Point-of-Care Testing in Special Populations

Disclosures: Some studies supported by NIH/NHLBI Training Awards 2011-16. Devices not used by UC Davis were donated by the manufacturer (Nova Biomedical and Alere). Hemoglobin study was supported by Radiometer America.
Learning Objectives
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• Describe the history of point-of-care testing (POCT)
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• Identify special populations that would benefit from POCT
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• Describe the history of point-of-care testing (POCT)

• Identify special populations that would benefit from POCT

• Describe special populations where POCT may be inappropriate or where caution should be used.
Background

**Total Testing Process:** The testing process is comprised of three key elements.
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Pre-Analytical
Background

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- **Pre-Analytical**
- **Analytical**
- **Post-Analytical**
Background

Total Testing Process: The testing process is comprised of three key elements.
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**Total Testing Process:** The testing process is comprised of three key elements.

- **Pre-Analytical:** Patient preparation, Sample collection, Transportation, Accessioning, Processing
- **Analytical**
- **Post-Analytical**
Background

Total Testing Process: The testing process is comprised of three key elements.

- Pre-Analytical
  - Patient preparation
  - Sample collection
  - Transportation
  - Accessioning
  - Processing

- Analytical
- Post-Analytical

Testing
**Background**

**Total Testing Process:** The testing process is comprised of three key elements.

- **Pre-Analytical:**
  - Patient preparation
  - Sample collection
  - Transportation
  - Accessioning
  - Processing

- **Analytical:**
  - Testing

- **Post-Analytical:**
  - Results interpretation
  - Entry to LIS/EMR
  - Contacting providers
  - Sample archiving
Background

**Total Testing Process:** The testing process is comprised of three key elements.

"Analytical Turnaround Time"

**Pre-Analytical** | **Analytical** | **Post-Analytical**

Temporal Metrics for Laboratory Testing
- Analytical Turnaround Time: Time from test start to finish
Background

**Total Testing Process:** The testing process is comprised of three key elements.

Temporal Metrics for Laboratory Testing
- Analytical Turnaround Time: Time from test start to finish (analytical time + post-analytical time)
- Total Turnaround Time: Time from initiating sample collection to result (pre-analytical + analytical + post-analytical time)
**Background**

**Total Testing Process:** The testing process is comprised of three key elements.

1. **Pre-Analytical**
2. **Analytical**
3. **Post-Analytical**

"Total Turnaround Time" = Pre-Analytical + Analytical + Post-Analytical

"Analytical Turnaround Time" = Analytical + Post-Analytical

"Therapeutic Turnaround Time" = Time from test order to TREATMENT

**Temporal Metrics for Laboratory Testing**
- Analytical Turnaround Time: Time from test start to finish (analytical time + post-analytical time)
- Total Turnaround Time: Time from test order to result (pre-analytical + analytical + post-analytical time)
- Therapeutic Turnaround Time: Time from test order to TREATMENT [this is what ultimately matters]
Automation can improve a lot...

**Total Testing Process:** The testing process is comprised of three key elements.

- **“Total Turnaround Time”**
- **“Analytical Turnaround Time”**
- **“Therapeutic Turnaround Time”**

**Laboratory Automation**

**Temporal Metrics for Laboratory Testing**

- **Analytical Turnaround Time:** Time from test start to finish (analytical time + post-analytical time)
- **Total Turnaround Time:** Time from test order to result (pre-analytical + analytical + post-analytical time)
- **Therapeutic Turnaround Time:** Time from test order to TREATMENT [this is what ultimately matters]
**When Automation isn’t Fast Enough...**

**Total Testing Process:** The testing process is comprised of three key elements.

- "Total Turnaround Time"
- "Analytical Turnaround Time"
- "Therapeutic Turnaround Time"

Tests requiring < 1 hour and perhaps < 30 min turnaround times
- Cardiac troponin
- Glucose
- Lactate
- Creatinine
- Others?

**HOW DO WE ACCOMPLISH THIS?**

"Total Testing Process"
When Automation isn’t Fast Enough...

