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Post analytical challenges in Microbiology

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UK NEQAS for Microbiology

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The laboratory

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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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Define the patient's context

- With data provided to information decided
- Context is defined as:

'Patient-specific data and the clinician's hypothesis to be tested concerning the patient's medical problem'

Goldschmidt 1995

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Brain to Brain Loop Process

- Lundberg created a concept 40 years ago, to encompass the thought processes involved from the brain of requesting clinician, to the brain of laboratory staff to the brain of clinician providing an overall laboratory test result.

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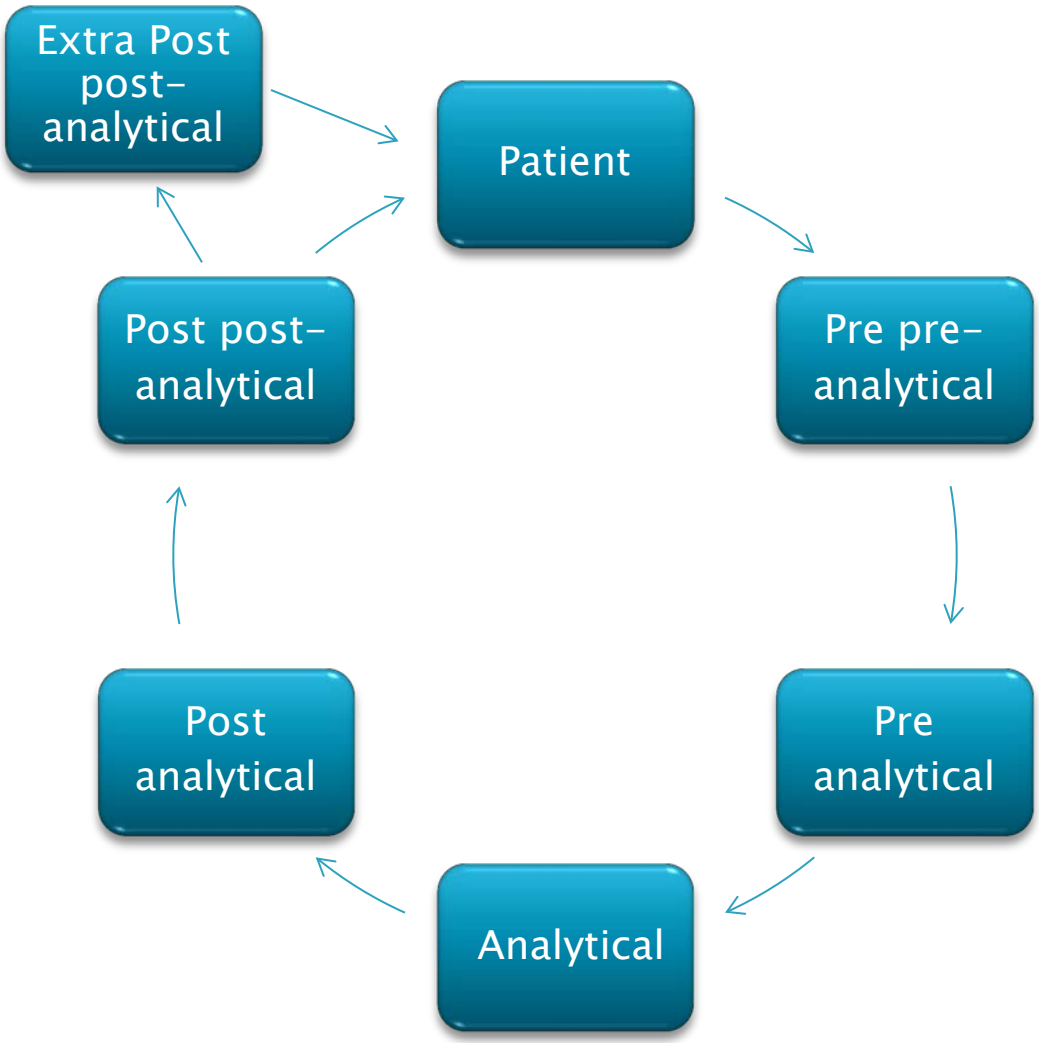
Total Testing Process



