Patient Safety: A Quality System Approach To POCT QC/QA

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Point-of-Care Testing Characteristics

A broad based process.

Unrestricted to location, personnel or test menu.

A collective, multi-disciplinary effort.

Simple to use technology

Potentially low volume testing

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POCT versus Central Lab Testing

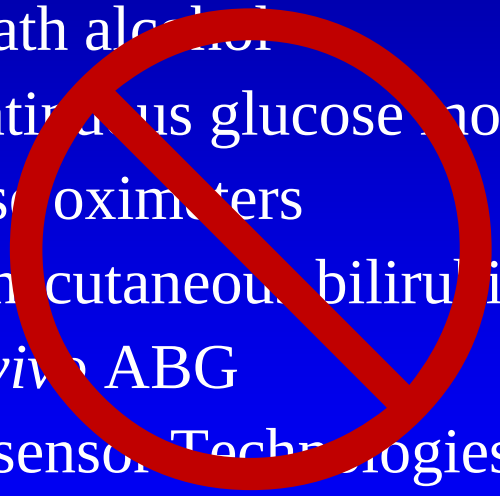
	Central Lab	POCT
Testing personnel	Pathologists,, PhDs, Med. Lab Technologists	Nurses, other care givers
Primary duties	Laboratory testing	Patient care
Knows laboratory testing	Extensive	Minimal
Understands instrument's quality checks	Extensive	Minimal
Can interpret QC data	Yes	Probably not
Skills to resolve problems, troubleshooting	Yes	No
Recognizes quality testing	Yes	Not necessarily

Potential Analytes for POCT

- Bilirubin
- Blood Gases
- BUN
- Cardiac Markers
- CBC
- Chloesterol/Trigs
- Drugs
- Fecal Occult Blood
- Gastric Occult Blood
- Glucose
- Gram Stains
- HgB/Hct
- HgB A1C
- Infectious Diseases
- Lactate
- Na, K, Ca^{++}, Cl, Mg^{++}
- O_2 Sat
- Platelet Function
- Pregnancy
- PT/PTT/ACT
- Urinary microalbumin/creatinine
- Urinalysis/Specific Gravity

Point-of-Care Tests (POCT)

- NOT considered laboratory testing
  - Breath alcohol
  - Continuous glucose monitors
  - Pulse oximeters
  - Transcutaneous bilirubinometers
  - *Ex vivo* ABG
  - Biosensor Technologies (monitors)



2001
Predicted Growth in POCT

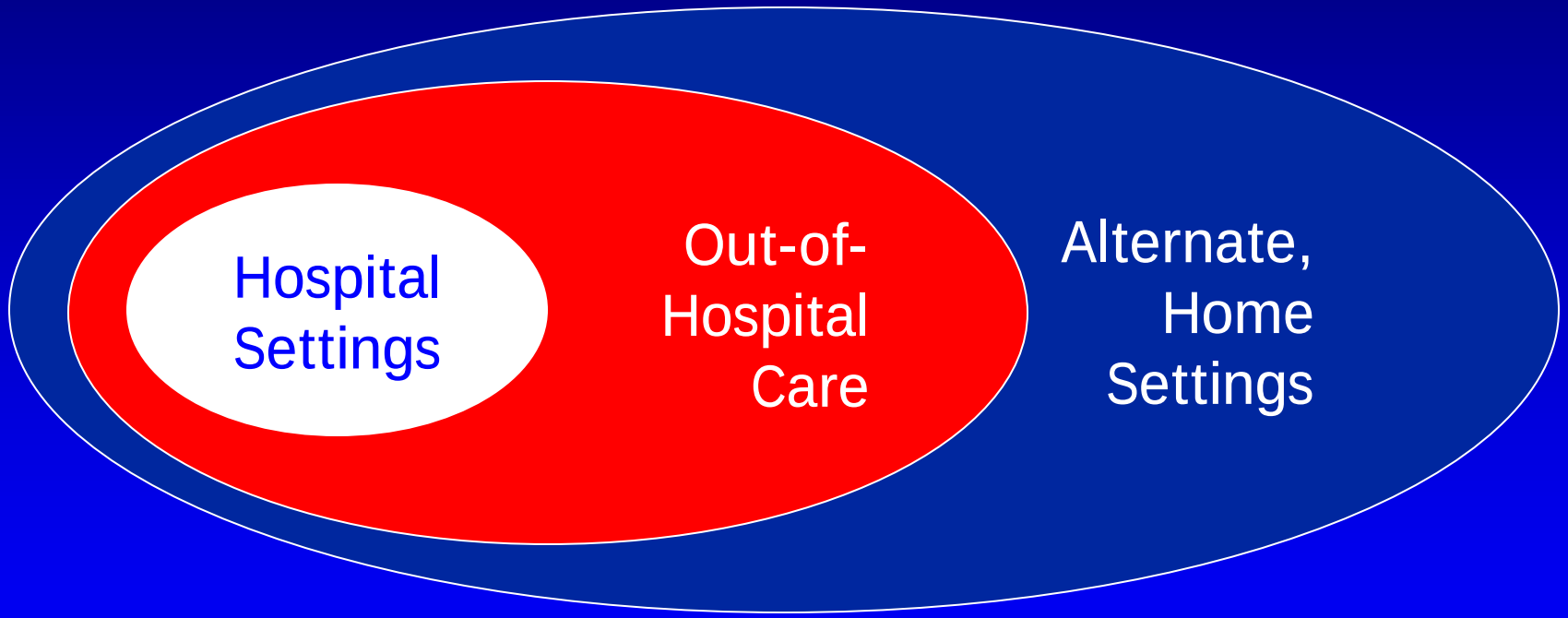
- 12-16% annual growth
- Currently 1 in 4 test done by POC
- In 10 years ~40% by POC
- Currently $450 million industry
- In 2025, $950 million industry