**Total Testing Process**: The testing process is comprised of three key elements.

- "Total Turnaround Time"
- "Analytical Turnaround Time"
- "Therapeutic Turnaround Time"

Tests requiring < 1 hour and perhaps < 30 min turnaround times
- Cardiac troponin
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POCT
Point-of-Care Testing (POCT)
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• **Definition**: “Medical testing at or near the site of patient care”
Point-of-Care Testing (POCT)

- **Definition:** “Medical testing at or near the site of patient care”
- **Goal:** Improve outcomes by reducing the therapeutic turnaround time (TTAT)
Point-of-Care Testing (POCT)

- **Definition:** “Medical testing at or near the site of patient care”

- **Goal:** Improve outcomes by reducing the therapeutic turnaround time (TTAT)

- **Note:** Definition excludes the size of the platform!

POCT Formats

- Disposable
- Handheld
- Portable
- Transportable
- Benchtop
- Monitoring
POCT Formats

- Disposable
- Handheld
- Portable
- Transportable
- Benchtop
- Monitoring
- Smart devices
Brief History of POCT:
How we got here...
Home Blood Glucose Monitoring (1970’s)

Diabetics and critically ill patients require frequent blood glucose testing to adjust insulin dosing.

**Reflectance-Based Glucose Monitor**
First glucose meter called the Ames Reflectance Meter (ARM). Invented by Tom Clemens and Michael Miller. Patented in 1971

Key study in 1983 detailed the potential clinical benefit of self monitoring glucose to guide insulin therapy.¹

¹ Geffner ME, et al. JAMA 1983;249:2913-2916
Today – the Ubiquitous ”Glucose Meter”

- Numerous blood glucose monitoring devices are commercially available today.
- Global market for home glucose monitoring was $1.7 billion in 1994, increased to $3.8 billion in 2000, and expected now exceeds $4 billion.
- Home glucose monitoring accounts for about 22% of the $39 billion in vitro diagnostics industry.

POCT in Critical Care: Special Populations

In the early 1980’s, surgeons and anesthesiologists require rapid blood gas and electrolyte measurements for monitoring oxygenation and tissue perfusion.

**Patient-Side Blood Gas Testing**

pH, PCO2, PO2, SO2%, hematocrit, hemoglobin, Na+, K+, Glu, Lactate, Ca++ or Cl-

UC Davis was one of the first hospitals to bring a whole blood analyzer into the operating room theater.

Numerous studies verifying the clinical impact of POCT whole blood analysis (Principles and Practice of Point of Care Testing, 2002, Kost GJ)
Today: POC Whole Blood Analyzers

**Handheld Clinical Analyzer**

*Format:* Handheld analyzer with disposable cartridges

*Analytes:* Electrolytes, metabolites, coagulation, hematocrit, hemoglobin, cardiac biomarkers, blood gases

**Portable Blood Analysis System**

*Format:* Portable analyzer with disposable cartridges

*Analytes:* Electrolytes, metabolites, coagulation, blood gases

**Benchtop Whole Blood Analyzer**

*Format:* Transportable analyzer

*Analytes:* Electrolytes, metabolites, blood gases
Special POCT Populations
Clinical Impact of POCT in Special Populations: A Value Proposition
Case 1: Acute Kidney Injury in Burn Patients

• Case example of early recognition of acute kidney injury (AKI) in severely burned patients requiring massive fluid resuscitation.

• Up to 58% of burn patients may experience AKI.
“Burn Shock”

**Burn Shock**

Occurs during the first 24-48 hours following burn injury. Manifested by hypotension due to systemic inflammation and significant evaporative water loss.

**Parkland Formula (Baxter 1978)**

4 mL Lactated Ringers Solution/TBSA/kg body weight, half given first 8 hours, remainder last 16 hours
Burn Shock

EXCESSIVE EVAPORATIVE WATER LOSS

INCREASED VASCULAR LEAKAGE
Inadequate Resuscitation

Under Resuscitation
Acute under resuscitation leads to hypoperfusion, organ dysfunction, and eventually death.

Long-term complications due under resuscitation includes increased risk for sepsis and acute kidney injury.

Over Resuscitation
Extravascular fluid accumulation leading to pulmonary edema, compartment syndrome, and prolongs mechanical ventilation.