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Laboratory Errors

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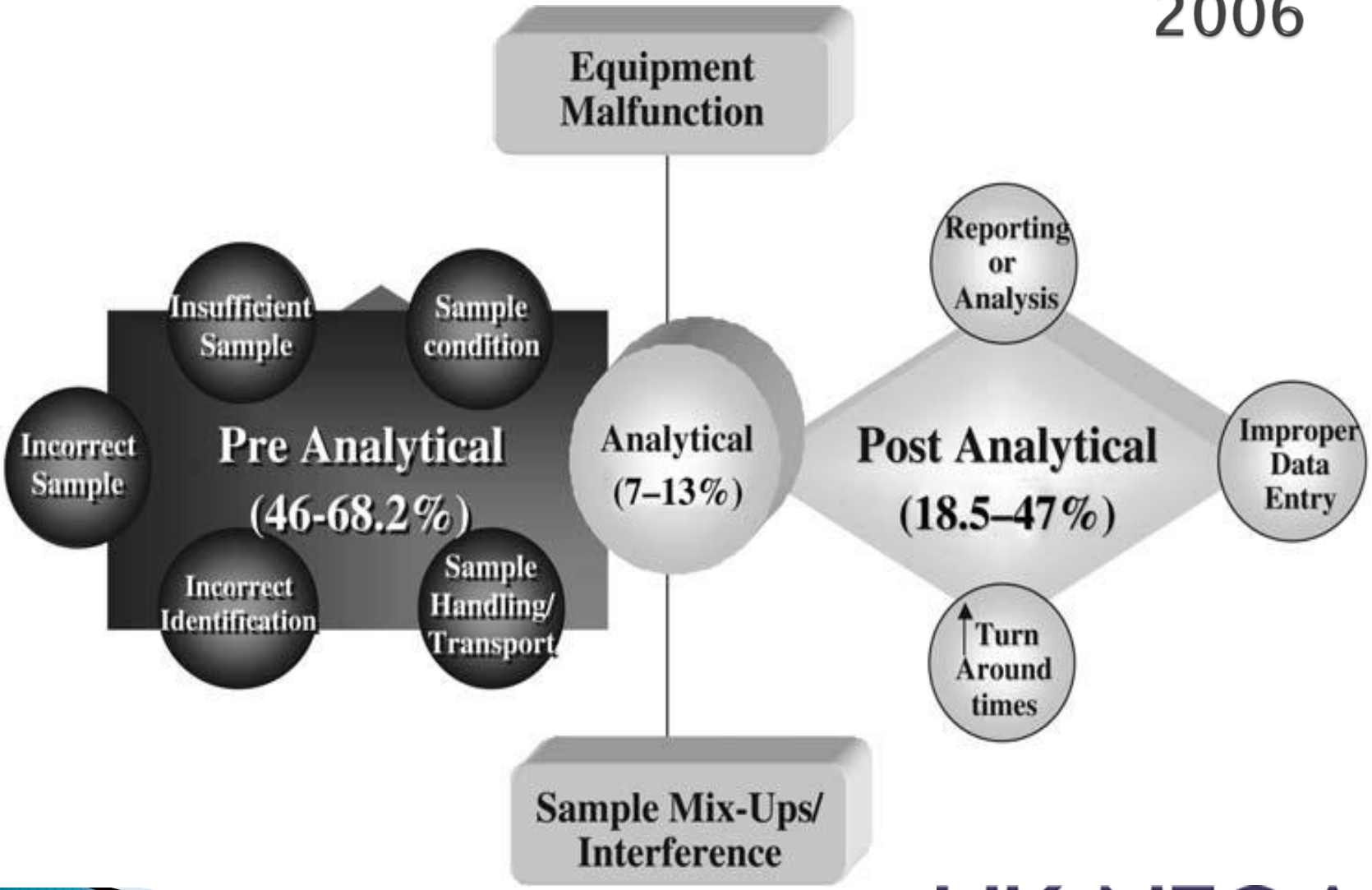
Laboratory Errors

