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Good Laboratory Practice

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Role of the Laboratory

- Laboratory services play a crucial role in both individual and population based healthcare

- The prime objective of laboratory medicine is the reporting of accurate and timely test results to the requesting clinician

- Laboratory tests are used to establish:
  - *The clinical status of a patient,*
  - *Diagnose infections and disease*
  - *Monitor its progress*
  - *Response to treatment*

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GLP Definition

- Encompasses a set of principles that provides a framework within which laboratory studies are planned, performed, monitored, reported and archived.

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History

- In fact GLP was first used in New Zealand in 1972
- In 1978 the FDA created the formal regulation of GLP.
- Although GLP originated in the United States, it had a global impact.
- Non-US companies started making GLP regulations in their home countries.
- In 1981 an organization named OECD (organization for economic co-operation and development) produced GLP principles that are of international standard.
- In Europe, adherence to the principles of GLP is governed by European Union (EU) law and, in compliance with EU Directives (UKAS)

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Why GLP?

- In the early 70's FDA became aware of cases of poor laboratory practice all over the United States.
- FDA decided to do an in-depth investigation on 40 toxicology labs.
- Discovered several fraudulent activities and poor lab practices.
- Examples of some of poor lab practices were:

1. Equipment not been calibrated to standard form
2. Incorrect/inaccurate accounts of the actual lab results
3. Inadequate test systems

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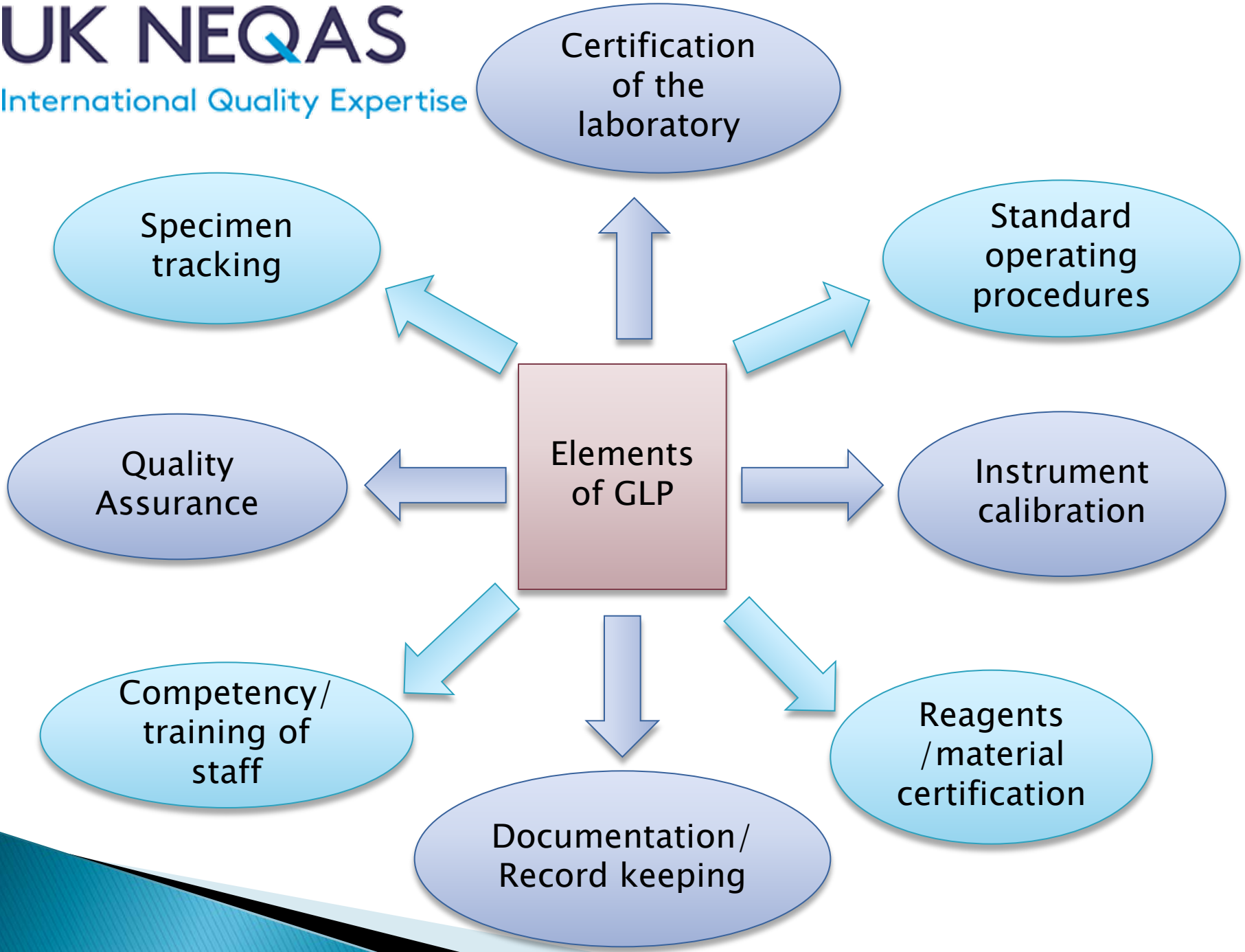

