

Introduction

Grand Challenges Canada project:

Investigating the feasibility of a multi-disciplinary point-of-care testing in an active HIV treatment clinic and determining the impact of POC testing on patient outcome PI: Prof. Wendy Stevens

- Randomized controlled trial with 2 branches: point of care (POC) and standard of care (SOC) for ARV initiation of eligible patients.
- POC instruments selected based on required criteria for ARV initiation according to national guidelines and availability at the time.
- One of the components of the study was the investigation and implementation of connectivity at point of care.
- The proposal to expand laboratory testing services to primary health clinics through the implementation of point of care testing (POCT) requires even stricter control of instrument, data and quality control (QC) management in order to ensure the quality of testing and accuracy of the results.

POC Trial Site-1

Botshabelo Clinic North West Zozo for 'POC Lab'



Middleware solutions and 3G routers installed at 2 clinics



Councillor and study nurse responsible for the instrument, data & patient management

Instruments

- Alere Pima (CD4)
- Cepheid GeneXpert (MTB/RIF)
- Roche Reflotron Plus (ALT/Cre)
- Quest Hemocue (Hb)
- Metacom routers

Middleware Solutions

- Laboratory Data Systems (AegisPOC)
- Conworx POCcelerator

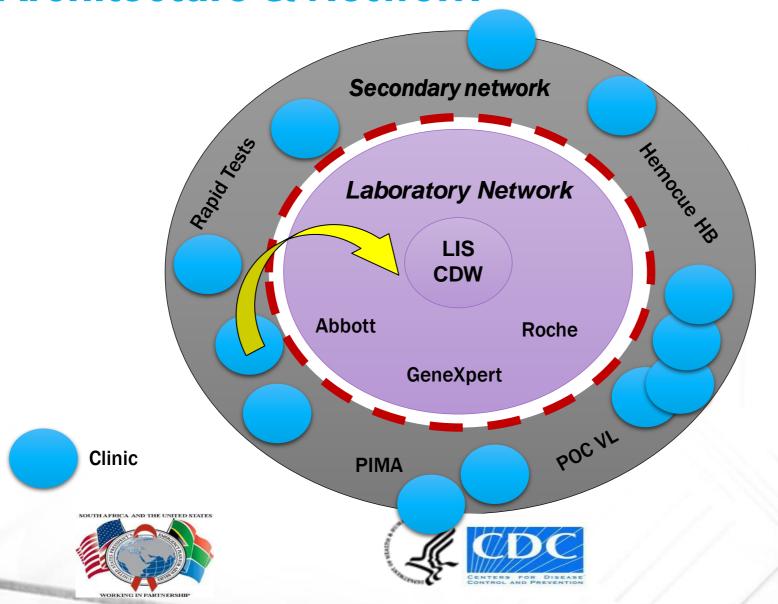








Architecture & Network



Centralised data for decentralised testing Host LIS/HIS HL7/ASTM **Bi-directional** /POCT1-A Communication Universal POC Devices Interface Program / Data Management System POCT1-A Proprietary HL7 **ASTM** POC POC POC POC Device Device Device Device #1 #2 #3 #4

Available Options for Connectivity

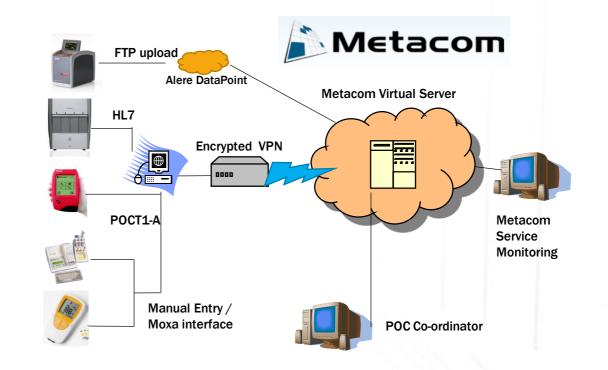
Product	Instrument Interfacing	Training and	QC and instr.	Patient	Result Management	Clinical Information	Visit Management
AegisPOC	cxtensive	Yes	Yes	Yes	Yes	No	No
POCcelerato	Extensive	Yes	Yes	Yes	Yes	No	No
Cobas IT	Lin: "od	Yes	Yes	No	Vaa		No
Identicare	Development	No	140	res	Yes	No	Yes
Therapy Edge	None	No	No	Yes	Yes	Yes	Yes
еКАРА	None	No	No	10	Yes	Yes	Yes

