Slide 1

POINT-OF-CARE TESTING: WHAT IS THAT ANYWAYS?

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OBJECTIVES

1. Define Point-of-Care Testing.
2. Recognize some commonly used POC tests.
3. Discuss advantages & disadvantages of POCT.
4. Discuss assessment of competency.

Slide 3

EARLY POINT-OF-CARE

- Many of the early *diagnostic tests* were first done at the bedside.
- Laboratory medicine began 6000 years ago with uroscopy.
  - Sumerian and Babylonian physician (4000 BC)
  - Ancient Sumer
  - Sanskit medical works (100 BC)
  - Hindu cultures
  - Areteus (2nd century)

Slide 4

EARLY POINT-OF-CARE

- Theory of disease causation
- Hippocrates (460-355 BC)
- Galen (AD 129-200)
- The Middle Ages (AD 500-1500)

Slide 5

WHAT IS POINT-OF-CARE TESTING?

As defined by CAP:
- Tests designed to be used at or near the where the patient is located
- Doesn't require permanent dedicated space
- Tests performed outside the clinical lab

POCT does NOT include limited service satellite laboratories with fixed dedicated testing space.

Source: College of American Pathologists

Slide 6

POINT-OF-CARE IS ALSO...

- Chemistry
- Hematology
- Coagulation
- Urinalysis
- Microbiology
- Phlebotomy
- Administrative
- IT
- Materials Management
- Maintenance

POCT IS EVERYWHERE...

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CLIA 88

- All facilities or sites in the US that conduct diagnostic testing or medical treatment using human specimens are subject to regulation under CLIA 88.

Source: Centers for Medicare and Medicaid Services

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WAIVED

Waived:
- A category of tests defined as "simple lab examinations and procedures which have an insignificant risk of an erroneous result."

Source: Centers for Medicare and Medicaid Services

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NONWAIVED

Nonwaived:
- Tests categorized as either moderate complexity (including provider-performed microscopy) or high complexity according to a scoring system used by the FDA.

Source: Centers for Medicare and Medicaid Services

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REQUIRED FEATURES OF POCT DEVICES

1. Simple to use
2. Reagents & consumables: robust & durable
3. POCT results align with established lab methods
4. Safe for use

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MORE SPECIFIC CRITERIA...

- Various guidelines exist for particular clinical settings
- ASSURED Guidelines by WHO
  › **A**ffordable
  › **S**ensitive
  › **S**pecific
  › **U**ser friendly
  › **R**apid and **R**obust
  › **E**quipment free
  › **D**elivered

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ADVANTAGES & DISADVANTAGES

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ADVANTAGES

- Neonatal & pediatric population
- Patients requiring frequent testing

Volume of specimen	Large test menu	Convenience	Clinical Outcomes	Portability	Turnaround time

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ADVANTAGES

- Fecal occult blood
- Gastric occult blood
- Urine dipsticks
- UPTs
- Rapid Strep
- Rapid Flu
- Cholesterol
- Blood gas
- ROM kit
- ACTs
- Troponins
- BNP
- Drugs of Abuse
- INR
- Ketones
- Chem8
- Lactate
- TEG
- Bedside glucoses
- and so much more....

Volume of Specimen	Large test menu	Convenience	Clinical Outcomes	Portability	Turnaround Time

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ADVANTAGES

- POCT brings convenience to the physician and patient

Volume of specimen	Large test menu	Convenience	Clinical Outcomes	Portability	Turnaround Time

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ADVANTAGES

- Use of POC testing can improve clinical outcomes
  - › Faster decision making
  - › Starting treatment early
  - › Improved adherence to treatment
  - › Patient satisfaction

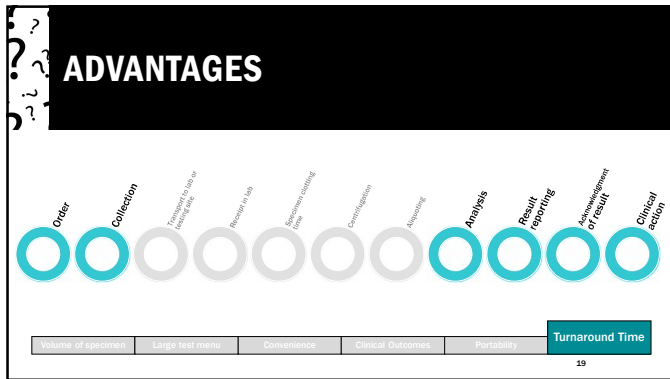| Volume of specimen	Large test menu	Convenience	Clinical Outcomes	Portability	Turnaround Time

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ADVANTAGES

- Allows for increased access to testing in a wider variety of settings
  - › Rural areas
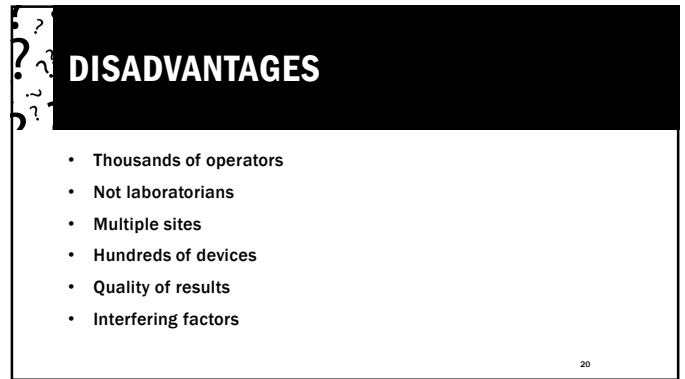 - › Accident sites
  - › Underserved populations