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Objectives of GLP

- GLP makes sure that the data submitted are a true reflection of the results that are obtained in the diagnostic test carried
- GLP also makes sure that data is traceable.
- Promotes international acceptance of tests.

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Standard Operating Procedures (SOP)

- Written procedures for a laboratories program.
- They define how to carry out protocol-specified activities.
- Most often written in a chronological listing of action steps.
- They are written to explain how the procedures are suppose to work

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SOP

- Routine inspection, cleaning, maintenance, testing and calibration.
- Actions to be taken in response to equipment failure.
- Limitations
- Analytical methods (ELISA, EIA)
- Definition of raw data
- Keeping records, reporting, storage, mixing, and retrieval of data

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Instrumentation Validation

- This is a process necessary for any analytical laboratory.
- Data produced by “faulty” instruments may give the appearance of valid data.
- The frequency for calibration, re-validation and testing depends on the instrument and extent of its use in the laboratory.
- Whenever an instrument’s performance is outside the “control limits” reports must be discontinued

An uncalibrated machine can measure fantastical values. And if you calibrate it, but select the wrong measurement mode, you can run into a situation where you grossly under- or over-measure how much analyte is inside your tube. Before using any piece of equipment, **make time** to ensure that it is properly calibrated first

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Instrument Validation (cont)

- Equipment records should include:
- Name of the equipment and manufacturer
- Model or type for identification
- Serial number
- Date equipment was received in the laboratory
- Copy of manufacturers operating instruction (s)

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Reagent/ Materials Certification

- This policy is to assure that reagents used are specified in the standard operating procedure.
- Purchasing and testing should be handled by a quality assurance program.

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Reagents and Solutions cont'd

- Requirements:
- Reagents and solutions shall be labeled
- Deteriorated or outdated reagents and solutions shall not be used
- Include Date opened
- Stored under ambient temperature
- Expiration date

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Scientist Certification

- Acceptable proof of satisfactory training and/or competence with specific laboratory procedures must be established for each healthcare scientist.
- Qualification can come from education, experience or additional trainings.
- Sufficient trained staff
- Requirements of certification vary

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Laboratory Certification

- Normally performed by an external agency
- Evaluation is concerned which include issues:
- Adequate space
- Ventilation
- Storage
- SAFETY

UKAS

UNITED KINGDOM ACCREDITATION SERVICE

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Specimen/Sample Tracking

- Varies among laboratories
- Must maintain the unmistakable connection between a set of analytical data and the specimen and/or samples from which they were obtained.
- Original source of specimen/sample (s) must be recorded and unmistakably connected with the set of analytical data.

