National Quality Assurance Programme in Radiology
Information Governance Policy

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Developed by

The Steering Group of the National QA Programme in Radiology

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1. Executive Summary

The Faculty of Radiologists, RCSI launched the National Quality Assurance Programme in Radiology 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 radiology 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 radiology departments 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 collect, store and analyse QA data will allow individual departments to access their own data, analyse and generate reports using this data. It will also allow individual departments 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 Radiology Departments, Cancer Centres and other relevant groupings selected. It will be the responsibility of the lead QA Radiologist and Chair of the Radiology Department/Administrative Head 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 a central component of the National QA programme in Radiology.To drive this QA programme the Faculty of Radiologists has developed guidelines of Quality Assurance in a number of key performance areas of Diagnostic and Interventional Radiology (2). These guidelines implementation are currently being commenced in all public, private and voluntary hospitals in Ireland with Radiology Departments. Once implemented, participating radiology departments will be expected to collect key performance data locally for ongoing review and improvement.

Key quality data will be recorded at participating sites at detail level on QA IT modules aligned with workflow, and at summary level directly onto a QA web interface, and will be routinely exported, de-identified and securely transmitted to a central data repository along with the data extracts of total accession number volumes and turnaround times from existing RIS/PACS. A local authorisation step is required before data is accessible to Faculty ensuring that local departments maintain ownership of data after it is transferred. The repository will primarily be used to facilitate local review and reporting of key quality data.

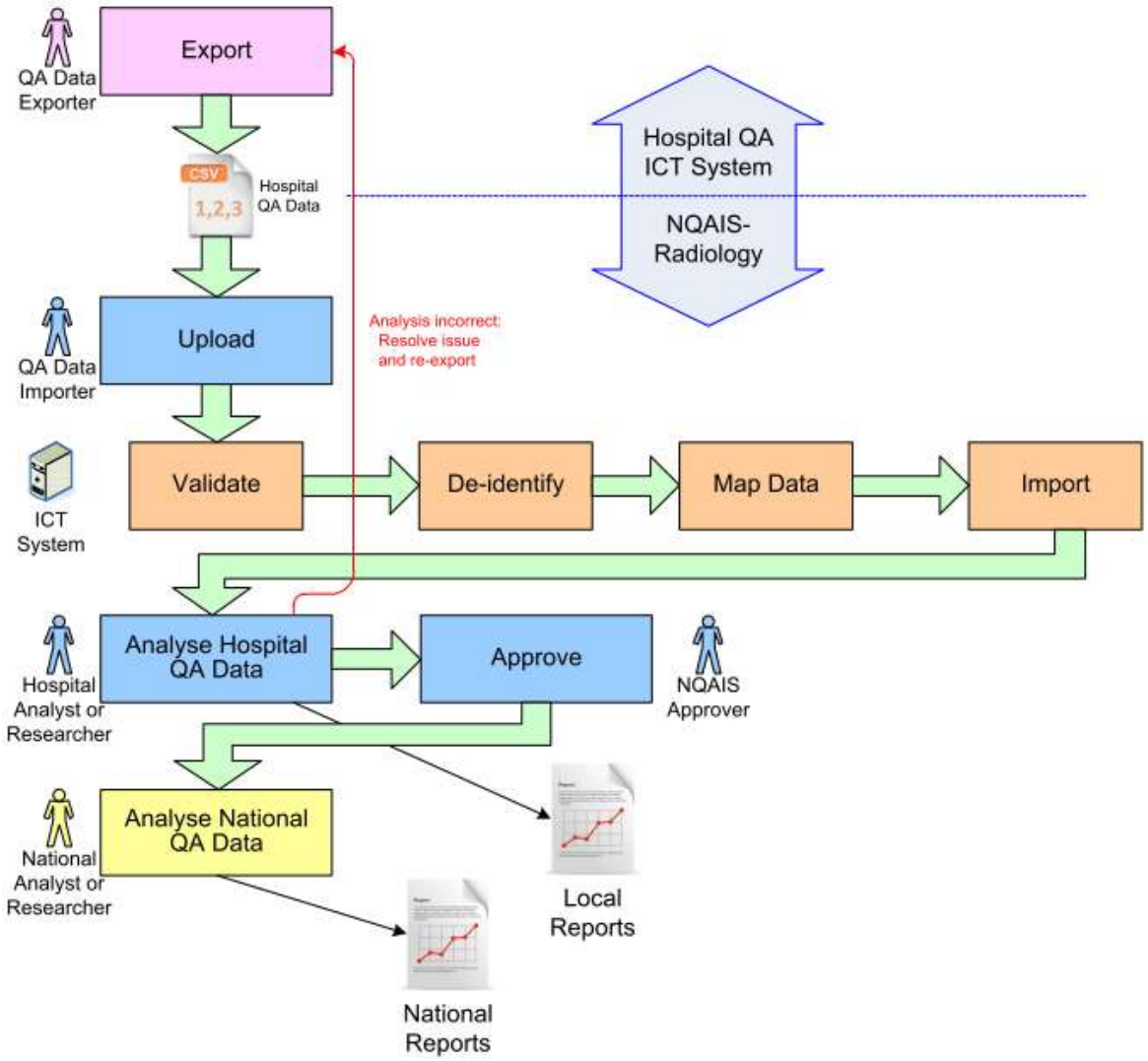
This key quality data consists of essential data items associated with each case and includes general details such as the accession number, referral source, modality, procedure date, case type, date/time image made available for reporting, date/time report finalised and details of quality activities applied to the case.

