

Problem statement and impact: IT systems allowing manual input of pathology results by clinical teams

It has been recently brought to the attention of <u>Serious Hazards of Transfusion</u> (SHOT) that the UK maternity patient data management system as supplied by Badgernet allows clinical staff to manually input patient pathology and other test results into the system. This may impact decisions related to patient care including blood group, red cell antibody screen and identification results. Other clinical systems that use pathology data may be similarly impacted.

These test results are used within the clinical system to drive algorithm-led treatment pathways such as that for a patient who is RhD negative or who has atypical red cell antibodies. If these, or other results, were entered incorrectly, this may cause the wrong algorithm pathway to be followed. There is therefore a risk associated with the manual inputting of results which can lead to a patient receiving the incorrect treatment. The requirement for manual input includes where an interface is in place for electronic transfer of laboratory test results, as the interfacing does not add the results to the data field that drives the algorithm.

A preliminary review of cases submitted to SHOT in the last 3 years revealed at least 12 incidents where the cause of the preventable error was a manual transcription error in the maternity IT system. These errors resulted in 6 cases where anti-D immunoglobulin (anti-D Ig) was not administered (omission); 3 cases where anti-D Ig was not given in a timely manner (late); and 3 cases of unnecessary administration where anti-D Ig was given to a RhD positive patient. In one case of late administration the transcription error was on the baby's group and in another case of late administration, the delay was caused by incorrect patient demographics entered onto the maternity IT system. In 2 of these cases the requirement for manual transcription has been noted by the reporter as a cause of error. While errors of manual transcription can be mitigated by a second check from another staff member following the manual entry, this may not always detect the error resulting in flawed decisions impacting patient safety as is evident from serial <u>Annual SHOT</u> <u>Reports</u>.

Transcription errors during manual data entry into clinical and laboratory IT systems can introduce several risks threatening data integrity, potentially resulting in misinterpretation and miscommunication with resulting adverse impact on patients. Where electronic interfaces for data transfer are in place an option for manual input of results may still remain, with continuing risk of transcription error. It is also important to recognise that not all incidents are SHOT reportable, and more errors may be occurring in practice.

This communication is to help improve awareness of this issue and to prompt necessary actions to improve patient safety. Some initial actions are suggested below.





Immediate actions requested:

System level actions such as automation and interfaces that negate the need for any manual transcription and should be implemented where possible. Where this is not fully implemented, the following actions are recommended to enhance safety:

- **Review clinical IT systems interfaced to the laboratory information management system (LIMS)** to identify those where manual entry of results is also available and/or required. Ensure adequate mitigation is in place to reduce the risk of transcription errors. Where possible, electronic systems should be configured to prevent manual entry of pathology results by clinical teams
- **User awareness and training** Please inform users in your organisations about the potential for transcription errors during manual data entry and the potential impact of these errors. Provide targeted training to reinforce best practices
- **Risk assessment** Perform a thorough risk assessment focusing on areas where transcription errors are most likely to occur, capture mitigations in place and any further actions required
- **Regular audits** Schedule regular audits of manual data entries to identify failures in current risk mitigations and address further actions
- **Haemovigilance reporting** Please ensure timely reporting to SHOT and MHRA of any relevant transfusion incidents
- Reporting to <u>Yellow Card</u> as appropriate
- Escalating concerns to IT supplier
- Ensure feedback loops are in place so that users can report issues
- **Record on organisation risk register and escalate concerns to senior leadership teams.** It is important to note that where the MHRA find errors threatening data integrity that the laboratory is not in control of, this may affect the regulatory status of the laboratory which the Chief Executive of the hospital is responsible for.

Thanks very much for your help in raising awareness of this issue and addressing safety concerns appropriately.