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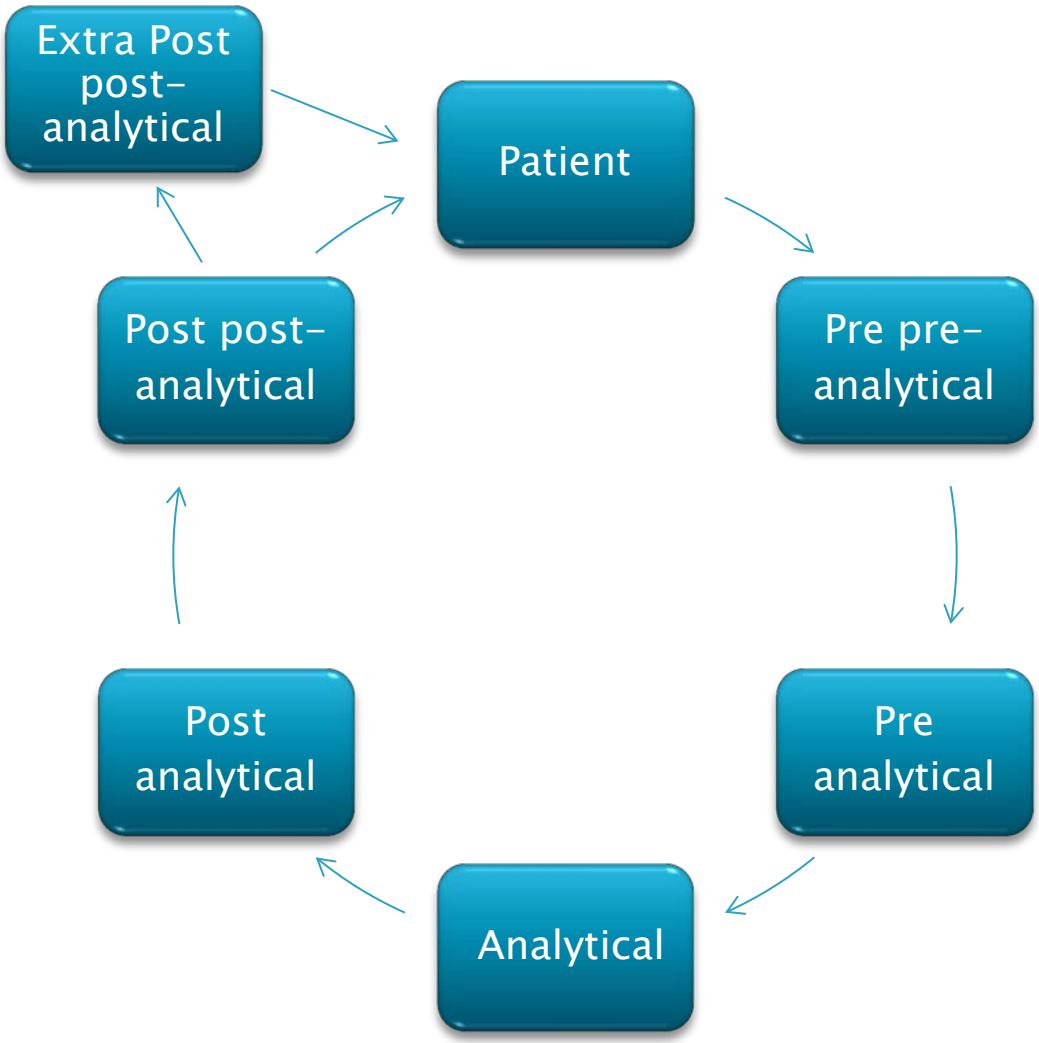
Total Testing Process