The detailed quality data will be recorded on QA IT modules for peer review and alerts (the communication of unexpected critical, urgent and significant findings) provided by HSE ICT centrally for the National QA Programme. The summary data will be entered into web interfaces as part of a new application to NQAIS, described below.

An existing application, National Quality Assurance Intelligence System (NQAIS) for use by the National QA Programme in Histopathology was adapted from the HSE Health Atlas system by Health Intelligence Ireland (HII) and this NQAIS system will be the central data repository for the programme. The NQAIS will be enhanced to store, analyse, access and report on key quality data locally and nationally for the QA Programme in Radiology. Essentially a Radiology module within HII will be configured to facilitate analysis of Radiology key quality data – this module will be referred to as the "National QA Intelligence System (NQAIS) for Radiology" within the broader context of the National Radiology 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 patient information will not be uploaded initially and there is a facility in the system to de-identified Medical Record Numbers (MRNs) before entering the central NQAIS database. However, it is recognised that to encourage participation in clinical audit and quality assurance 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). As such, this Information Governance Policy has been developed in order to manage the confidential processing and communication of quality data pertaining



to individual Radiology 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 Radiology 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 Radiology will be entered into local QA modules integrated with the RIS/PACS and web interfaces for selected summary data at each participating site. Data is extracted and de-identified at each site before it is securely transferred to the National QA Intelligence System (NQAIS) for Radiology. 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 QA Modules, the web interfaces and the Radiology NQAIS (Central Repository) 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 Radiology are the participating Radiology departments.

Responsibilities of all members of the Data Originator:

- The Chair of the Radiology Department/Administrative Head of the Radiology Department must identify a designated QA Lead Radiologist locally with overall responsibility for the programme
- 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 Radiology QA Programme activities, in compliance with local policy
- Process data according to local protocol and incompliance with this information Governance Policy

Responsibilities of the designated **QA Lead Radiologist**:

- Identify a designated person or two persons locally with responsibility for the operational management of the programme on an ongoing basis
- Authorise local user access rights and access levels to the QA Modules, the QA Extracts from the RIS/PACs, the NQAIS web interface and the NQAIS central repository for this programme
- Identify centrally generated report recipients e.g. all Radiologists 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 Radiology QA Programme activities, in compliance with local policy

Responsibilities of the **Local Operational Manager**:

- Ensure all QA activity is accurately recorded on the the RIS/PACs, on the QA modules and the QA web-interface modules
- Provide accurate list(s) of locally implemented codes to Data Controller to facilitate mapping to agreed national codes e.g. modalities and exam type
- Maintain local code mapping tables on the NQAIS
- Ensure data extracted from the RIS/PACs and all QA modules and web entry modules are accurate and complete
- De-identify sensitive data (i.e. Medical Record Number, Consultant ID) before QA data leaves the department using encryption facilities provided
- Routinely transmit QA data to the central repository 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
- Collect KQI information in relation to audits

Where a quality activity is conducted across a number of hospitals, for example a discrepancy meeting, a clone of the aggregate result is entered for each hospital.