Actual Growth in POCT

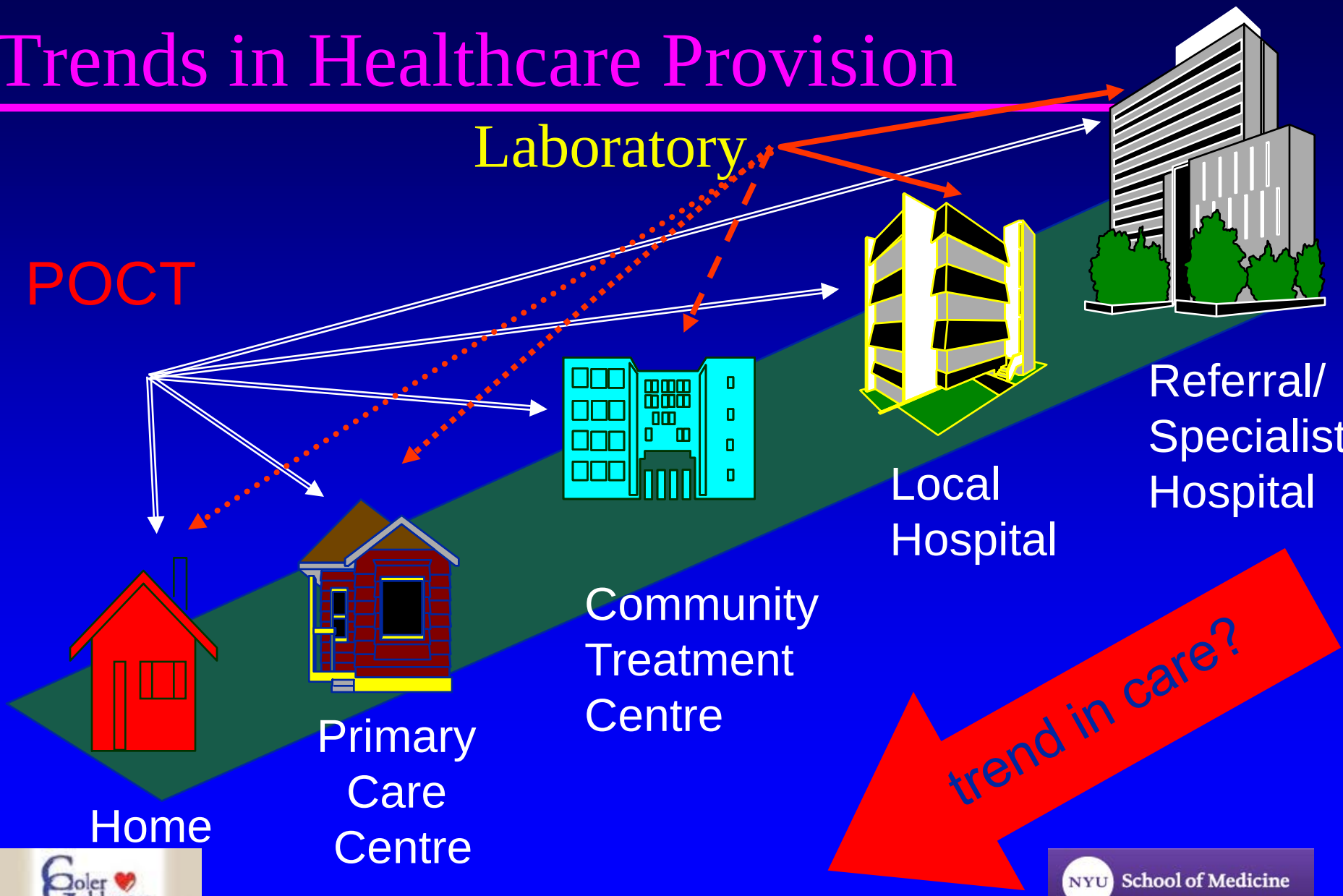
- 2008 Worldwide IVD Market - $42.1 Billion (46B in 2010)
- 2008 Worldwide POCT Market - $13.1 Billion (31%)
- 2010 Worldwide Professional POCT Market - $4 Billion
- ~10-12% annual growth

POC Testing Environments

- All testing performed at the patient's side



Trends in Healthcare Provision



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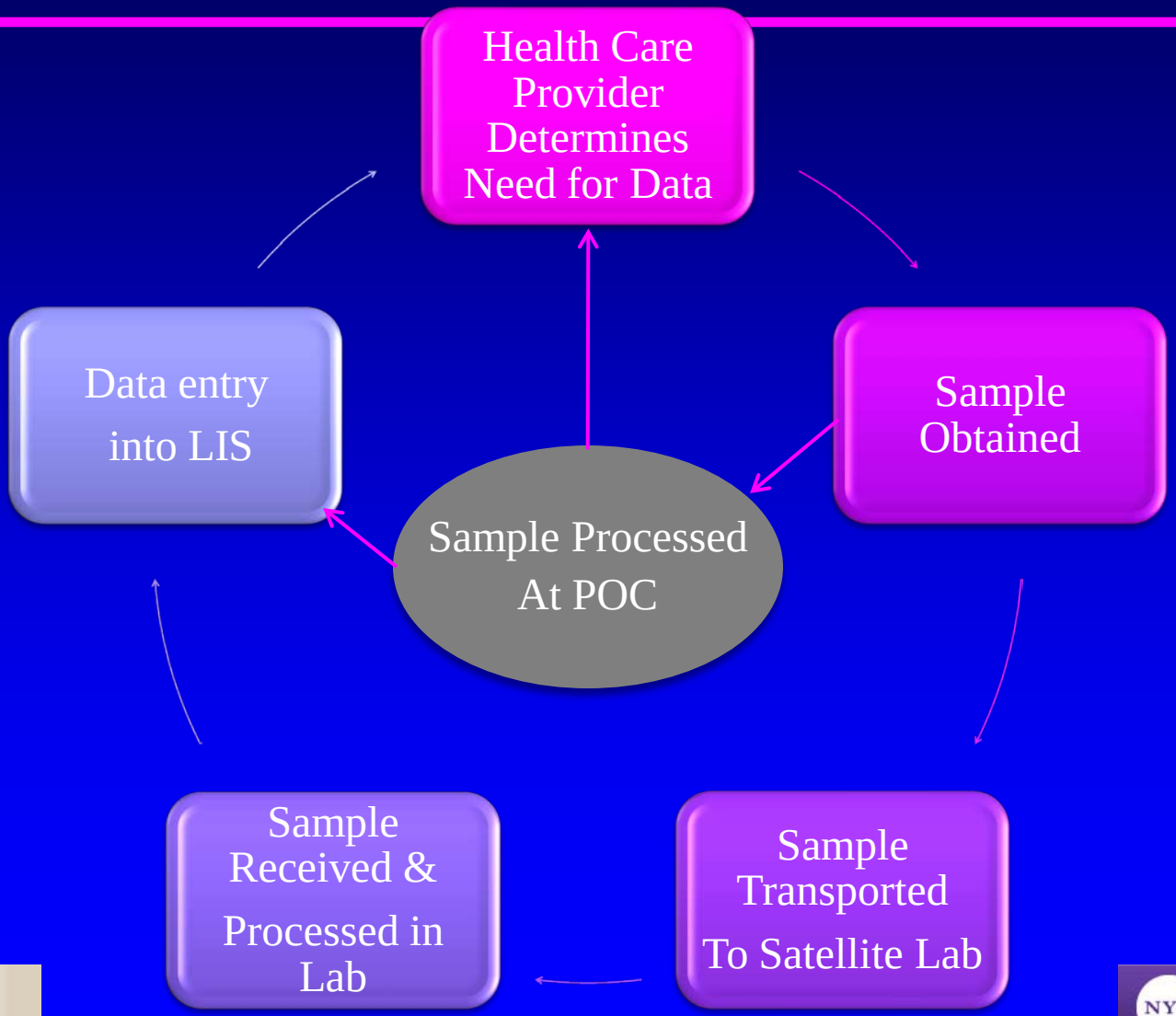
Moderators of POCT Growth

- Quality Assurance
- Quality Control - Matrix/Electronic
- Regulatory Requirements
- Record Keeping/Data Management
- Finances

POC Testing Knowledge Flow



POCT Quality Assurance Dilemma

Due to the rapid availability of results with POCT, data can be seen and acted upon prior to any QC checks or other external mechanism of assuring test results can be applied to these systems.

QA Issues With POC Testing

- Who performs testing and their training
- Pre-analytical variables and the ability to recognize them
- Reagent Testing
- Instrument verification
- Maintenance requirements
- Result reporting & charting

Quality System Hierarchy

POCT as a TQM Project

- Multidisciplinary team approach
- Looking at entire system, rather than individual performance
- On-going evaluation & refinement (CQI)
- Cost savings
- Improvement in delivery of critical laboratory services

Quality Management System Model

Laboratory's Path of Worklow

QSEs encompass the entire path

What is a Quality System?

The quality management system approach applies a core set of “quality system essentials” (QSEs), basic to any organization, to all operations in any health care service’s path of workflow (ie, operational aspects that define how a particular product or service is provided).