Increases risk for heart failure and pneumonia.
Monitoring of Fluid Resuscitation

Central venous pressure (CVP)
- Poor relationship between CVP and blood volume. Poor association with changes in CVP during fluid challenges.\(^1\)

Serum creatinine
- Rises in creatinine occur after 50% or more damage to nephrons. Creatinine half life also slow.\(^2\)

Urine output (UOP)
- High UOP may not be representative of renal status during acute resuscitation. In critical illness, GFR can be altered, yet UOP may remain the same.\(^2\)

Biomarkers for Under-Resuscitation

Prediction of Acute Kidney Injury (AKI)

- Several biomarkers have been shown to be predictive of kidney injury.\(^1,2\)

- NGAL in particular has been shown to be predictive of AKI (OR 3.73, 95% CI: 1.26 to 11.01).\(^3\)

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Point-of-Care NGAL Measurements

Multiplex NGAL Assay Specifications
Sample Volume: 240 μL EDTA whole blood
Turnaround Time: 15 - 20 minutes
Methodology: Sandwich Immunoassay
Measurable Range: 15 – 1300 ng/mL

*NOT AVAILABLE IN THE UNITED STATES

1. Add sample to the device.
2. Insert device into the meter.
3. Read results on the display.
Handheld Creatinine Meter

Patient Blood Drop Applied
1.2 Microliter Sample

Micro-Capillary Vent Layer
Capillary Vent

Micro-Capillary Sample Layer
Capillary Channel

Electrode Well Layer
Electrode Wells
For Measuring Creatinine, Hematocrit, and Interferences

Base and Conductive
Gold Layer
Electrochemical Measuring Surface

Electrical Contact End to Meter
## Demographics: AKI vs. No-AKI Patients

<table>
<thead>
<tr>
<th>Variable</th>
<th>AKI (n = 14)</th>
<th>Non-AKI (n=16)</th>
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<tbody>
<tr>
<td>Age (years)</td>
<td>39.9 (15.5)</td>
<td>38.2 (13.2)</td>
<td>0.796</td>
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<td>TBSA (%)</td>
<td>49.7 (26.0)</td>
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<td>Gender (M, F)</td>
<td>11, 3</td>
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<tr>
<td>Fluid Rate (mL/hr)</td>
<td>974.5 (452.1)</td>
<td>778.8 (343.8)</td>
<td>0.213</td>
</tr>
<tr>
<td>BUN (mg/dL)</td>
<td>10.2 (3.5)</td>
<td>9.9 (4.1)</td>
<td>0.137</td>
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<td>Creatinine (mg/dL)</td>
<td>0.90 (0.19)</td>
<td>0.83 (0.13)</td>
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<td>MAP (mmHg)</td>
<td>78.7 (12.5)</td>
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<td>CVP (mmHg)</td>
<td>14.9 (11.9)</td>
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<td>UOP (mL/hr)</td>
<td>85.5 (36.3)</td>
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**Abbreviations:** AKI, acute kidney injury; BUN, blood urea nitrogen; CVP, central venous pressure; F, female; M, male; MAP, mean arterial pressure; TBSA, total body surface area; UOP, urine output
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<td><strong>NGAL (ng/mL)</strong></td>
<td><strong>184.7 (86.3)</strong></td>
<td><strong>111.6 (47.8)</strong></td>
<td><strong>0.014</strong></td>
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**Abbreviations:** AKI, acute kidney injury; BUN, blood urea nitrogen; CVP, central venous pressure; F, female; M, male; MAP, mean arterial pressure; NGAL, neutrophil gelatinase associated lipocalin; TBSA, total body surface area; UOP, urine output
NGAL in AKI Patients (n = 30)

NGAL in AKI vs. No-AKI Patients
184.7 [86.3] vs. 111.6 [47.8] ng/mL, P = 0.014
OR 1.3, 95% CI 0.03 – 0.59, P = 0.039*

*Controlled for age and TBSA
Urine Output in AKI Patients (n = 30)

UOP in AKI vs. No-AKI Patients
83.2 [36.3] vs. 86.0 [26.7] mL/hr, P = 0.858

Urine Output Goal = 30 mL/hr
Creatinine in AKI Patients (n = 30)

Creatinine in AKI vs. No-AKI Patients
0.90 [0.19] vs. 0.83 [0.13], P = 0.078

Upper Limit of Normal = 1.2 mg/dL
Case 2: Molecular Infectious Disease Testing

- Only recently has molecular diagnostics moved to the point of care.
- Previously, almost unheard of for molecular infectious disease testing to be used at the bedside.
- Multiple products now existing using polymerase chain reaction or isothermal amplification techniques for mainly respiratory pathogens.
- Test quality and cost-effectiveness are key concerns.
Enhancing Care Paths with Molecular POCT
Enhancing Care Paths with Molecular POCT

