The Royal College of Pathologists
Pathology: the science behind the cure

Patient Safety Bulletin

The downside of efficiency

What happened and what were the issues/implications?

Multiple cases of clotting errors or spurious results in serum samples from patients suspected to be on therapeutic anticoagulation were reported by our acute biochemistry section.

It transpired that with increasing efficiency of electronic requesting, sample transport and automation, as well as increasing requirements for fast laboratory turnaround times to support patient flow, serum samples in separator gel tubes from these patients were not given sufficient time to clot. Delayed clotting caused analytical issues, which were occurring in a random manner.

This issue was not apparent for lithium heparin plasma samples. These do not rely on sample clotting for cell separation and removal of fibrinogen prior to centrifugation, and use an anticoagulant preservative instead.

The procedure is to reject samples with visible serum clots and request a repeat, leading to a delay in results and patient management, in addition to repeating phlebotomy for the patient. In cases where the clot was not apparent and we suspect a 'microclot' may have been present, the sample would have to be re-centrifuged and re-analysed. This would again cause a delay in reporting results. Most concerning are the cases where no analyser error is identified. In these cases, spurious results may be reported and picked up in clinical validation if they are abnormal or outside of the patient's trend.

What actions were taken?

A preliminary audit was undertaken within biochemistry to compare the monthly average sample rejection rate for clotting issues from cardiology locations (where patients are frequently on therapeutic anticoagulation) to the average sample rejection rate for clotting issues from all locations. There was an increased sample rejection rate due to clotting issues from cardiology versus all other locations (monthly average 7.5% compared with 0.1%). This confirmed the association that was being reported in the laboratory.

An internal safety notice was issued to highlight this problem to all secondary care clinical users and to recommend the use of lithium heparin plasma collection tubes when patients are on anticoagulant medications. Separate discussions took place with the cardiology and phlebotomy teams to highlight the change.

Electronic requesting profiles were set to default to lithium heparin plasma collection tubes for requests from cardiology locations/users, with a reminder notice flagging this change on the electronic requesting platform.

There was a particular concern, given the significant proportion of COVID-19 patients on higher dose thromboembolism prophylaxis, that this would affect a higher proportion of patients within the hospital setting.

What did you learn?

Laboratory staff involved in the routine analysis of samples are well placed to identify and report important patient safety issues. The problem identified can be subtle and go un-noticed, particularly when single results are being validated.

Multidisciplinary team working and involvement of the end user is important in effective communication and management of potential patient safety problems, particularly when implementing a change in practice.

How was the learning shared?

When making the initial changes and recommendations to users, we discussed the issue with colleagues in haematology and immunology. They had not seen a similar problem due to the batching of their assays and different sample requirements. We therefore ensured that instructions to clinical teams were clearly applied to biochemistry tests only. Within the department, the learning was shared at a quality and safety meeting.

It was also documented as a quality improvement project on our quality management system. In addition to direct communication with the end users, an offer has been made to attend cardiology team meetings to explain the issue and reasons for requesting a change in more detail.

An initial re-audit of rejection rates of biochemistry samples from cardiology locations due to clotting has been undertaken to complete the audit cycle. This has, unfortunately, not demonstrated the improvement we were hoping to see (7.6% rejection rate from cardiology compared with 0.1% from all locations). A short prospective audit has also been undertaken to identify sample issues as they occur within the laboratory. This demonstrated the most common locations with visibly clotted serum samples were either in cardiology or intensive care. Half of the samples with visible clots were from patients who could be identified to be on therapeutic anticoagulation, with some other affected samples from patients with abnormal coagulation profiles.

The average time from sample collection to sample receipt from patients on anticoagulants was 34 minutes, which is likely too short for complete clotting to take place as per CLSI guidelines.[1] Further communication has taken place to explain this association to teams in these specialties.

We hope to re-audit this work after several more months to allow for possible changes in practice. Given that association cannot prove causation, we can only hope that ensuring best practice in phlebotomy for patients who will be prone to this issue will reduce sample rejections and strengthen our recommendations.

Reference

1. CLSI. GP44-A4. *Procedures for the handling and processing of blood specimens for common laboratory tests.* 2010;Section 5.3.1.1.