Quality Assurance by Liz McChlery

- Define QA and Total Quality Management
- Describe Quality Control
- Define and distinguish Accuracy and Precision
- Define a Biological Reference Interval
- Describe ISO15189 within the medical Laboratory
- Outline Harmonisation as it relates to laboratory medicine
- Outline Internal and External Assessment Bodies
- Outline the concept of document control
- Outline Quality feedback from Customers

Define TQM and QA

- **Total Quality Management (TQM)** is a comprehensive and structured approach to organizational **management** that seeks to improve the **quality** of products and services through ongoing refinements in response to continuous Feedback
- **Quality Assurance**: The maintenance of a desired level of **quality** in a service or product, especially by means of attention to every stage of the process of delivery or production.
Define: Quality Assurance and Total Quality Management

Describe Quality Control

- Quality control (QC) is a procedure or set of procedures intended to ensure that a manufactured product or performed service adheres to a defined set of quality criteria or meets the requirements of the client or customer.
**Laboratory quality control** is designed to detect, reduce, and correct deficiencies in a laboratory's internal analytical process prior to the release of patient results, in order to improve the quality of the results reported by the laboratory.

- Quality control is a measure of precision, or how well the measurement system reproduces the same result over time and under varying operating conditions.
- Laboratory quality control material is usually run at the beginning of each shift, after an instrument is serviced, when reagent lots are changed, after calibration, and whenever patient results seem inappropriate.

Assays which are subject to drift or interference have more regular quality control checks. To ensure confidence in the results being produced.

- QC results on automated machinery is plotted into graphs to monitor performance and detect drift or failure.
- QC Material can be commercial
- Reproducibility checks using comparisons of patient samples across machines or sites such as NSH/WTK
Regardless of the type of examination that is performed, steps for implementing and maintaining a QC programme include:
- establishing written policies and procedures, including corrective actions
- training all laboratory staff
- ensuring complete documentation
- reviewing quality control data.

Quantitative tests
- Controls are usually available in "high", "normal" and "low" ranges.
- For some assays, it may be important to include controls with values near the low end of detection.
Semi Quantitative and Qualitative Testing

- As with quantitative procedures, it is important to verify that results of qualitative and semi quantitative examinations are correct prior to reporting them to the requesting health care provider.
- Conducting QC for many of these tests is not as easily accomplished as with quantitative tests. Therefore, it becomes essential that other processes within the quality system are carefully conducted, in addition to traditional QC methods. Following are some important overarching concepts for quality that apply to qualitative and semi quantitative tests.
  - Dedicated, professional staff who understand the principles of QC are key to quality.
  - Incubators, refrigerators, microscopes, autoclaves and other equipment must be maintained and monitored carefully.
  - Positive and negative controls must be used to monitor the effectiveness of test procedures that use special stains or reagents and tests with end-points such as agglutination, colour change or other non-numeric results.
  - Reagents should be stored according to the manufacturer’s instructions, labelled with the date they are opened and put into use, and discarded at the expiration date.
Sample management is important in all laboratory testing. Examinations that are dependent on a viable organism in the sample may need closer monitoring and better communication with non laboratory staff.

7.3 Accuracy and Precision

- Think of accuracy like a dart board. The desired result is a bulls eye. If you hit it or close to it you have high accuracy.

- Precision is achieving the same result repeatedly.
Accuracy and Precision

- What is the difference?

- You could achieve a result consistently in the outer ring but it is not necessarily accurate.
Labs endeavour to be both
We like to be highly accurate and very precise

<table>
<thead>
<tr>
<th>Define a Biological Reference Interval</th>
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</thead>
<tbody>
<tr>
<td>Biological Reference Intervals are based on Clinical results for an analyte from a <strong>SPECIFIC</strong> population</td>
</tr>
<tr>
<td>Large numbers of tests are performed and plotted into a graph which shows the “normal distribution”</td>
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</table>
What do we mean by Reference Interval (RI)?
- It is the range of values in which the laboratory can objectively interpret/report the generated results.
- This interpretation includes comparing test values against the population-based reference values. In other words, the normal values mean that the obtained values are typical of the values found in a specific population at large.
- Statistically, the values of the RI must be distributed in a bell-shaped (symmetrical Gaussian distribution).