Case Example:
Diagnosis of Respiratory Tract Infections (RTI) in the ED

qSOFA
SIRS
Suspicion of RTI
Enhancing Care Paths with Molecular POCT

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Multiplex Molecular Respiratory Panel ($109/test)
Enhancing Care Paths with Molecular POCT

Case Example:
Diagnosis of Respiratory Tract Infections (RTI) in the ED

VALUE ADDED by Enhancing Quality of Care:
PCT aids in determining the risk for bacterial infection.
✓ PCT negative and PCR viral panel positive can avoid the need for antimicrobial therapy.
✓ PCT positive and PCR bacterial panel positive helps target appropriate antimicrobial therapy
✓ Optimizes molecular revenue generation
Enhancing Care Paths with Molecular POCT

Case Example:
Diagnosis of Respiratory Tract Infections (RTI) in the ED

qSOFA
SIRS
Suspicion of RTI

+PCT

Multiplex Molecular Respiratory Panel ($109/test)

OPTIMIZING MOLECULAR TESTING:
• Addition of bedside targeted molecular testing for common pathogens such as Flu/RSV and Strep A improves the cost-effectiveness.
Key Considerations for Molecular POCT

• It may not be appropriate or desirable to report on every result. Multiplexing may not always be better.

• Test utilization will be key for cost-effectiveness. Healthcare providers still have to use good judgement when ordering!

• Not all platforms are created equal. Example isothermal amplification may not be the same as PCR.

• Consider manufactures that have a robust molecular portfolio. This means potential for other tests.
Limitations of POCT in Special Populations: “POCT is not an excuse for inaccuracy”
FDA MAUDE Database
FDA MAUDE Database

<table>
<thead>
<tr>
<th></th>
<th>BGMS A</th>
<th>BGMS B</th>
<th>BGMS C</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Timeframe</strong></td>
<td>1997-14</td>
<td>2013-14</td>
<td>2007-11</td>
</tr>
<tr>
<td><strong>Adverse Events (Deaths)</strong></td>
<td>28 (13)</td>
<td>5 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td><strong>Erroneous Results</strong></td>
<td>557</td>
<td>168</td>
<td>15</td>
</tr>
<tr>
<td><strong>Non-Clinical Event</strong></td>
<td>387</td>
<td>59</td>
<td>21</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>1094</td>
<td>232</td>
<td>36</td>
</tr>
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>12,000 glucose meter related issues reported annually to FDA, with 12,762 adverse events reported from 2004-2008 alone – most due to erroneous results from operator error and interferences leading inappropriate treatment.
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Example 1: Common Confounding Factors for Glucose Meters

Anemia and polycythemia causes falsely high or falsely low results respectively.
Example 1: Common Confounding Factors for Glucose Meters

Oxidizing and reducing substances interfere with electrochemical sensors causing falsely high or low results.
Example 1: Common Confounding Factors for Glucose Meters

Specimen temp alters biosensor enzyme kinetics. Hypotension/shock affect capillary specimens.
Example 1: Common Confounding Factors for Glucose Meters

Some glucose meters cannot differentiate between certain non-glucose sugars (e.g., maltose, galactose)
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Some glucose meters cannot differentiate between certain non-glucose sugars (e.g., maltose, galactose).

What is the impact?
Automatic Hematocrit Correction

Glu Oxidase, Amperometric*

Glu Oxidase, Photometric

Glu Oxidase, Amperometric


MPE = mean percentage error

MPE = mean percentage error

Glu Oxidase, Photometric

Glu Oxidase, Amperometric

Glu Oxidase, Amperometric*

---

60 mg/dL

500 mg/dL
Comparison of an Autocorrecting vs. Non-Correcting BGMS: A Story of 12 Adult Patients with Severe Burns

Hypothesis: Accurate BGMS Testing Improves Glycemic Control
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BGMS A Glucose
- New glucose meter
- Automatically corrects for hematocrit and ascorbic acid interference (among others)

Automatic Hematocrit and ascorbic acid interference CORRECTION

High accuracy and precision due to autocorrection
Hypothesis: Accurate BGMS Testing Improves Glycemic Control
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BGMS B Advantage
- Existing UC Glucose Meter (2011)
- Anemic Samples → falsely high results
- Polycythemic Samples → falsely low results
- Ascorbic acid → falsely high results

Erroneous measurements from confounding factors!
Hypothesis: Accurate BGMS Testing Improves Glycemic Control

Study Funded by NIH/NCRR MCRTP Project

Patients with >20% TBSA survivable burns randomized 1:1 to BGMS A vs. BGMS B.

