

Current & Future Applications of Point of Care Testing

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Point of Care Testing

- **Definition**
 - *tests designed to be used at or near the site where the patient is located, that do not require permanent dedicated space, and that are performed outside the physical facilities of the clinical laboratories (College of American Pathologists)*
 - **Classic example: bedside glucose testing in the hospital**

Point of Care Testing

- **What about laboratory instruments used at the point of care, e.g. benchtop blood gas analyzer in the respiratory intensive care unit?**
- **What about point of care devices used in the laboratory, e.g. B-type natriuretic peptide device in the core lab?**
- **Testing distinctions and boundaries are becoming more and more blurred**

What is Going On?

Non-traditional operators

“Non-professional setting”

Traditional operators

“Professional setting”

Settings & Operators

Scenes

Non-medical
facilities

Home

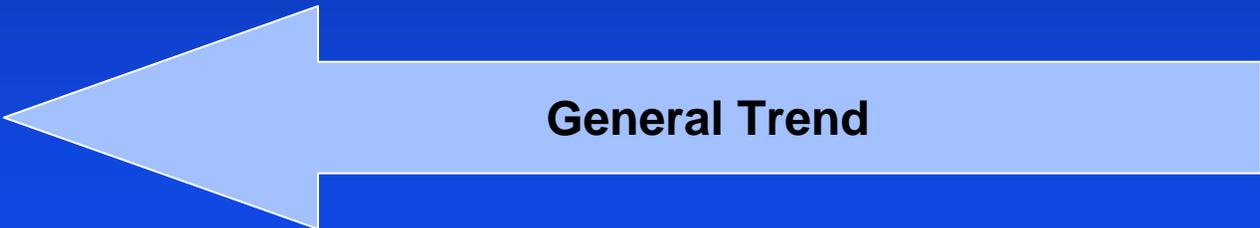
Assisted
living

Clinic

Hospital

Lab

General Trend



Waived

Moderately complex

Highly complex

Tests

The Drivers

- **New testing opportunities**
 - Home INR testing
 - Accident scene blood gas/electrolyte testing
 - Emergency department HIV testing
 - Underdeveloped countries
- **New counseling opportunities**
 - Clinic-based INR testing
 - STD clinic HIV testing

The Drivers

- **Care process optimization**
 - Rapid creatinine testing for cardiac catheterization lab
 - Arterial blood gas testing in the ICU
 - Physician office laboratories
- **Patient care outcomes**
 - Intensive insulin therapy in critical care patients
 - Intraoperative transfusion algorithms

The Drivers

- **Patient care outcomes**
 - Intensive insulin therapy in critical care patients
 - Intraoperative transfusion algorithms
- **Disaster recovery**
 - Internal & external – Hurricane Katrina
 - Emergency preparedness
 - Epidemics / outbreaks
- **Testing platforms**
 - Availability – BNP example
 - Match to test volumes – POL example

The Drivers

- **Regulatory requirements**
 - Ease of waived testing requirements, both CLIA and Joint Commission
 - Many POCT programs and physician office laboratories intentionally limit their menus to waived tests only
- **Attractiveness and potential of waived testing market to industry**

The Drivers

- **Workforce issues**
 - **National laboratory technologist shortage**
 - **Projected need for 710,000 technologists by 2012**
 - **~12,200 new technologists needed each year**
 - **4,000 – 6,000 new graduates each year**
 - **Movement toward licensure in multiple states**

Educational Background of Testing Personnel

| | 1998 | 2005 |
|---|------------|------------|
| Clinical Laboratory Scientists (4 yr degree) | 33% | 24% |
| Bachelor of Arts / Bachelor of Science (4 yr degree) | 33% | 57% |
| Clinical Laboratory Technician (2 yr degree) | 33% | 17% |

POCT: Common Use

- **Glucose**
- **Blood gas analysis/electrolytes**
- **Activated clotting time for high dose heparin monitoring**
- **Urine dipsticks, including pregnancy**
- **Occult blood**
- **Hemoglobin**
- **Rapid strep**

