A National Framework for Quality Assurance in Cellular Pathology – The Irish Approach
June 25th 2015

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Background

- Irish population = 4.5 million
- 23,000 new cases of cancer annually
- 7,500 cancer-related deaths annually
- Projected doubling of new cases by 2020
- High profile cancer misdiagnosis cases in 2007 & 2008
- No formal measures to reassure the public that Pathologists practice to the highest international standards
- No national standards or benchmarks for key aspects of diagnostic service
Vision of National QI Programme

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

- West – 7 Departments
- South/SE – 3 Departments
- Mid Leinster – 1 Department
- North East – 2 Departments
- Dublin – 14 Departments
- 7 Private Laboratories
Programme Model

Process

Initiation (2008)
1. Engagement
2. Definition
3. Governance
4. Working Group

Design (2009-2010)
1. Guidelines
2. ICT
3. Schedule

Rollout (2011-2012)
1. Training & support
2. Phased Implementation
3. National Database

Measure (2013)

Control
Governance Overview

Steering Committee
Members: HSE Quality Improvement Division, National Cancer Control Programme, HSE ICT, HSE service management, Independent Hospitals Association of Ireland (IHAI), Dept of Health, Faculty, RCPI
Observer: HIQA

Faculty of Pathology
Programme Management
Quality & Clinical Care, Programme Manager, RCPI
HSE ICT

Clinical Working Group
Reference Panel

Local Hospital Participant Teams **

** Note Data owner is the local unit & governance of the data is with that unit’s local, regional and national governance structures
## Summary of Guidelines

<table>
<thead>
<tr>
<th>Monitor</th>
<th>Key Indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inter-institutional review</td>
<td>% Agreement</td>
</tr>
<tr>
<td>Intradepartmental Consultation</td>
<td>% Cases</td>
</tr>
<tr>
<td>Frozen Section Correlation</td>
<td>% Concordance, % Deferral, TAT</td>
</tr>
<tr>
<td>Cytological/histological correlation &amp; TAT</td>
<td>% Discordant, % False positive, % False negative, % TAT &lt; 20 minutes</td>
</tr>
<tr>
<td>Retrospective review (Focused real time / report completeness)</td>
<td>% Agreement / % Completeness</td>
</tr>
<tr>
<td>Multi disciplinary Team meetings</td>
<td>% Agreement, % of total cases discussed</td>
</tr>
<tr>
<td>Non-conformance (NC) reporting</td>
<td>No. of non-conformances, Clinical impact</td>
</tr>
<tr>
<td>External Quality Assessment</td>
<td>List of Schemes (NEQAS), results</td>
</tr>
<tr>
<td>Turn around Time</td>
<td>TAT by case type</td>
</tr>
<tr>
<td>Addendum Reports</td>
<td>Quantity, Error classification, Clinical impact</td>
</tr>
<tr>
<td>Critical Diagnosis reporting</td>
<td>No. of cases communicated directly to clinician</td>
</tr>
</tbody>
</table>
Data Collection & Extraction

- **Data collected**
  - QI activity data coded into LIS
  - Extract program developed by LIS Vendors

- **Data extracted**
  - MRN Encrypted before data leaves hospital

- **Data encrypted**
  - Data transferred to central repository: NQAIS

- **Data transferred**
  - Data transferred to central repository: NQAIS
How the Data becomes information

**Local reports**
- Departmental data
- Access restricted

**National reports**
- National aggregate data
- Access restricted

Unit responsibility for unit data lies with the unit’s local governance

Published Q mark
National QA Intelligence System (NQAIS)

Local Ownership
- Each unit/lab can log on to analyse and view its own data
- Local data must be signed off before inclusion in national average

No league tables
- Comparison with peers shown in summary format not individually hospital by hospital

At a glance
- Report format not long and complex
- All key data can be seen at a glance in the same format

Web enabled
- Possible to log onto system from your desktop or laptop

Confidential
- Access is password protected
- Access roles clearly defined and managed

Open Source
- No expensive licensing fees

Evolving
- System designed to be easily modified over time
Log in to system from the desktop
At a Glance Reporting - TAT

Turnaround Time analysis now displays metrics in Percentage by Day instead of Medians and Inter-quartile ranges. Outline bar shows performance against target i.e. white above, red below.
### At a Glance – Intradepartmental Consultation

<table>
<thead>
<tr>
<th>(# labs) (BM)</th>
<th>% cases</th>
<th>Snapshot % cases</th>
<th>Trend % cases</th>
<th># cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>(28)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All cases with intraD consult. (Q006)</td>
<td>6.26</td>
<td><img src="image" alt="Graph" /></td>
<td><img src="image" alt="Graph" /></td>
<td>154</td>
</tr>
<tr>
<td>(28)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Histology cases with intraD consult. (Q006)</td>
<td>5.81</td>
<td><img src="image" alt="Graph" /></td>
<td><img src="image" alt="Graph" /></td>
<td>168</td>
</tr>
<tr>
<td>(26)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cytology cases with intraD consult. (Q006)</td>
<td>12.59</td>
<td><img src="image" alt="Graph" /></td>
<td><img src="image" alt="Graph" /></td>
<td>21</td>
</tr>
</tbody>
</table>
Oversight of data - Environment