All BGMS measurements record over their ICU stay. Medications also recorded.

Outcome Measures
• Frequency of hypoglycemia
• BGMS vs Lab Performance
• Glycemic variability
• Insulin rates
# Patient Demographics

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<th>BGMS B Group (n = 6 patients)</th>
<th>P-Value</th>
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<tbody>
<tr>
<td>Mean (SD) Age (years)</td>
<td>35.7 (6.2)</td>
<td>40 (15.1)</td>
<td>NS</td>
</tr>
<tr>
<td>Mean (SD) TBSA (%)</td>
<td>44.5 (6.5)</td>
<td>57.8 (12.4)</td>
<td>NS</td>
</tr>
<tr>
<td>Mean (SD) MODS</td>
<td>5.4 (4.3)</td>
<td>5.4 (12.4)</td>
<td>NS</td>
</tr>
<tr>
<td>Mean (SD) Hematocrit (%)</td>
<td>26.1 (4.9)</td>
<td>25.3 (5.2)</td>
<td>NS</td>
</tr>
<tr>
<td>Inhalation Injury</td>
<td>0/6</td>
<td>0/6</td>
<td>NS</td>
</tr>
<tr>
<td>Diabetes</td>
<td>1/6</td>
<td>1/6</td>
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<td>Gender (M, F)</td>
<td>4, 2</td>
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**Abbreviation:** F, female; M, male; MODS, multiple organ dysfunction score; NS, not significant; SD, standard deviation; TBSA, total body surface area.
Between Group Comparisons

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<tr>
<td>MAGE (SD)</td>
<td>29.6 (5.4)</td>
<td>48.4 (13.1)</td>
<td>0.015</td>
</tr>
<tr>
<td>Mean (SD) Insulin Rate (U/hr)</td>
<td>2.66 (1.8)</td>
<td>4.02 (3.7)</td>
<td>&lt;0.001</td>
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<tr>
<td>Hypoglycemic Events</td>
<td>2</td>
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**Abbreviations:** BG, blood glucose; CONGA, continuous overall net glycemic action; CV, coefficient of variation; IQR, interquartile range; MAGE, mean amplitude of glycemic excursions; MODD, mean of daily differences
### Between Group Comparisons

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**CENTRAL LAB RESULTS**
## Between Group Comparisons

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**BGMS patients experienced**
- Falsely high glucose meter results
- Nearly twice as much glycemic variability
- Nearly twice as much hypoglycemic events

**Abbreviations**: BG, blood glucose; CONGA, continuous overall net glycemic action; CV, coefficient of variation; IQR, interquartile range; MAGE, mean amplitude of glycemic excursions; MODD, mean of daily differences
Clinical Impact of Accurate Glucose Monitoring in Children with Severe Burns

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<td>7.1 (4.9)</td>
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<td>Mean (SD) TBSA (%)</td>
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<td>46.5 (46.7)</td>
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<td>Inhalation Injury (%)</td>
<td>15.2</td>
<td>17.5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>ICU length-of-stay (days)</td>
<td>31.4 (30.5)</td>
<td>46.5 (46.7)</td>
<td>NS</td>
</tr>
<tr>
<td>Ventilator Days</td>
<td>23.5 (20.8)</td>
<td>28.2 (35.6)</td>
<td>NS</td>
</tr>
<tr>
<td>Gender (M, F)</td>
<td>38, 21</td>
<td>35, 28</td>
<td>NS</td>
</tr>
</tbody>
</table>

**Abbreviation:** F, female; ICU, intensive care unit; M, male; NS, not significant; SD, standard deviation; TBSA, total body surface area.

