The Cold Chain
When the Milk Turns

Angela Green
Trust Transfusion Coordinator and Quality Lead
East Kent Hospitals

Cold Chain

What does it mean?

Is it important?

What if we don’t bother every time?

Our Consumer Rights

Well looked after

Fresh

Fit for purpose

Isn’t going to make us ill

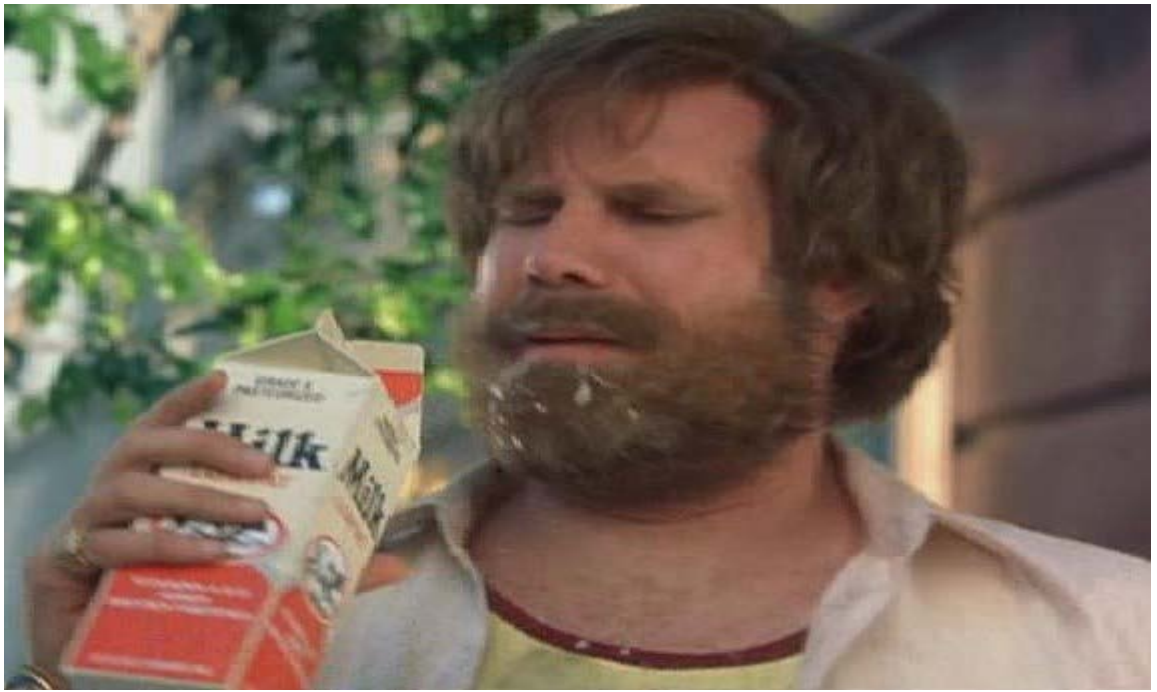
What we do next is our decision

Put it Away?

Leave it out all Day?

Sniff Test

Taste Test



Maybe Not

Hope for the Best

Correct Storage Conditions are Important

Definition – from Google

A **cold chain** is a temperature -controlled supply chain. An unbroken cold chain is an uninterrupted series of storage and distribution activities which maintain a given temperature range.

Where Did Cold Chain Come From

- BSQR – Part 4 STORAGE, TRANSPORT AND DISTRIBUTION CONDITIONS FOR BLOOD AND BLOOD COMPONENTS
  - Transport and distribution of blood and blood components at all stages of the transfusion chain must be under conditions that maintain the integrity of the product.

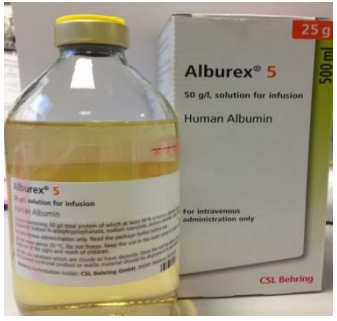
MHRA

- **Refrigerated medicinal products, part 1: receipt and storage - some things to consider**
- These are often referred to as 'cold chain products' or 'fridge lines' and wholesale dealers are expected to store and distribute them in strict accordance with the product labelling requirements as stated in the EU GDP Guidelines - chapters 5.5 (Storage) and 9.2 (Transport) give more information.

