhancements could be signed off as suitable for live use and consequently target dates were missed.

Later in the project, the biggest factor in the delay was that roll-out on each site was estimated to take around 10 days of effort spread over 2-3 months. In practice many roll-outs took well over 6 months, with the longest taking 12 months. On some sites, issues with the QA extract software was a factor but in many cases the unavailability of lab staff was the primary source of the prolonged implementation.

It should be noted that no additional resourcing was provided to the laboratories with many of them having to implement the programme using current resources. Addressing growing service demands at a time of resource constraint posed difficulties for many laboratories. In this context, it was important to emphasise the benefits of the programme and to counter any perception that it involved additional work with limited gain.

Concerns regarding monitoring

While there was strong support for the concept of a National QA programme, there was some concern about the potential use of the data. There was a fear that individual professionals would be identified, that the data could potentially be trawled to the detriment of individual practitioners or departments, or that the data would be used to construct league tables of hospitals. In particular there was a fear that immature and potentially flawed data could be misinterpreted if published prematurely. A robust information system is an essential requirement for any such programme. It is hoped that the promised Health Information Bill will address the issue of exemption of clinical audit and quality assurance activities from access under Freedom of Information requests without adversely affecting patient rights to relevant information about their care.

Range & diversity of local practices & coding systems

Quality assurance in Histopathology is not a new concept and QA activities have been practiced by individual laboratories in Ireland for a number of years. However, prior to the establishment of the National QA programme in Histopathology there was evidence of variability in practice of these activities between laboratories and there was no formal standardised system in place throughout Ireland to monitor these activities.

Range & diversity of local IT support systems

Below can be found the list of Laboratory Information Systems used across all laboratories in the country.

1. Clinisys – Winpath and Labcentre. (9 Labs)

2. iSoft – APEX and Telepath. (16 Labs)
3. Meditech Magic (2 Labs)
4. SBCNE – AP Easy (1 Lab)
5. Sunquest – Copath (4 Labs)
6. Netacquire custom software (1 Lab)

The range and diversity of these systems effectively meant that multiple ICT solutions were required, which added to the scale of work involved.

Key to Success

Clinical leadership & participation

The fact that clinicians led and developed the programme increased other clinicians' trust in the programme and their buy in to its implementation. This was facilitated by strong support and leadership from the Faculty of Pathology. This trust was further increased by developing and communicating a clear information governance policy.

An effective and enthusiastic working group was essential with all members of the group ensuring their organisations were involved and championed the programme amongst colleagues at other hospitals. The involvement and work of Medical Laboratory Scientists was integral to the success of this programme's implementation.

This programme also benefited from having wide representation on the steering committee from key health organisations and having a clear governance structure with defined reporting relationships. The programme steering committee involves multiple organisations and groups: Faculty of Pathology, HSE ICT, relevant HSE departments, HSE Directorate of Quality and Patient Safety (DQPS), Department of Health, Health Information and Quality Authority (HIQA) (as an observer), Independent Hospital Association of Ireland (IHAI) and consultant histopathologists.

As the programme progressed it was necessary to establish a reference panel to investigate certain implementation issues and provide a consultation group for the working group. This group was incorporated into the existing governance structure and ultimate decision making remained with the working and steering groups.

The National QA Programme in Histopathology supports the implementation of the guidelines through project management and governance structures of the QA Programme, focused workshops and stakeholder involvement.

The implementation of the QA Programme in addition to the publication of the guidelines ensures dissemination of the guidelines to all public and private hospitals in Ireland.

Collaboration

The programme benefited from clear governance structure and reporting relationships. The wide representation on the steering committee helped set up the collaborative nature of the programme and all members made valuable contributions to the programme.

A collaborative approach was used with all participating labs in the implementation of the guidelines and the ICT solution.

Communication

The governance of the programme resulted in a significant number of communication channels and so a formal communications strategy and plan was important.

Regular communication with all hospitals ensured implementation of the guidelines, participation in the programme and prioritisation of the programme by participants.

Figure 13

Name of consultation	Date	Attendance
Forum to discuss the Introduction of Quality Assurance Programmes in Histopathology, RCPI	17/06/2008	72 attendees
Opening workshops, RCPI	28/05/2009 17/06/2009	42 attendees
Presentation at ISSP Annual Meeting, Cork	25/09/2009	90 attendees
Programme Update, RCPI	14/09/2010	46 attendees
Presentation at ISSP, Annual Meeting, Killarney	24/09/2010	140 attendees
Presentation at Faculty of Pathology AGM, RCPI	11/02/2011	Approx 100 attendees
Practical aspects workshop, RCPI	25/10/2011	53 attendees
Update workshop, RCPI	13/06/2012	81 attendees
Update workshop, RCPI	09/05/2013	74 attendees
Presentation at ISSP Annual Meeting, Cork	11/10/2013	Approx 100 attendees