**Note:** Removal of patients with inhalation injury did not significantly change glycemic variability, hypoglycemic events, or insulin rate results between BGMS A vs. B patients.
### BETWEEN Group Comparisons (BGMS A vs. B)

<table>
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<tr>
<th>Variable</th>
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<th>BGMS B (n = 63)</th>
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<tr>
<td>Mean (SD) Bias (mg/dL)</td>
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**Hypoglycemic Events (P<0.001)**
- BGMS A Group: 12 total from 4 patients (6.7% of patients)
- BGMS B Group: 90 total from 26 patients (28.9% of patients)

**Abbreviations:** BG, blood glucose; CONGA, continuous overall net glycemic action; CV, coefficient of variation; IQR, interquartile range; MAGE, mean amplitude of glycemic excursions; MODD, mean of daily differences; NS, not significant
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**SUMMARY:**
- Not everyone glucose meter is created the same.
- Confounding factors have a significant impact on accuracy.
- Accuracy DOES matter!
Example 2: Inaccurate Hemoglobin Measurements

Each year, the FDA receives several hundred thousand medical device reports (MDRs) of suspected device-associated deaths, serious injuries and malfunctions. The FDA uses MDRs to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of those products. The MAUDE database houses MDRs submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers.
Case Study – Inaccurate Hemoglobin Measurements

**Background:** FDA MAUDE database reports a case (03P76-25) of a neonatal patient with discrepant point-of-care (POC) hemoglobin values compared to the laboratory. The POC device used a conductance-based method of hemoglobin measurement, while the laboratory used a spectrophotometric method.
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- Transfusion was stopped halfway after the laboratory reported a hematocrit of 40% and hemoglobin of 11.7 g/dL.

- Post-transfusion POC and lab hematocrit values were 45 and 50% respectively.
Overview of POC Hemoglobinometry Techniques

Conductance (Impedance)

- Red blood cell membranes are not conductive.
Overview of POC Hemoglobinometry Techniques

Conductance (Impedance)

Electrode

- Red blood cell membranes are not conductive.

![Diagram showing resistance vs. hematocrit](image-url)
Overview of POC Hemoglobinometry Techniques

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• Red blood cell membranes are not conductive.

• The number of red blood cells is proportional to the change in conductance and conforms to Ohm’s Law ($V = IR$)
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• Conductance-based methods measure hematocrit. The hematocrit can then be used to calculate hemoglobin based on a conversion factor ($\text{estimated hemoglobin} = \frac{\text{hematocrit}}{3.4}$)*
Overview of POC Hemoglobinometry Techniques

Conductance (Impedance)

Electrode

VS.
Overview of POC Hemoglobinometry Techniques

Conductance (Impedance)

Electrode VS.
Overview of POC Hemoglobinometry Techniques

Spectrophotometric Techniques
Overview of POC Hemoglobinometry Techniques

Spectrophotometric Techniques
Overview of POC Hemoglobinometry Techniques

Spectrophotometric Techniques

Light source (typical red/IR) is sent through a specimen with or without lysis of the red blood cells.
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Problems with Conductance Based Methods

Conductance (Impedence) \( \bullet \) = Plasma Protein

Electrode

High Resistance

- Plasma protein content contributes to hematocrit measurements for conductance-based systems.
Problems with Conductance Based Methods

**Conductance (Impedence)** $\bullet = \text{Plasma Protein}$

Electrode

- Low Resistance from low plasma protein concentration!

- Plasma protein content contributes to hematocrit measurements for conductance-based systems.

- Conductance-based systems assumes a relatively fixed protein concentration. Therefore, during hemodilution, hematocrit may be falsely lower and causing an underestimation of total hemoglobin.
Problems with Conductance Based Methods

**Conductance (Impedence)** \(\bullet = \text{Plasma Protein}\)

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- Plasma protein content contributes to hematocrit measurements for conductance-based systems.

- Conductance-based systems assumes a relatively fixed protein concentration. Therefore, during hemodilution, hematocrit may be falsely lower and causing an underestimation of total hemoglobin.

- **UCDMC Study**: Comparison of a handheld blood gas analyzer using conductance-based measurement of hemoglobin versus a benchtop blood gas analyzer using a spectrophotometric-based method for hemoglobinometry.
Clinical Impact of Hemodilution for Point-of-Care Hemoglobin Measurements

- Sixty patients requiring cardiac surgery were evaluated.
- Paired specimens were tested using a handheld POC analyzer and spectrophotometric methods through the core laboratory.
- Mean (SD) bias was \(-1.4 \pm 1.1\) g/dL, \(P = 0.011\).
- Based on core laboratory results 12 patients would have received unnecessary transfusions.
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\[ \$219 \times 12 = \$2,628 \text{ POTENTIALLY WASTED} \]

Analytical Performance of Optical vs. Conductance-Based Hemoglobinometry

Notes: *** P<0.001, Lab = Beckman LH hematology analyzer
Analytical Performance of Optical vs. Conductance-Based Hemoglobinometry

Serial Testing at Transfusion Cut Offs

• Serial testing revealed significant analytical bias between spectrophotometry vs. conductance-based measurements.