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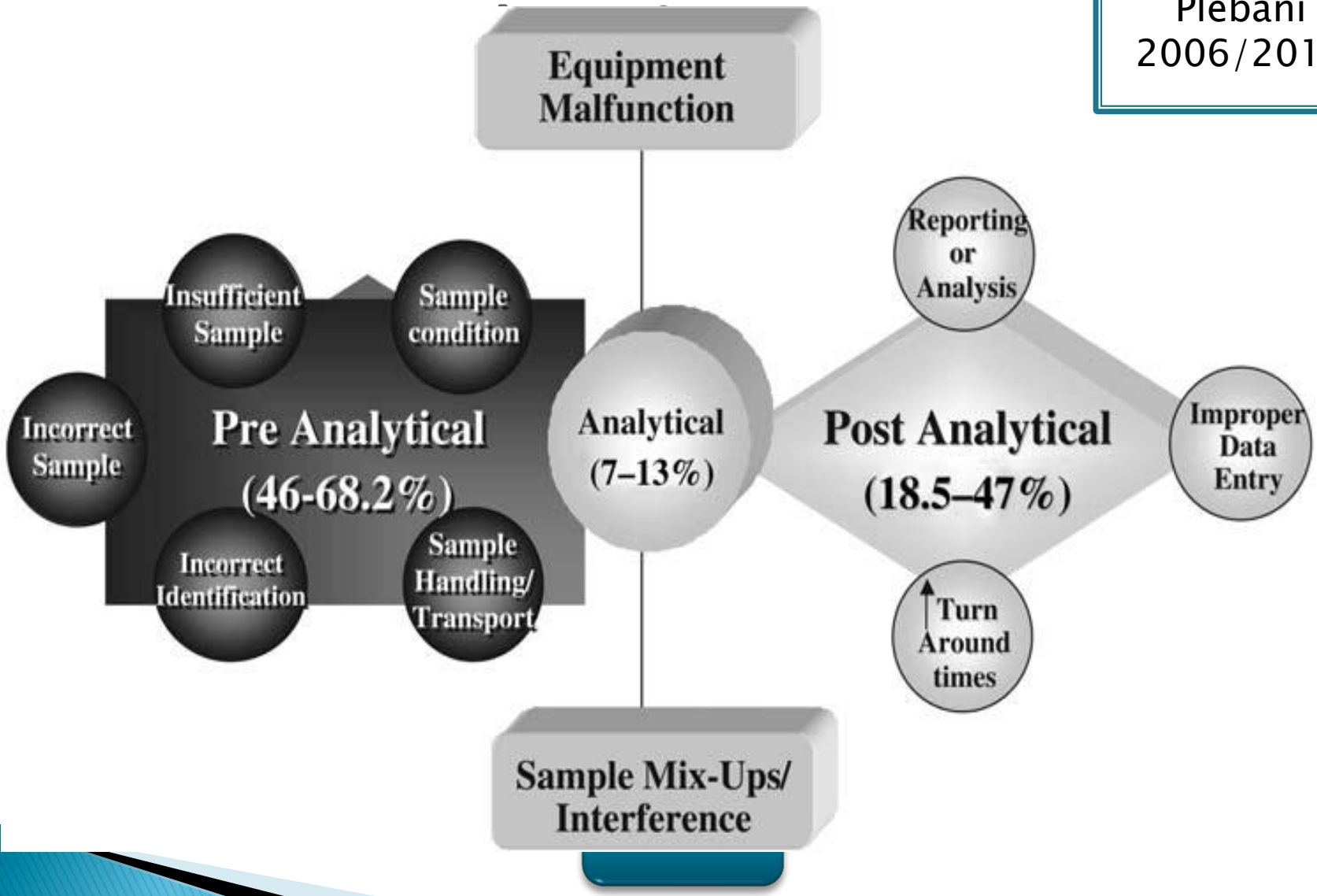