Products


AB
D NEGATIVE


AB
Rh D POSITIVE


Alburex® 5
50 g/l, solution for infusion
Human Albumin
25 g
For intravenous administration only
CSL Behring

Simple Times

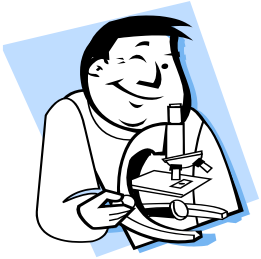
Blood Fridge

Chart recorder

Alarm

Switchboard

Laboratory



Blood Box

Cold Chain

It is expected that storage facilities will comply with the requirements of Part 4 of the Blood Safety and Quality Regulations, e.g. 2-6 ^{o}C for red cell storage.

Calibration limits applied to monitoring devices should also be appropriate. If alarm settings or storage specifications are outside these limits, a scientifically-based justification should be provided.

JPAC WEBSITE– Cold Chain

Cold Chain-Receipt of Product to Transfusion

Logistics

- Where do we store / move product
- What equipment are we going to use
    - How do we know the equipment is fit for purpose
- Who is involved
    - How can we be sure they do the right thing
- How do we monitor all of this and prove its safe

Storage

- SOP on Management of Fridges & Freezers
  - Fridge locations – who is responsible
  - Cleaning
  - Maintenance
  - Continual temperature monitoring
  - Alarm testing
    - Local and satellite

Storage

- SOP on Management of Fridges & Freezers
  - How often are alarms tested
  - Calibration
    - Recognised standard
  - Contingency if unit fails
  - Documentation proving all this
  - Keep the evidence

WILLIAM HARVEY HOSPITAL – BLOOD TRANSFUSION DAY TASK LIST

Year: …… Month: …… Week Beginning ……..

Task & SOP No	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Check handover log, whiteboard & workstations for outstanding work							
Dispose of old samples							
Manual Bench Controls							
Return blood to stock **(INC. BENENDEN) & QUARANTINE ALL EXPIRING UNITS**							
Record BSMS stock levels							
Phone K+C/QEQM informing them of any products due to expire within the next 3 days							
Stock order for pm delivery							
Daily in use reagents log INC.checking expiry dates/dispose of expiring reagents							
Restock previous HEMS blood							
New HEMS blood issued							
Record temperatures (LP BLT 032) & check pens and charts recording disks are working							
Daily clean centrifuges LP BLT 089							
Decontaminate bench & sinks							
SAHARA (ONE) clean							
SAHARA (TWO) clean							
Check supplies of Saline/dist H20 + Virusolve levels							
Replenish consumables eg tubes, pipette tips, printer paper etc							
Seal & discard full sharps/waste bins . Check sharp bin labels are filled out							

WILLIAM HARVEY HOSPITAL – BLOOD TRANSFUSION MONTHLY TASK LIST

MONTH: ……YEAR: ……

TASK	SIGN	DATE
REPLACE TRAUMA BLEEP BATTERIES FIRST WEEK OF EVERY MONTH		
REPLACE TEMPERATURE CHART BATTERY AND PEN FIRST WEEK OF DECEMBER AND JUNE. BLOOD BANK ISSUE FRIDGE		
REPLACE TEMPERATURE CHART BATTERY AND PEN FIRST WEEK OF DECEMBER AND JUNE. BLOOD BANK STOCK FRIDGE		
REPLACE TEMPERATURE CHART BATTERY AND PEN FIRST WEEK OF DECEMBER AND JUNE. PLATELET INCUBATOR		
REPLACE TEMPERATURE CHART BATTERY AND PEN FIRST WEEK OF DECEMBER AND JUNE. SANYO FREEZER		
REPLACE TEMPERATURE CHART BATTERY AND PEN FIRST WEEK OF DECEMBER AND JUNE. FFP (FRSP) FREEZER SPARE		
REPLACE BATTERIES IN ALL THERMOMETERS (use housekeeping log for reference) REPLACE FIRST WEEK OF DECEMBER AND JUNE		
REPLACE TEMPERATURE CHART BATTERY AND PEN FIRST WEEK OF DECEMBER AND JUNE (FRSP3) FREEZER		
BATCHED AND NON BATCHED RECALL TEST AUGUST AND FEBRUARY ONLY		
CLEAN BLOOD BANK 1 (6/12) (Issue)		
CLEAN SEALS, DOOR GLASS, INTERNAL DOOR, HANDLES AND BOTTOM OF FRIDGE – BB1 (ISSUE) (1/12)		
CLEAN BLOOD BANK 2 (6/12) (Stock)		
CLEAN SEALS, DOOR GLASS, INTERNAL DOOR, HANDLES AND BOTTOM OF FRIDGE – BB2 (STOCK) (1/12)		
CLEAN PLATELET INCUBATOR (3/12)		
CLEAN SEALS, DOOR GLASS, HANDLES AND BOTTOM OF PLATELET INCUBATOR (1/12)		
CLEAN & DEFROST FFP (FRSP) FREEZER SPARE (6/12)		
CLEAN SEALS, DOOR GLASS, INTERNAL DOOR, HANDLES AND BOTTOM OF FREEZER – (FRSP) FFP FREEZER SPARE		
SAHARA (ONE) MONTHLY CLEAN/MAINTENANCE		

