

Workshop B – Cold Chain

Topic - Management of components between laboratory and patients

1. What do you need to do?

Within hospital

- What boxes/containers to use
- What packaging materials
- Validate storage time using data loggers including extreme and external temperatures
- Identify maximum time units can be stored
- Identify how to or the need to seal boxes
- What to do with units returned in boxes with broken seal
- What temperature for storing cool packs/ice pack
- How long can be stored in container prior to use

Outside hospital

- As above plus
- Mode of transport
- Seasonal variation

2. What documentation would you put in place to support this?

- SOP for consistent packaging
- SOP for all stages for lab use and clinical areas
- SOPs for deviations
- SOPs for concessionary release
- SOP and exemption document if using sealed boxes
- Validation protocol / acceptance criteria
- Documented results of validation
- Transfer forms/labels to attach to boxes, time packed, time expired
- Procedures for routine and emergency transport requirements
- Collection register paper or electronic
- Time out of controlled storage
- Training and competency records
- Audit records

3. What are the barriers? (Staff and money are givens)

- Training of staff using the fridge, boxes etc
- Time out of controlled storage – understanding, requirements
- Purchase of data loggers/ which logger
- Calibration of data loggers (annually)
- Training of staff to use data loggers
- Understanding at the clinical end the need to follow protocols with regard to storage of blood

4. What processes will you introduce to manage deviations?

- Training of clinical staff
- If using sealed boxes – compliance with storage form(exemption document)
- Incident reporting/training
- Root Cause Analysis – determine the root cause of any incident and document corrective actions for all deviations

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5. What can OIG/BSMS do to help?

- Standards – see reference list
- Produce examples of model validation scripts/specifications/maintenance records
- Share documents

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