The Impact of CBC Testing on Treatment Decisions



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Disclosure

I have a strategic consulting relationship with PixCell Medical, Inc.

Dates of Consulting: October 2022 - Present Type of Consulting Services Provided: Strategic planning, market research, and business development Potential Conflicts of Interest: While I strive to provide unbiased insights and recommendations, my consulting relationship with PixCell Medical, Inc. may impact my perspective on topics related to the medical device industry.

Note: PixCell Medical, Inc. is a medical device company focused on developing innovative diagnostic solutions to improve patient care.

Disclosure

I am an Anesthesiologist at the University of Cincinnati.

Employment: Anesthesiologist Dates of Employment: August 2012 - Present Type of Employment: Clinical and Academic Potential Conflicts of Interest: While I strive to provide unbiased insights and recommendations, my employment at the University of Cincinnati may impact my perspective on topics related to healthcare and medical education.

Note: The University of Cincinnati is a public research university with a comprehensive healthcare system, including the UC Health network of hospitals and clinics.

Objectives

- Evolve our **understanding of healthcare process**, *and* reveal how Lab Diagnostics plays an "outsized" role in said process, setting up Laboratorians and Directors to be leaders in process improvement and system efficiency.
- Reconsider **Point of Care as a critical tool for streamlining** a patient's path through their care and system efficiency.
- Discuss real world examples where Lab Diagnostics can dramatically improve throughput and patient process, especially through Point of Care.
- Labs=Data=Decisions=Throughput=Healing



The Point of Care: Healing People



Healthcare Process



Healthcare Process



Healthcare Process





| Locations | Staff/Teams | Contributors |
|---|---|--|
| ER Radiology OR Hosp Floor | EM Rad Surgery Anesthesia PT / OT | LabPharmacy |



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| ER | Surgery | Lab |
|----------|---------|----------|
| Revenue | Revenue | Revenue |
| Expense | Expense | Expense |
| GI Suite | OR | Pharmacy |
| Revenue | Revenue | Revenue |

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\$

Expense

Expense











Safety net hospitals in Georgia are at risk. Atlanta Medical Center is just the latest example

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Doctors' strike threatens tackling backlog, warn NHS bosses



14 MANAGEMENT PRINCIPLES FROM THE WORLD'S GREATEST MANUFACTURER



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Second Edition



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The Point of Care: Hospital Process Management



The Point of Care: Hospital Management



















The Point of Care: Objectives

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Point of Care: Throughput Accelerator



Labs = Decisions = Throughput

Point of Care: Throughput Accelerator








x 1000's

Point of Care

| | Test Revenue | Test Cost | Test Accuracy | Test Timing | Test Scope |
|--------------|-----------------|-----------|------------------|-------------|------------|
| In House Lab | MEDIUM | LOW | HIGHEST | MEDIUM | MEDIUM |

| | Test Revenue | Test Cost | Test Accuracy | Test Timing | Test Scope |
|------------|-----------------|-----------|------------------|-------------|------------|
| Outsourced | HIGH | HIGH | HIGH | SLOW | HIGH |

| Test Revenue | Test Cost | Test Accuracy | Test Timing | Test Scope |
|-----------------|-----------|------------------|-------------|------------|
| LOW | HIGH | DEPENDS | FASTEST | LOW |

| | Test Revenue | Test Cost | Test Accuracy | Test Timing | Test Scope |
|--------------|-----------------|-----------|------------------|-------------|------------|
| In House Lab | MEDIUM | LOW | HIGHEST | MEDIUM | MEDIUM |

| Test Revenue | Test Cost | Test Accuracy | Test Timing | Test Scope |
|-----------------|---|---|--|---|
| HIGH | HIGH | HIGH | SLOW | HIGH |
| | | | | |
| Test Revenue | Test Cost | Test Accuracy | Test Timing | Test Scope |
| LOW | HIGH | DEPENDS | FASTEST | LOW |
| • | Test Revenue HIGH Test Revenue LOW | Test RevenueTest CostHIGHHIGHTest RevenueTest CostLOWHIGH | Test RevenueTest CostTest AccuracyHIGHHIGHHIGHTest RevenueTest CostTest AccuracyLOWHIGHDEPENDS | Test RevenueTest CostTest AccuracyTest TimingHIGHHIGHHIGHSLOWTest RevenueTest CostTest AccuracyTest TimingLOWHIGHDEPENDSFASTEST |