Storage Additional Evidence

- Temperature Mapping
  - Have an SOP
  - Method of what is to be done
  - Who can perform the task
  - Duration of the test
  - Acceptance criteria

When to map

- New cabinets
  - Map as part of the pre use validation (empty)
  - Map again when in use (full)
- Map annually to ensure it continues to function
- Map following changes
  - Fridge is moved
  - Fridge is mended etc

Temperature Mapping

- Calibrated sensors positioned throughout the cabinet
- Minimum of 3 points, top, middle bottom, adjust according to size of cabinet
    - Larger fridge 4 corners top and bottom and centre
- Cabinet can be used during mapping
- Record amount and type of product in cabinet during test

Temperature Mapping

- Maximum logging interval is 5 minutes
- Map for at least 24 hours
  - Larger fridges will have two fans mapping period must cover both
- Door event log can solve sudden unexpected peaks
- Write a report and compare findings to routine monitoring probe data

Which Logger ?

- Does it meet your needs?
  - Transportable and robust & waterproof
  - Satellite fridge
  - Transport boxes
- Easily programmed
  - Manual start option
  - Memory space
  - Data is easy to retrieve
- Calibrated
  - To a recognised standard
  - Easy to organise in the future

Calibration

- Ensure equipment is calibrated to the points you are going to use them

- No good having it calibrated at 4^0C if always used at -40^0C!

- Calibrated to a recognised standard- ISO 17025

Where do We Move Product

- To the ward to a satellite fridge in same building
- Transport to another satellite fridge in another building
- Transport to another Trust- swapping
- Transfer with a patient
    - Getting the product accepted is a challenge

Transportation

It is expected that storage facilities will comply with the requirements of Part 4 of the Blood Safety and Quality Regulations, e.g. 2-6 ^{o}C for red cell storage.

BSQR 2005

Different Boxes / Different Uses

Hand transport 30 minutes – 72 hours

Box Verification

- Have a Verification Plan
  - Method of what is to be done and how
  - Duration of the test (how long do you want the box to work for)
  - Acceptance criteria (HEMS 2-6^{oc} for 48 hours minimum)
  - Use loggers calibrated to ISO 17025
    - When getting loggers calibrated state that ISO is required

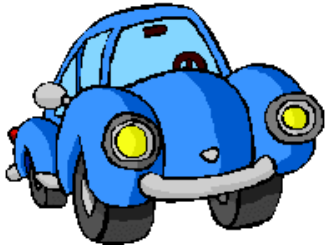
Box Verification

- Cold chain – things to consider
  - Route and time
  - Seasonal variations – challenge the box
  - Nature of the load – red cells, platelets, other – how many as minimum and maximum loads?

Box Verification

– HEMS BOXES

- Boxes were validated at ambient temperature
- In a microbiology incubator 30^0C (held temperature in excess of 48 hours)
- In a freezer – held temperature for 6 hours before dropping to below 2^0C.
- In a bike shed in the snow (ambient was -2^0C held temperature for 48hrs)



Transportation

- Pack box according to SOP & how box was verified
- Fill dead space
- Add cool packs
- Don’t let ice come in contact with product
- Ensure transport packs have been at desired temperature for long enough

Documentation- Prove the cold chain

Transfer Documentation

- What time was it packed
- Who packed it
- What is in the Box
- How long can the product remain in the box
- Not been tampered with
    - » Seal the box

Collection-Who Is Involved other than BMS

Kent Surrey Sussex

Air Ambulance
A Charity That Saves Lives

SERV
SERVICE BY EMERGENCY
RIDER VOLUNTEERS

Blood Component Collection

- Who collected
- What did they collect
- Where did it go
- Task is only to be performed by appropriately trained staff- maintain the cold chain

Blood Component Collection

- Restrict Access to Product – Issue Room
  - Prevent untrained staff from accessing product
  - Key pad on fridge- this needs occasional changing
  - Locked issue room
  - Blood Tracking System

Training

- Friendly Transfusion Practitioner

- Competency Assessment
  - All staff who collect blood and blood components
  - Includes packing if they pack product

Manual System has Element of Trust

- We rely on colleagues integrity-
  - How accurate is the porters watch & time recorded?
  - Did the lid go back on the box?
  - Did the blood remain in the box?
  - How accurate was the time when signed back in?
    - » Did they round up or down?