Quality Service Essentials (QSEs)

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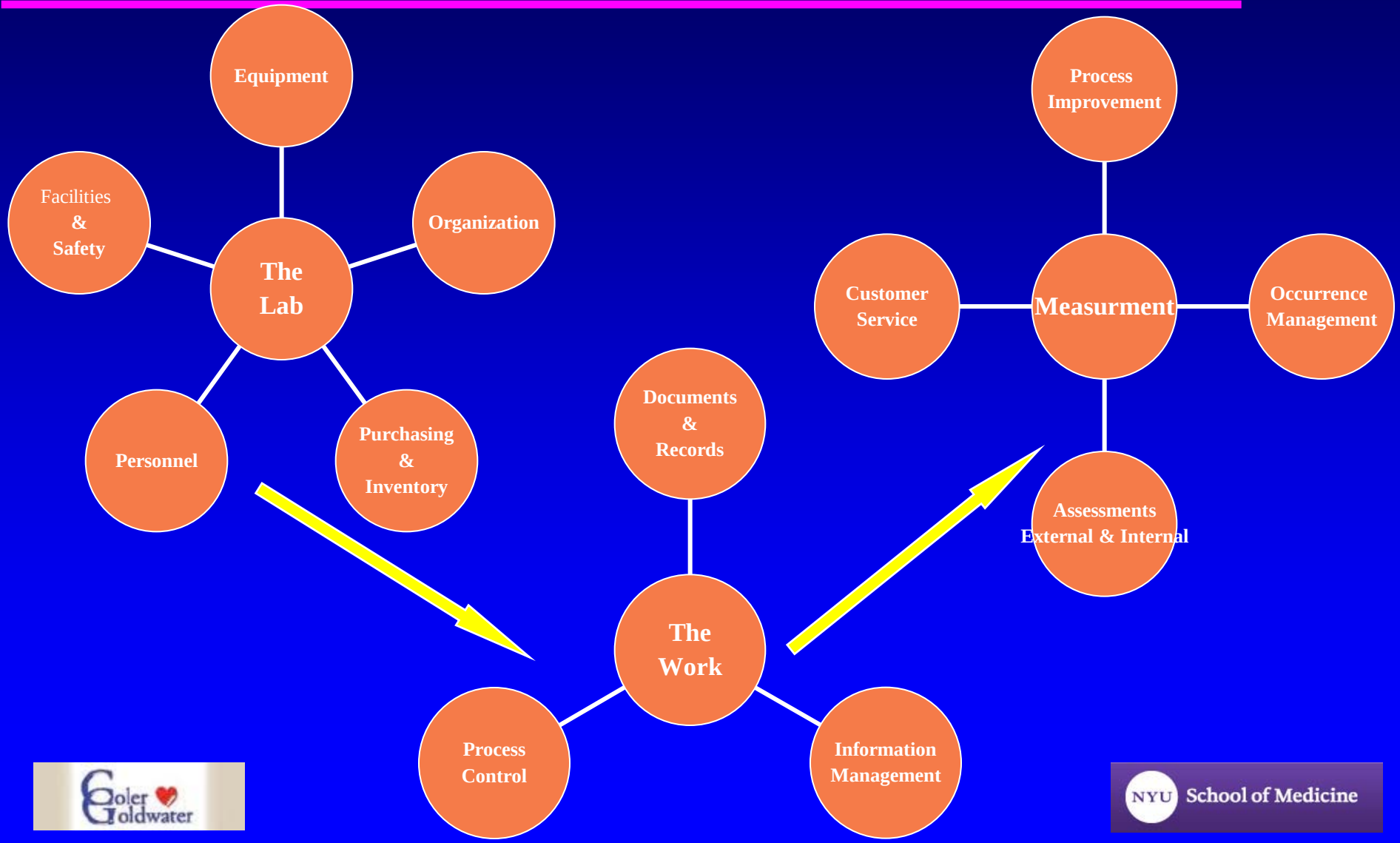

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Quality of Health Care in U.S.

- Institute of Medicine
  - Medical errors cause 44,000 to 98,000 deaths each year
    - » Equivalent to 200 deaths each day in airline crashes
    - » Fifth leading cause of death in U.S.
      - Ahead of diabetes, breast cancer, HIV
    - » Lab testing certainly contributes to deaths
      - Lab is looking for built-in safeguards to prevent errors

To Err is Human: Building a Safer Health System. Washington, DC, National Academy Press; 2000

Sources of Testing Error

	1997	2007
Preanalytical	68%	62%
Analytical	13%	15%
Postanalytical	19%	23%

Plebani M, Carraro P, Clin Chem 1997;43:1348-1351

Carraro P, Plebani M, Clin Chem 2007;53;1338-1342

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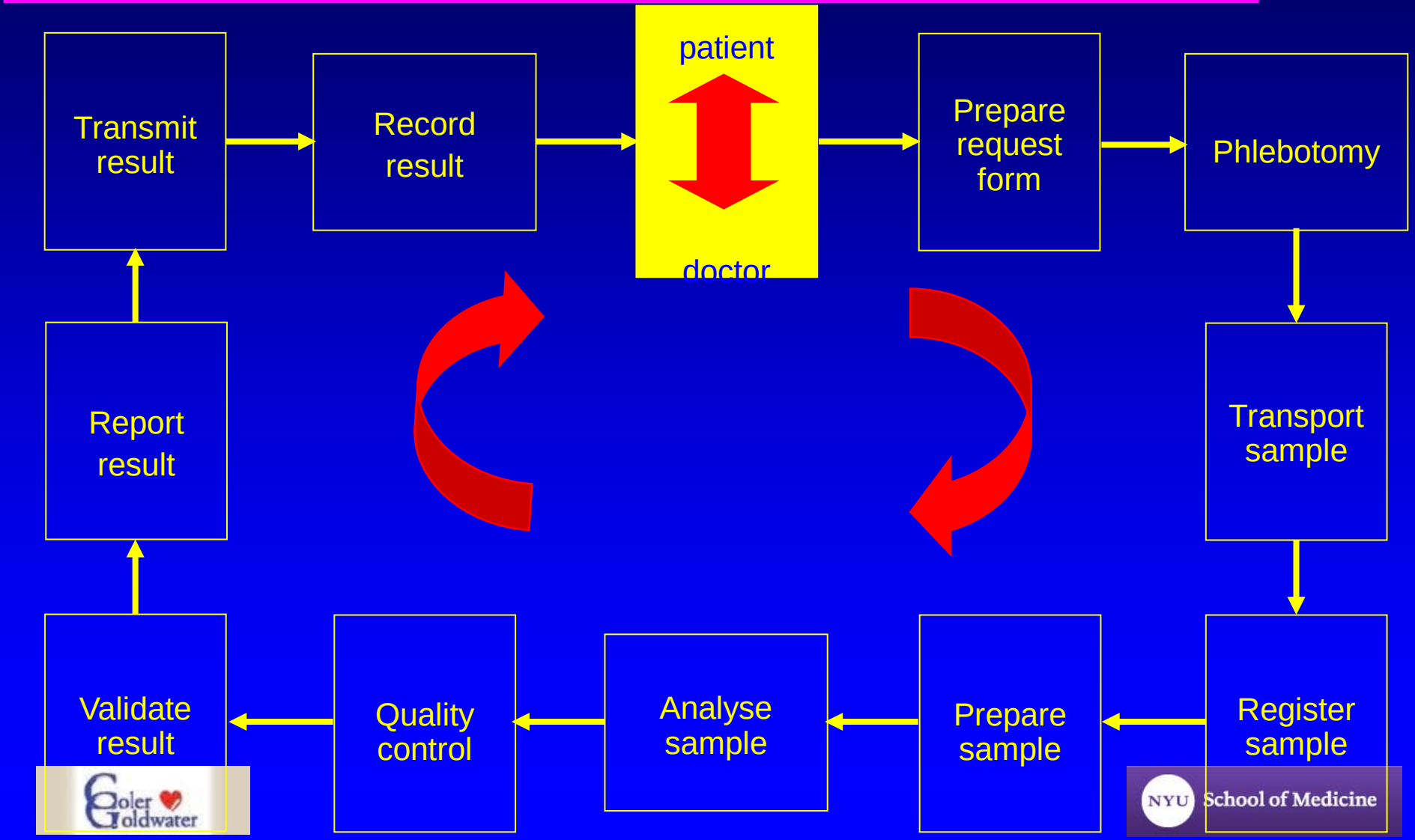
Laboratory Testing
Potential Sources of Errors