In House Lab

"STAT" Labs:

- 35 Minute Average Time
 - Sample Time + Results + Information to provider
- 90th Percentile = 87min

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Point of Care

Systems

- 3-5 minute run time
- Sample Time + Results + Information to provider
- 90th Percentile ~ 10 minutes



Less Quality Control needs



- Less Quality Control needs
- Higher accuracy



- Less QC
- Higher accuracy
- Simplified User Interface



- Less QC
- Higher accuracy
- Simplified User Interface
- Reduced user error and training needs











Labs



Labs = Decisions



Labs = Decisions = Throughput





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 Healing

 The Point of Care







Patient #1

56yo M, Hx of alcohol abuse, Hep C. Patient comes in because he "fell out." Has been throwing up dark vomitus, looks like coffee.

- Esophageal tear
- Cirrhosis Varices
- Peptic ulcer Disease
- Others



Patient #2

75yo F, Hx of GERD, HTN, Hyperlipidemia, stroke last year. Started throwing up blood this morning. 3 episodes since, bright red.



- Cirrhosis
- Peptic ulcer Disease
- Other: Anticoagulation



GI Bleed

- GI Bleeding:
 - 149.8 cases per 100,000 persons per year
 - >80yo: 524.6 cases per 100,000



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 - 1 in 10 people in the US are on some form of anticoagulation
 - 1.5% to 2.7% have GI
 Bleeds



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Next Step: Urgent/Emergent Endoscopy



Urgent/Emergent Endoscopy = Diagnosis and Treatment in One



Can the patient tolerate the procedure?

- Will pt need transfusion before or can we proceed?
- Will we need platelets be able to stop the bleeding?
- Is it okay to proceed with General vs. MAC sedation

Urgent/Emergent Endoscopy





Can the patient tolerate the procedure?

In 10 minutes:

- HgB= 8.2
- Platelets=200
- Proceed with GA for aspiration risk
- No platelets
- Type and Cross RBC but proceed



Labor and Delivery - Epidurals and Complications

- 9 million epidurals in OB (L&D) per year
- 10% to 20% High Risk
- Risk: Epidural Hematoma increases with Platelets <70
- 67% of C-Sections under epidural (1.2 million)
- Each year, about 14 million women experience postpartum hemorrhage resulting in about 70,000 maternal deaths globally



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HEALTH

U.S. Maternal Mortality Hits Highest Level Since 1965

Black mothers are the most affected, 2021 data show


Patient Scenario #3

26yo F, G2P1. Hx of pre-eclampsia, previous C-section. Wants (Vaginal Birth After Cesarean (VBAC) Arrives at 5cm dilation. Requesting epidural.



Neuraxial Anesthetic Placement for Labor & Delivery or Cesarean -Epidural and Spinal



What does the patient need now and before the procedure?

Is the Platelet count >70?

Neuraxial Anesthetic Placement for Labor & Delivery or Cesarean -Epidural and Spinal





Can the epidural be placed so patient is ready for Labor and complications?

- 10 min
- Platelet Count=120

Patient Scenario #3 Part 2

Same patient, successfully delivered vaginally. 30 minutes later, called to room because of profuse vaginal bleeding.

Emergent Need:

- **NEW CBC:** Do we need to transfuse?
- **NEW Platelets:** will we be able to stop the bleeding?

Maternal Hemorrhage



What does the patient need now and before the procedure?

- NEW CBC
- NEW Platelet Count

Maternal Hemorrhage





What does the patient need now and before the procedure?

- HgB=7.3
- Platelets= 90
- Get RBCs and Platelets and transfuse immediately
- Prep OR for evaluation



Acute Surgical intervention

- 10.6 million surgeries are Emergent/Urgent
- Of the 40-50MM surgeries per year
 - 17% Emergent (within 1 hr)
 - 25% Urgent (within 6 hours)



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Considerations of Surgery

Higher likelihood of underlying medical conditions

Surgery

OR

Lab

STOP

- Higher risk of bleeding
- Higher risk of infection
- Anesthesia complications
- Need for more intervention pre-surgery
- Lack of preparation for surgery by patient



Would do we need to get to the OR?