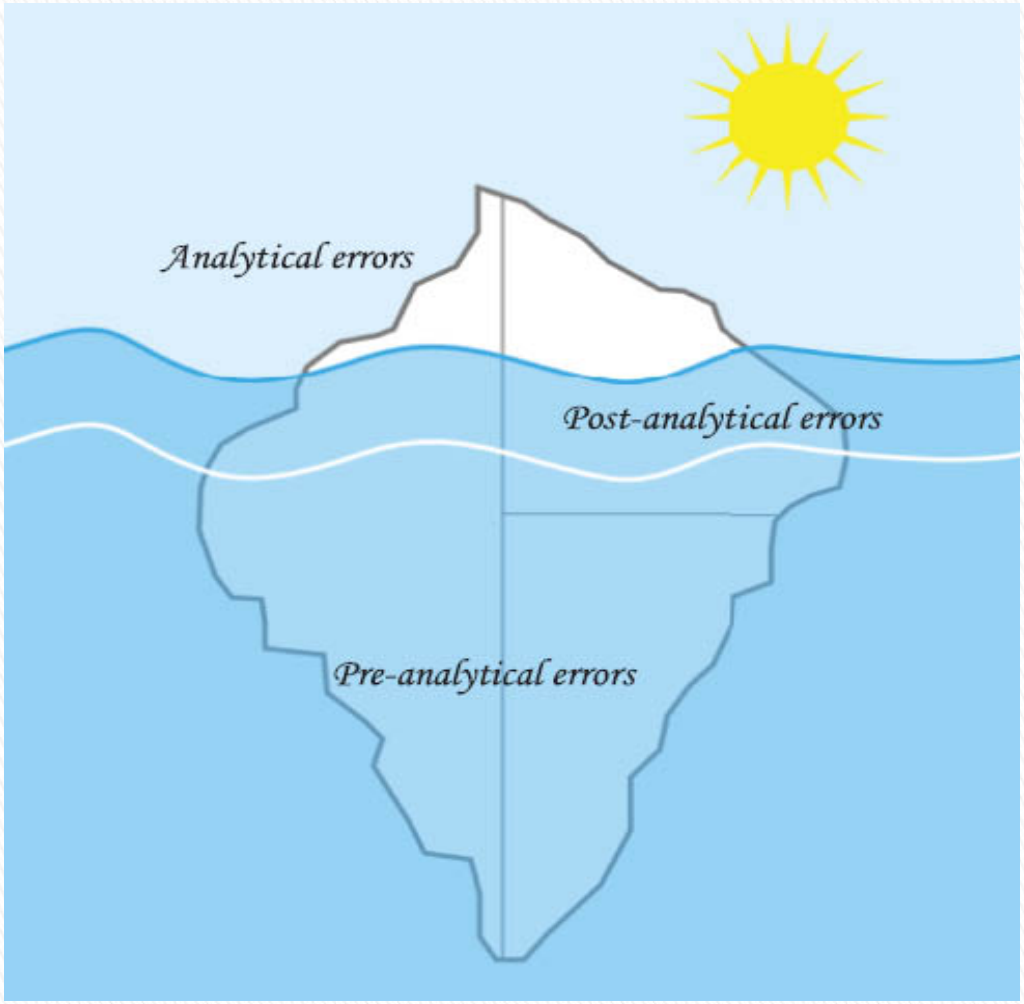
Plebani
2006/2012