POCT: Available but Variable Use

- Cardiac markers
- Drug/toxicology
- INR
- Heparin
- Coagulation for hemostasis assessment (TEG)
- D dimer for thromboembolism
- Magnesium
- Lactate
- Transcutaneous bilirubin
- Lipids
- Hemoglobin A1c
- Microalbumin, creatinine
- HIV
- Influenza
- Helicobacter pylori
- Other bacteria

POCT: Come & Gone

- **Basic metabolic panel**
- **ABO typing, crossmatch**

POCT: Emerging

- Complete blood count
- White blood cell count
- Coagulation for transfusion algorithms
- Platelet function testing
 - Transfusion needs
 - Anti-platelet therapy

POCT: Future

- **Microbiology**
 - Outbreaks / epidemics
 - Methicillin resistant staph aureus
- **Endocrine testing to guide surgical therapy**
 - Parathyroid hormone
 - ACTH
 - Gastrin
 - Growth hormone
- **Sepsis markers**
- **Stroke markers**
- **DNA testing**

POCT Issues

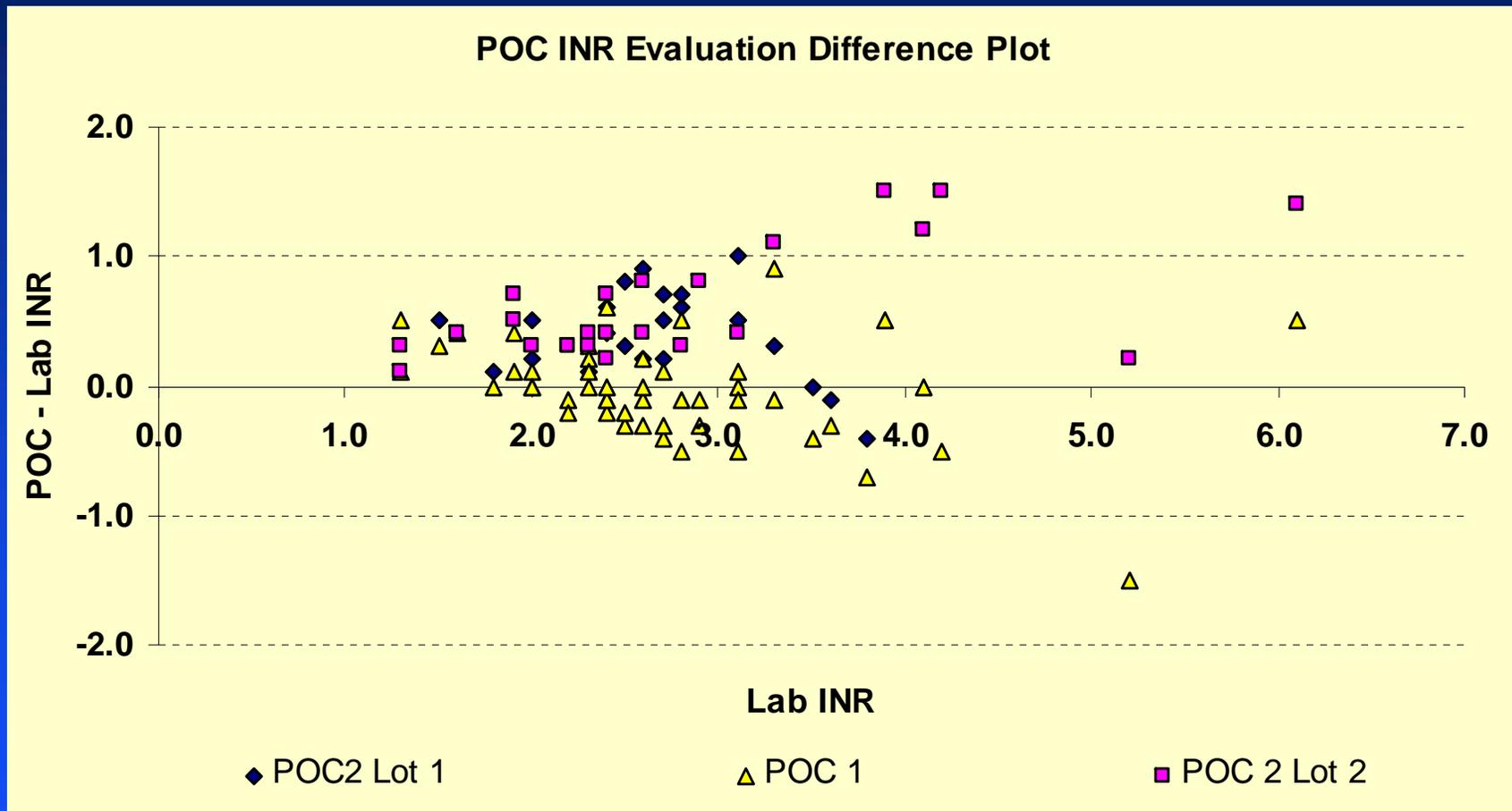
- Evidence base for effectiveness is very mixed
 - NACB Laboratory Medicine Practice Guideline on Evidence-Based Practice for POCT
 - Systematic review and grading of available scientific evidence related to:

