100% Connectivity in Point of Care Testing is Achievable

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Disclaimer

* Duke Health Point of Care Testing Program uses the Alere RALS® Web3 interface. Disclosed because several screen captures are included in the presentation. Not intended as a commercial endorsement.

* Former member of the Alere RALS® Advisory Board (2013 to 2015).
Beginning your journey.... ask yourself?

- What are your connectivity goals?
- What is your current state?
- What is your 5-year growth plan?
- What is your 10-year growth plan?
- What Health Information System are you using?
- What Laboratory Information System are you using?
What are your connectivity goals?

- Operator/End User management?
- Flow of patient’s results from the instrument to the patient’s Electric Medical Record (EMR)?
- Quality Management? (QC review, reports, etc.)
- Improved documentation of Compliance?
- Instrument management?
- Interface all instruments?
- What about Manual Test results?
What is your current state?

- What is your current state?
  - What types of instruments do you have?
    - How many of each?
  - What are your connectivity options?
    - Ports
    - Computers
    - Wireless
  - How many locations?
  - How many operators/end users?
  - Do you want to report your manual testing results?
  - Are there connectivity solutions limitations with any of instruments?
What are your growth expectations?

- Are you expecting to add new locations?
- Are you expecting to add multiple facilities?
- Additional instrument options?
- Change instruments?
- Adding non-waived testing?
- POCT Staffing?
Information solutions

- Are there any limitations connecting to your Laboratory (LIS) or Hospital Information Systems (HIS)?
- Are there limitations with the POCT middleware connecting to your current instruments or LIS/HIS systems?
- Can operator/end users competency information be pulled from your current employee training system?
See what middleware solutions are out there. This field is constantly changing.

- What options do each have to meet your goals?
- Do you want a very flexible or rigid system?
- How robust of a system do you need?
- Cost
  - What is the upfront cost?
  - What is the cost to maintain?
  - What is the cost to add modules or instruments?
- What type of support does the vendor offer?
- Do they customize or one size fits all?
Some glucose meters offer the option of entering these results.
Some middleware solutions offer modules to enter your results.

Both options have good and bad points. You need to decide which is the best option for your program/hospital. Could be a combination of both.
Gather Key Players

You will need support and “buy in” from key players. This is a journey and will take several different groups to make it a smooth process. Invite or include individual or a representatives from:

- Laboratory Medical Director
- POCT Director
- POCT Lead
- LIS and HIS
- Finance
- Procurement
- Compliance
Visit like institutions using your top two choices.

- How long have they had the system?
- How do they use the system?
- Does it meet their needs?
- Ask what they like about the system and what they don’t?
- What would they change about the system?
- How often does the system go down?
Once your system is built, you might not be able to easily change it. Build for the future……

- Floor vs unit?
- Do your instruments move between units? Assign to general location or units?
- Do your Operators float to different units? Assign to general location or unit?
- Do you want to name your instruments or use serial numbers?
- Manage Operator/End User competency in the system or outside the system?
- Make sure each location/unit has the required ports or wireless access and electrical outlets needed. If not who will pay for it?
Test Environment

* Build your Test Environment to match exactly what you want your Live environment to look like.

* Look at:
  - Result ranges
  - Evaluation criteria
  - Comments
  - Reagent lock out
  - Operator lock out
  - QC lock out

* Run tests on every instrument type to test: result ranges, comments, settings, evaluation criteria, location vs meter assignment, patient’s not at that location at the test date/time, patient IDs when not valid.

Now try to beat the system.
Go Live

Rome wasn’t built in a day, start small.

- Pick one instrument/test and a few locations to bring up.
- Once you determine everything is working as it should, things are stable, and you are comfortable add more locations.
- Then add other testing/instruments.

As you add tests/instruments you will know your system and may be comfortable adding all of those remaining at once. You set the pace...
Entire Care Team has rapid and ready access to POC results via the Electronic Medical Record to make informed care decisions.

Automated billing.

Facilitates maintenance of Operator database and certifications/competency.

Allows central control/oversight of QC, device maintenance/configuration/upgrades, troubleshooting device and interface errors.

Enhances productivity of the POC Staff.
Challenges to Achieving POCT Connectivity

- Institution Must Implement Electronic Medical Record (EMR)
- Required Capital Investment in POC Connectivity Middleware and Support
- Development of Business Associates and Data Security Agreements between Institution and Vendor
- Available Institutional IT Resource(s) and Coordination Among POC Staff, Institutional and Vendor IT Resources to Develop a Plan, Maintain Momentum and Reach Project Milestones on Schedule (Assigned Project Manager)
Lessons Learned

* “There will be bumps in the road.”
* “You can’t prepare for everything.”
* “This is a journey, not a race.”
* “Celebrate your victories.”
* “No single middleware solution will be perfect, select based on your priorities.”
* Must haves:
  * Compatibility with all middleware programs.
  * Bi-directional connectivity.
  * Operator lockout controlled at the middleware.
  * Reagent lockout controlled at the middleware.
  * Quality Control lockout.