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 Radiology is the Faculty of Radiologists, RCSI under the direction of the Programme Steering Group.

In the context of this programme the Faculty of Radiologists, RCSI is defined as the Dean of the Faculty with advisory Faculty members as follows: the Chair of the Radiology Subgroup and members of the National QA Programme in Radiology 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 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
- 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 Radiology QA programme on an ongoing basis
- Authorise national user access to the NQAIS for this programme
- Use data in the setting of National Benchmarks in response to requests through the Faculty
- 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 radiology diagnoses and reports

Responsibilities of designated **National Operational Manager**:

- Support the ongoing development and use of the central repository (e.g. additional analyses/reports & departments), 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
- Assist Data Originators with the mapping of local / national codes
- Liaise with local radiology departments 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
- 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 central repository, and standardised RIS/PACs extracts and interfaces, QA modules and QA web interfaces, in collaboration with the National Programme Manager and Health Intelligence Ireland
- Procure software development services (as necessary) to facilitate the enhancement of the HII and RIS/PACs extracts and interfaces, QA Modules and QA 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 repository

- Lead the detailed design, development, testing and implementation of all necessary RIS/PACs extracts and interfaces, QA modules 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 RIS/PACs , the QA Modules and the web-interfaces 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 Health Intelligence Ireland and the Operational 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)

5.4. Health Information, Health Intelligence Ireland (HII), HSE

The Health Information Unit, HSE, in collaboration with the National Programme Manager, HSE ICT Directorate, and other stakeholders will lead the enhancement of the NQAIS for the Radiology QA Programme, which builds upon the existing NQAIS functionality and infrastructural design.

Responsibilities:

- Identify a designated HSE System Manager with overall responsibility for the ongoing management of the NQAIS system, enhanced for QA radiology functionality and the QA Modules
- Lead the detailed design, development, testing and implementation of the NQAIS (e.g. user interfaces, analyses, displays and report formats) based on the existing NQAIS and supporting infrastructures, in light of the specified Radiology QA requirements and in collaboration with the National Programme Manager and HSE ICT Directorate
- 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)
- 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 the approved vendor(s) of the various QA ICT systems described in this document, HII, 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 and QA Modules in collaboration with the Data Originators System Managers
- 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

ICT system and service providers (i.e. the QA modules and NQAIS, will be contracted by the HSE ICT 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, HSE ICT Project Manager, HSE Health Intelligence Unit and participant Radiology 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 Data Controller (i.e. potential data processor role)

6. Access

Access to the QA Modules data will be restricted to authorised local users who are defined members of the defined Data Originator.

Access to the QA web interfaces that will be on NQAIS will be restricted to authorised local users who are defined members of the defined Data Originator.

It has been agreed that the existing Health Intelligence Ireland NQAIS application and supporting infrastructure will be enhanced to facilitate the NQAIS for the QA Radiology 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 central repository 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. De-Identification

There is no transfer of sensitive data (i.e. patient Medical Record Numbers or Radiologist IDs). Hence no de-identification step will be required. Should the Information Governance Policy be changed with the agreement of the Faculty of Radiologists RCSI , de-identification of any sensitive data which is extracted from the local RIS/PACs, QA Modules and QA web interfaces, sensitive data (i.e. MRN) can be de-identified locally and all data for that period will be saved and transferred securely to the NQAIS. In the event that a Unique Health Identifier is introduced the de-identification process will ensure that records for the same patient in different radiology departments are not linked together (i.e. they will not result in the same identifier following de-identification).

This Information Governance Policy does allow the transfer of accession numbers which are also on the existing RIS/PACs systems. Access to the RIS/PACs information locally must be controlled according to local procedure.