- Hgb
- Platelets
- K+
- Type and Screen
- Electrolytes
- Glucose
- Renal Panel





Would do we need for the next step?

- Hgb
- Platelets
- K+
- Type and Screen
- Electrolytes
- Glucose
- Renal Panel

Other Examples



- Ambulatory Surgery Centers Hgb
- Kidney Transplant K+, Hgb
- Liver Transplant Take Backs CBC, Plt
- Post-Transfusion Pre-op CBC
- Spinals before Rad-Onc procedures CBC, Plt
- IR Stroke Stat: CBC, Plt
- SICU Bleed CBC, Plt
- Out of OR Procedures CBC, Plt, K+
- Out of OR intubations K+
- PACU Bleeding, Hypotension CBC
- Pain Clinic Neuraxial Plt
- Regional Anesthesia Plt
- Cardiac Surgery
- Introperative Data CBC, Plt, Electrolytes
- Discharge Labs: confirming stability Various



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Point of Care: Throughput Accelerator





Labs = Decisions



Decisions = Throughput







The Impact of CBC Testing on Treatment Decisions



Angela Wolff, MT(ASCP)

Director, Point of Care Quest Diagnostics

- Discuss the challenges of administering traditional hematology instrumentation at the point of care
- Identify the options that improve on the quality of testing at the point of care



Program Background – End to End POC Support from the Lab, from Largest to Smallest

POC Program

CLIA Licensure: 56 total licenses: 31 Moderate / 25 Waived

Complete support of Ascension St. Vincent Hospitals, Community Health Network, and Ortho Hospitals throughout Indiana from Quest Laboratories

POC Specialists: 7 licensed MTs serving as Technical Consultants POC Support Techs: 7

Testing Personnel: RNs and Medics

Program Background – POC Staff Duties

POC Specialists

- Assist with CMS116, CMS209, Enclosure I submissions/changes
- Assist with the upkeep of Accreditation accounts (CAP or Joint Commission)
- Lead all Accreditation Surveys
- Research/Test/Lead any device changes
- Write/Revise Procedures
- Write/Revise/Annually assess IQCP
- Perform/Evaluate all required studies
- Review Quality Control
- Review Maintenance
- Maintain Inventory
- Upkeep of middleware (Operators/Daily results/Inventory/Report)
- Maintain Proficiency Program (Ordering/Distribution/Submission/Review of results/Failure investigations)
- Troubleshooting
- Monthly QA Reports
- Competency Program (Writing of education/Sign-off/Charting)

Program Background – POC Staff Duties

POC Support Techs

- Monthly QC (New lot/QC baggies)
- Inventory Control (Ordering/Dot system/Delivery)
- Middleware (Operators/ Daily result review)
- Studies for new devices, Annual studies (Linearity/Correlations)
- Troubleshooting
- AUDITS (Device/Reagents)

Program Background – POC CBC Testing

Neighborhood ED Laboratories

Oncology offices

Student health services

Surgical Units

Rural / Critical Access – backup analyzers

Program Background – CBC testing challenges

Testing Personnel are not laboratorians!

Quality Control:

- Correct handling of control material (warming to room temperature, proper mixing)
- Multiple repeat testing on failed controls
- Ability to evaluate H/L flagging for acceptability
- Failure rate: 8 20%

Program Background – CBC testing challenges

Maintenance:

- Monthly (~1 hour) and Six-month (~1-2 hours) required
- Performed by POC Specialist
- Drain issues

Calibration:

- Required 2X per year
- Performed by POC Specialist

Reagent Inventory: 20L cubes of diluent / 5L Lyse

- Cubes are heavy
- RNs/Medics do not like to change reagents
- Temperature documentation

Program Background – CBC "wishlist"

- Easy to use
- Ability to have a 5 part differential
- IQCP Eligible
- Fewer reagents
- No maintenance
- Eliminate calibration
- Easy troubleshooting
- Easy training/competency

Thank You



Angela Wolff, MT(ASCP)

Director, Point of Care Quest Diagnostics

