

Identifying and reducing errors in point-of-care testing

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ABSTRACT

Point-of-care testing (POCT) refers to diagnostic testing performed outside of the central laboratory, near to the patient and often at the patient bedside. This testing is generally performed by clinical staff who are not laboratory trained and, as such, often do not appreciate the importance of quality assurance (QA) activities aimed at ensuring the quality of testing performed. Within hospital environments, it is typically the central laboratory that oversees POCT and that ensures QA practices are in-place. Audits for compliance of POCT users with policies and procedures in place are key to informing quality improvement initiatives. Here, audit and follow-up data and the results from three quality improvement initiatives are discussed. These examples demonstrate where QA audit practices led to a reduction in POCT errors and improved the quality of result interpretation.

INTRODUCTION

Point-of-care testing (POCT), as defined by the International Federation of Clinical Chemistry (IFCC) POCT working group is diagnostic testing at or near the site of the patient [1]. POCT is performed outside the central laboratory and is most often performed by clinical staff rather than laboratory trained staff [2].

Quality assurance practices are key to ensuring that POCT results are accurate and reliable. This is especially important given that POCT results are immediately available to clinicians for action, with no prior review by a laboratory technologist, as would be the case with central laboratory reported results. International guidelines for POCT and local Laboratory Accreditation standards include many quality assurance practices that must be adhered to [3-5]. Performance of regular audits for compliance of POCT operators with policies and procedures is an important component of quality assurance [4-5]. Audit data reveals areas for improvement and provide a useful starting point for further investigation, follow-up and education. At The Ottawa Hospital, audits are performed annually, at minimum for each POCT program.

Here, data and follow-up from QA three audits performed at The Ottawa Hospital are discussed. Positive patient identification, Charting of POCT glucose results and Inter-instrument comparisons. These examples demonstrate the importance of various QA practices in place for POCT in improving quality and reducing errors in POCT.

METHODS

Patient data for POCT

POCT glucose patient results were obtained from Cobas IT 1000 POCT data management software (Roche, Laval QC). Prior to October 2017, activated clotting time (ACT) patient results were

retrieved manually from the Medtronic ACT plus instruments for analysis. In October 2017, the ACT instruments were connected to Cobas IT 1000 POCT data management software and patient results were obtained from Cobas IT 1000 for analysis.

Patient chart audits

Chart audits were performed using the hospital electronic medical record (EMR). These studies were deemed to be quality assurance and did not require research ethics board (REB) approval.

Inter-instrument comparisons

Glucose measurements by the Roche Accucheck Inform II glucose meters used for POCT are regularly compared to glucose measurements by the central laboratory chemistry instrument (Siemens Vista) and central laboratory blood gas analyzer (Radiometer ABL90). Comparisons are made using whole blood (ABL90 and glucose meter) and plasma from the same specimen (chemistry analyzer). A sub-set of glucose meters (n=20) undergo inter-instrument comparison each month.

Inter-instrument comparisons for all blood gas instruments in use, both in the central laboratory and for POCT, are performed monthly using whole blood specimens.

RESULTS

Positive patient identification

In 2016, an audit of the Activated clotting time (ACT) program was completed for testing performed in the operating room. Of the 306 results audited, 141 (46%) were documented in the Anesthesia record in the patient chart. A detailed chart audit indicated that 55 of the 306 results may have been tested using an incorrect patient medical record number (MRN). The chart audit found that these tests were performed

outside the date and time the patient was in the operating room, according to the case notes. Follow-up with the clinical area revealed that clinical staff performing POCT were not entering the patient MRN before performing each test. An investigation by the POCT team found that the instruments were programmed such that they did not require entry of a patient MRN prior to each test. This practice had been in place for a long time as a convenience to the clinical staff, given the large number of tests performed during cases in these Operating Rooms (ORs).

These audit findings raised concerns at a time as there was an ongoing initiative to connect the ACT instruments to the laboratory information system (LIS) and EMR. This could have resulted in patient results transmitting to an incorrect patient chart and this implementation had to be delayed given the risk. The POCT team worked closely with leaders in the clinical area to educate all clinical operators performing ACT testing of the importance of entering a valid patient MRN prior to each test. Barcode scanners were installed for each instrument to make it easier for clinical staff to enter the MRN quickly and accurately. A two-hour time-out feature was activated on the ACT instruments so that the instruments required entry of a patient MRN more frequently, lowering the likelihood of tests being performed under the wrong patient MRN. A follow-up audit in 2017 found that only 5/199 (2.5%) of results were suspected to have been performed under the incorrect patient, indicating that the barcode scanners and time-out feature were effective. Prior to the ACT instruments being connected to transmit results to the LIS and EMR, the instrument settings were configured so that a patient MRN must be entered prior to each test performed.