Most errors are due to pre-analytical factors while a high error rate of total errors have been found in the post analytical phase compared to the analytical phase

- Bonini et al Clin Chem 2002: 48 691-698
- Plebani Clin Chem lab 2006; 44 750-759
- Plebani Ann Clin biochem 2010: 47 101-110
- Hawkins Ann Lab Med 2012: 35 5-16

Plebani
2006



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Definition of post analytical

- The ultimate check on the consistency of pre and intra analytical quality can be considered as the overall quality---**the result**
- Literature defines as post and post-post analytical process
- Post analytical: one phase performed within the laboratory
- Post post-analytical: in which the clinicians receive, interpret and react to laboratory results.

Post analytical errors

1. Post analytical data entry error
2. Misinterpretation of results
3. Oral miscommunication of results
4. Turn around times
5. Clinician or other provider fails to retrieve test result
6. Failure to communicate critical value
7. Provider misinterprets lab result

Cognitive errors

- A smaller percentage of errors are due to the lack of knowledge
- A Galactomannan (GM) index of 0.6
- What does that mean? *Is it a true positive*? *Does one repeat the test? Ask for a repeat? Report this result urgently?*
- Report on the heavy isolation of *Pseudomonas aeruginosa* in a wound (deep seated abscess) swab
- *Report as pathogen?*
- Consult standard microbiology investigations
- Check clinical details

Non-cognitive errors

- Due to interruption or lapse in a normally automatic task

can be exacerbated by

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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Post Analytical Errors

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1.Transcription errors (n=21) 2013-2014

Type of error	Number
Misinterpretation of susceptibility (disk diffusion)	8
Transcription Error from report to website	5
Misinterpretation of automated susceptibility result	3
Specimen results switched	2
Inexperience staff reporting result	1
Results reported in incorrect units	1
Lack of attention to detail	1

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2. Misinterpretation of results

- In our Antimicrobial Susceptibility EQA scheme

- There are some differences in the reporting of susceptibilities--

  (dependant on the guidelines followed).

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2. Misinterpretation of results

For example: *Staphylococcus* species

Clindamycin susceptibility exhibiting induced resistance in the presence of a macrolide.

Susceptible

Resistant

Susceptible (Dissociated Resistance)

Resistant (Dissociated Resistance)

- Both EUCAST and CLSI **currently** recommend that staphylococci with dissociated resistance to clindamycin should be reported resistant.

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3. Oral miscommunication of results

- Clinician calls the lab for a GM ELISA test result
- The scientist communicates a previous negative result, rather than the current positive result

Consequence

- Patient does not receive appropriate management and urgent antifungal empirical therapy

  as results not considered in diagnosis

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4. Turnaround times (TAT) - results delivery

- Distributions sent in October and November 2014 , and TAT were collated and analysed
- Three week period to return results
- Not a true reflection of current laboratory practice, in treating EQA specimens as clinical samples

