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

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

Relevance: Beginning in 2014, the Centers for Medicare and Medicaid Services (CMS) will allow IQCP's based on risk management as an option to satisfy federal quality control requirements under the Clinical Laboratory Improvement Amendment (CLIA). Implementing a comprehensive risk management program in a complex clinical setting will require an allocation of personnel, time, and resources. Since most healthcare systems will be dealing with this initiative for the first time, it is of strategic value to understand the resource and time requirement to implement IQCP's based on risk management programs.

Methodology: In this study, one or more healthcare organizations will develop Individualized Quality Control Plan's for a moderately complex test system, specifically the GEM 4000® blood gas analyzer (Instrumentation Laboratory, Inc., Bedford, MA). Participants will keep an activity log and track the time and resources that were required to become familiar with the federal requirements and to complete and implement their IQCP. Furthermore, to assess the utility of software applications designed to facilitate IQCP's, participants will create a second IQCP with the assistance of EZ-QCP™ (CarePoint Solutions, Inc., Lowell, MA) and compare their experience and results with each approach. In addition to capturing general observations, resource requirements will be depicted in a time allocation table, broken out by the following categories: Educational, Information Gathering, Policy Development, Staff Consultations, Performing Risk Assessment, Mitigation Action Planning, Review Assessment, and IQCP Documentation.

Conclusion: The study is currently underway and results will be presented at the Critical and Point of Care meeting in San Diego.