A study of the time and resources required in the development of an Individualized Quality Control Plan for a moderate complexity test system

Karen Clark, BS,MT(ASCP)SH, POC Manager Baptist Memorial Hospital, William R. Donohue, MS, CarePoint Solutions, Inc., Richard Lebo, BS,MT(ASCP), CarePoint Solutions, Inc., Lisa Durish, BS,MT(ASCP), CarePoint Solutions, Inc., Susie Scoggins, BS,MT(ASCP) CarePoint Solutions, Inc., Beverly, MA

Objective:

This study seeks to estimate the time and resources required for a typical healthcare organization to implement an Individualized Quality Control Plan (IQCP) for a moderate complexity point-of-care test method following Clinical Laboratory Standards Institute Guideline EP-23A: Laboratory Quality Control Based on Risk Management.

Relevance:

Beginning in January 2014, the Centers for Medicare and Medicaid Services (CMS) will allow quality control plans based on risk management principles as an option to satisfy federal quality control requirements under the Clinical Laboratory Improvement Amendment (CLIA). Performing a comprehensive risk assessment in a complex clinical setting such as point-of-care testing requires an allocation of personnel resources and a potentially significant time investment. Since most healthcare delivery systems will be undertaking this initiative for the first time, and since many are resource challenged in today's tight reimbursement climate, and as IQCP's could impact not only the continuity of testing but the quality of patient outcomes, it is prudent for healthcare administrations to budget the resources to implement IQCP's appropriately.

Methodology:

In this study, a healthcare organization (Baptist Memorial Hospital, Memphis, TN) developed an Individualized Quality Control Plan (IQCP) for a moderate complexity test system, specifically the GEM Premier 4000® blood gas analyzer (Instrumentation Laboratory, Inc., Bedford, MA). The Point-of-Care Manager (POCM) maintained an activity log to track the time and resources required to both become familiar with the new federal requirement and to complete an IQCP for the GEM Premier 4000 analyzer. Furthermore, the utility of a web-based software application, designed to guide users through a comprehensive risk assessment to facilitate the development of an IQCP was evaluated (Pro-QCP™, CarePoint Solutions, Inc., Beverly, MA).

Results:

The resource requirements are depicted in a time allocation table, delineated by the following categories: IQCP Education, Develop & Update Policies, Performing Risk Assessment, Residual Risk Evaluation, Risk Mitigation Planning and IQCP Development. Based on these data, the software program Pro-QCP saved 50 hours in the development of the IQCP.

Furthermore, the software suggested opportunities to further mitigate risk in practically every aspect of the point of care testing program.

Conclusion:

While much time was expended for education, and can be considered a one-time investment, the time and resources required to complete a comprehensive risk assessment and mitigation plan for a moderate complexity test system was found to be significant. This study also demonstrated the time savings, the benefit of taking a systematic approach, and the opportunity to identify numerous quality initiatives/enhancements when using the software utility. Also worthy of note, Pro-QCP provided additional value by 'proceduralizing' the implementation of the IQCP and facilitated a process review of the entire point of care testing program.

