
CONNECTIVITY INDUSTRY CONSORTIUM (CIC)

The Universal Standard for Point of Care Connectivity

POINT OF CARE COORDINATORS WORKSHOP SUMMARY

September 9, 2000 Atlanta, Georgia



This document summarizes the essential details of the Point of Care Connectivity Industry Consortium (CIC) Point-of-Care (POC) Coordinators' Workshop, held September 9th at the Sheraton Buckhead Hotel in Atlanta, Georgia. Five POC Coordinators from leading healthcare institutions shared the status of their current POC testing programs, the obstacles they face to efficient POC test management, and their vision for POC testing over the next 5-10 years. The meeting participants also composed a set of actions to ensure further contribution by POC Coordinators to the CIC's standardization efforts.

EXECUTIVE SUMMARY

The CIC invited five leading Point-of-Care (POC) Coordinators to provide feedback on the requirements and use case scenarios that are being used to develop POC device interoperability standards. Each invited participant manages an extensive menu of POC tests and devices at their institution. The objectives of the meeting were to:

- Prioritize a list of connectivity-related user requirements
- Describe the 5-10 year vision for POCT connectivity
- Review and refine the CIC's use cases for point-of-care ordering
- Review and refine the CIC's use cases for QC/QA
- Review and refine the CIC's bi-directionality requirements
- Create an action plan for future, ongoing POC coordinator review

All the meeting's objectives were accomplished. The participants developed and prioritized a comprehensive list of user requirements. The top five requirements closely mirrored those identified at the October 2, 1999, POC User Focus Group. Both groups identified bi-directional communication as the most important requirement:

1. Bi-directional communication
 - Critical ranges
 - Comments
 - Device location information
 - Synchronization of time/date
2. Manual test result capture
3. Vendor-independent connectivity infrastructure
4. Customizable to meet the needs of each facility
5. Ease of use for end user

The participants also described their 5-10 year vision for POC testing and connectivity. Many elements of these visions were shared in common, and included elements such as "real-time" result availability at the LIS, and fully integrated data capture programs.

All of the Point-of-Care Coordinators who participated were very eager to continue to contribute to the CIC's efforts toward POC connectivity standardization. A number of avenues for ongoing participation were identified, and are being addressed by the CIC organization.

A videotape record was made of these proceedings. If you would like a copy of these tapes, please send an e-mail message to info@med.labs.agilent.com, or contact Kendra Whittier (650 485-2301).

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I PARTICIPANTS

Twelve individuals attended this workshop: five point-of-care coordinators and seven individuals representing the CIC.

Point of Care Coordinators

Maureen Bush, MT (ASCP)
POC Coordinator/Laboratory
Bay Medical, Florida

Roseanne Dolega, MT (ASCP)
POC Testing Coordinator
Department of Pathology, Henry Ford Hospital, Michigan

Karen Jenkins, MT (ASCP)
POC Coordinator
Emory University Hospital, Georgia

Lou Ann Wyer, MT (ASCP)
POC Coordinator
Sentara Norfolk General Hospital Laboratory, Virginia

Regina Durham, MT (ASCP)
POC Coordinator
Southern Regional Medical Center, Georgia

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Marcy Anderson
CIC Workflow Team Leader
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Michael Higgins PhD
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II OBJECTIVES AND CONCLUSIONS

The CIC invited five leading POC Coordinators to contribute to the requirements and use case scenarios that will be used to develop point-of-care device interoperability standards. The participants are responsible for managing extensive menus of POC tests and devices. Their input and feedback will be used to refine and direct the Connectivity Industry Consortium's standard. The objectives of the meeting were to:

- Prioritize a list of connectivity-related user requirements
- Describe the 5-10 year vision for POCT connectivity
- Review and refine the CIC's use cases for point-of-care ordering
- Review and refine the CIC's use cases for QC/QA
- Review and refine the CIC's bi-directionality requirements
- Create an action plan for future, ongoing POC coordinator review

All the meeting objectives were accomplished. The participants developed and prioritized a comprehensive list of user requirements. They also described their 5-10 year vision for POC testing and connectivity. The use case discussions brought insight and understanding of the needs of POCCs to the table. A variety of avenues were identified to provide the CIC with further POCC input in the future.

III INTRODUCTION

Suzanne Cross opened the meeting with a brief overview of who CIC is and how much the organization's vision and goals are dependent upon the input gained from point of care coordinators and users in the field.