Most errors are not in the analytical phase

The Iceberg of Laboratory Errors

- Clinical Chemistry and Laboratory Medicine (CCLM). Volume 53, Issue 3, Pages 357–370, ISSN (Online) 1437–4331, ISSN (Print) 1434–6621, DOI: 10.1515/cclm–2014–1051, December 2014



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Analytical errors

- Sample mix up
- Inappropriate tests carried out
- Diagnostic tests performed incorrectly
- Automation failure
- Mis-identification of the intended organism
- Report the contaminant(s)
- Test system not calibrated
- Reagents prepared incorrectly, stored inappropriately or used after expiry date
- Equipment malfunction

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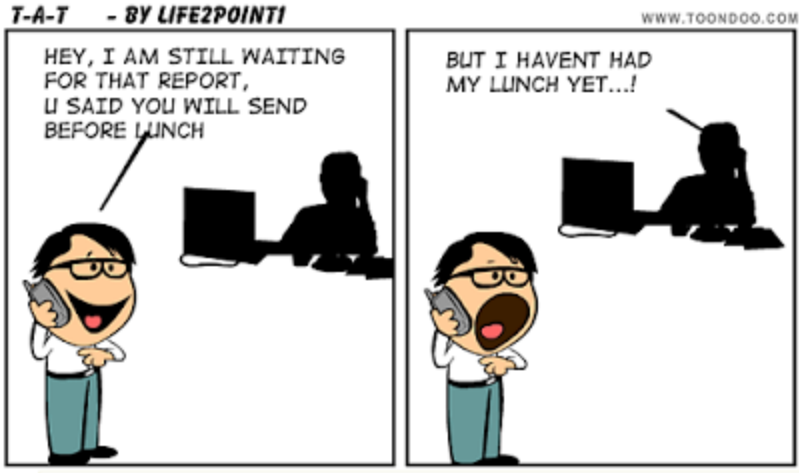
Post analytical errors

1. Post analytical data entry error— transcription error
2. Turn around times– date results entered onto the web
3. Clinician or other provider fails to retrieve test result – non return
4. Failure to communicate critical value
5. Provider misinterprets lab result
6. Misinterpretation of results by requester
7. Oral miscommunication of results



Impact of laboratory errors (on post post-analytical phase)

- Mismanagement of patient
- Misdiagnosis
- Incorrect/inappropriate treatment
- Lack of treatment
- Delay in treatment
- 24-30% of laboratory errors have affect on patient care, 3-12% cause potential or actual patient harm

Plebani 2010, Hawkins 2012

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Documentation and Maintenance of Records

- Maintenance of all records provide documentation which may be required in the event of legal challenges due to repercussions of decisions based on the original analytical results.
- General guidelines followed in regulated laboratories is to maintain records for at least five years

Important questions to be answered for any analytical instrument

- What is the equipment being used for?
- Is the instrument within specification and is the documentation to prove this available?
- If the instrument is not withinspecifications, how much does it deviate by?
- If the instrument is not within specifications what action has been taken to overcome the defect?
- Can the standards used to test and calibrate the instrument be traced back to national standards?

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Good Lab practices…….to state a few more:

- Good housekeeping
- Lab maintained clean and clutter free
- PPE
- Do not work alone
- Store chemicals and reagents according to manufacturers instructions
- Equipment used correctly
- Fire exits clear

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Group Exercise

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Possible non compliances

- Failed QC during analytical procedures
- Incorrect result reported to requestor
- Incomplete documentation for processes
- Failure to follow up and document non compliances in real time
- Failure to prepare, retain, or submit written records required for accreditation standards
- ‘doctoring’ information related to testing~ protocols, ingredients, observations, data equipment, etc.

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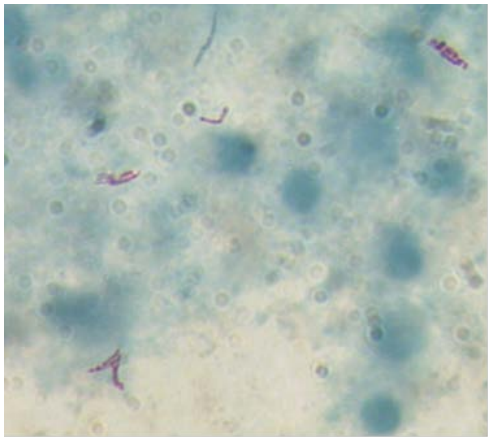
NON compliances

- Incorrect result reported
- Report to requestor
- Discuss the non conformance with whom?

What do you do first?

