CASE STUDY
Midlands Air Ambulance and Wolverhampton New Cross Hospital
21.03.18

Maximising Compliance with Mobile Cold Chain Temperature Monitoring

RePHILL (Resuscitation with Pre-Hospital Blood Products) is a multi-centre randomised controlled trial of pre-hospital blood product administration versus standard care for traumatic haemorrhage, funded by the National Institute for Health Research (NIHR) Efficacy & Mechanism Evaluation Programme.

The trial will test the hypothesis that Pre-Hospital Blood Products (PHBP) resuscitation with up to two units each of packed red blood cells (PRBC) and lyophilised plasma (LyoPlas N-w) will improve tissue perfusion (as measured by lactate clearance) and reduce mortality in trauma patients with haemorrhagic shock compared to the current standard practice of crystalloid (normal saline) resuscitation.

The Monitoring need

Compliance to EU transfusion guidelines drives the monitoring need at this cutting-edge emergency trauma unit. Temperature monitoring to ISO15089 standards is mandated for blood products and continuity of compliance was required to MHRA Blood & Safety Quality Regulations with MHRA oversight for pharmaceutical clinical trials.

Mobile monitoring was needed to ensure box validity up to 72 hours from packing for the blood products in transit during the programme; specifically, emergency O Neg Red Cells and Lyoplas (freeze dried group AB plasma) on the air ambulance service when deployed.

The search began a for a mobile monitoring system that would meet these particular specifications, paired with a cost that was manageable.

The Tutela Monitoring Solution

The pathology department at Wolverhampton New Cross Hospital are already users of the Tutela Genesis 3 Temperature Monitoring System and selected the Tutela TTMU (Transport Temperature Data Logger) for the purpose of maintaining compliance of the blood products in transit.
2 sites were initially piloted, then the Tutela TTMU was rolled out to 11 further centres around the UK.

During the trials, to ensure end to end cold chain resilience, the Tutela TTMU data loggers were randomised between blood and saline (standard resuscitation) with a maximum of 8 boxes being monitored simultaneously.

With the Tutela Geneses 3 system deployed already in Pathology, full use is made of additional services from Tutela such as temperature mapping, and monitoring dashboards. Being web based, the Tutela system meets the highest level of record security to its customers being fully compliant with FDA CFR 21 part 11, and allows comprehensive access to customer data at anytime, anywhere through the use of Smartphone, Tablet or Laptop or any device able to support a web browser.

Installation required minimal involvement of IT resources. The system was calibrated to ISO17025 by Tutela engineers.

Key points

- Temperature sensitive products are often unmonitored in critical parts of the cold chain.
- Only by monitoring products in transit, can compliance be maximised with no gaps.
- Remote alarming by real people is crucial for maximum inventory protection.
- Secure web access to the user interface allows isolated units to be addressed.
- Specialist providers offer more focussed solutions.
- The importance a calibrated system to meet MHRA compliance.

"A robust and easy to use solution for the monitoring of precious group O Neg red cells and group AB Lyoplas was required for the recycling of these products not required in the RePHILL trial. Various dataloggers were considered but Tutela became the preferred option due its simplicity of use and it's plug and play downloads of data into a pdf format."

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