Notes: *** P<0.001, Central Lab = Spectrophotometric Method, n = 20 patients
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Disaster and Field Settings: A Very Unique Special Population
Asian Tsunami 2004

- 9.3 earthquake near Sumatra
- Killed over 250,000 people
- Impacted 14 countries with waves up to 100 ft high
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Severity of Damage (Clinic)

Electrolyte Testing

O₂ Saturation Monitors [Pulse Oximeters]

DISASTER POINT-OF-CARE TESTING
HURRICANE KATRINA - 2006
Recommended Timeline

- Disaster-specific mobile laboratories arrive by day 4
- Critical care analyzers and transportable POCT arrive
- Local rescue units equipped with handheld POCT respond
- Triage immediately using battery-operated POCT

Legend
- H Open Hospital
- M Mobile Medical Care Unit
- Seaborne Special Assistance

Area Affected (darker = severe)
- 80% flooded, some under 6 m
- 12 New Orleans hospitals inoperable
- Helipads out of service

Abbott (day 3)
- Semi-truck mobile laboratory
- Equipped with transportable and handheld whole-blood analyzers for hematology and chemistry
- Deployed to Houston Astrodome to serve evacuees

USS Iwo Jima (day 4) and USNS Comfort (day 9)
- Ships have a bed capacity of 1,600
- Equipped with transportable whole-blood analyzers and portable cardiac biomarker testing
- Facilities include helipads, ORs, ICU, imaging, laboratories, pharmacy, and patient wards
- Docked near New Orleans to provide medical aid, communications, and logistics support to the region

Carolinias MED-1 Mobile Hospital (day 5)
- Semi-truck level-1 trauma mobile medical facility
- Supports up to 113 patients
- Equipped with ICU, OR, pharmacy, laboratory, and imaging services
- Deployed to Bay Saint Louis

USS Bataan (day 1) and other ships provided relief and air rescue

US Army 14th Combat Support Hospital (day 24)
- Deployed to Louis Armstrong International Airport, New Orleans
- Supports up to 200 patients (789 with enhancements)
- Equipped with POC whole-blood analyzers (portable and handheld), blood typing instruments, and coagulation analyzers
- Facilities include ICUs, ORs, pharmacy, laboratory, and imaging
Disaster Medical Assistance Teams (DMAT)

Background: A 35-person National Disaster Medical System (NDMS) special team which is designed to provide medical care during disaster or other events.

Total of 55 DMATs in the United States plus specialty teams for burn, pediatric, and veterinary medicine.

DMAT Requirements:
- Have a sponsoring organization (e.g., major medical center or public health agency)
- Deploy within 6 hours of activation, have the resources to deploy to disaster sites with sufficient supplies and equipment to sustain themselves for 72 hours.
- Provide emergent care within 30-minutes of arrival, and be operational within 6 hours of arrival.
- Provide ambulatory care for 250 patients.

POCT During Hurricane Katrina

DISASTER POINT-OF-CARE TESTING
Haiti Earthquake - 2010
2010 Haiti Earthquake - Infrastructure Damaged

- The earthquake shut down the health care and transportation small-world networks, then was followed by a cholera epidemic
- Disaster responders equipped with point-of-care testing would be better prepared in resource-poor disaster sites
- For example, in Haiti disaster responders required rapid and highly sensitive HIV testing following inadvertent needle sticks

2010 Haiti Earthquake

- Power loss and physical disruption of communication networks following the earthquake resulted in connectivity failures.
- Cell phone service was not available for 17 days in the capital, Port-au-Prince.
- Lack of communications resulted in lack of situational awareness and uncoordinated responses by multiple non-government organizations (NGO).
- Patient referral between NGOs and other health care providers was slow and frustrating.
- Patient tracking technology was often unavailable. Example: Patient requiring emergency surgery was transported to USNS Comfort. Family was not able to follow. Patient died and family was not able to locate body.