Michael Higgins then spoke about the point of care data management survey conducted by Enterprise Analysis Corporation in 1999. This survey detailed the type and quantity (by %) of POC testing typically found in a healthcare setting. This showed that blood glucose, coagulation, and blood gases fared the highest. The number of POC applications instituted within hospitals resulted in at least 2-3. When rating available quality features of a good POC program, data management and connectivity rated the worst out of 11 categories. Point-of-care coordinators do not believe these two issues are addressed thoroughly.

Mike also addressed the current POC Connectivity Landscape from device to various workstations, to the LIS and then the HIS. He concluded with the statistics stating that only 15% of the POC data is downloaded to the hospital LIS electronically. This information came as no surprise to the POC Coordinators at this meeting.

IV REPRESENTED POC ENVIRONMENTS

Each of the participants was asked to present an overview of the POCT environment in each of their respective institutions. They were then asked to describe any connectivity requirements and give their 5-10 year vision for point-of-care testing.

Maureen Bush

Point-of-care Coordinator/Laboratory, Bay Medical, Florida

Bay Medical Center is a 430-bed facility with 435 nursing personnel. Their POCT program is CAP accredited and the institution is JCAHO. They have 40 Roche Advantage blood glucose meters (HQ and GTS), 7 Hemochron ACT instruments, 1 Hepcon HMS, and 1 Diametrics IRMA. The manual tests include the CLO test, urine dipsticks, and Hemocult sensa occult bloods. Their LIS is HBOC. They have the RALS-G scripted interface for blood glucose connectivity. All other POCT lacks connectivity.

Maureen explained that the features she liked and wanted to continue to see in any standard included: operator lock-out, QC lockout, automatic downloading, bi-directional functionality, and the ability to configure each location differently. Maureen summarized the effects of connectivity on Bay Medical. The highlights included:

- The ability to charge for 98% of all glucoses performed
- Glucose tests are included in the laboratory report
- The POCC now has the resources to monitor compliance
- CAP documentation requirements are met

The future of POCT at Bay Medical includes coagulation testing (PT/PTT), upgrading to RALS-Plus, and cardiac markers in the ER. Maureen sees that the distant future will bring an increased role for POCT in healthcare, better regulatory features on instruments, connectivity for all tests through the same software, and bar-coded i.d. bands.

Whatever standard is developed, it must address user definable options, lockout features, and route of entry for non-automated tests. Maureen would love to see an inventory control module as part of any future lock-out features and required maintenance as a lock-out or prompt.

Roseanne Dolega

POC Testing Coordinator, Henry Ford Hospital, Michigan

Henry Ford Health System in Detroit, Michigan is a five-hospital health system that also includes a Home Health Care environment. They have a glucose volume of 300,000 strips/year using the Lifescan One Touch II meters. They also have 4 ACT coagulation monitors and 18 DCA 2000 whole blood PT/PTT monitors. There are two Thromboelastograph instruments, and 4 blood gas and co-ox instruments. The manual tests include: occult bloods, urine pregnancies, urine macro and micro, strep A screens, fetal scalp pH, and hematocrits. The PPMP's performed at the Henry Ford Health System include KOH/wet mounts, fern testing, and dermatology.

The Connectivity architecture shows the Henry Ford Hospital and the medical centers being linked via a network. The LIS is Sunquest and the EMR is "Care Plus". Their connectivity requirements for the near future include an HL7 interface for high-volume tests (glucose and coag) and bi-directional information flow.

They would like to see data transfer via network for high volume sites and would prefer not to use web-based transfers. They want validity checks with the HIS and simple steps for staff end users. Roseanne would like to see paperless QC/QA workflow and electronic signature. She wants the ability to recalculate CV ranges and immediate feedback of QC pass/fail to operators. Roseanne stated that individual PCs for data management is unacceptable and that data should be made available from remote sites.

The future in POCT for Henry Ford Hospital includes the following:

- “Hot tests” such as cardiac markers and lipid profiles
- Patient self testing
- Pediatric anti-coagulation
- Drug therapy monitors
- Non-invasive testing
- Miniaturization of current lab tests
- Real-time data transfer to PDA’s, pagers, and phones

Roseanne’s wish list included real time downloads and no docking stations.