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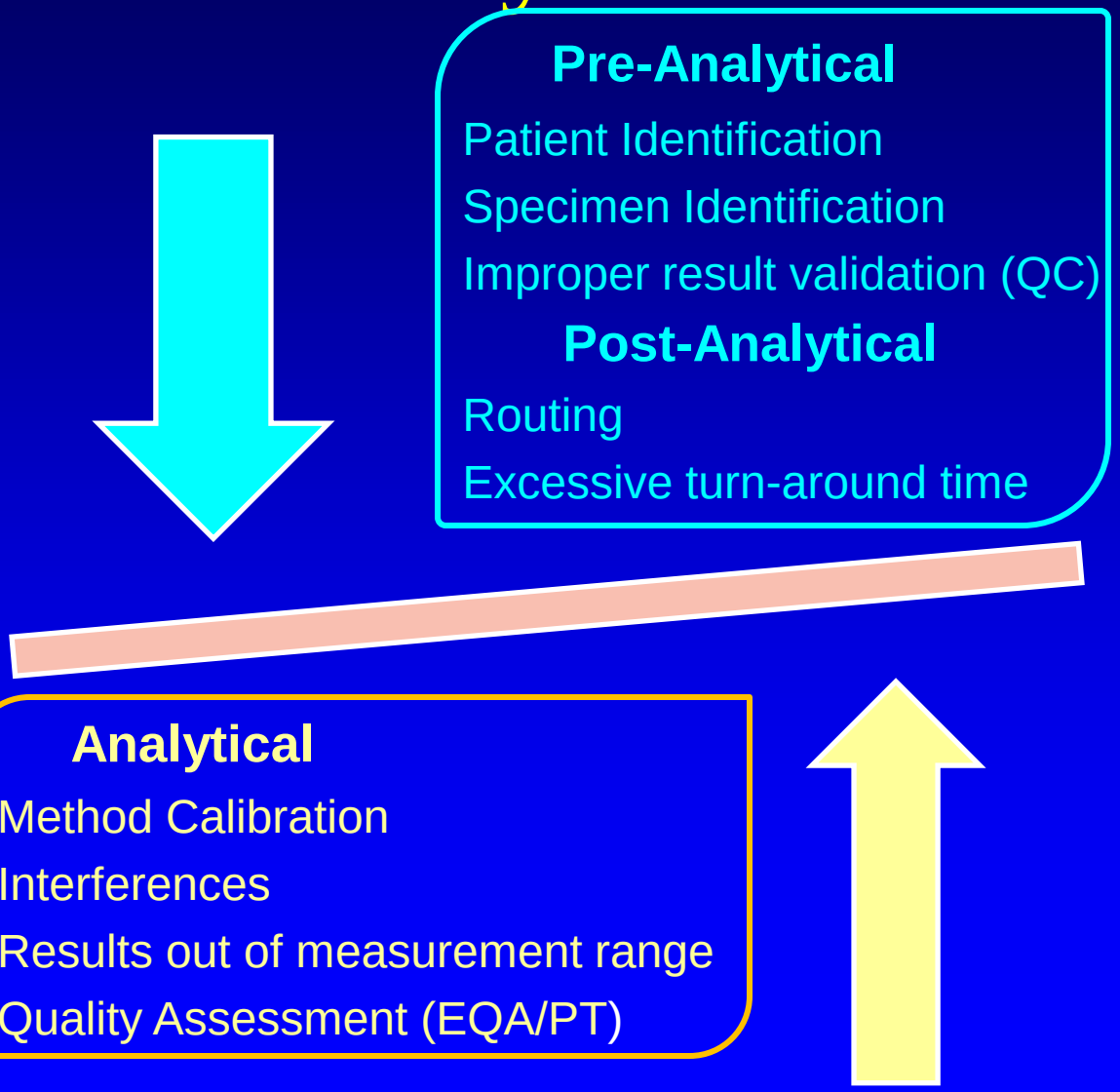
Potential Impact of POCT on Laboratory Errors



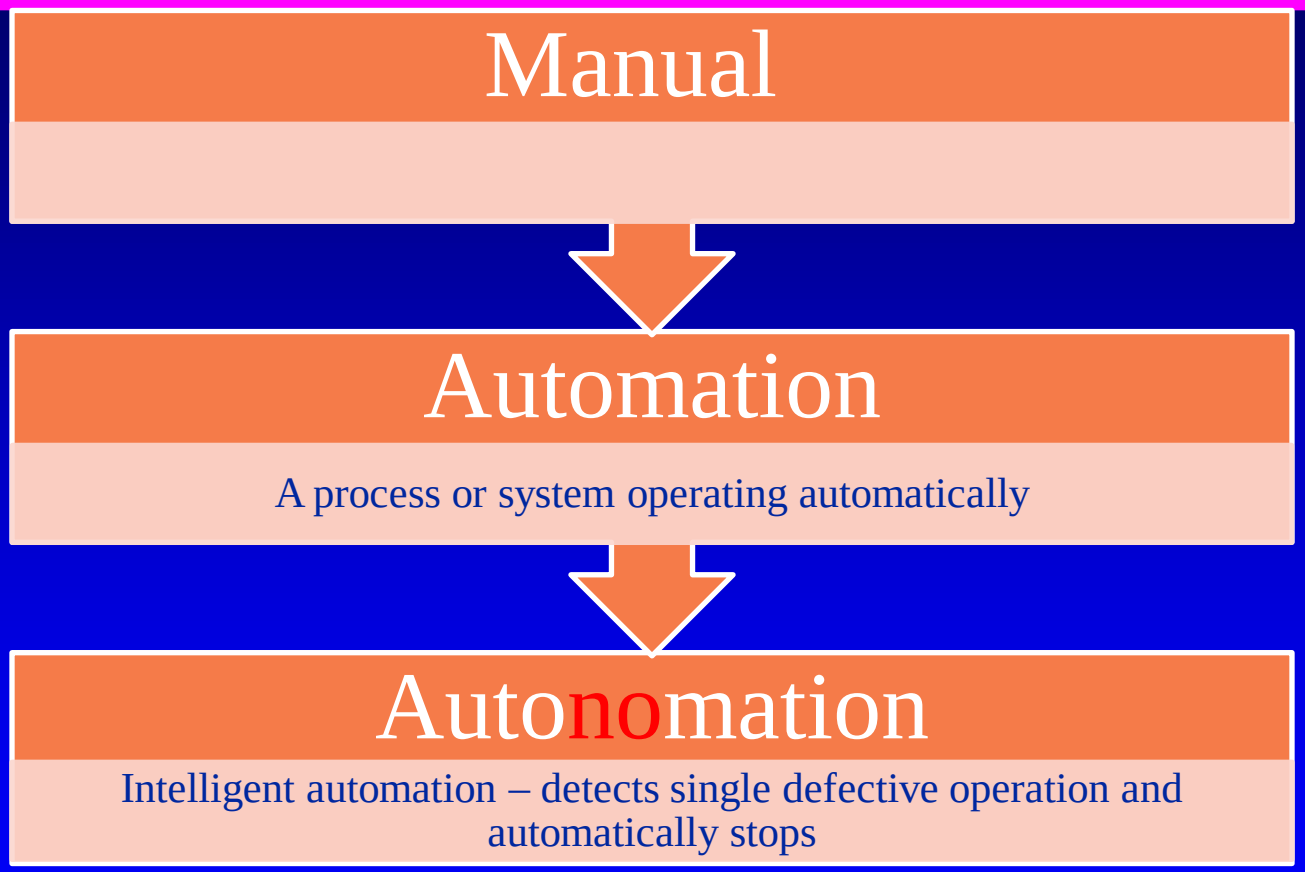
POCT & Patient Safety: Quality Testing Criteria