* If special software needed, should be compatible with all middleware programs. (Sit quietly in the background).
Duke Health’s Journey to 100% Connectivity
DUHS Clinical Laboratories Organization
DUH Point of Care Testing Program

DUHS Nurse Leadership

Laboratory Management

DUH POCT Oversight Committee

DUH Nursing Leadership

Duke Private Diagnostic Clinics Leadership
DUH POC Testing Program had Oversight At:

- Duke University Hospital (DUH)
- Duke Clinics (Hospital-based Clinics)
- Duke Children’s Hospital
- Duke Private Diagnostic Clinics (PDC)

Our connectivity solution: downloading glucose meters only to a computer in the laboratory. Only glucose results reporting to EMR. No more “sneaker net”...

Total of 50 locations (10 of which were offsite) and 102 instruments mostly glucose meters and 6 orderable tests

2- FTEs, 1- 0.7 and 1-0.5
DUH POC Testing Program had Oversight at:

- Duke University Hospital (DUH)
- Duke Clinics (Hospital-based Clinics)
- Duke Children’s Hospital
- Duke Private Diagnostic Clinics (PDC)

Two Instrument types connected and reporting to EMR. Point of Care Testing middleware was now loaded on a server located with the Laboratory Information System (LIS).

Total of 91 locations (23 of which were offsite) and 137 instruments mostly glucose meters and 6 orderable tests
3 FTEs and 1-0.5
FY2016 DUH POCT Had the 3rd highest test volume for DUHS Clinical Labs
DUH POC Testing Program had Oversight at:

- Duke University Hospital (DUH)
- Duke Cancer Center
- Duke Clinics (Hospital-based Clinics)
- Duke Children’s Hospital and Health Center
- Duke Medicine Pavilion
- Duke Private Diagnostic Clinics (PDC)
- Home Care & Hospice

All Instrument types connected and reporting to EMR. Just starting the process of interfacing the manual test through the meters and middleware module.

Total of 150 locations (40 of which were offsite), spanning 4 counties
19 different orderable tests and 485 instruments.
4 FTEs
Oversight for POC Testing at:

- Duke University Hospital (DUH)
- Duke Cancer Center
- Duke Clinics (Hospital-based Clinics)
- Duke Children’s Hospital and Health Center
- Duke Medicine Pavilion
- Duke Private Diagnostic Clinics (PDC & CPDC)
- Home Care & Hospice

All Instrument types connected, all manual testing entered through either glucose meter or middleware module and reporting to EMR.
DUH POCT Program Today (contd.)

* 179 locations (65 offsite locations) spanning 5 counties
* Currently supporting 29 different orderable tests
  * Moderately Complex testing
  * Waived testing
* Responsible for 629 instruments (10 separate devices)
* >8,000 certified operators
* 610,546 Units of service as of 3\textsuperscript{rd} Quarter FY2017; 0.01 Worked Hour/Unit of Service (WHUOS)
* Utilize manual test entry through Nova glucose meter and RALS \textsuperscript{®} MTE module
* Accredited by:
  * DUH hospital-based locations: College of American Pathologists (CAP)
  * PDC’s/CPDC’s: Joint Commission (TJC)
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<th>DUHS</th>
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<th>Mayo</th>
<th>Hopkins</th>
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DUH POCT Achieves Full Connectivity to Maestro EHR via Alere RALS® Web3 - September 2015
Manual Test Entry

Patient Result Entry: Because we validate each box and place a tracking label on the box, we can drill down to the exact box being used for testing. The Box ID is entered in the Kit Lot field.
Manual Test Entry
Flagged results are marked, triggering a double check by the operator entering results.
Managing Operators

![Image of a screenshot of the Alere RALS System interface showing managing operators functionality. The interface includes options for device type, home location, assigned location, certifications, role management, recertification, and certification summary. The table below lists operators with their ID, device type, initial certification, last certification, expiration date, home location, and institution.]
Levey-Jennings
Linearity Charts

QC Calculations
- Total Results: 10
- Excluded Results: 0
- Levels Used: 5 of 5
- Slope: 0.97
- Y Intercept: 0 mg/dL

Review Information
- Reviewer: STREMPIE KATIE
- Review Date: 05/23/2017
- Review Note: ILQC Level 1: -0.8%, Level 2: -2.7%

Chart Parameters
- Device Type: Nova StatStrip® GLU
- Device ID: 00026617054
- Location: DUH-LIFE FLIGHT
- Chart Date: 05/23/2017
- Product: Glucose
- Analyte: Glu
- Linearity Lot: Multiple Lots
- Reagent Lot: 0316117349

- In Range
- Out of range
- Best Fit Line
- Target Line
Conclusion

- Connectivity benefits patients by ensuring the entire medical team can rapidly and readily access test data generated at the point-of-care to render informed decisions.

- Connectivity facilitates quality oversight of even large, complex programs by a relatively small number of knowledgeable and dedicated technologists.

- Achieving a high degree of connectivity requires commitment and coordination of significant financial, technical and IT resources, but the potential rewards can justify the effort.