Regina Durham

POC Coordinator, Southern Regional Medical Center, Georgia

Southern Regional Medical Center is a 410-bed hospital located in Georgia. The point-of-care testing program is regulated by CAP, the State of Georgia and JCAHO. The Information System is HBOC for both the laboratory and the patient care environment. This institution uses Roche HQ meters with the RALS-G system. There are approximately 800 users with 32 active meters running 10-14,000 results/month. They have several Avoximeters, Hemocue for hemoglobin, a variety of manual tests such as urine dipsticks, PPMs, and occult bloods.

The connectivity requirements Regina discussed include: barcode capability, manageability by one technologist, e-mail reports to go to other hospitals, run on a network environment with network back-up, ease of use for end users. In addition, an electronic QC tracking/manager system would be nice. QC lock-out and operator lock out are a must. Up-loadable operator data, 24-hour service, and a reasonable cost must also be a part of the equation. Regina then discussed the fact that HIPPA compliance must be considered, the CIC must make sure they develop a standard that avoids vendor bias and have a space sensitive solution.

Regina’s future vision for POCT in her institution included adding POCT in the ED, critical and Women’s facility areas; tracking patient testing via barcodes; electronically documenting manual tests; staff members being able to review and add comments to tests from a network PC; reflex lab draw orders for critical results requiring a laboratory confirmation; and no separate docking stations for each instrument type.

Lou Ann Wyer

POC Coordinator, Sentara Norfolk General Hospital, Virginia

Sentara Healthcare is a multi-hospital health system located in Virginia from Norfolk to Williamsburg. The POCT environment includes 140 Lifescan Surestep Pro glucose meters used by 2875 operators. There are 90 i-STAT analyzers with 1125 operators, 21 Hemochrons, 16 urine dip units, 5 Hemocues, 4 HCT centrifuges, 2 Rapid Point coag instruments, 1 urine pregnancy unit, and 1 strep screen unit. In addition,

there are 47 Hemocult units and 36 Gastrocult units. The growth for POCT will be seen in the coagulation and cardiac marker arenas for this healthcare system.

Lou Ann expressed that the connectivity solutions needed for these institutions must be easy, fast and inexpensive. She expanded on the data management piece stating that it is necessary to include data review from off site locations, data must be made available into statistical applications, manual tests must be addressed and wireless transmissions are needed. She would also like to see inventory management incorporated into the data management system. This would include logging new shipments, developing PAR levels, automated ordering, longer expiration dates, sequestered lots, and room temperature storage checks.

Lou Ann's vision for POCT is to have bar coded armbands, true operator lock-outs, eliminate wet QC, "real time" results, and cumulative performance rates. She would also like the ability to download software updates from the World Wide Web, interactive training, and support for order processing and status review.

Karen Jenkins

POC Testing Coordinator, Emory Healthcare, Georgia

Emory Healthcare consists of 2 hospitals, one geriatric facility and one clinic that serve over 30 sites. For the two hospitals which total 800 beds, the POCT program is JCAHO accredited and the main laboratory is CAP. The point-of-care program at Emory is very large, including blood glucose, occults blood testing, ACTs, urine pH, Hemocue hemoglobins and glucose, pyloritek, Protime, cholesterols, urine pregnancy, nitrazine pH, Hemoglobin A1C, platelet function, TEG, blood gases, strep testing and numerous PPMs. There are over 140 blood glucose instruments, 35 ACT instruments, 12 Hemocues, 7 Coagucheks, 1 DCA, 4 Ultegra RPFAs, and 2 Cholestechs.

Emory is looking at standardization, increasing blood gases and upgrading the blood glucose system. Karen explained that their requirements for connectivity solutions include:

- Integrated capture of all test results - manual and electronic
- Utilize ADT information
- Ability to utilize Clinical Data Repository or Powerchart
- Bi-directionality
- Single site for device downloads ("daisy chain" capability)
- Use existing connections and be cost effective

She also listed POCC requirements for her office, which included:

- Ability to review all sites from one workstation,
- Electronic signature,
- One software package to handle all results,
- HL7 protocol for observation reporting

Her 5-10 year vision included more tests at the bedside such as cardiac, hematology, blood gases, and more extensive chemistry testing. Her concerns are that the nursing staff will not be able to handle this increased volume of POC testing. Thus, connectivity and more efficient solutions are a must.

V USER REQUIREMENTS

The POCC participants were asked to list and prioritize their requirements for point-of-care connectivity. Bi-directional data flow was the most widely and extensively mentioned topic. Within this requirement, we were able to identify several detailed issues of interest, which are indicated by bullets in the following listing.