- Correct test ordered
- Correct patient
- Correct time for collection
- Correct specimen and processing
- Correct (accurate) test result
- Correct patient record
- Correct clinical interpretation of POCT result(s)
- Correct and timely clinical response

Best Practices for Glucose POCT

- Positive Patient ID- two identifiers
- Operator Certification
- Regular Calibration & QC
- Use Fresh Reagents
- Prevent Reagent Contamination
- Prevent Substance Interference
- Prevent Blood Sampling Errors

Evolution of POCT

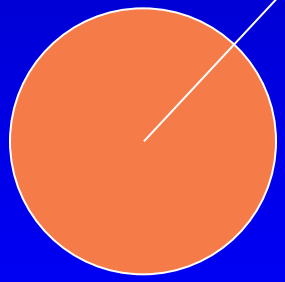


Ehrmeyer S, Lassig R. Clin Chem Lab Med 2007;45(6):766-773

Managing Sources of POCT Errors

- Designed out of the product
- Tested for
- Warned about

Evolution of Glucose POCT Technology



Manual Testing

- Incorrect sample amount
- Incorrect reagent amount
- Incorrect mixing
- Wrong position of testing device
- Wrong wait time
- Color blindness

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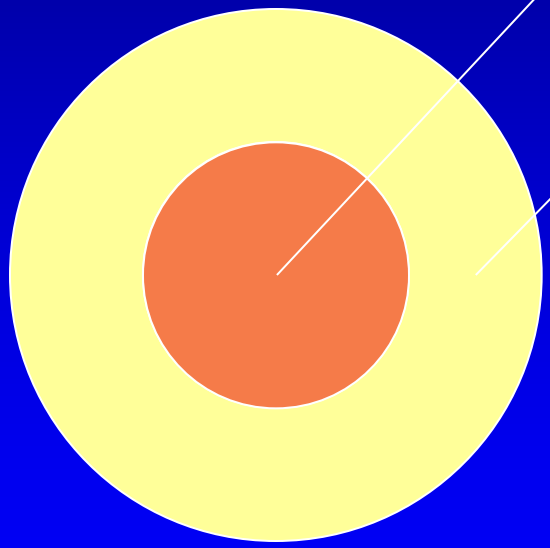
Evolution of Glucose POCT Technology

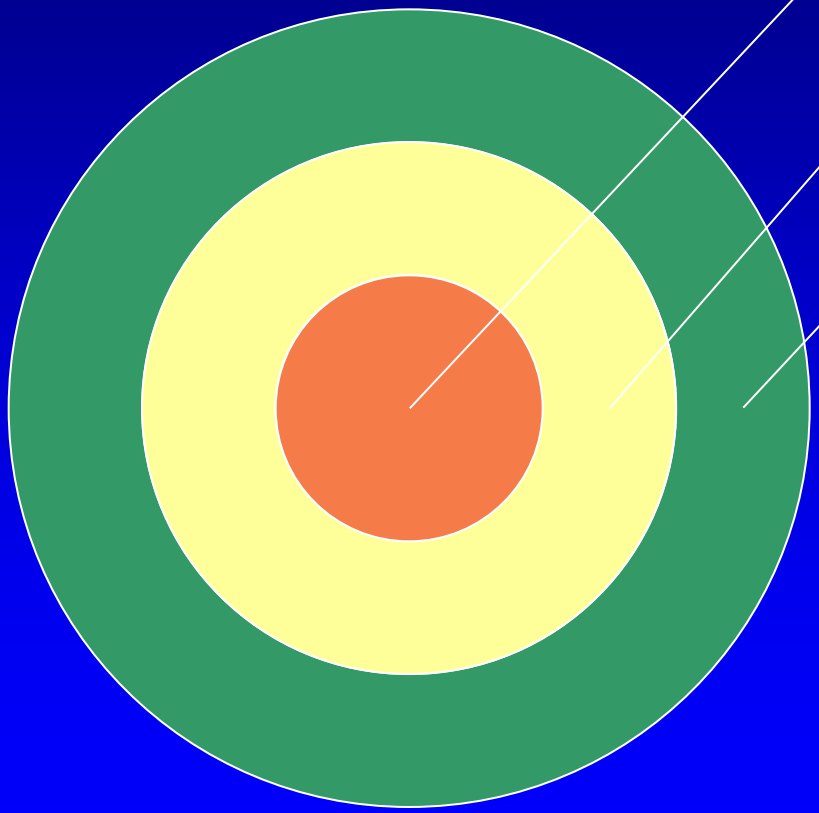


Manual Methods

1st/2nd Generation Instruments

- Wipe/Wipeless technology
- Operator ID / Patient ID
- Reduced operator intervention
- Operator prompts
- Check on reagent viability
- QC lock-outs
- Rudimentary Data Management

Evolution of Glucose POCT Technology



Manual Tests

1st/2nd Generation Instruments

Current Technology

- Electrochemical Technology
- Ability to use universal specimen types
- Extended linearity
- Minimally Invasive Technology (<3 uL Sample Size)
- Consolidated Testing Platforms
- Real Time Data Management and Connectivity

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Precision PcX

- **Reduces Interference Risk**
  - Glucose-specific strip technology
  - Minimizes interference from many non-glucose substances in the blood.
  - Patient safe for patients undergoing peritoneal dialysis using Extraneal™ (icodextrin).
  - Individually foil wrapped and bar-coded strips - reduces risk of contamination and helps assure fresh reagents for each test.
- **Reduces Risk of Sampling Errors**
  - Test begins when adequate sample is detected, reducing risk of short-sampling and over-sampling errors

safePICO Blood Gas Syringe

- Pre-barcoded arterial syringe for positive patient identification
- Establishes and Maintains Sample ID throughout testing process

Unit use and POCT devices

- It is often suggested that QC has no role in a unit use device because…
  - QC of a single unit (good or bad result) does not inform about other units [same argument would apply to non POCT analyzers in main lab that use discrete (unit use) reagent packs]
  - IMS fulfills QC role in unit use devices
- Unit use and continuous flow systems are not that different