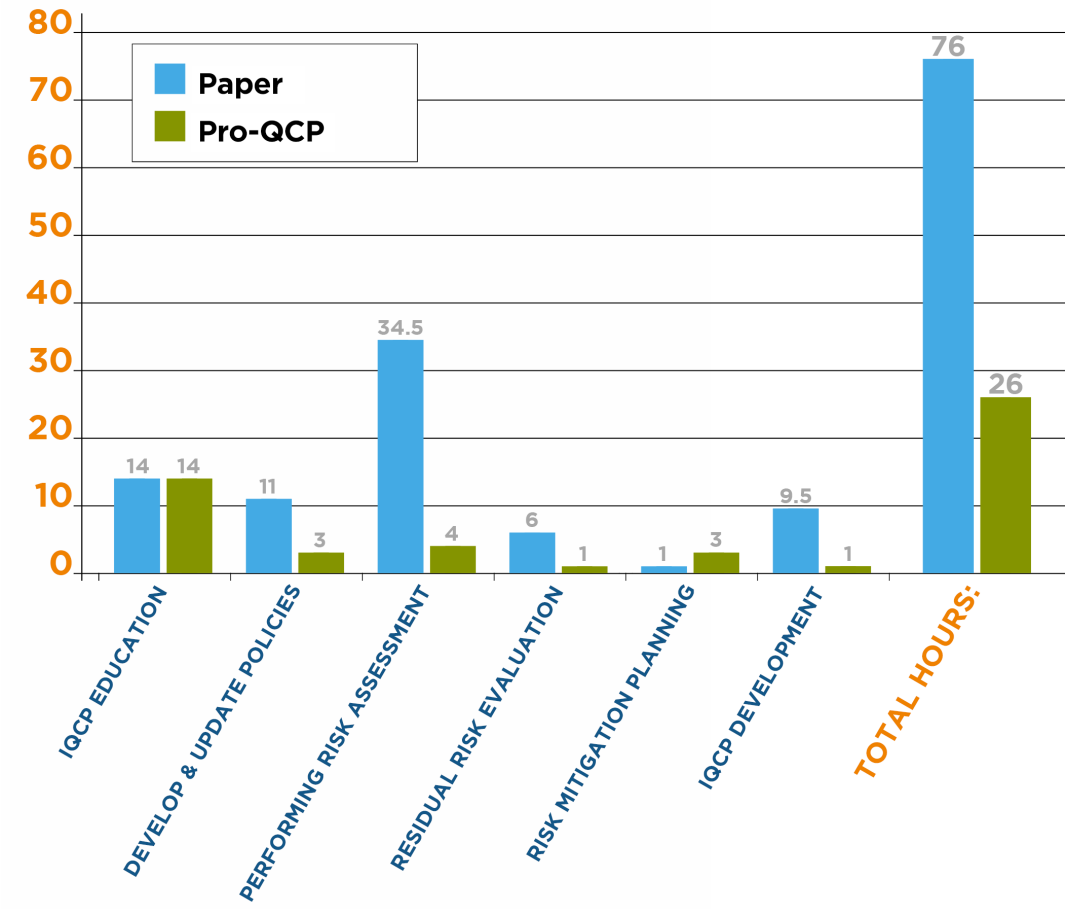
Presented at:
Critical and Point-of-Care Testing 25th International Symposium, San Diego, CA, September 17 - 20, 2014

About Pro-QCP by CarePoint Solutions, Inc.:
Pro-QCP is an online, web-based software program that facilitates the creation of Individualized Quality Control Plans (IQCP's) consistent with EP-23 guidelines. This specialized program was designed to simplify and streamline the challenging and time consuming process of developing IQCP's. Pro-QCP is available by annual subscription with specialized modules specific for each test device or method. For more information on Pro-QCP visit: www.Pro-QCP.com

Charts and tables:

1) IQCP and risk assessment time allocation by resource category
2) Time spent on IQCP development:

IQCP and risk assessment time allocation by resource category:



	Paper IQCP	Pro-QCP
IQCP Education	14	14
Develop & Update Policies	11	3
Performing Risk Assessment	34.5	4
Residual Risk Evaluation	6	1
Risk Mitigation Planning	1	3
IQCP Development	9.5	1
Total Time:	**76** hours	**26** hours

Time spent on IQCP development:

	Paper	Pro-QCP
IQCP Education		
Initial IQCP Education - Common to both methods	14	14
Development & Update of Policies		
Reviewing CE material from previous webinars	2.0	0
Developing and typing IQCP procedure	4.0	1.0
Developing flowsheets - Process Map, Fishbone diagram, & QCP diagram	2.0	0
Writing checklist & reading	2.0	0
Reviewing and correcting procedure	1.0	2.0
Performing Risk Assessment		
Reading, reviewing GEM 4000 Procedure Manuals	2.0	0
Reading, reviewing Respiratory's GEM Procedure	1.0	0
Researching interfering substances on Gem 4000	2.0	0
Developing Risk assessment spreadsheet	2.0	0
Inventorying each risk	4.0	0
Risk assessment spreadsheet 1	4.0	0
Risk assessment spreadsheet 2	4.0	0
Risk assessment spreadsheet 3	4.0	1.0
Risk Evaluation spreadsheet	6.0	1.0
Risk Eval with Respiratory	2.0	1.0
Performing Risk Assessment with testing personnel		
Risk Eval with Respiratory	1.5	0.5
Risk Eval 2 with Respiratory	2.0	0.5
Review Assessment = Residual Risk Scoring		
Address basic tools in QCP spreadsheet	6.0	1.0
Risk Mitigation Planning		
Reports from Respiratory: turbidity numbers, percent of accession numbers entered manually added to Performance Improvement scorecard	1.0	3.0
IQCP Development		
Developing and typing IQCP checklist	2.0	0
Developing and typing QCP spreadsheet that addresses basic tools	2.0	0
Reviewing overall IQCP process	1.0	0
Developing IQCP document	3.5	0
Finishing touches on IQCP Document	1.0	1.0
Total Time Invested:	**76 hours**	**26 hours**