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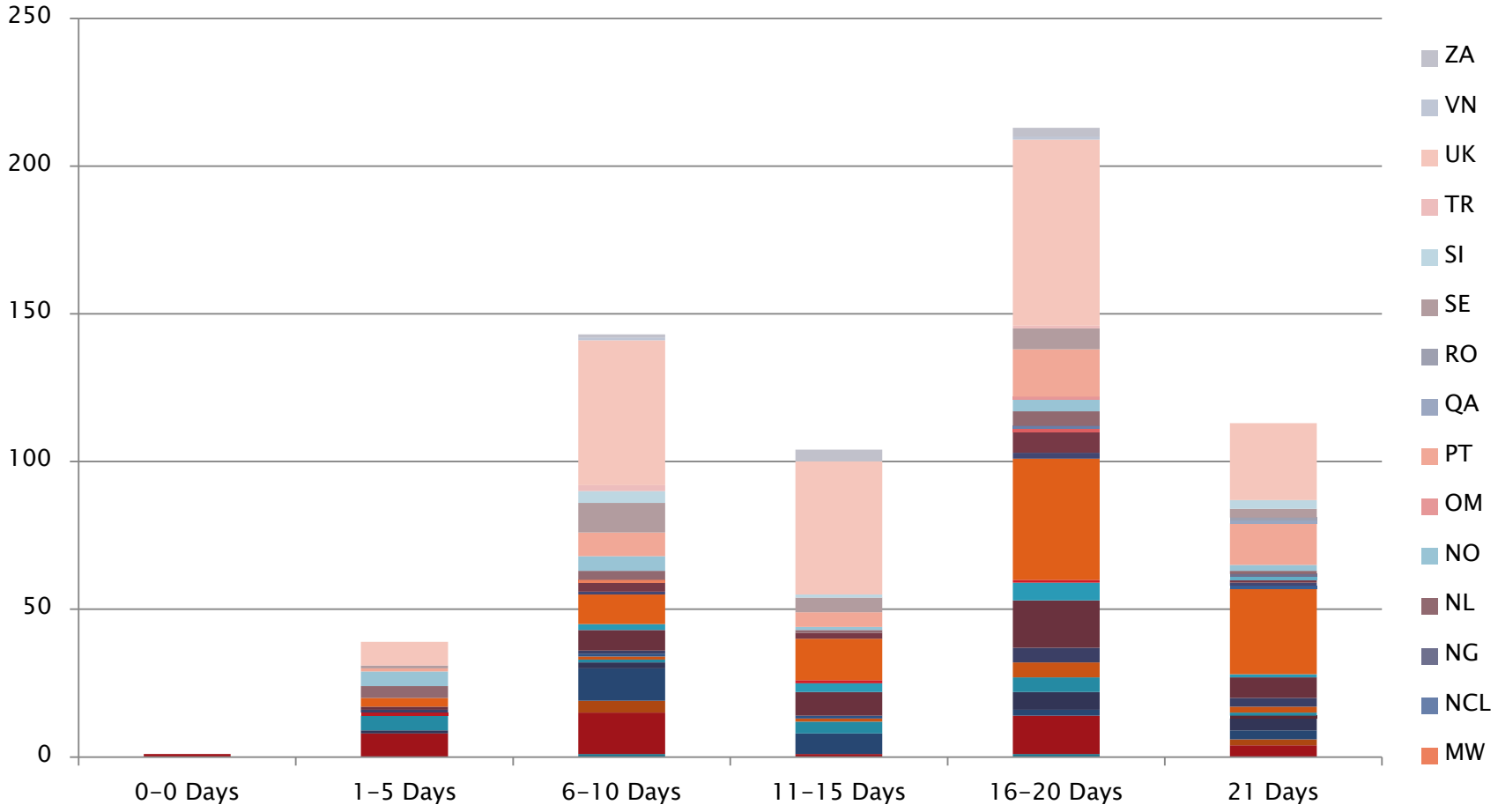
UK NEQAS:General bacteriology distribution 3554 October 2014