| | |
|---------------------|--------------------|
| pH | Reproduction |
| Cardiac markers | Drug testing |
| Parathyroid testing | Infectious disease |
| Bilirubin | Occult blood |
| Coagulation | Renal |
| Critical care | Diabetes |
 - <http://www.aacc.org/AACC/members/nacb/LMPG/OnlineGuide/PublishedGuidelines/poct/default.htm>

POCT Issues

- **Standardization / comparability**
 - **With multiple ways of performing the same test, this is becoming a critical issue for larger systems**
 - **POCT, Physician Office Lab, Stat Lab, Hospital Lab, Reference Lab**
 - **Examples**
 - **Episodic POC INR testing prior to an invasive procedure**
 - **Cardiac markers in the ED**

POC INR: Ongoing Monitoring vs Episodic Testing



POC Cardiac Markers

| | POC Tnl 1 negative | POC Tnl 1 positive |
|--------------|--------------------|--------------------|
| TnT negative | 26 | 0 |
| TnT positive | 11 | 8 |
| | | |
| | POC Tnl 2 negative | POC Tnl 2 positive |
| TnT negative | 20 | 5 |
| TnT positive | 6 | 13 |

POCT Issues

- **Complexity of data management and oversight**
 - Training & competency assessment for potentially thousands of individuals
 - Quality control documentation
 - Quality performance
 - Reporting
 - Billing
 - Process control