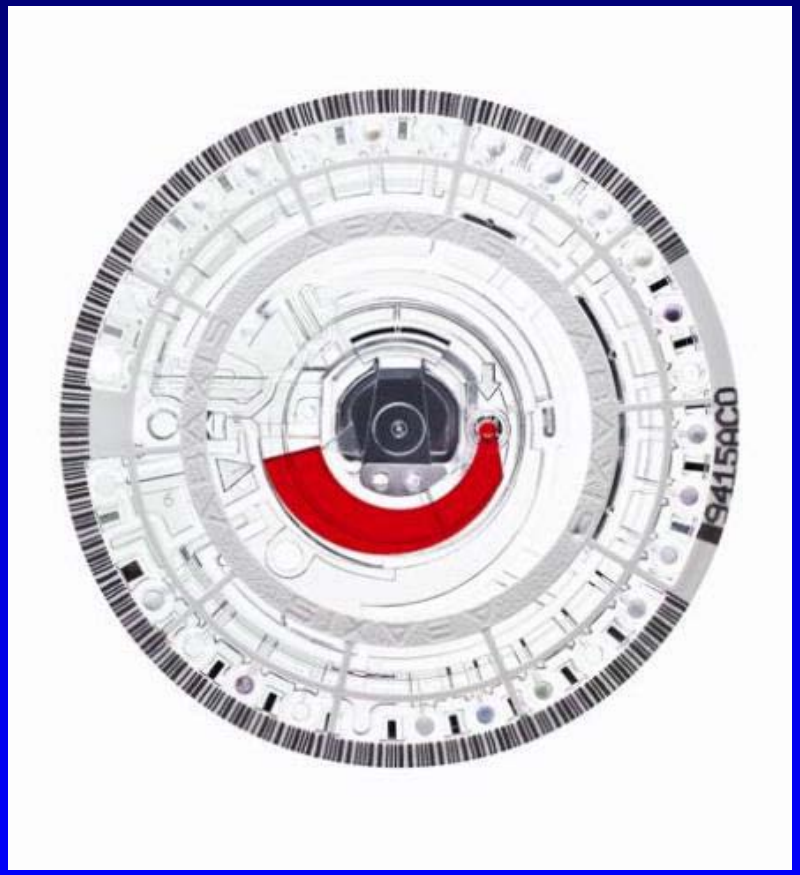
Characteristics of Unit-Use Test

- The container where the test is performed is always discarded after each test.
- Reagents, calibrators, and wash solutions are typically segregated as one test. There is no interaction of reagents, calibrators, and wash solutions from test to test.

Nature of QC Procedures

- Use of electronic checks, including any instrument software features that serve as error detection or prevention mechanisms
- Use and number of surrogate samples, where appropriate, to be included as part of the QC procedure
- Testing of controls that are engineered into the test system

Abaxis Piccolo



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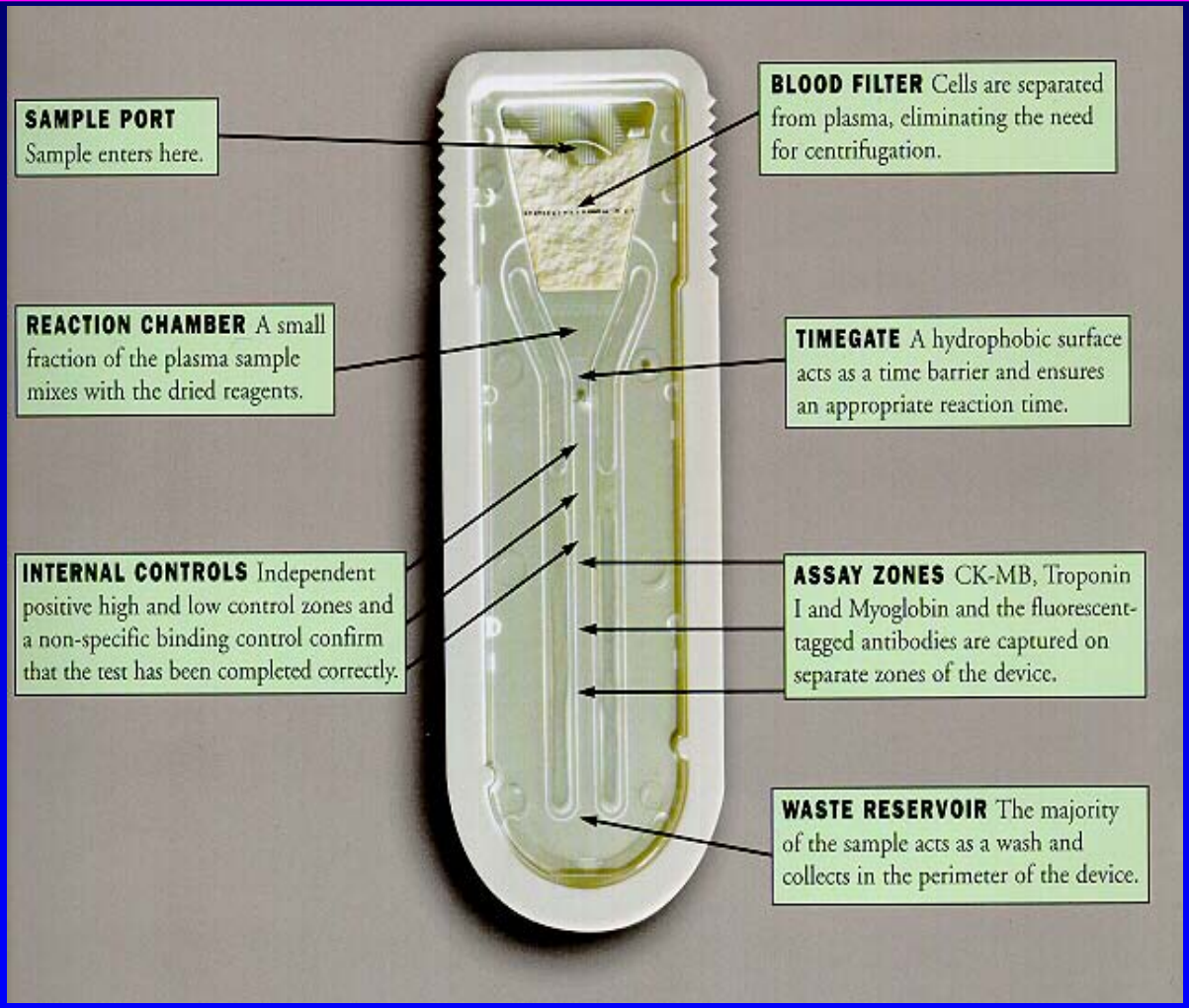
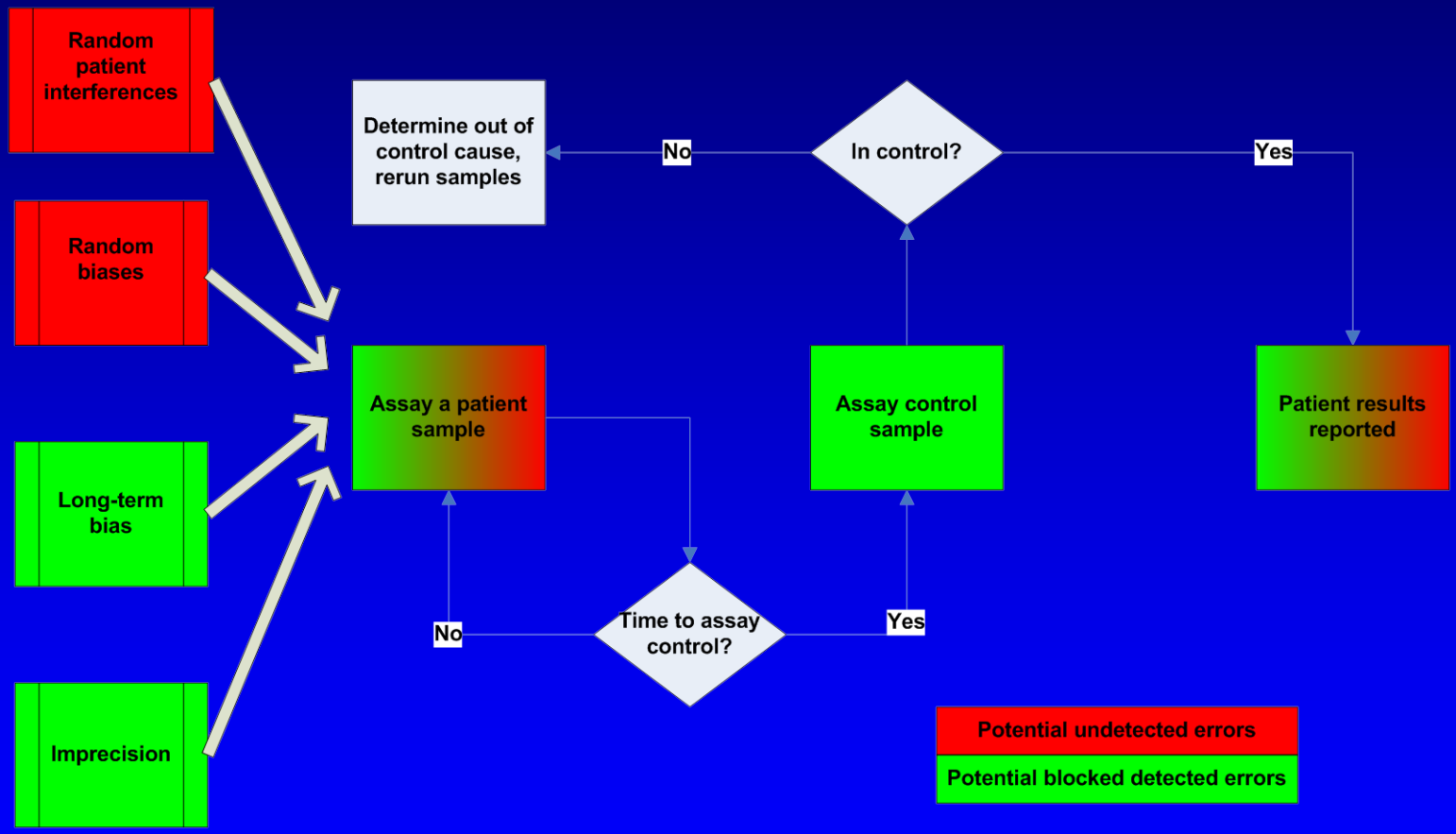
Triage – Cardiac Markers



