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

Patient Safety Bulletin

Never do without the (software) glue

What happened and what were the issues/implications?

A spoke laboratory (processing only in-patient samples) did not report acute kidney injury (AKI) alerts on U+E requests. This went unnoticed for two weeks, during which time around 5,500 U+E samples were processed. This happened as a result of a change in analyser system, lack of middleware and insufficient checks.

Middleware is software that lies between an operating system and the applications running on it ('software glue'). It optimises the flow and management of data between an analyser and the laboratory information management system (LIMS), and converts the communication from the analyser(s) to a format the LIMS can 'understand'.

Due to the imminent cessation of the existing managed service contract in April 2020, it was agreed that the new analyser system (which would align the laboratory's equipment with the rest of the network) needed to be implemented at this time. Unfortunately, because the middleware was not ready for implementation, the new analyser system had to 'go live' without the benefit of middleware.

Before 'go live' day, all the chemistry assays were set up and end-to-end testing of the process was performed manually. The serum creatinine assay was set up to report to one decimal place, as per the existing and new analyser specifications.

However, no one realised that as the AKI alert algorithm (housed in the LIMS) could only process whole number creatinine results, alerts would not be generated. While the IT team and laboratory staff conducted checks of all tests, the AKI calculation was tested manually and a whole number for creatinine was tested.

What actions were taken?

An incident report was submitted and the issue was discussed with the hospital's risk and safety team, as well as the medical director. A 'look-back' exercise was arranged to identify avoidable harm to patients.

An investigation was conducted to understand why this incident had happened and to identify learning. Fundamental issues were the lack of middleware and the lack of 'live' end-to-end testing of all assays, especially calculated results.

What did you learn?

The importance of a whole systems approach to include middleware has been highlighted. Middleware supports appropriate post-analytical processing of results. In this example, the previous system had been rounding serum creatinine test results to a whole number from the one decimal place generated by the analyser before being picked up by the AKI alert algorithm in the LIMS.

Discussion with the wider team in the laboratory revealed that transfusion medicine uses a specific validation strategy that ensures comprehensive, appropriate performance checks of IT systems when changing LIMS.

This takes into account the principles of good automated manufacturing practice (GAMP5, 2008) as set out in the British Committee for Standards in Haematology (BCSH) *Guidelines for Validation and Qualification, Including Change Control for Hospital Transfusion laboratories* (BCSH 2012a), and the International Society of Blood Transfusion *Guidelines for the Validation of Automated Systems in Blood Establishments* (ISBT, 2010). The Clinical Biochemistry laboratory will be adopting this approach.

How was the learning shared?

The case was discussed within the Blood Sciences teams both at the spoke site and across the network, and was also shared across pathology.

The case has also been flagged to UK NEQAS, as it highlights the need for an external quality assurance scheme for AKI alerts.