Instrument and Data Management

Patient Management

Metacom – Connectivity Provider

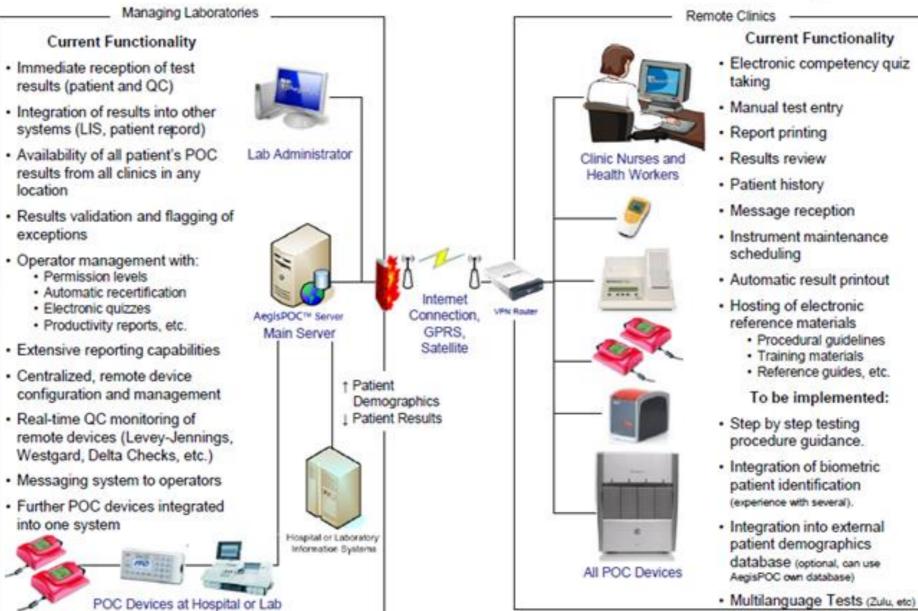
- Provide stable and secure connectivity
- Mobile Transmission options
 - GSM (3G, multiple sim cards)
 - Satellite
 - Short-range radio
- Fixed line solutions:
 - Diginet, ADSL, Frame Relay and X25
- Remote management and security of connection



Slide courtesy Juan Venturello (LDS)

AegisPOC™ Remote Clinic Management Benefits





Implementation

Information processing on Middleware platforms

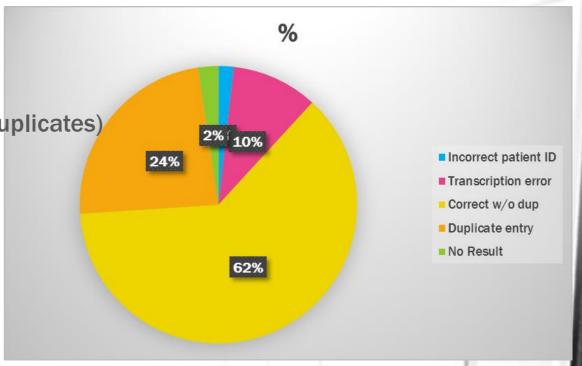
Instrument	AegisPOC	Conworx
GeneXpert	Automatic	Automatic
Hemocue	Automatic	Automatic
PIMA*	via DataPoint	No
Reflotron Plus	Manual Entry	Automatic

- POCcelerator create patient with ID and all tests automatically linked
- AegisPOC create new test entry with patient information and results

Data Entry Analysis

Total captured patient tests n = 169 (including duplicates)

Measurement	n	%	
Incorrect patient ID	3	1.78	
Transcription error	17	10.06	
Correct w/o dup	105	62.13	
Duplicate entry	40	23.67	
No Result for			
comparison	4	2.37	
Total	169	100%	



- Number of results not captured (either Creatinine or ALT) n = 39
- Number of patients not captured n = 34 (i.e. 68 results)
- Average time to capture result
 - AegisPOC (n=25): 2min
 - Conworx (n=11): 2.72min

Data Analysis

- Manual data entry for POC testing is error prone unless strictly controlled
- 49% of results had at least 1 issue
 - 20% of duplicate entry could be a training issue
- In this case, under-reporting of results would have occurred (107 results).
- Automatically reported results without issue (when correctly linked to patient)

Middleware Models

SaaS / Cloud System	Local installation
No installation required	Installation per machine
Unable to operate offline	Works offline
Requires (stable) internet connection to prevent workflow interruptions	Requires internet connection only for central uploads
PC-swap out simple	PC requires installation and customization per site
Access through web-browser	Access through application interface

POC Coordinator

- Regardless of the implementation model, a full-time administrator (POC coordinator) is required
 - Review QC and operator performance
 - Manage stock levels
 - Capture and release consumable lots and batches
 - Capture and release QC material and configure levels and expected results
 - Capture of material expiration dates and instrument calibration requirements
 - Review flagged results
 - Manage / configure operator certifications

Recommendations

- Internet connection is a problem in remote regions (even on dual-networks)
 - Can be aided by the installation of antennae (300% signal increase after YAGI installation)
 - Satellite is an option
- Strict internet access control, firewalling and restrictions requires
 - Number of instances recorded of internet abuse and multimedia downloads
- Full access to PC promotes misuse.
- Anti-virus with regular updates essential.
 - GeneXpert PC's at both sites required replacement due to viruses
- · Backup of server data

Experience meets Expectations?

Expectation	Experience
Connectivity solves patient data management issues	Connectivity aids quality data management but requires strict control & (re)training
Quality of data increased with middleware solutions.	Yes but garbage in = garbage out.
Connectivity lightens the burden of POCT staff	Automates certain tasks and workflows when implemented correctly
A connectivity-enabled POC Coordinator can manage hundreds of sites	2 sites = (approx.) 20-30 hours per week, likely less once structured model but realistic limitation
Requires staff with high levels of computer literacy	Computer literacy definite advantage. Depends on the amount of tasks leveraged on the user vs Coordinator
Internet availability and signal strength is a problem in remote areas.	Yes, but there are a number of options to attempt before ruling it out. (Antennae, satellite, etc.)
All instrument interfaces are equal.	Adoption of standards and recommendations is improving
Can the quality of a POCT programme be guaranteed without connectivity?	No. Data is the key to informed decision making.

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- Clinical Partners (WRHI, CHRU/RTC, PHRU)
- Suppliers forum/ working group (hardware and software suppliers) for technical support, platforms and reagents.