Documentation of POCT glucose results

Up until late in 2014, POCT glucose results were charted manually using paper-based patient

medical records, which were scanned into the patient EMR at The Ottawa Hospital. An audit from February 2014 analyzed compliance with documentation of POCT glucose results in patient charts by clinical staff in the Emergency Departments. Of the 106 results audited, 48 (45%) were found documented in the patient chart and only 31 (29%) of those were specified as POCT results. None of the results were associated with a reference interval or units of measurement. In September 2014, POCT glucose meters at The Ottawa Hospital were interfaced to the Laboratory Information System and EMR via POCT data management software. A follow-up audit in February 2015 for the Emergency Department found that 93% of results were documented in the patient electronic medical record and were documented with appropriate reference intervals. Those results that were not documented were from instances where an “unregistered patient identification number” was used for testing. These numbers are available to the Emergency Department for urgent testing required at Triage prior to the patient being registered. Results are manually documented in the patient EMR once the patient is registered.

Inter-instrument comparisons

At the Ottawa Hospital, we perform regular comparisons between POCT instruments and central laboratory instruments that measure the same analyte. Data from these analyses revealed a small positive bias (0.3-0.4 mmol/L) for glucose measurements below 3.0 mmol/L for the glucose meters in our institution compared to the central laboratory. This information was invaluable when I was contacted by the Nurses in Neonatology regarding what they considered clinically significant differences between POCT and central laboratory glucose measurement in patients being investigated for hypoglycemia. The comparison data available from our regular

inter-instrument comparisons was used to modify the algorithm being used by Neonatology to guide treatment of neonatal hypoglycemia. These findings demonstrate the importance of understanding any bias that exists between POCT and central laboratory instruments.

In another example, during a regular comparison between the central laboratory blood gas instrument and the instruments used for POCT in the OR, one instrument was noted to have discordant pCO₂ values compared to the other POCT and central laboratory instruments. This finding prompted removal of the instrument from clinical service for investigation. Review of the internal QC data from the instrument found that the pCO₂ QC had failed during several measurements but the instrument still provided pCO₂ results to the operator. The central laboratory instruments are configured to repress results for any analytes with QC failures. Further investigation of the POCT instrument in question revealed that it was not configured exactly as the central laboratory instruments. This was corrected. Several patients had inaccurate pCO₂ results reported during the time frame the instrument remained in service with QC failures. The attending physicians for all of these patients were made aware of the issue and, fortunately, there were no negative outcomes.

DISCUSSION AND CONCLUSIONS

Following implementation of POCT glucose results transmission to the EMR, feedback received from physicians was - how much easier it was to find POCT glucose results in the patient chart - which offered a huge benefit in them being able to access the electronic results from home when on-call. In a 2001 study, Kost et al. [4] surveyed forty-six experts in POCT on how medical errors can be prevented related to POCT. The consensus from the survey was that bidirectional connectivity capability was key.

The use of POCT data management software also provides a platform for analysis of patient data related to quality initiatives. Tighter glycemic control in hospitalized patients is recognized as important for improved outcomes and the availability of electronic patient blood glucose results from POCT can be used to analyze success of initiatives aimed at improving glycemic control [5].

Physicians will use POCT results and central laboratory results for the same analyte interchangeably, making it imperative for physicians to be aware of differences between these results that could be clinically significant [6-7]. This has been demonstrated by other studies [8-9] as well as in the current study, highlighting the importance of regular comparison studies between POCT and central laboratory instruments.

Quality assurance practices for POCT, overseen by laboratory professionals are key to ensuring high quality POCT programs and results. The examples of quality assurance described here demonstrate the importance of proper oversight of POCT programs, which is relatively well-defined and in-place in hospital environments. As POCT moves outside of regulated hospital environments, consideration must be given to how these programs will be managed and overseen to ensure appropriate quality assurance practices are in place.

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