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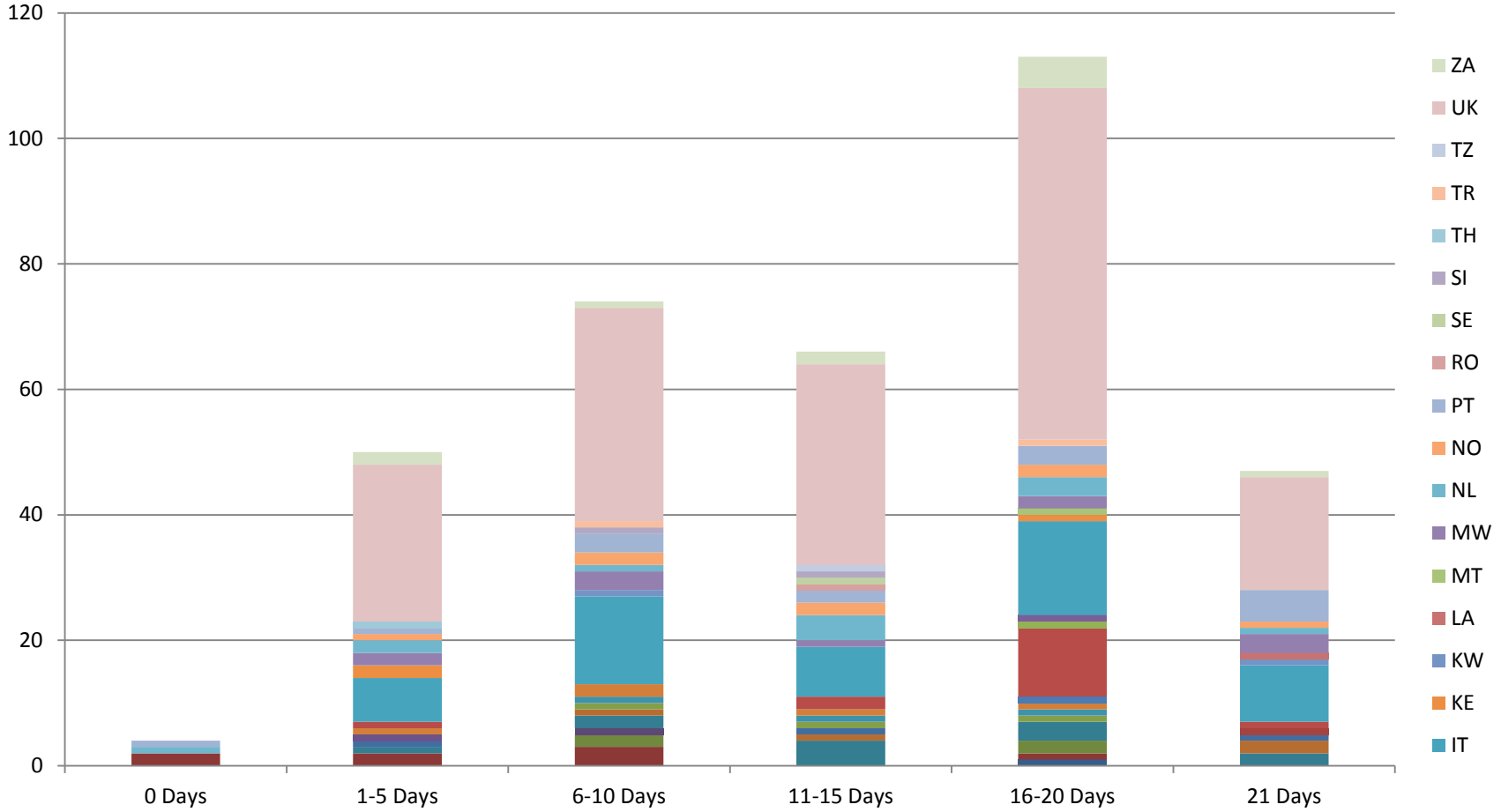
UK NEQAS:General bacteriology distribution 3560 November 2014