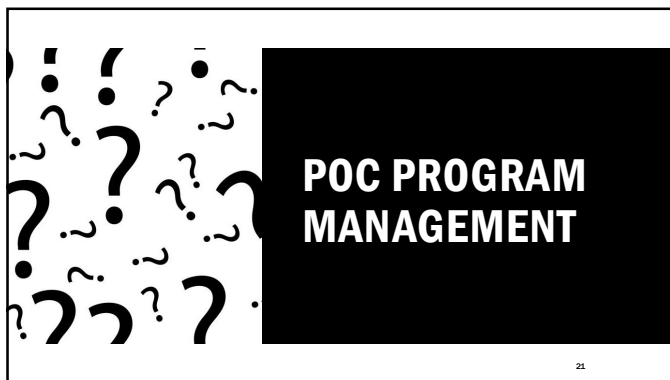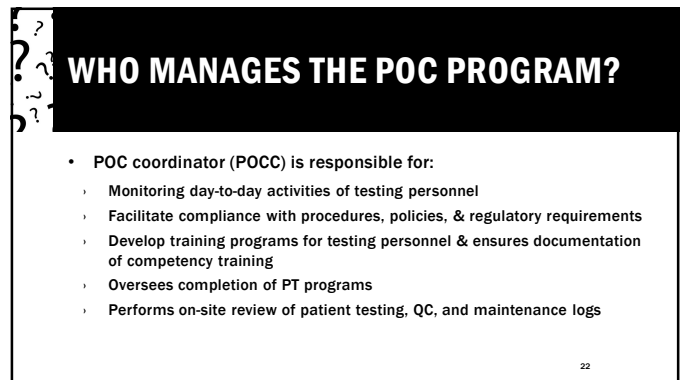| Volume of specimen	Large test menu	Convenience	Clinical Outcomes	Portability	Turnaround Time

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ADVANTAGES

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DISADVANTAGES

- Thousands of operators
- Not laboratorians
- Multiple sites
- Hundreds of devices
- Quality of results
- Interfering factors

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POC PROGRAM MANAGEMENT

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WHO MANAGES THE POC PROGRAM?

- POC coordinator (POCC) is responsible for:
  › Monitoring day-to-day activities of testing personnel
  › Facilitate compliance with procedures, policies, & regulatory requirements
  › Develop training programs for testing personnel & ensures documentation of competency training
  › Oversees completion of PT programs
  › Performs on-site review of patient testing, QC, and maintenance logs

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TRAINING

- Training is what happens before someone begins patient testing and prior to reporting patient results.
- Training should include:
  - Pre-analytic, analytic, and post-analytic phases of testing on all instruments, methods, and specimen collection techniques.
- More education & training produce higher quality results.

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WHO REQUIRES COMPETENCY ASSESSMENT?

- EVERYONE!
  › AABB
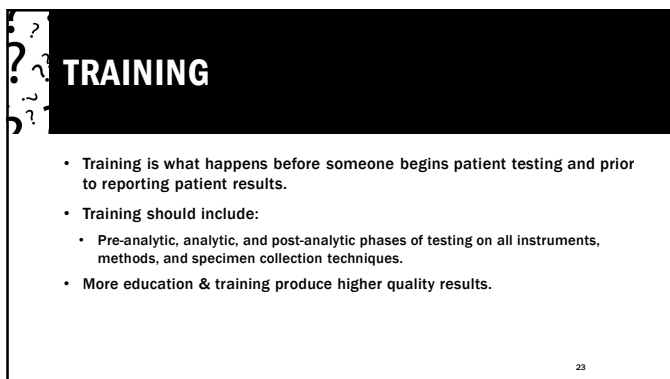 › FDA
  › Joint Commission
  › CMS
  › CAP
  › State regulations

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WHAT IS COMPETENCY & COMPETENCY ASSESSMENT?

- Competency: *the ability of personnel to apply their skill, knowledge, and experience to perform their laboratory duties correctly.*
- Assessment: *is used to ensure the laboratory personnel are fulfilling their duties as required by federal regulation.*

Source: Centers for Medicare and Medicaid Services

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WHAT IS REQUIRED FOR COMPETENCY ASSESSMENT?

The following six procedures are the *minimal* regulatory requirements for assessment of competency for all personnel performing **nonwaived** laboratory testing:[5]

1. Direct observation of routine patient test performance
2. Monitoring the recording and reporting of test results
3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records
4. Direct observations of performance of instrument maintenance and function checks
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples
6. Assessment of problem-solving skills

Source: College of American Pathologists

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HOW OFTEN DOES COMPETENCY ASSESSMENT HAVE TO BE PERFORMED?

For **nonwaived testing**:

- At least semiannually (first assessment within 7 months from the start of testing and second assessment no later than 12 months from the start of testing) during the first year (*new employee*)
- At least annually after testing personnel has performed assigned duties for one year
- When problems are identified with an individual's performance

Source: College of American Pathologists

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HOW OFTEN DOES COMPETENCY ASSESSMENT HAVE TO BE PERFORMED?

For **waived testing**:

- After an individual has performed his/her duties for one year and at least annually thereafter
- When problems are identified with an individual's performance

If more stringent state or local regulations are in place for competency assessment for waived testing, they must be followed.

Source: College of American Pathologists

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CHALLENGES OF POCT

- Accreditation & federal requirements
- Manual POCT results
- Training/competency for large number of testing personnel
- POCT reagents & supplies
- QC performance and documentation
- Proper identification of patient and/or testing personnel
- Cleaning & disinfection of devices

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COMMUNICATION & RELATIONSHIPS

Communication and building relationships are important for a successful POC program.

› Regular inspections at POC sites
› Relationships with work care facilities, department managers, & operators

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THANK YOU FOR LISTENING!

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