# Wireless Solutions in Disasters

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Description</th>
<th>Range</th>
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<tbody>
<tr>
<td>MobileSAT</td>
<td>Provides 802.11x WiFi capability via satellite communications</td>
<td>Unlimited due to satellite and WiFi range (150ft)</td>
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<tr>
<td>Worldwide Interoperability for Microwave Access (WiMAX)</td>
<td>Wireless system (IEEE 802.16) that can transmit via an internet backbone</td>
<td>4-6 mile radius</td>
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<tr>
<td>Wireless Internet Information System for Medical Response in Disasters (WIISARD)</td>
<td>WiFi to WiFi mesh network to cellular or satellite</td>
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<td>Tactical Network Transmissions (TNT)</td>
<td>Satellite and troposcattering microwave signals to provide 4G data connectivity in battlefield settings.</td>
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Ebola Crisis of 2014: Bringing the Experience Together
Background

Largest Ebola epidemic in history (24,907 cases and 10,326 deaths. Index case appears to have originated in Guinea around December 2013.)
Ebola Testing at UCDMC

- Feedback from Emory, Nebraska, and NIH Medical Centers clearly indicated a need for an expanded POCT menu.

- Patients infected with Ebola virus may lose substantial fluid loss and electrolyte derangement.

- Existing chemistry panel not adequate – needed total Mg testing!

- UCDMC identified Davis 11 (2 rooms) to serve as the isolation unit.

- Nursing requested laboratory to perform all POCT in contrast to the original plan for testing to be performed at the bedside.
EBOLA PERSONAL PROTECTIVE EQUIPMENT (PPE)

- Powered Air Purifying Respirator (PAPR) and hood
- Surgical hair cover
- Nitrile gloves (two pairs)
- Impervious coverall (over scrubs, under gown)
- Impervious gown
- Impervious leg/shoe covers

UC DAVIS MEDICAL CENTER
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Trauma Nursing Unit Layout
Ebola Isolation Unit
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**EBOLA RESPONSE LABORATORY TESTING**

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<tr>
<td><strong>Blood Gas/Co-Ox:</strong> pH, pCO2, pO2, TCO2, SO2%, Hb, Hct</td>
<td><strong>Complete Blood Count:</strong> Hct, Hb, WBC (3-part diff), platelet</td>
<td><strong>Bacterial:</strong> 8 Gram positive, 11 Gram negative, 5 fungal, and 3 resistance genes</td>
<td><strong>Blood Culture:</strong> All culturable pathogens</td>
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<td><strong>Chemistry:</strong> Na+, K+, Cl-, Ca++, tMg, dBil, dBil, BUN, creatinine, glucose, lactate, ALP, AST, ALT, GGT, albumin, total protein, amylase</td>
<td><strong>Coagulation:</strong> PT/INR, aPTT, and ACT</td>
<td><strong>Respiratory:</strong> 18 viral pathogens, and 3 bacterial pathogens</td>
<td><strong>Malaria:</strong> Plasmodium falciparum, P. vivax, P. ovale, and P. malariae</td>
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**Abbreviations:** ALP, alkaline phosphatase; ALT, alanine aminotransferase; AST, aspartate transaminase; BP, blood pressure; BUN, blood urea nitrogen; CVP, central venous pressure; dBil, direct bilirubin; EKG, electrocardiogram; GGT, gamma-glutamyl transpeptidase; MRSA, methicillin resistant S. aureus; NBP, non-invasive blood pressure; PAWP, pulmonary artery wedge pressure; SA, Staphylococcus aureus; tBil, total bilirubin; tMg, total magnesium
Conclusions

• POCT in special populations can significantly improve outcomes.

• However, caution is advised where POCT performance may not provide accurate measurements—resulting in erroneous treatment.

• Confounding factors such as specimen matrix, interfering medications/substances, among others, can impact POCT accuracy.

• Proper integration of POCT for special populations is critical to avoid excessive testing especially for more expensive tests.

• Disaster and field POCT represents a unique special population.
Acknowledgements

Studies were supported in part by the National Institutes of Health through a POCT Center grant (NIBIB U54) and K30 training award. Investigated devices not in routine use at UC Davis were donated by the manufacturer (Nova Biomedical and Alere). Radiometer America sponsored the hemoglobin comparison study.
QUESTIONS?