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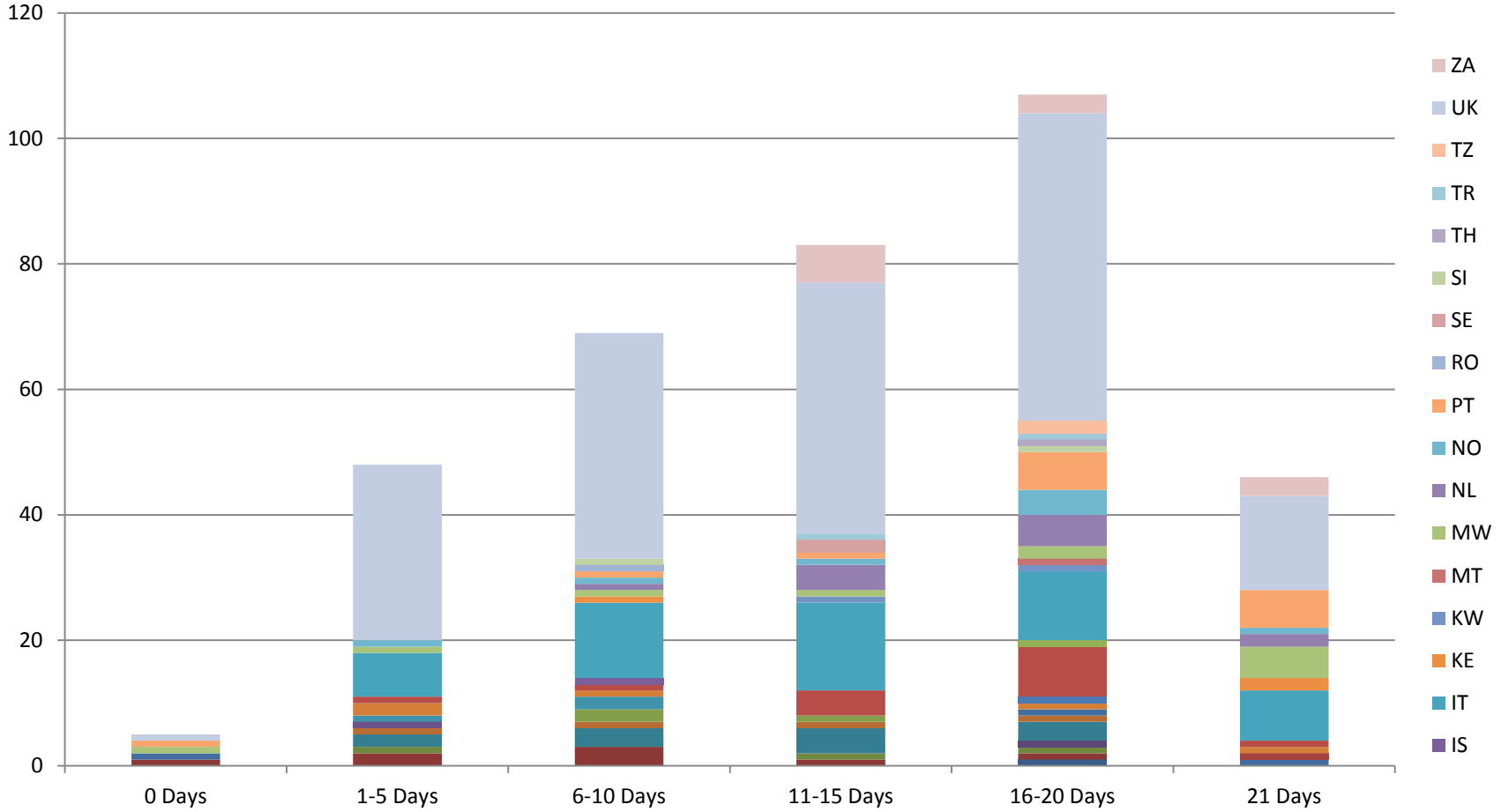
AAFB microscopy distribution 3519 (Sept 2014)



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5. Failure to receive/retrieve results

Example:

- Clinician orders a test for *C. difficile*, and forgets to retrieve it.

Consequence

- By the time the result, which is positive, reaches a provider, the hospitalised patient has had serious complications from diarrhoea

- Occurs for approximately 5% of tests and a significant source of post analytical error.

