Pitfalls and impact of POCT in the Diagnostic Micro Lab:

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Personal Beliefs

• Support use of POCT in Micro laboratory
  – <TAT, results backed by quality systems & trained staff
• Believe that microbiology can be more timely clinically relevant
• Early ID, early Rx, better patient survival, fewer antibiotics, <MRO,
Definition

• Point-of-care testing (POCT), is medical testing at or near the site of patient care.
• These are simple medical tests which can be performed at the bedside. eg, urine test strips and imaging (with a portable ultrasound device) and regular observations such as ECG's
POCT in the Diagnostic Laboratory

- Oxymoron **BUT**
- **Lab** staffed by scientists who understand quality systems, can interpret results and communicate findings
- **Clinics**: busy, staff minimal training, no QA, no dedicated space, ? Interpretation, recording & reporting?
Antonie van Leeuwenhoek 1632–1723

Louis Pasteur 1825–1895

Sir Alexander Fleming 1881–1955
The Past, Present, & Future of POCT

“Everything old is new again” by Peter Allen (1944 – 1992), Australian songwriter & entertainer.

Bedside → Central laboratories → POCT
In the beginning....

all testing was performed near the patient.

a. By 1500 BC urine was noted in relation to diabetic symptoms in Egypt (ants were attracted to the sweetness of urine)

b. One of the earliest diagnostic practices was uroscopy, in which urine was visually examined and assessed for sweetness by tasting!
Then...

• Testing moved to central laboratories as hospitals were built (1800-1900’s) and testing technologies were developed
And...

- Need for simple, robust testing tools in:
  - developing countries
  - other sites, e.g.
    - military
    - disaster,
    - underserved (rural or remote) populations.
<table>
<thead>
<tr>
<th>Diagnostic Method</th>
<th>Time for Pathogen Identification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microscopy</td>
<td>Morphology in minutes</td>
</tr>
<tr>
<td>Gram stain</td>
<td>General category in minutes</td>
</tr>
<tr>
<td>Culture and phenotypic biochemistry on/in artificial media (bacterial, mycobacterial, fungal)</td>
<td>Days to weeks</td>
</tr>
<tr>
<td>In vitro antimicrobial susceptibility</td>
<td>Days to weeks</td>
</tr>
<tr>
<td>Acute and convalescent antibody</td>
<td>Weeks</td>
</tr>
<tr>
<td>Monoclonal antibodies</td>
<td>Hours</td>
</tr>
<tr>
<td>Antigen detection</td>
<td>Minutes to hours</td>
</tr>
<tr>
<td>Real-time polymerase chain reaction for microorganisms and drug resistance genes</td>
<td>One to several hours</td>
</tr>
<tr>
<td>Mass spectrometry</td>
<td>Seconds to minutes, after growth on/in media</td>
</tr>
</tbody>
</table>
Clinician DEMANDS

- Faster turnaround times & testing platforms to facilitate patient care (e.g. ICUs, POLs)
- Creation of specialty clinics (STD, ED)
- Desire for self-testing & patient control
- Mergers and reorganizations of healthcare systems, (decreased numbers of central laboratories, further apart)
Then....

• Shifts from the central laboratory to POCT and steady growth in the type and number of POC tests performed (late 1900’s to date) due to:
  • Technological advancements including:
    – 1. Method and operation simplification
    – 2. Lockouts and failsafe mechanisms
    – 3. Electronic quality control
    – 4. Interconnectivity with IS
    – 5. Portability
Economic barriers

• Fees
• Cost per test
• Markup fees
• Funding
• Insurance cover
Challenges for non lab POCT

• 1. Gaining physician and nurse support/education
• 2. Teaching non-laboratorians about QC
• 3. Interpretation, communication and reporting of results
• 4. Reducing transcription errors
Challenges (cont)

- Microbes are evolving.
- Crisis in medical technology education,
- The aging pathology workforce,
- Difficulty in recruiting and retaining technologists have resulted in fewer technical specialists in anaerobic bacteriology, mycology, mycobacteriology, and parasitology
Management Challenges

• Responsibility, Location
• Staff training and competency maintenance
• Reliability of POCT results (sensitivity/specificity)
• Quality Control
• Costs
• Interdisciplinary collaboration
POCT Challenges for End Users

• Data Management
• Noncompliance with procedures (specimen labeling, QC, proficiency testing etc.)
• Interpretation
• Reporting/recording
• Infection Control
• Billing
IDSA Policy document

- Improved Infectious Diseases Diagnostics • CID 2013:57 (Suppl 3) • S139
- Tests should be easy to use and provide a rapid result (ideally within an hour) to have a positive impact on care
- Results must be effectively communicated
Diagnostics

• have a tremendous impact on the management of patients with infectious diseases
• are essential for outbreak detection and response, and
• public health surveillance
Test selection

- T/S vv NPA vv NPS, cotton vv flocked,
- ` Ag vv PCR
Where to perform?

- At bed side?
- In Clinic/ED?
- Remote site?
- Theatre?
- Other?
Who performs test?

- Doctor?
- Nurse?
- Scientist/Technician?
- “assistant”
- Student?
Tip 1 Specimen Collection

• Most laboratory errors (~60%) are associated with pre-analytical issues:
  – Incorrect test request
  – Poor or incorrect sample
  – Failure to identify sample
  – Failure to ensure that the sample comes from the patient
  – Transport delays

• Ref: Plebanic M Detection and prevention of errors in laboratory medicine Ann Clin Biochem 2010;47:101-110
Actions

• 1. training of collectors
• 2. simple clear instruction manual (on line)
• 3. feedback
• 4. “Rulz”
• 5. regular and timely reviews of the testing processes
Tip 2 Specimen ID

- Label specimen at time of collection!
- Sign sticky label?
- Handwrite label?
- Check that label and patient match!
Actions

• Coordinated whole of laboratory approach
• Electronic Record of failures to comply
• Regular audit of failures
• Training/workshops
Tip 3 QA/Controls

• Clinical staff do not understand quality procedures!
• Exclude testing from scope of clinical practice unless in a remote area
• Training, audit and feedback
  – Kit storage requirements and monitoring,
  – use and interpretation of controls,
  – labelling
  – Waste disposal
Tip 4 Training/Competency

• Essential for all staff
• Should be accompanied by certification
• Regular and additional if new tests implemented
• (estimated that analytical errors 0.002%)
Tip 5 Interpretation

• Knowledgeable staff performing tests according to set procedures using in date and quality controlled tests that have been stored according to manufacturers instructions
  – Not in cupboard if require refrigeration
  – Lid tightly closed to prevent moisture absorption
• Reason for test, interpretation of the result according to pre-test cut off
• Sensitivity and specificity of test known
Tip 6 Reporting/recording

• An unrecorded test is useless
• The clinician needs to receive and acknowledge the result
  – Message
  – Email
  – Screen
  – LIS
• Critical result handling processes need to be in place
POCT in Diagnostic Micro lab

• Can provide a rapid result compared with C&S
• Assist with antibiotic selection, antimicrobial and pathology stewardship
• Ensure appropriate PPE and patient isolation to prevent cross infection

• BUT
Accredited laboratory

• Need cheap, sensitive and specific tests
• Processes in lab needed to facilitate TAT
• Knowledgeable staff
• Interdisciplinary collaboration
• Management support
• Clinical support/communication
• Budget/funding stream
Micro lab of the future

• Rapid TAT with relevant & accurate “field POCT) results” (eg WW)
• Research back up for AMS, organism ID, emerging trends, audit, sample repositories, world wide collaboration
• “Tiered laboratories”
• Reliable infrastructure, QA & training