Fuzzy Line

Blood has been in a box validated for 4 hours- for 4hours 5 minutes

Paper System – open to the human factor

Electronic Systems don’t have the fuzzy line

Broken Cold Chain

If the cold chain can’t be proven and there is doubt about the conditions the product has been exposed to then the product is wasted

Wastage is expensive and our components are a precious resource

Potential Changes = More Logistics

30 Minute Rule – has now been challenged

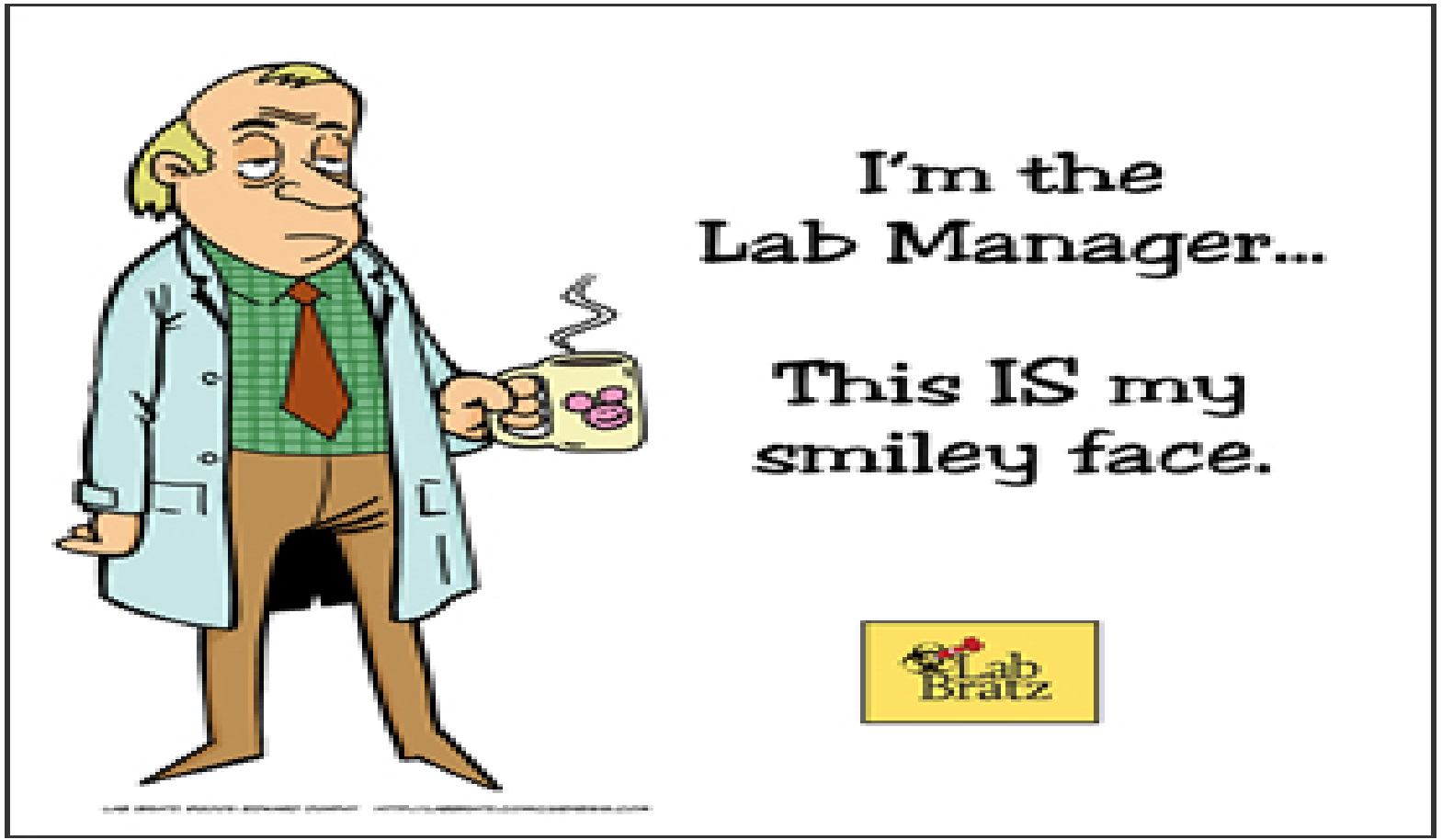
30 Minutes to 60 Minutes

RBC returned to temperature controlled areas will need time to return to regulatory requirements before re-release or going back to usable stock

minimum 4 hour

More Logistics

- Temperature excursions would be cumulative
  - Identify the units
  - Record the number of excursions
  - Can LIMS do this
- Manual Methods – could be just too difficult
- Being Contentious – Maybe a 45miute rule!
- Human Factors


I'm the
Lab Manager...
This IS my
smiley face.
Lab
Bratz

Perfect Conditions Matter

Any Questions ?