Surrogate QC doesn't detect all errors

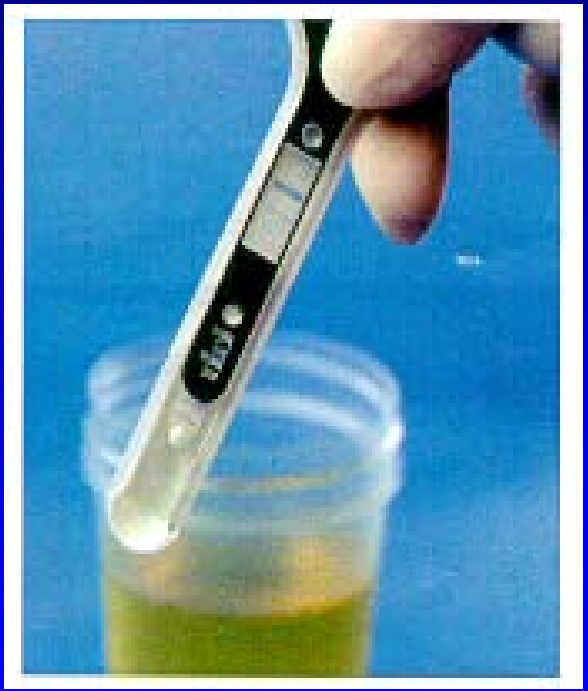


Non-Surrogate Sample QC

Includes all forms of quality control other than the measurement of a surrogate sample, usually integrated into the device

- electronic QC (which simulates signals electronically), ex. i-STAT
- automated procedural controls (which ensure that certain steps of the procedure occur appropriately), ex. Immunochromatography test kits
- automated internal quality controls (which may, for example, ensure the quality of a raw signal), ex.
- diagnostic pattern recognition systems, ex. GEM iQM

Immunochromatography – Urine Dipstick



Gem Premier 4000

- Continuously monitors all critical components of blood gas testing in real time to assure accurate results
- Automatically assures that each test meets demanding quality specifications
- Immediately detects, corrects and documents errors
- Eliminates labor and material costs associated with traditional QC
- Assures that optimal quality control protocols are followed at all times, regardless of operator training

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Internal monitoring systems (IMS)

- IMS are a collection of hardware and software that detect errors and prevent the effect of the error from occurring
  - Example: Noise in the signal of a patient sample is detected, the result is flagged and not reported
- IMS are not new – although always improved, they have been in systems for over 30 years

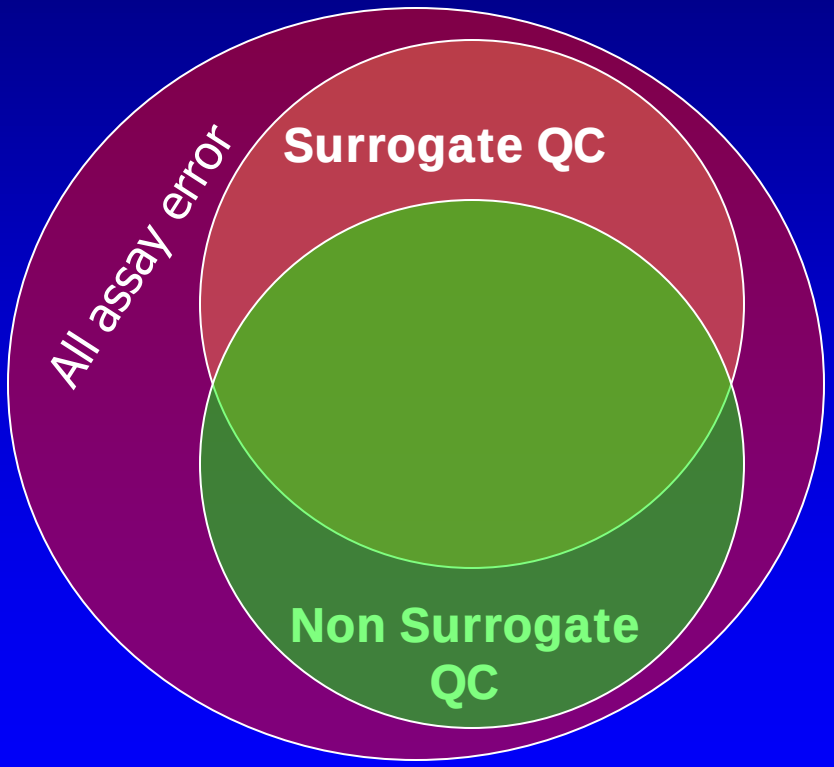
Internal monitoring systems

- Internal monitoring systems don't detect all errors, because
  - Complexity of instrument systems prevents perfect failure mode models
  - There is management pressure to release new products quickly
  - There is insufficient knowledge to "design things right the first time"