Project management approach

Project Management support is provided through professional project management services namely to:

- Facilitate clinical input to the development of the programme
- Develop and manage the project schedule
- Support the development of Key Programme Research and Documentation
- Act as a liaison between the Working Group, HSE ICT, local hospital teams and the Steering Committee
- Report programme issues, obstacles and conflicts as they arise
- Organise Working Group & Steering Committee meetings and prepare agendas
- Manage the roll out of the QA programme to all participating hospitals
- Manage participant queries
- Support development of local SOPs
- Gather and share best practice
- Develop and disseminate National targets in order that hospitals can monitor the quality of their services locally

The project team is in regular contact with all participating hospitals to assist with the ongoing implementation of the guidelines, consult with them on guideline development and inform them of any updates on the programme. This communication occurs through regular participant workshops, telephone calls, conference calls, email and letters.

Next steps

Data quality

To ensure the accuracy and quality of the National dataset, measures have been embedded throughout the various steps of the data collection and analysis.

First it is important that the standard measures and definitions provided are understood by the participating laboratories. To ensure this the following methods have been introduced by the QA programmes.

1. QA Guidelines outline KQIs and describe how they should be reported
2. Recommended codes document standardises the codes that should be applied to the case
3. A series of consultative workshops were held at the beginning of the QA Programme implementation
4. SOPs for standardising practice have been developed
5. Validation of ICT system
 - a) The ICT implementation process ensured that the QA extract software was validated to ensure that accurate local reports were produced by the NQAIS-Histopathology system
6. Ongoing validation of local data
 - a) A detailed analysis of the QA report is carried out during implementation but it is important that a basic analysis is carried out each month to maintain confidence in information presented in the QA report. Each month laboratories should check that the overall case count is as accurate as possible and should check a sample of the other KQIs. The KQI Export for the Total Cases parameter provides a list of all cases included in the QA report. This is useful for finding cases without procedure codes or for tracking missing or incorrect quality codes. Running and analysing a Data Quality Report may also help in understanding specific reasons why cases are included or missing from KQIs.
 - b) It is recommended that locally the Quality Committee should review the quality of local QA data and develop means of improving this data quality. The quality of local QA data may be enhanced through the development and review of local SOPs for all QA programme activities and training of new staff.
7. Validation of data at a national level
 - a) The accuracy of national data will be evaluated on a regular basis by the National Operational manager using the NQAIS data quality report facility. This will assess at a national level the number of cases without procedure codes, anomalies or inconsistencies in codes or linkages that do not conform to NQAIS standards or conventions. Summary reports of this data will be published on a quarterly basis as a means of highlighting areas where data quality could be improved and identifying methods of improving this data on a national level.

Setting National Targets

A methodology document for the development of national targets for the Quality Assurance Programme in Histopathology has been developed.

Defining a methodology for the setting of targets requires careful consideration and input from a number of advisors. This document describes a proposed process for the development of these targets. In the approach, documented targets will be developed using real performance data collated over a period of time whilst taking relevant international benchmarks and any existing national benchmarking systems into account.

Gather & share best practice

The programme is unique in that both public and private laboratories are participating and therefore sharing best practice at the workshops held. Evidence of this could be seen at the most recent workshop in May 2013.

Communication on a national and international stage

The QA Programme has presented at a number of national and international conferences. It is hoped to increase awareness of the programme in 2014 through the further development of the communications strategy.

Figure 14

Name of conference	Date	Audience
Academy of Medical Laboratory Science in Ireland (AMLS)	September 2011	Medical Scientists
Clinical Indemnity Scheme March newsletter (article)	March 2012	Public
St Luke's Symposium Public Meeting "Perspectives in Medical Error: Understanding Uncertainty in Medicine"	November 2012	Public
International Forum on Quality and Safety in Healthcare (poster displayed)	April 2013	All healthcare professionals
National workshop of the QA Programme in GI Endoscopy	October 2013	Consultant endoscopists
National workshop of the QA Programme in Radiology	December 2013	Consultant radiologists
United States and Canadian Academy of Pathology (USCAP)	March 2014	

National QA Programmes in Radiology and GI Endoscopy

The National QA Programme in Histopathology has led the way for two QA Programmes in other diagnostic specialties.

The QA Programme in Radiology, led by the Faculty of Radiologists, commenced in January 2010 and is presently leading out on the implementation of the ICT solution provided.

The QA Programme in GI Endoscopy, led by the Conjoint Board of RCPI and RCSI, commenced in April 2011 and three units are currently live on NQAIS generating QA reports.

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