What does this Mean?
All results from a large Population are plotted on a graph
In a Normal distribution 68% of all results will lie within 1 standard deviation of the mean
95% of results will lie within 2 std Dev of the mean
99.7 will lie within 3 std. dev from mean
2) What are the factors affecting RI?

The database of RIs for the same test can be different from one study to another. This is due to many factors which can be summarised as follow:

a. **Endogenous**: this factor cannot be controlled. Age and sex are the main inherent factors. For example many circulated hormones can be affected by age and/or sex during the lifespan.

b. **Exogenous**: this factor can be controlled. Fasting status, exercise and pregnancy are examples of factors which can be modified.

c. **Genetics and/or ethnicity**: this is a population dependant factor. Also, the geographical location can be RI determinant.

3) How RI can be derived?

The CLSI and IFCC recommendations can be followed to calculate the RI for any target population. The detailed statistical methods provided in these recommendations must be strictly adhered.

Generally clinical Laboratories do not perform this function. Suppliers of reagents provide RI for each assay.
What does this mean?
Blood tests are interpretable and relatable through all Labs in NZ

Why?
E.g. Patient with anaemia is tested in the community HB =65 is that g/l or g/dl (harmonisation)
Arrives at Hospital HB is now 45 g/l
Is it a Sampling error? Or lack of conformity in testing?
Or does it represent a life threatening bleed?

ISO 15189
International Organisation for Standardisation has produced a Quality document designed specifically for Laboratory environments (collaborative)
Each year the laboratory is inspected to the ISO15189 v 2012 standard by IANZ(International Accreditation New Zealand)
This covers:
- **Organisation and Management**: Structure, Meetings Management Reviews.
- **Quality Management System**: Application of Internal and external Quality Controls. Maintenance, Recording Temps., Calibrations,
- **Document Control**: how our Documents are managed and updated.
- **Service Agreements**: with our users Contracts, Maintainence, Clients
- **Examination by Referral Laboratories**: are they accredited?, do they meet the same standards
- **External Services and Supplies-Quality**: products that conform to industry standards. Documented suppliers lists
- **Resolution of Complaints**: What is our process? How to we manage complaints, Record keeping
- **Identification and Control of Non-Conformities**: How do we find non conformities. Documentation of what we do when identified. Examinations and reporting halted until resolved
- **Corrective Actions**: to eliminate cause of non conformities, notification to appropriate personnel including customers

- **Preventative Action**: determine the cause and introduce steps to prevent reoccurrence. Root cause analysis
- **Continual Improvement**: Continuous review of all systems against the stated intentions in the Quality Policy
- **Control of Records**: documented procedures for ID, Collection, Indexing, Access, storage, maintenance amendment and safe disposal of quality and technical records
- **Evaluation and Audits**: Implementation of Internal Audits which include pre-analytical, testing and post examination stages to ensure conformity to standards, Staff suggestions, Risk Management
- **Management Review**: annual MRM to ensure Suitability, Adequacy, effectiveness to support patient care
- **Technical Requirements**: Personnel: Qualified, Current APC, Current Competency Signoff, Education, CPD
- **Accommodation and Environment**: Space, Environment, Waste management
- **Laboratory Equipment Reagents and Consumables**: Acceptance testing, Validation Instructions for, Calibrations, Servicing, Maintenance, Use, Traceability, Adverse Incidents
- **Pre examination Processes:** Patient Information, Laboratory Intranet pages, Test Library, Request forms. Instructions for Collecting, transport. Sample reception, Handling Preparation Storage
- **Examination Processes:** Selection Verification and Validation of Exam procedures. QC, Inter lab Comparisons. UOM for quantitative results
- **Quality of Examination Results:** Documentation Standard SOP, Document control
- **Post examination processes:** Review of results, Storage and retention of clinical samples
- **Reporting of results:** Considerations printed, electronic, accurate understandable , unique identifier, date. Release control. LIS,

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**Harmonization**

- The Clinical and Laboratory Standards Institute refers to a definition of ‘harmonization’ as ‘the process of recognizing, understanding, and explaining differences while taking steps to achieve uniformity of results, or at a minimum, a means of conversion of results such that different groups can use the data obtained from assays interchangeably’.
- Standardisation of pathology units and terminology.
- Harmonisation of report formats where there are patient safety issues, e.g. left to right versus right to left reporting.
- Harmonised reference intervals (RIs) and decision limits.
- Best practice evidence for test requesting.
Internal Audits