Top 5 User Connectivity Requirements

1. Bi-directional communication
 - Critical ranges
 - Comments
 - Device location information
 - Synchronization of time/date
2. Manual test result capture
3. Vendor-independent connectivity infrastructure
4. Customizable to meet the needs of each facility
5. Ease of use for end user

Other Important Connectivity Requirements

- Bi-directional communication
 - Device status
 - QC ranges
 - Lot numbers and expiration dates
 - Operator I.D.
 - ADT
 - Operator notification (certification)
- Wireless physical connection and continuous communication
- Integrate all data from multiple institutions
- One-stop connection solution
- Lock-out enforcement of workflow

VI ISSUES

There were a number of issues and concerns that came out of the requirements discussion. The POCCs present wanted to make sure that any and all standards consortiums or agencies keep these issues in mind as more standards are developed and introduced.

- Cost: Needs to be reasonable
- IT challenges

- Make it easy to add new instruments (plug and play)
- 24 hour service or at least know who owns the system
- No vendor bias
- Security
- Regulatory concerns
- Management of training and competencies
- Need multiple command and control programs on a single data manager
- Billing: Who gets the money, what are you charging for, coding requirements

VII ORDER ENTRY USE CASE SCENARIOS

A physician can place a number of different types of orders. The list includes standing orders, standard of care orders and a single order as needed.

In relation to a test result, two use cases govern how orders may be placed:

- Order placed by the POCT device
- Order is placed directly into the LIS

The POCCs broke down the list of data entry requirements into two categories: one at the Data Manager level and the other at the Device level.

At both Data Manager and Device level:

- Test id
- Patient id
- Operator id
- Instrument id
- Test date and time
- Result
- Episode/Encounter information
- Location (nursing unit)
- Collection date and time
- Profile information (especially for blood gas instruments)

At the Data manager Level there must also be:

- Lot number
- Expiration date
- Comment codes
- Flagged results

Occasionally needed attributes:

- Physician
- Patient demographics

Roseanne Dolega proposed the option of going straight to the HIS from the device. All POCC's agreed that there should be alpha/numeric order entry options at the device level.

VIII QA/QC BI-DIRECTIONAL USE CASE SCENARIOS

Much of what was discussed concerning the bi-directional use cases is addressed above in Section V – User Requirements. The following list expands and prioritizes those requirements:

Must Haves:

- QC timeout/QC out of control (be based on Operator change, Reagent lot number change, running x number of tests, or using a new vial)
- Valid Operator ID/Operator Certification List
- Valid Reagent list/Valid Control List

Often Needed:

- Patient ID (valid!)
- Result timeout (as an alert to remind people to download from the instrument to the data manager)
- Analyte-specific lockout

Seldom Needed:

- Service or ad-hoc lockout

IX 5-10 YEAR VISION

The POC coordinators were asked to share their vision of the future of point-of-care testing. Many elements of their visions were held in common. We have combined these common elements where possible, and have come up with the following 'consensus' vision for point-of-care testing in the next five to ten years:

- Bar coding systems widely deployed
- Elimination of wet QC
- "Real time" results presented at the point-of-care, and also immediately available from the LIS
- Cumulative performance rates and competencies
- Inventory management
 - Longer expiration dates
 - Sequestered lots
 - Room temperature lots
 - Bar coded
- Automatic ordering

- Web-based software applications
- Hot tests - risk assessment and prevention (cardiac markers and lipid profiles)
- Patient self-testing
- Non-invasive testing
- Lower costs
- Reduced responsibilities for end users
- Fully integrated data capture programs for manual entry
- JCAHO will get stricter while CAP will become less strict
- POC testing volumes will increase

X ACTION PLAN

All POCC participants were eager to continue to contribute to the CIC's effort. Toward that end, all participants exchanged ideas on how to continue to obtain ongoing POCC review and input for the standard. The following idea list was composed, and is being addressed by the CIC organization.

- Monthly conference calls:
 - CIC status updates
 - Solicitation of feedback form POCCs
 - Allow select members of the AACC-POCT list serve to listen to these calls?
- Regional POCC conference calls?
- Establish a CIC list server
- Compile a binder containing:
 - Information about your hospitals
 - Results of this meeting
- Work with LIS managers in hospitals; gather a focus group of these individuals
 - Build support for POCT within hospitals
 - Potential avenue to increase LIS vendor participation
- Advertise better so that more POCCs are aware of the CIC