Hawkins 2012

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Critical values

- The use of different, sometimes erroneous, reference intervals may markedly affect the clinical interpretation of laboratory data, leading to errors in clinical decision-making

Critical values: Misinterpretation

- The ELISA for the detection GM antigen has been recently introduced as a fungal bio marker for diagnosis of invasive aspergillosis in conjunction with other diagnostics tests (radiotherapy/histopathology).
- The critical index of >=0.5 defines the presence of circulating antigen in the patient
- This index was originally set at 1.5 and has been reduced to 1.0 and now set at 0.5

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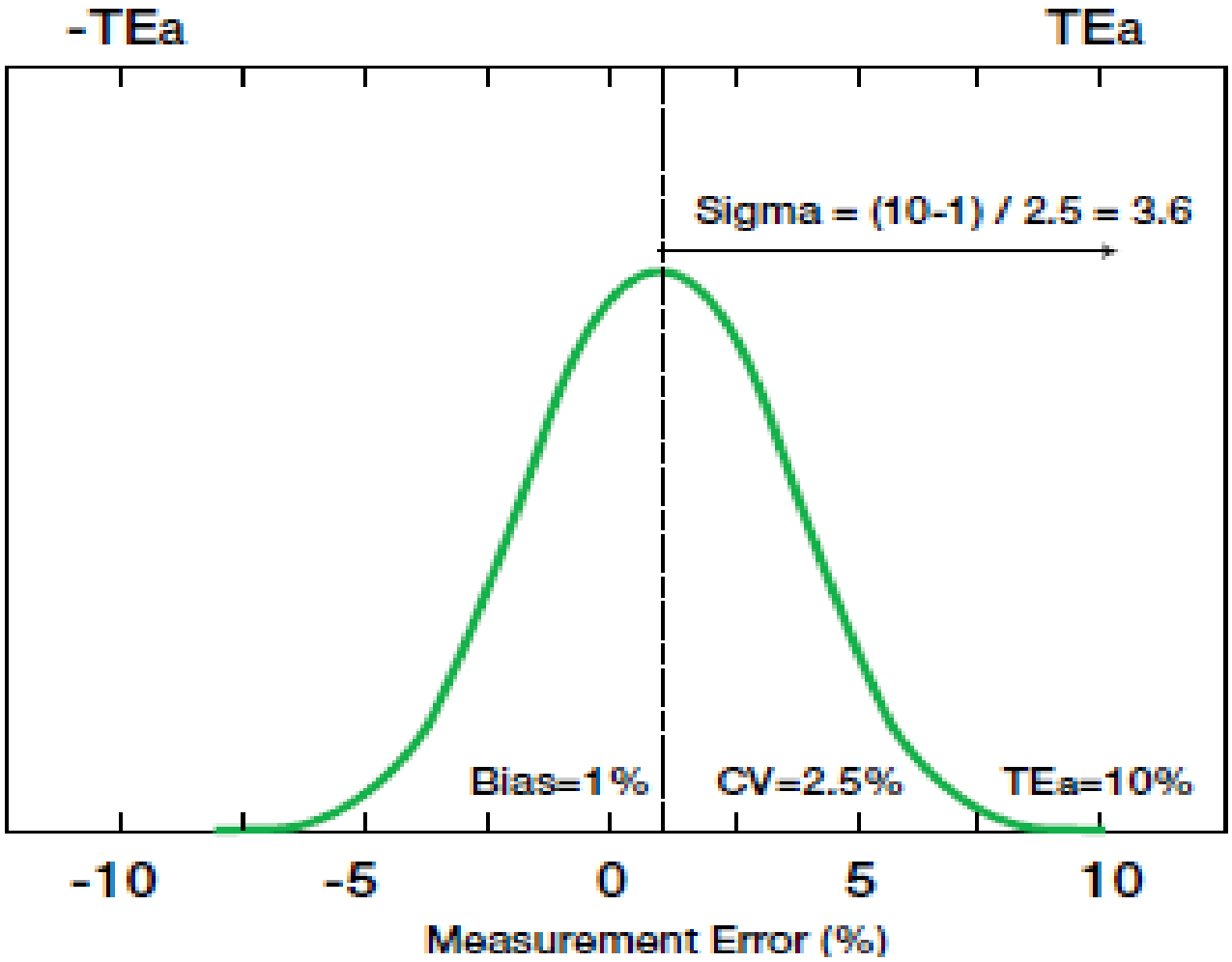
Sigma