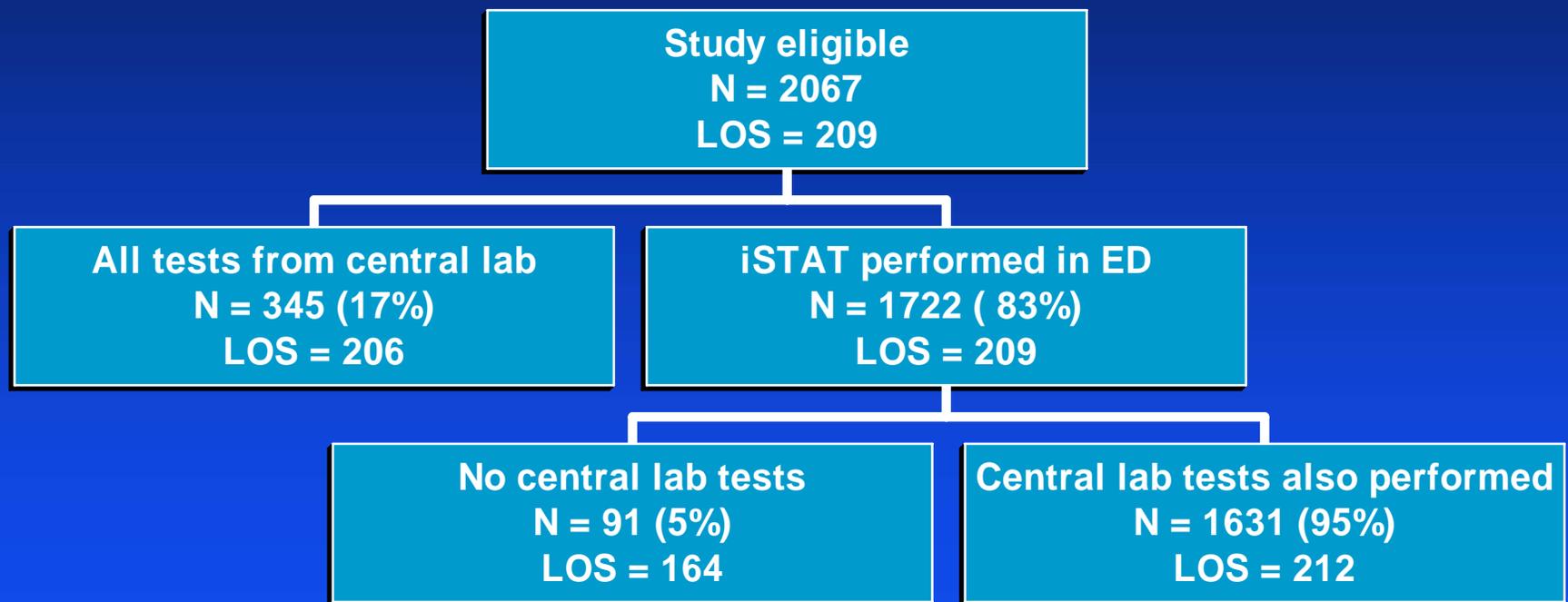
POCT Issues

- **Complexity of data management and oversight**
 - **Multiple testing platforms**
 - **Vendor specific vs vendor neutral data management systems**
 - **Interfaces to laboratory and/or hospital information systems**
 - **Manual POCT methods**

POCT Issues

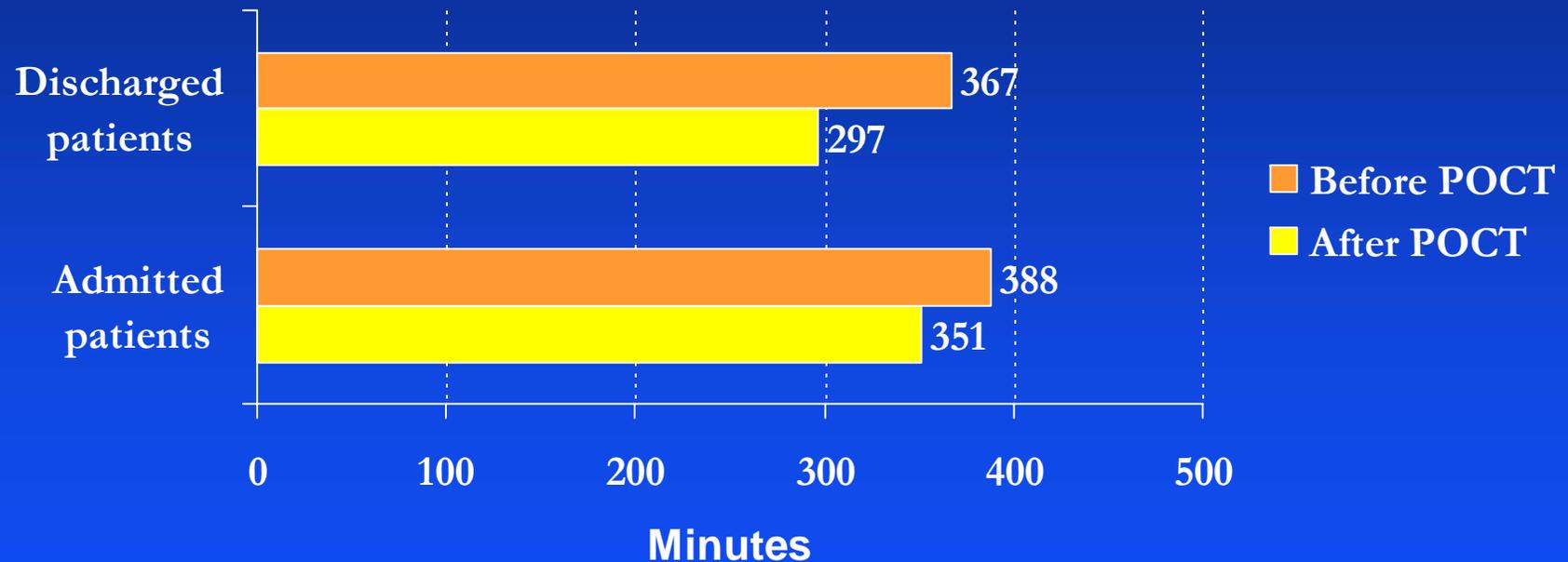
- **Importance of process to achieve effective use of POCT**
 - **Is faster always better?**