Non-Surrogate QC and QC

Surrogate and Non-Surrogate QC

- are not completely redundant
- do not detect all errors



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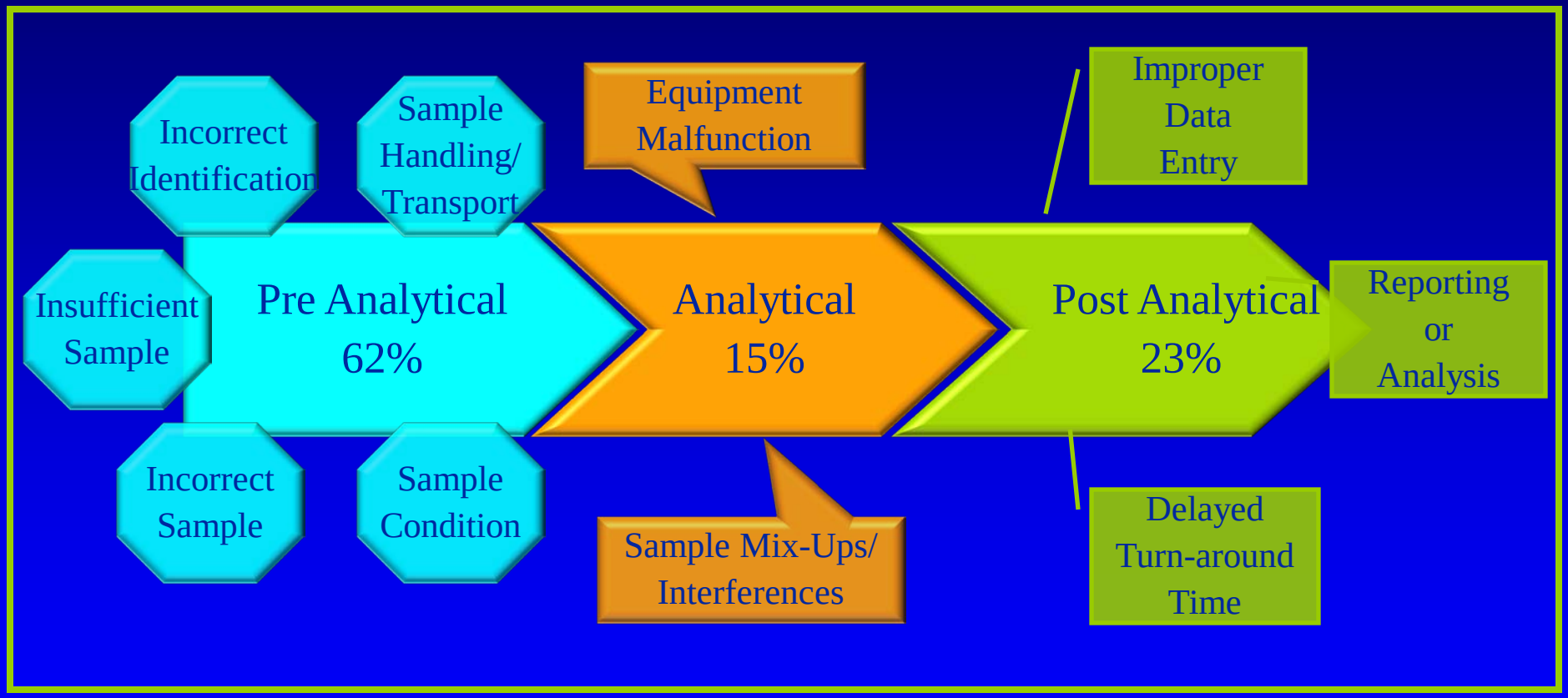
- QC must be able to detect mistakes to enable immediate correction
- Risks and costs must be weighed
- QC is only one part of the quality management system
- Not all laboratories have the same competencies and organization
- Science and common sense must converge

Thinking in the POCT Box



As autononmation reduces errors in the box, further reductions must occur outside the box.

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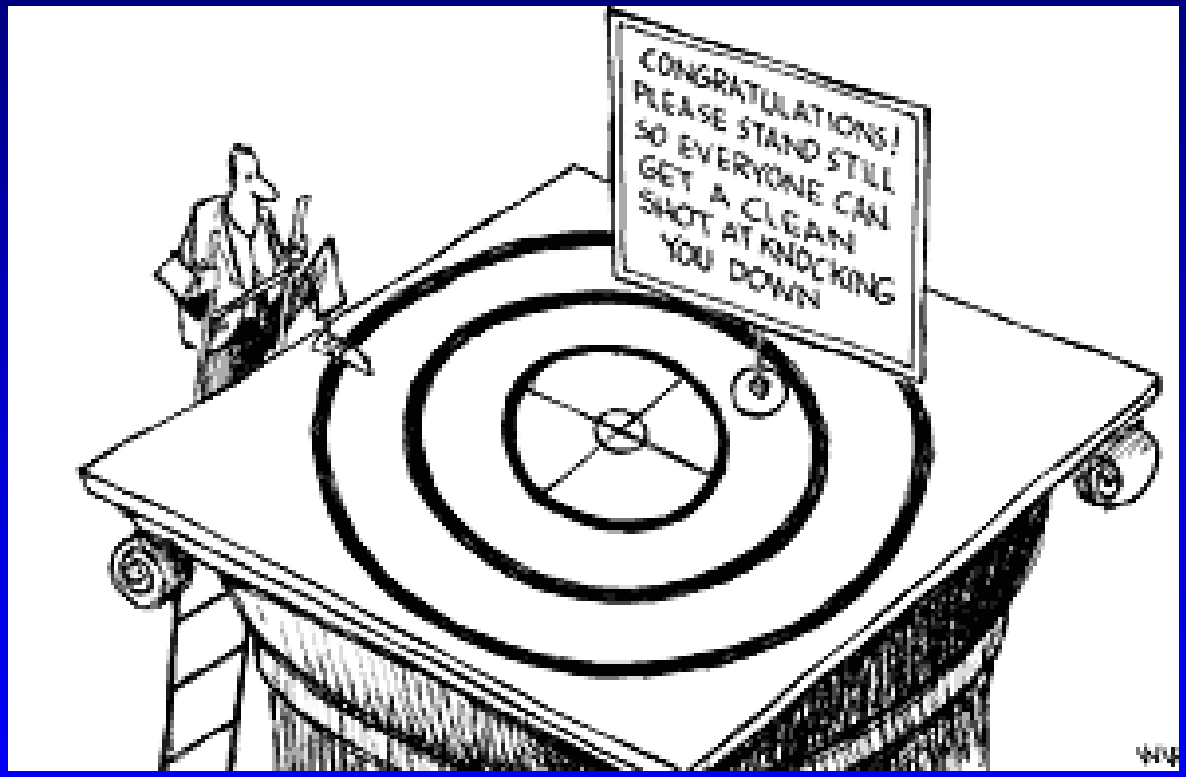
Thinking Outside the POCT Box

Pre-pre: Phsician must consider

- » What POCT is available?
- » What POCT will best serve the patient?
- » Will an immediate answer improve the patient's outcome?

- Post-post: Is the Physician?
  - » Receptive to using an immediate POCT result
  - » Able to interpret result in the patient's context
  - » Amenable to initiating an immediate response

The Problem with Pedestals



QUESTIONS

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