- Each year laboratories perform an Internal Audit.
- This is an inspection by our staff.
- We follow a template which covers all aspects of the laboratory.
- Review and make recommendations for improvements
- Ensure that any corrective actions are implemented before sign off

WDHB uses our Internal Audit as a preparation for IANZ and use the ISO15189 as our audit tool.
External Audits

- External Auditing Bodies
- NZBS- both Clinical Audits of Transfusion Notes and Technical Audit of Laboratory Compliance
- Ministry for Primary Industries: for sites handling organisms and GM bacteria which are “new” to NZ
- Strict handling and disposal criteria apply to control the risk of exposure or release of harmful organisms

IANZ

- IANZ: International Accreditation New Zealand
- Provide Labs with their “accreditation” which allows them to provide their service.
- All clinical laboratories must have IANZ accreditation.
- IANZ has the power to shut down laboratories by removing their accreditation if they feel the Quality of the testing is not up to standard.
- IANZ performs an annual Audit and makes requests for CAR Corrective Action Requests (Non Conformances)
- SR Strong Recommendations (potential non conformities)
- R Recommendations (opportunity for Improvement)
Document Control

- What constitutes a document?
  - Paper, File, PDF, Electronic files, Emails
  - Any document that may vary over time e.g. flow charts, Procedural manuals, RI's
- Principles: Safe, Retrievable, Unchanged by time
- A permanent audit trail of changes

- Permanent record (25yrs for infant medical records)
- (3 yrs. for QC files)
- Computer records of data results
- What happens if RI changes?
  - Manuals need to be archived if significant changes are being made and a new document released.
  - **All** previous versions must be removed from the point of use
Documents are required to be authorised before put into use.

Title

Unique Identifier

Current edition

Page numbers

Authority for issue

National Pathology Accreditation Advisory Committee

The document *Requirements for the Retention of Laboratory Records and Diagnostic Material* represents the *minimum* standards for retention of records and materials. Individual Laboratories may choose to exceed these minimum requirements based on local circumstances and historical practice.
<table>
<thead>
<tr>
<th>Reference</th>
<th>General</th>
<th>Minimum Time</th>
<th>Storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>GDA 10.5</td>
<td>Audit Reports: Internal/External</td>
<td>10 years</td>
<td>On site or off site at Crown Storage</td>
</tr>
<tr>
<td>GDA 13.2</td>
<td>Personnel: Current/Resigned</td>
<td>7 years post resignation to meet WDHB policy</td>
<td>In training records in Service Lead office</td>
</tr>
<tr>
<td>GDA 13.4</td>
<td>Retain</td>
<td>7 years</td>
<td>In training records</td>
</tr>
<tr>
<td>NPAAC 1.3</td>
<td>Equipment/Instrument Maintenance</td>
<td>Life of the instrument + 3 years</td>
<td>On site or off site at Crown Storage</td>
</tr>
<tr>
<td>GDA 2.7</td>
<td>QC and QA records</td>
<td>3 years</td>
<td>On site or off site at Crown Storage</td>
</tr>
<tr>
<td>GDA 2.8</td>
<td>Laboratory Methods/Procedures (manuals)</td>
<td>While methods current plus 3 years superseded</td>
<td>Electronically archived</td>
</tr>
<tr>
<td>GDA 2.9</td>
<td>Worksheets, Instrument printouts, calculations etc.</td>
<td>3 years</td>
<td>Electronically or in a notebook as convenient form</td>
</tr>
</tbody>
</table>

**Quality Feedback**

- **Who can we get feedback from?** DR, Nurses, Patients, Clients,
- **Surveys**, GP and Hospital user Survey. Annually
- **Rate the service. Give suggestions for improvements**
- **Complements: What we did right**
- **Complaints**
- **Which do we learn more from?**
• Should not take as negative, each feedback is an opportunity to improve and refine our service

• Promotion of NO BLAME culture important.
• Reporting errors/incidents allow us to improve.
• And make changes which prevent future incidents and service development.

“All in all your just a-nother brick in the Wall”

Quality System Essentials

Documents and Records. Information Management. Non conforming event management


Facilities and Safety. Disaster Management. Health Risk Assessment Process