Point-of-Care Testing ED Length Of Stay

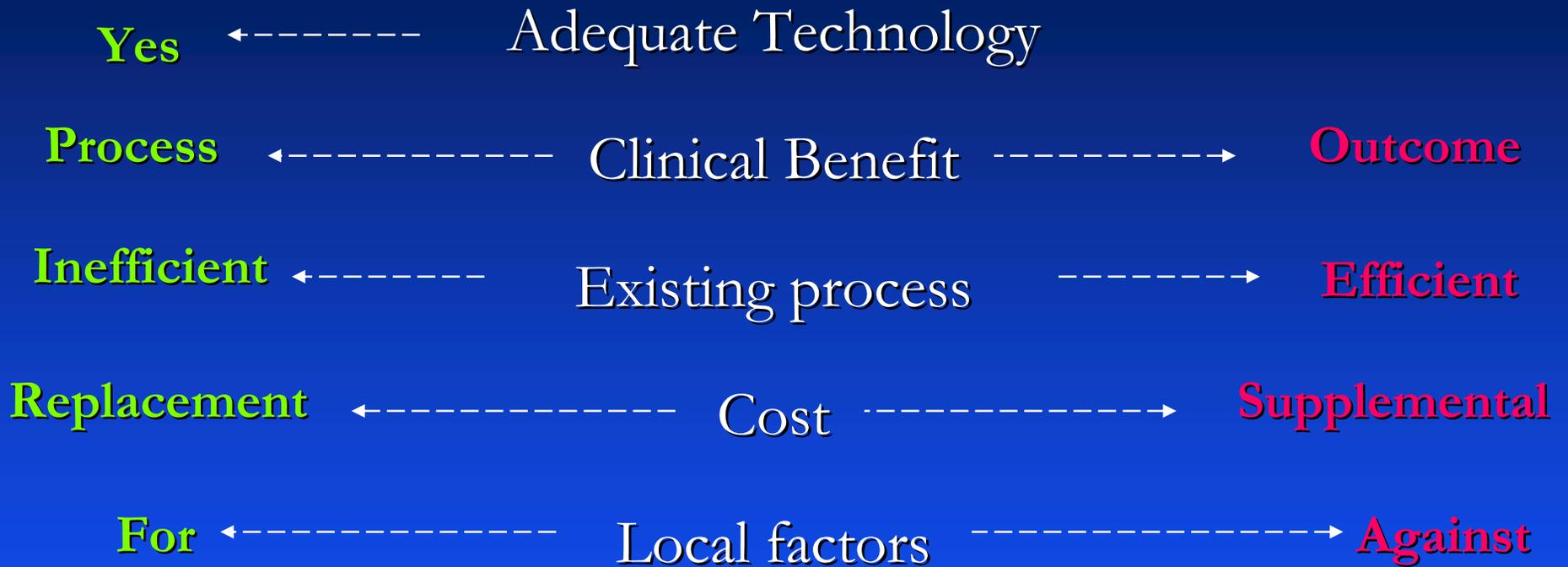


POCT in a Lab Setting Point-of-Care Kiosk in the ED

ED Cardiac Length of Stay



POCT in the ED - Will we adopt it?