- Who was involved?
- Why?
- When?
- Where?
- What?
- How?
- Investigate
- Correction action
- Impact of non conformance



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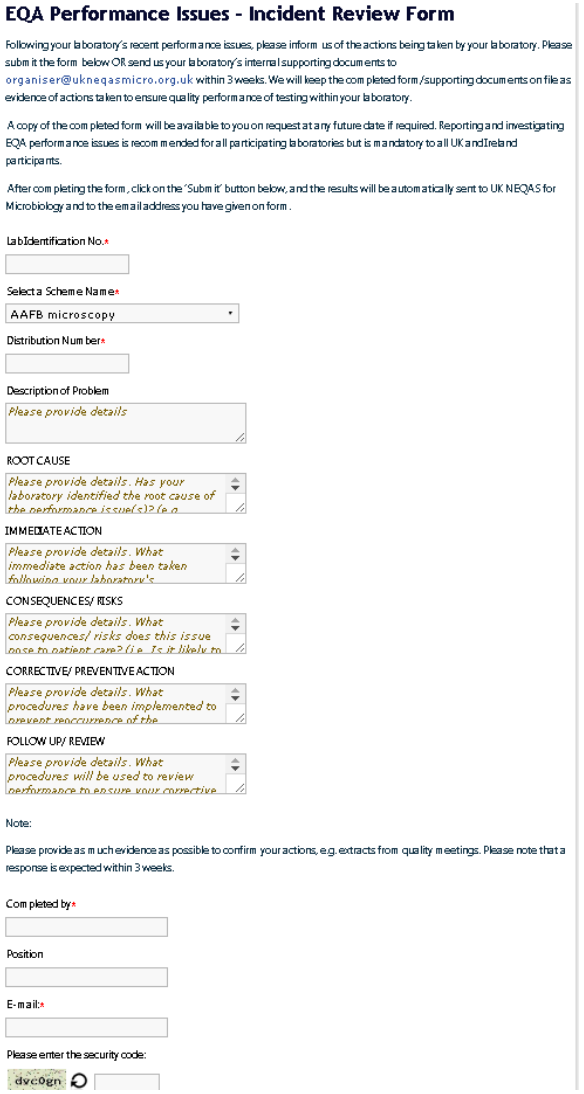
EQA Performance Issues - Incident Review Form

- Lab Identification No.
- Scheme Name
- Distribution Number
- Description of Problem
- ROOT CAUSE
- IMMEDIATE ACTION
- CONSEQUENCES/ RISKS
- CORRECTIVE/ PREVENTIVE ACTION
- FOLLOW UP/ REVIEW
- Completed by
- Position
- E-mail



EQA Performance Issues - Incident Review Form

Following your laboratory's recent performance issues, please inform us of the actions being taken by your laboratory. Please submit the form below OR send us your laboratory's internal supporting documents to organiser@uknegasmicro.org.uk within 3 weeks. We will keep the completed form/supporting documents on file as evidence of actions taken to ensure quality performance of testing within your laboratory.

A copy of the completed form will be available to you on request at any future date if required. Reporting and investigating EQA performance issues is recommended for all participating laboratories but is mandatory to all UK and Ireland participants.

After completing the form, click on the 'Submit' button below, and the results will be automatically sent to UK NEQAS for Microbiology and to the email address you have given on form.

Lab Identification No.*

Select a Scheme Name*

AAFB microscopy

Distribution Number*

Description of Problem

Please provide details

ROOT CAUSE

Please provide details. Has your laboratory identified the root cause of the performance issue(s)? (e.g.

IMMEDIATE ACTION

Please provide details. What immediate action has been taken following your laboratory's

CONSEQUENCES/ RISKS

Please provide details. What consequences/ risks does this issue pose to patient care? (i.e. Is it likely to

CORRECTIVE/ PREVENTIVE ACTION

Please provide details. What procedures have been implemented to prevent reoccurrence of the

FOLLOW UP/ REVIEW

Please provide details. What procedures will be used to review performance to ensure your corrective

Note:

Please provide as much evidence as possible to confirm your actions, e.g. extracts from quality meetings. Please note that a response is expected within 3 weeks.

Completed by*

Position

E-mail:*

Please enter the security code:

dvc0gn