TRI-STATE POC NETWORK
October Meeting Minutes
October 8, 2014

The 2014 Fall meeting with Vendor fair was held at the Doubletree Hotel in Alsip, Illinois on Wednesday, October 8th from 8:30 AM to 3:00 PM. The meeting was attended by 57 registered healthcare professionals and sponsored by Alere and Nova Biomedical. Registered vendors included: Abbott, Accriva, Alere, Alere MAS, BD, Carepoint Solutions, Chek Diagnostics, Conworx Data Solutions, Fisher HealthCare, Helena Laboratories, Hemo Cue/Beckman, IL, Innovative Medical Systems, Qiagen, Radiometer, Sekisui Diagnostics, Siemens and Telcor.

The meeting commenced with opening remarks by Darlene Sobucki, founder of the Tri-State POC Network. Members of the core group include: Wendy Denk, Ingalls Hospital, Harvey, IL; Gil Salas, Univ of Illinois – Chicago, Chicago, IL, and Sandra Curran, Univ of Illinois.

The first session, **"Quality Management and Personnel Requirements for the Point of Care Lab"**, was presented by Rodney Stewart from CAP. Quality Management is the act of overseeing all activities and tasks needed to maintain a desired level of excellence. This includes creating and implementing quality planning and assurance, as well as quality control and quality improvement. For Point of Care and Laboratory testing this includes Pre-analytic, Analytic and Post-analytic phases. Quality Management requirements are found in the Lab General Checklist and should be included in the lab QM plan (objectives and goals, responsible parties, reporting mechanisms, indicators, quality initiatives, review for effectiveness). The POC Checklists include the Organizational chart (who reviews it?), review of unusual results (procedure for out of range results?), troubleshooting duties, manufacturer instructions, and PPM QM program. The QM is also part of the Common checklist (.03810), is there a documented QM Plan?

Most of the errors made are in the pre-analytic phase (such entering patient identification into the BGM meter). Post-analaytic error include the documentation of critical values and repeat verification.(lab required?). Another common error is not having a review for effectiveness of the QM plan. Having a summary report is a good idea as well as the review of the QM Plan by the POC Committee.

Personnel Records was the most common deficiency in 2013 and citations were given for the lack of academic diplomas or transcripts in the personnel files; Licensure is not enough. Personnel performing Moderate Complex testing require at least a High School diploma and in all cases, training documents must be present in the file. Non-waived testing require a semi-annual competency assessment during the first year and an annual on the anniversary date and all assessments require the 6 elements in GEN.55500. Supervisors need to be assessed by the director. PPT.09500 requires initial training, credentialing is no longer accepted by CAP and the Lab Director determines the level of acceptable training and testing.

"PPMP CLIA Certificates" was presented by Raymond Castillo from CMS. Raymond reviewed the history of CLIA, defined CLIA test complexity, and identified the CLIA Certificate types. PPM Procedures include: all direct wet mount preparations for the presence or absence of bacteria, fungi, parasites and human cellular elements; all KOH preparations; Pinworm examinations; Fern test; Post-coital direct, qualitative examinations for vaginal or cervical mucous; urine sediment examinations; nasal smears for granulocytes; fecal leukocyte examinations and qualitative semen analysis. He also reviewed

the requirements for the type of CLIA certificates, medical director and testing personnel requirements (medical assistants cannot perform PPM testing), proficiency testing requirements, record retention, SOP, microscope maintenance, storage and labeling of reagents and documentation of room temperature. PPM labs may also perform waived testing and are required to follow manufacturer instructions.

Following the Vendor Fair and lunch, **"IQCP – What it is and what it means"** was also presented by Raymond Castello. IQCP = Individualized Quality Control Plan includes key concepts from CLSI EP-23 (Laboratory Control Based on Risk Management) but labs are not required to incorporate EP-23 as IQCP is not EP-23. IQCP is not a regulation but EQC will no longer be an acceptable QC option under CLIA once IQCP once published in Appendix C of the State Operations Manual. IQCP is not intended to reduce QC requirements but it is intended to ensure effective QC for each laboratory and the tests it performs. The Medical Director continues to have overall responsibility for QCP and needs to sign off on the plan. The Medical Director may delegate in writing the responsibility for establishing the IQCP as part of the laboratory's overall QC program to the Technical Consultant/Technical Supervisor and specific portions of the IQCP tasks to other qualified laboratory employees. There will be no grandfathering for current systems using EQC however historical data may be used in the development of the plan. All CLIA specialties/subspecialties will be included except for Pathology, Histopathology, Oral Pathology and Cytology.

An IQCP includes Risk assessment, a Quality Control Plan and Quality Assessment. The 5 requirements in the Risk Assessment include: specimen, environment, reagent, test system, testing personnel. The entire testing process (pre-analytic, analytic and post-analytic) must be considered and the data must be the laboratory's data, not published data. The QC Plan must monitor over time the accuracy and precision of test performance, include the number, type and frequency of QC and define criteria for acceptability of QC. If indicated, the evaluation of the risk assessment, the QCP may also include electronic controls, procedural controls, training and competency assessment and other specified quality control activities. The Quality Assessment includes a system to review on-going monitoring of the effectiveness of the QCP that includes at least following testing personnel, environment, specimens, reagents and test systems. When a process failure is determined, an investigation to identify the cause of the failure and its impact on patient care must be documented and appropriate modifications made to the plan. If necessary, changes must be made to the risk assessment with the new information.

The final topic, "**Pre-analytical Systems, Partners in Achieving Better Quality and Safer Work**", was presented by Anita Yanek, RN for BD. Anita worked through the financial impact of pre-analytic errors (redraw costs, retesting costs, potential lab instrumentation downtime costs, patient treatment costs). One high-risk accidental needlestick costs on an average of $5144, the lifetime cost of treating a single seropositive employee can be upwards of $1.7 million and OSHA fines are $11,340 per incident for non-compliance with the activation of safety devices. Anita also discussed proper order of draw, use of leur lock devices, blood transfer devices, discard tubes and needle safety devices.

There will be no spring meeting; the next meeting with a Vendor Fair will be in October, 2015 at the Doubletree Hotel in Alsip. Check the pointofcare.net website for meeting dates.

This is the last report to be written by me as I will be retiring from Ingalls Hospital May 1, 2015 after 42 and a half years. It's been a pleasure to meet so many of you over the years and I wish you continued success in all that you do to keep the profession alive.

Respectfully Submitted,

Wendy Denk, MT(ASCP)