IMPACT OF GMP ON THE USE OF REFRIGERATORS IN BLOOD TRANSFUSION

A professional panel and question time. Friday 14th September

Panel Members:

Stephen Bates, Cheltenham & Gloucester Hospital: Chair **(SB)**
Dr Ian Stewart, MHRA **(IS)**
Joan Jones, Chair of the OIG **(JJ)**
Martin Slatford, Labcold Ltd **(MS)**
Latif Alayoub, Trackflow Ltd **(LA)**

SB – The meeting has been convened as there is confusion regarding the requirements of GMP. The OIG website is intended to give clarification, but has possibly increased confusion.

	Alarms
MS	In British Standard 4376, alarms are ALL air temperature and are set at 2^0C and 8^0C. MHRA identified that GMP requires 6^0C liquid alarm, as the liquid temperature cannot go above 6^0C. The further cold chain clarification specifies a 200ml liquid load in the same position as the chart recorder liquid load. This alarm must be immediate, with no delay.
JJ	It must be understood that blood storage is at 2-6C. The air alarm is an alert alarm. It MUST be certain that the CORE BLOOD has not gone out of the 2-6 range.
IS	The Blood Safety and Quality Regulations specify 2-6^0C. You must DEMONSTRATE that blood is stored at 2-6^0C.
	Should core temperature be measured using blood as water does not have the same specific heat capacity?
MS	There needs to be a standard. 200ml of water was chosen following work done for British Standard in 1991. If a pack size is smaller eg paediatric, then a judgement should be made.
IS	Blood has a limited shelf life and would need changing frequently. There would also be a hazard in case of spillage so a water liquid load is more practical.
	How often should alarms be tested?
IS	The regulations state "Regularly" I suggest annually, although this is not written in any standard. Annual checking is accepted in Pharmaceutical industry. A valid, robust justification for 18 month or other timescale would be looked at and considered. Mapping should be annual. Checking alarms – most blood banks check the alarm function weekly.
Floor	Comment that resources are stretched and don't want to overdo the checking.
IS	Document the rationale eg provide validation data to support the methodology and you will not be challenged.
	There followed a showing of hands on the frequency of checking alarms; Once a week – approx 20% Checking the alarm at below 2^0C by putting the probe next to an ice pack, only 3 people out of over 100
LA	FDA require CFR21 compliance regarding software based systems. MHRA have detailed requirements for validation. LA is surprised that testing is required once a week as IQ and OQ covers this and sets up procedures for PQ to test the system in detail, prove it after a while, so that calibration tests of sensors are then all that is required.
JJ	Many check the alarms above 8C, few test them below 2^0C, but this is more important! The reason is that it is perceived as difficult. Alarm TESTING is often well documented, but alarm EVENTS are not usually documented so well – e.g. if the air alarm goes off and the load remains within limits, this should be documented. People need to learn a different way of working in this

	new era. If the alarm goes and the load is OK – WRITE IT DOWN.
IS	It is often the case that alarms are not tested or users don't know what will happen when an alarm is triggered, so MHRA ask that alarm testing is carried out. An assumption that it will work is not enough. In the future, people will adopt the proving of the system as suggested by LA.
MS	Checking the alarm (with a cold pack or warm water) is not always easy. Manufacturers have in the past chosen positions which comply with type testing but were not easily accessed in order to reduce damage to the probes . (Richard Lambert of Lorne also corroborated this from another manufacturers point of view) Labcold blood banks have 5 separate probes in different locations with different functions. It cannot be expected of our customers to know which is which, although we are looking to make probes more accessible. Opening the door to challenge (or test) alarms does not work as it is a complex system and this may actually trigger the cold alarm.
Floor	Having a Maintenance Contract, is this not enough for alarm testing? Is the Manufacturers engineer not the best person to test alarms?
JJ	Is (testing the alarm) once a year sufficient?
Floor	Should there not be enough confidence in the alarm system to test once or twice per year?
IS	If there is data to support this. There is not usually enough data in blood banks to do this with confidence.
JJ	A recent SABRE incident, switchboard was not notified, so there are also problems from human error.
Floor	Switchboard response is part of our alarm testing. Testing is only a snapshot.
Floor	So we shouldn't need a liquid load temperature action alarm if we can prove blood temperature has not been out of limits?
JJ	If you can show the alert alarm went and there was no blood temperature increase beyond limits, that's fine, but there MUST be data.
IS	Caution on how long the alarm has been active. This is OK if for a short period.
Floor	Do we have to do this for a year?
JJ	You have to have the data
IS	This is an important detail. You need ENOUGH DATA – not do it for 1 year or 2 years etc. You have to JUSTIFY your technical argument to the inspector. The ONLY way to do this is to have the data.
	The maintenance company that our hospital are forced to use for satellite fridges in a managed unit have no idea on blood bank regulations and settings. Is there a site to direct them to that they can use to pick up on blood bank regulations?
MS	It is wise to use the manufacturer or the manufacturers appointed service company. Local contractors appointed by Estates may come out quickly, but the manufacturer understands the products. The manufacturers service department should provide sensible advice to qualified service personnel about certain things (e.g. the compressor). This may not be possible with very complex issues such as the controllers.
RL*	* Richard Lambert, Lorne Laboratories Agreed. It is very important for non-domestic fridges. Cooling is fine, but alarms etc are not understood by refrigerator firms. They MUST speak to the manufacturer or manufacturer's representative. RL's experience is that mostly these fridge firms are not competent or qualified to service and maintain blood banks.
IS	It is down to the competence of the engineer. MHRA doesn't mind who carries out the servicing, but they must be competent. It is the responsibility of the blood bank to assess and review the service work. You can argue that "we are not the experts" but work with the manufacturer and know what is expected. Define the maintenance requirements and ensure that they are carried out.
Floor	Anyone know the phone no. for Brentwood?
MS	They have ceased trading.

