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

PATIENT SAFETY

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Molecular Matters

This edition brings together learning from across molecular pathology, reproductive science and genetics. Patients trust our results – and clinicians act on them. This includes delivering life-changing therapies that can sometimes put patients at risk of severe complications. Getting these results right is key to keeping patients safe.

Shaken and stirred

An agitating shaker with a multi-well plate containing genetic samples was used in an analytical pathway in a genetics lab. Anomalous results were found in a quality control sample. On investigation, it was found that the shaking was creating droplets that spread sample material from one open well to another, creating anomalous results and potentially putting patient results at risk. A different type of shaker was introduced, with covered wells, and contamination quality monitoring was instituted on a more regular basis.

You have to hand it to me

A multi-well tray of genetic samples for a major programme was lost after it was dropped in a laboratory. As the incident was followed up, it transpired that no back-up material was available. The material was irreplaceable, and specific patient consent had been obtained for the taking and processing of the samples.

As a result of these events, there was much consternation and soul searching about what to do and how to let the patients know what had happened. There are two key learning points from this. First: physical manual transfer has a general level of risk for all laboratory processes and therefore must be minimised. Some laboratory items are not specifically designed to be safely handled without dropping, including most multi-well plates. Second: always consider whether you need to ensure a back-up is in place in case a specimen is lost. An assessment of how precious and 'unique' a sample is should be a key part of pathway preparation. This should take into account, for example, how the patient would feel if a problem occurred with their cerebrospinal fluid or fresh tumour samples.

Machine learning

A robotic system was in place in one laboratory to pick selected samples for genetic analysis. One sample was selected by the robot and tested for a mutation that was not the one intended. The intended test for cystic fibrosis carriage was replaced by one for Lynch syndrome.

The finding of a variant was very distressing for the individual and all staff involved. On investigation, it appeared to have been a software issue. There are a couple of questions to consider here:

- How are you assured that the hardware and software are doing what they are supposed to be doing?
- What is your approach to an unexpected finding?

Should we be SHOT of errors?

A patient had a bone marrow transplant on the basis of a molecular result that turned out to be incorrect. The implications for the patient were particularly serious. There are some questions to consider to mitigate against these errors:

- Do you and your clinical teams know the accuracy or likelihood of error of your results?
- How confident are you that the result is the right one?

Through programmes such as the Serious Hazards of Transfusion (SHOT) reporting system, we have learnt a lot from 'wrong blood in tube' events and laboratory handling errors in transfusion. These have led to a two-sample system. Should we be thinking about this approach for molecular pathology and genetics in certain circumstances – especially when the consequences of error in some clinical settings can be so severe?