6.2 Access Levels to Local Hospital QA Information on, QA Modules and QA web interfaces

6.2.1 The QA Modules – Peer Review and Communication of Unexpected Findings

Role	Access to Local Hospital QA Information	Expected Users
Hospital System Administrator	Create user accounts and assign roles to users Establish hospital peer review groups System configuration	Radiologist manager or designate
Radiologist	Create peer review records View peer reviews records and the peer review archive where the radiology report was finalised by the user or the peer review was created by the user View own peer review work list Create radiology alerts View own radiology alerts	All radiologists
Lead QA Radiologist	All access available to Radiologist role Create, view or modify peer review records View all peer review work lists and peer review archives Collate exams for discrepancy and other meetings View all radiology alerts	Lead QA radiologist
Radiology Admin Staff	View all radiology alerts Create communications for radiology alerts	Radiology admin staff
QA Data Exporter	Export QA data	Assigned radiologist or admin

6.2.2 The NQAIS web interface for summary data entry

Role	Access	Expected Users
Summary Data Editor	List, create, modify or delete the summary QA records* for the hospital	All radiologists or as assigned admin

* Examples of QA records are the information recorded for a MDT meeting or for a focused audit.

6.3 Access levels to the NQAIS central repository of data

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

Role	Access	Expected Users
NQAIS System Administrator	Create, modify or delete NQAIS-Radiology system user accounts, including assigning user roles, for the hospital Modify or delete identifier values and mapping tables for the hospital Access to hospital QA data as required for ICT support purposes	Radiologist manager or designate
QA Data Upload	Upload and import detailed QA data for the hospital	Assigned radiologist or admin
Hospital Analyst	Execute quality reports on the QA records for the hospital	All radiologists
Hospital Drill-down Analyst	All access available to *Hospital Analyst* role View detailed quality reports showing more information on the QA data used to produce a summary report for the hospital	All radiologists
NQAIS Sign Off	Approve the QA records of the hospital	Lead radiologist

6.3.2 National Access levels

Role	Access	Expected User
National Analyst	Execute quality reports on aggregated anonymised quality data	Members of the Data Controller
National Administrator	Access to data from all participating hospitals including hospital IDs. The purpose of this access is programme administration (trouble shooting, participant queries etc).	QA operational manager designated by Data Controller

Table 1: Summary of user access levels to central data repository

Access Level		Local			National	
		Analyst	Import	Sign-off	Analyst	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 De-identified	Yes	Yes	Yes	No	Yes
	National De-identified	Yes	Yes	Yes	Yes	Yes
	Hospital ID's	No	No	No	No	Yes
Access Controller		Data Originator			Data Controller	

7 Reporting

The central repository will provide functionality for the development of standard and ad hoc reports using National Radiology 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 Radiology 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) Other relevant Hospital Groups

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/Research

Access to data in the central repository 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

1) The Commission on Patient Safety and Quality Assurance. Building a Culture of Patient Safety. 2008.

2) Guidelines for the Implementation of a National Quality Assurance Programme in Radiology. Faculty of Radiologists, RCSI

3) Information Governance Policy for the National Quality Assurance Programme in Histopathology, Faculty of Pathology, RCPI

4) The Department of Health and Children. Discussion Document on Proposed Health Information Bill. June 2008.

5) The Department of Health and Children. Proposed Health Information Bill. 2009.

6) The Health Information and Quality Authority. An “As Is” Analysis of Information Governance in Health and Social Care Settings in Ireland. 2010.

7) The Health Information and Quality Authority. International Review of Information Governance Structures. 2009.

8) The Data Protection Act 1988.

9) The Data Protection (Amendment) Act 2003.

10) 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.

11) The Office of the Data Protection Commissioner. Data Protection Guidelines on Research in the Health Sector. 2007.

12) The National Cancer Registry, Ireland. Data Confidentiality in the National Cancer Registry - General policy, procedures for release of data and staff guidelines. 2007.

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

14) The Office of the Data Protection Commissioner. Data Protection Acts 1988 and 2003 - A Guide for Data Controllers. 2008.

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

16) 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.

17) World Alliance for Patient Safety, WHO Draft Guidelines for adverse event reporting and learning systems. World Health Organisation 2005

18) 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

19) Data Processing Agreement between Caredoc Limited and the Health Service Executive, 2005

Revision History

Version	***Date***	***Editor(s)***	***Changes***
1.0	13.09.11	LC	