	What is the difference between a "Blood Establishment" and a "Blood Bank" as this is not clear?
IS	A "Blood Bank" stores, receives, tests (grouping, cross matching) and issues blood. A "Blood Establishment" does all the above, but carries out processing of blood, e.g. washing and pooling. PROCESSING is the key difference.
SB	Is there a difference in the inspection process?
IS	Yes! It is 5 days instead of 1 in a large Establishment. It encompasses the entire process, including collection from donor centres, transfers, processing inspection and mandatory testing techniques
	Why is there so much emphasis on Good Manufacturing Practice when hospital blood banking are not manufacturers?
IS	The blood industry constitutes a number of steps, which is a process. GMP applies across the board from collection to issue and blood banks are part of the process ie storage. As for a blood establishment, blood has to be tested and records kept. GMP is not only manufacture but covers other parts such as documentation. So it is seen as a whole process.
	Recording data. We use data loggers to monitor temperatures of fridges, freezers and FFP freezers , which can be download to a computer and get rapid build up of data. This supplements alarms.
IS	Lots of places collect data but don't review it!
LA	There are systems available that force users to review data. They also provide an audit trail of who logged and acted on an alarm. The data can't be altered. The cost is equivalent to that of a data logger. The loggers used must be regularly calibrated and the calibration data kept on file .
	If a fridge breaks down and is repaired, what validation I required?
IS	It depends on the nature of the repair. Replacing a fuse would not require a re-mapping of temperatures but replacing the compressor would. A judgement must be made at the time on the significance of the failure and the impact on operation. Always document WHY you made the decision.
Floor	What about failure of the control panel?
IS	If the control panel is linked to the alarm it MAY be that there is not a need to remap but does the alarm work?
	What are your thoughts on frequency of cleaning and materials? How do you know if the blood bank is clean?
SB	Manufacturers instructions. What and how?
IS	Do you mean defrosting?
Floor	Evidence of cleaning is asked for in inspections, but what is required.
IS	That is the responsibility of the blood bank! You have more knowledge on the usage of the blood bank. Growth and moulds may increase risk in the use of blood.
Floor	Guidelines – even a minimum would be helpful
IS	You don't put guidelines against everything in life. I have seen rusty, dirty 30 year old blood banks that have never been cleaned. You should know the risks. If it looks dirty, clean it.
JJ	It depends on the lab. The old "pig tail" does spatter blood but not all labs use it.
IS	Clean quarterly and if you discover that it is not dirty, document that and don't clean it so frequently.
SB	**Are there any questions on temperature mapping?**
	What period? Should it be loaded or unloaded?
IS	We expect new blood banks to be mapped empty as part of OQ. Routine, in-service, (PQ) mapping is better with product. Don't need to map empty. It is best to map "as it is used". Record the contents. Minimum 24 hours 5 min or less logging frequency Probe positioning – generally in a tall unit, top, middle and bottom. Map round the outside of shelves. The OIG website suggests 4 top, 4 bottom in the corners as the "worst case".
JJ	What you do if, once mapped , the fridge is out of specification is important.

Floor	We took the bottom shelf out ours of service as it was a hot spot
IS	That is fine. The area of fridge in use must be within limits.
LA	You could try to adjust thermostat and remap. Then you may be able to use that area.
IS	It is fine doing mapping, but the results MUST correlate with the liquid load probe. May have to adjust setting or bias on the logger to accommodate this.
MS	The results WILL be different between air and load. No-one will put a logger in 200ml water.
JJ	You should map on liquid load temperature and put a probe from a logger into 200ml water.
LA	Comment from how things are done in the Pharmaceutical Industry; Mapping is carried out once per year The easiest way is with data loggers with internal probes, measuring air. Need to confirm the load temperature Mapping over a week to pinpoint hot and cold spots. Hot and cold spots should then be continuously monitored. Air temperature is the best indicator to identify problem spots. For the continuous monitoring, a load probe is recommended. External temperatures MUST also be recorded to show clear correlation between external and internal probes. Mapping is recommended for a period longer than 24 hours as it is a better snapshot of the operation.
Floor	**The clinical impact of uncertainty of action should be considered when a fridge breaks down e.g. our A&E fridge is not in use as they are scared to put it in use?**
SB	We must make sure that there is not significant clinical impact from all of this. Old ladies should not be travelling for 3 days to get a transfusion because the community hospitals are scared to put their blood fridge into use.