- Laboratory quality specifications are often defined in terms of allowable total error limits (TE_a)
- If the difference between the true concentration of an analyte and the reported concentration in a patient's specimen exceeds TE_a the result is considered unreliable
- The sigma metric expresses the number of analytical standard deviations of the test system process that fit within the specified allowable total error limits

Sigma values in the laboratory



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Interventions

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Possible interventions

- **Weak**: Retrain the scientists
- **Intermediate**: Raise non compliance; review documentation, conduct an audit
- **Strong:** Results centralised (call centre) provides results, redesign or results screen for requesting clinician (automation)

Automation

- Most laboratory results are collated and managed by a sophisticated computer system capable of sending electronic reports to the health care provider by direct transfer to the GP's computer or hospital information system
- Some sophisticated systems can alert scientific staff of an unusual finding, e.g. a critical value.
- Laboratory reports generated by information systems can also highlight values outside the expected or reference range to help the clinician focus on the tests that are of most concern

Quality Management

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ISO standards

ISO technical specification documentation:

- allows to achieve a consensus on the definition of the classification of laboratory errors
- importance of implementing and reviewing corrective and preventative actions

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EN ISO 15189: 2012

ISO 15189 documentation stipulate post examination process requirements

- Reporting of results
- Report attributes and its contents
- Release of results
- Use of automation for generation of reports
- Production and release of results from the laboratory

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Post Post Analytical Phase (quality management)

- Includes the review and evaluation of the effectiveness of the corrective actions
- Procedures and policies to prevent recurrences
- Accuracy and completeness of results and reports
- Disposition of unacceptable specimens and turnaround times.

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Reducing errors: Improve in Quality

- Quality Control procedures
- Quality assessment service providers
- Accreditation of laboratories
- Certification of Educational programmes

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Root Cause Analysis

- Root Cause Analysis (RCA) is based on a retrospective analytical approach
- Focuses on identifying the latent conditions underlying variation in medical performance
- Developing recommendations for improvements to reduce the probability of a similar incident occurring in the future

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UK NEQAS schemes

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Interpretative comments

- The role of interpretative comments in improving patient outcomes has been acknowledged
- UK NEQAS for Microbiology deliver an interpretative comments scheme to provide the opportunity for medical personnel to participate in inter-laboratory communication on previous clinical case reports
- The results obtained indicate that interpretation provided by laboratory professionals with inadequate expertise can be detrimental to the care of the patient, and highlight the need for improvement in the standard of interpretation
- The possibility of Interdepartmental cooperation (Round robin testing) may help avoid errors in medical laboratories
- Is available free of charge to medical personnel registered to UK NEQAS schemes.

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Pan UK NEQAS
(pre and post monitoring- PREPQ)

- Assessing provision of a pre and post analytical monitoring service in all disciplines of laboratory medicine.
- An aspect of the quality management to investigate post analytical errors.
- Investigate variable factors:
  - age of specimen
  - quality of specimen e.g correct specimen type
    volume received
  - type of test performed (appropriate tests requested)
  - turn around time (time taken to reporting results)
  - interpretation of results (correct/incorrect)
- Data collated presently on the pre-pilot distributions

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Conclusions

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Conclusions

- The total testing process is the unique framework in revealing and resolving errors in laboratory medicine
- Implementing a quality management system to investigate systemic and random errors in the post analytical phase
- Monitoring performance of the laboratory and skills of scientific and medical staff
- Use of comprehensive equipment
- Adhering to turn around times (TAT)
- Use auto validation and verification (where possible)
- Consultation

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Thank You For Listening

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