- Health environment evolving - policies & legislation: Unique Health Identifier, Open Disclosure, Health Information bill, Hospital Groups, Data governance.
- Concerns hospital autonomy & league tables ‘big brother’ change, voluntary participation.
- Hospital licensing/accreditation will be implemented in the future
- Maturity of ‘QI culture’ and full understanding of conducting, recording and reporting on quality assurance and quality improvement.
- Concern about individualising data and identifying data owner; legal implications
- Appropriateness of college / Faculty being involved in identifying outliers
- National LIS implementation overhaul of the programme and activities.
<table>
<thead>
<tr>
<th>Aspect</th>
<th>Improvement</th>
<th>Accountability</th>
<th>Research</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aim</strong></td>
<td>Improvement of care (efficiency &amp; effectiveness)</td>
<td>Comparison, choice, reassurance, motivation for change</td>
<td>New knowledge (efficacy)</td>
</tr>
<tr>
<td><strong>Methods:</strong></td>
<td>Test observable</td>
<td>No test, evaluate current performance</td>
<td>Test blinded or controlled</td>
</tr>
<tr>
<td>• Test Observability</td>
<td>Accept consistent bias</td>
<td>Measure and adjust to reduce bias</td>
<td>Design to eliminate bias</td>
</tr>
<tr>
<td>• Bias</td>
<td>&quot;Just enough&quot; data, small sequential samples</td>
<td>Obtain 100% of available, relevant data</td>
<td>&quot;Just in case&quot; data</td>
</tr>
<tr>
<td>• Sample Size</td>
<td>Flexible hypotheses, changes as learning takes place</td>
<td>No hypothesis</td>
<td>Fixed hypothesis (null hypothesis)</td>
</tr>
<tr>
<td>• Flexibility of Hypothesis</td>
<td>Sequential tests</td>
<td>No tests</td>
<td>One large test</td>
</tr>
<tr>
<td>• Testing Strategy</td>
<td>Run charts or Shewhart control charts (statistical process control)</td>
<td>No change focus (maybe compute a percent change or rank order the results)</td>
<td>Hypothesis, statistical tests (t-test, F-test, chi square, p-values)</td>
</tr>
<tr>
<td>• Determining if a change is an improvement</td>
<td>Data used only by those involved with improvement</td>
<td>Data available for public consumption and review</td>
<td>Research subjects’ identities protected</td>
</tr>
</tbody>
</table>

Quality Programme Data Flow

- Quality activities occur at hospital
- Quality activities Inputted into LIS
- Quality Data Transmitted to NQAIS
- Internal Quality report by Hospital
- Quality meetings and Report reviews
Programme Model

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Control

1. Data Collation & Analysis

March 2015

1. National Quality Targets (KQI)  
2. Embedding
Objectives for Target Setting Methodology

• Keep it simple

• Compare to international standards

• Avoid setting unachievable targets but also ensure targets set are credible

• Use the national data gathered

• Tailor each one to clinical practice in Ireland
National NQAIS Report 2014

Small Biopsy (P01) Turnaround Time Percentage Completed by day 5 - per month
All Hospitals (Inc. CC/NonCC Split)
National Report 2014 – Cytology TAT

Non Gynaecological Cytology FNA (P06) TAT Percentage Completed by day 5 - per month
All Hospitals (Inc. CC/NonCC Split)

All Hospitals
Cancer Centers
Non Cancer Centers
Target of 80% by Day 5
Frozen Section Correlation (Q007) - per month
All Hospitals (Inc. CC/NonCC Split)
National Report 2014
Intradepartmental Consultation

Percentage Intradepartmental Consultation (Q006) per month
All Hospitals (Inc. CC/NonCC Split)

- All Hospitals
- Cancer Centers
- Non Cancer Centers
- Minimum Target
- Achievable Target
Intradepartmental Consultation

- Range 0 – 11.8%
- Un-weighted mean = 4.3%
- Total Cases (2013) = 17,977
- MDT cases = 37,911 (11%)
- Combined peer review rate = 12.9% (45,795 cases)

Mod Pathol 2014;27;515A
## National Histopathology Workload

<table>
<thead>
<tr>
<th>Type</th>
<th>No. (Cases) 2013</th>
<th>No. (Cases) 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimens</td>
<td>566,912 (357,249)</td>
<td>570,975 (355,929)</td>
</tr>
<tr>
<td>Blocks</td>
<td>950,791</td>
<td>951,162</td>
</tr>
<tr>
<td>Total Stains</td>
<td>2,030,484</td>
<td>2,039,228</td>
</tr>
<tr>
<td>Routine H&amp;E</td>
<td>1,448,313 (319,245)</td>
<td>1,468,899 (313,009)</td>
</tr>
<tr>
<td>Extra H&amp;E</td>
<td>224,022 (47,266)</td>
<td>213,067 (47,529)</td>
</tr>
<tr>
<td>IHC stains</td>
<td>248,920 (35,491)</td>
<td>246,389 (38,144)</td>
</tr>
<tr>
<td>Frozen Section stains</td>
<td>6,757 (1,482)</td>
<td>6,918 (1,437)</td>
</tr>
</tbody>
</table>
Keys to success

Established governance structure

Communication & Consultation

Collaboration – HSE, NCCP, HSE ICT, IHAI

Clinical Leadership and Engagement

Real Time Data and ICT support

Successful implementation
Achievements

- A completely unique national programme
  - Across public and private laboratories
  - Across 8 different Laboratory Information Systems (LIS)
  - Across small and large hospitals with different levels of resourcing

- Development of a central repository NQAIS-Histopathology

- Collection of national data for Histopathology
  - Never before collected on this scale

- Confidence in the data to understand in real time our workload and extent of quality activities

- Ability for us to set national targets based on our data
Programme Benefits

- Improved **patient care and public confidence**
- **Less need** for large scale look backs
- QI data for local **service enhancement**
- Identification of **good practice**
- Identification of **areas requiring development**
- **Improved communication** between institutions leading to strategic links/networks
- Development of **National Targets** for QI activities
- Model for other National QI Programmes (Radiology, Endoscopy)
www.rcpi.ie for Programme information
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