POCT in the ED

- **Faster does not always lead to better outcome**
 - Lab tests are rarely the rate limiting factor in ED disposition
- **Process analysis is the key understanding and improving patient throughput in the ED**
- **Test menu selection is a critical component of the potential application of POCT**
 - Match available tests to disposition decisions
 - May only decrease length of stay for a small subset of patients

POCT in Radiology

- **Need for creatinine measurement prior to administration of contrast**
 - Referral patients may come without a recent measurement – POCT would be useful to decrease waiting time for result
 - Decision points: 1.5 mg/dL for diabetic patients, 2.0 mg/dL for non-diabetic patients
- **Device accuracy & precision not good enough at these decision points**
- **Designed new process to provide rapid results from lab**

JHH CVDL Outcomes Trial

- Cardiac catheterization setting
- POCT improved wait times over core laboratory, but not significantly
- Significant changes only occurred after unit workflow reorganized to optimize use of POCT results
 - Decreased wait times 63 minutes for coag (n=9, p=0.014) and 47 minutes for renal (n=18, p=0.02)

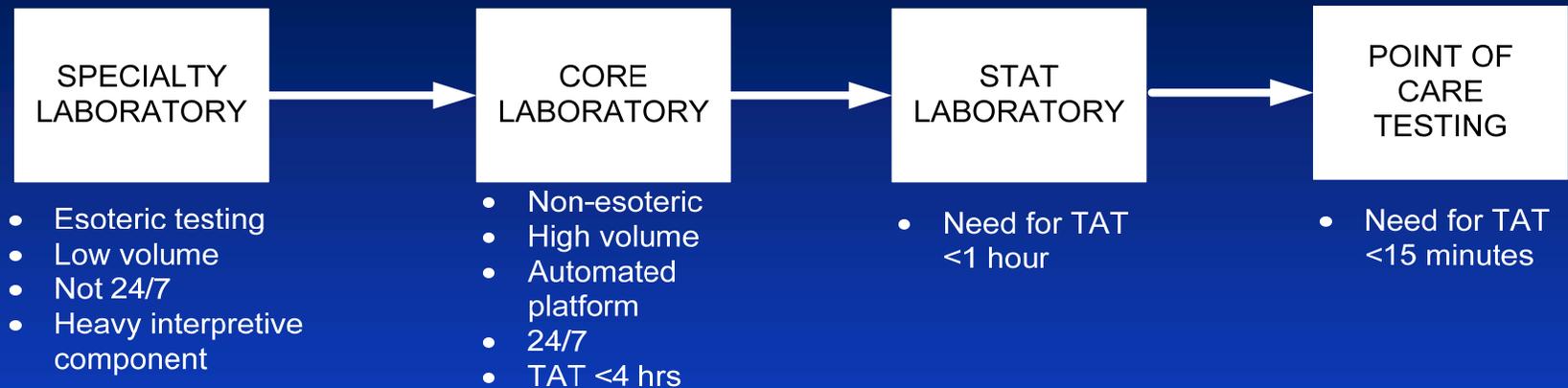
POCT Issues

- **Verification and monitoring of analytical performance**
 - Quality control
 - Calibration verification
 - Analytical measurement range verification
 - Method comparability
- **Complicated by multiple instruments and multiple cartridges**
- **WE JUST DON'T KNOW WHAT THE PROPER APPROACH SHOULD BE**

Ultimate Question

- Will point of care testing eventually replace the clinical laboratory?
- My opinion: no
- Why: spectrum of testing is always changing

Spectrum of Patient Care Testing



- **Tests often evolve through this spectrum**
 - What's esoteric today may be POCT tomorrow with advances in technology, new therapeutic options, and new care models
 - New esoteric testing will grow substantially with the maturation of genomics and proteomics