

Handling biopharmaceuticals in the pharmacy

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Learning objectives

- Sources of information
- Good distribution practice
- Teaching others
 - Pharmacists, nurses, patients, carers
- Risk assessments
- Build confidence in the use of these agents

Conflict of interest declaration

- Roger Tredree
 - Boehringer Ingelheim
 - Amgen
- Friedrich Moell
 - None

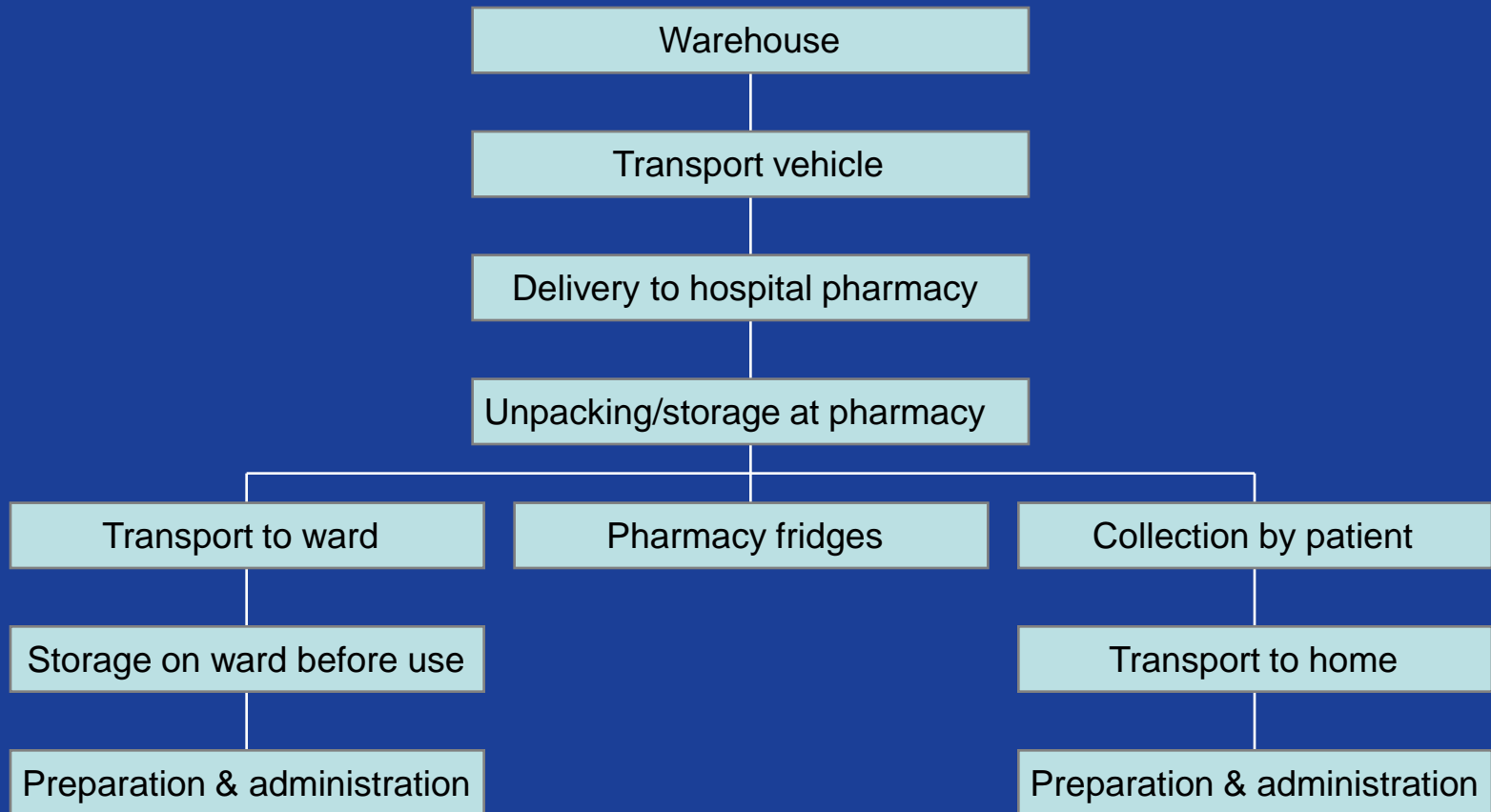
Delivery to the hospital pharmacy

- Medicinal products should be stored and transported under conditions which ensure the quality of the product is maintained according to the manufacturer's recommendations and comply with the terms of the product licence
(MCA Guidelines MAIL 99, Jan/Feb 1997)
- Many pharmaceuticals require a low temperature environment
- 2–8° C to ensure potency and efficacy

Delivery to the hospital pharmacy

- Cold chain
- Difficult to establish whether the recommended temperature has been maintained throughout the journey unless continuous monitoring is undertaken
- MCA recommendation:
 - Temperature monitoring devices
 - Refrigerated transport for large volumes/transit times >3 hours
 - Portable data logger
 - Temperature indicating strips

Supply chain



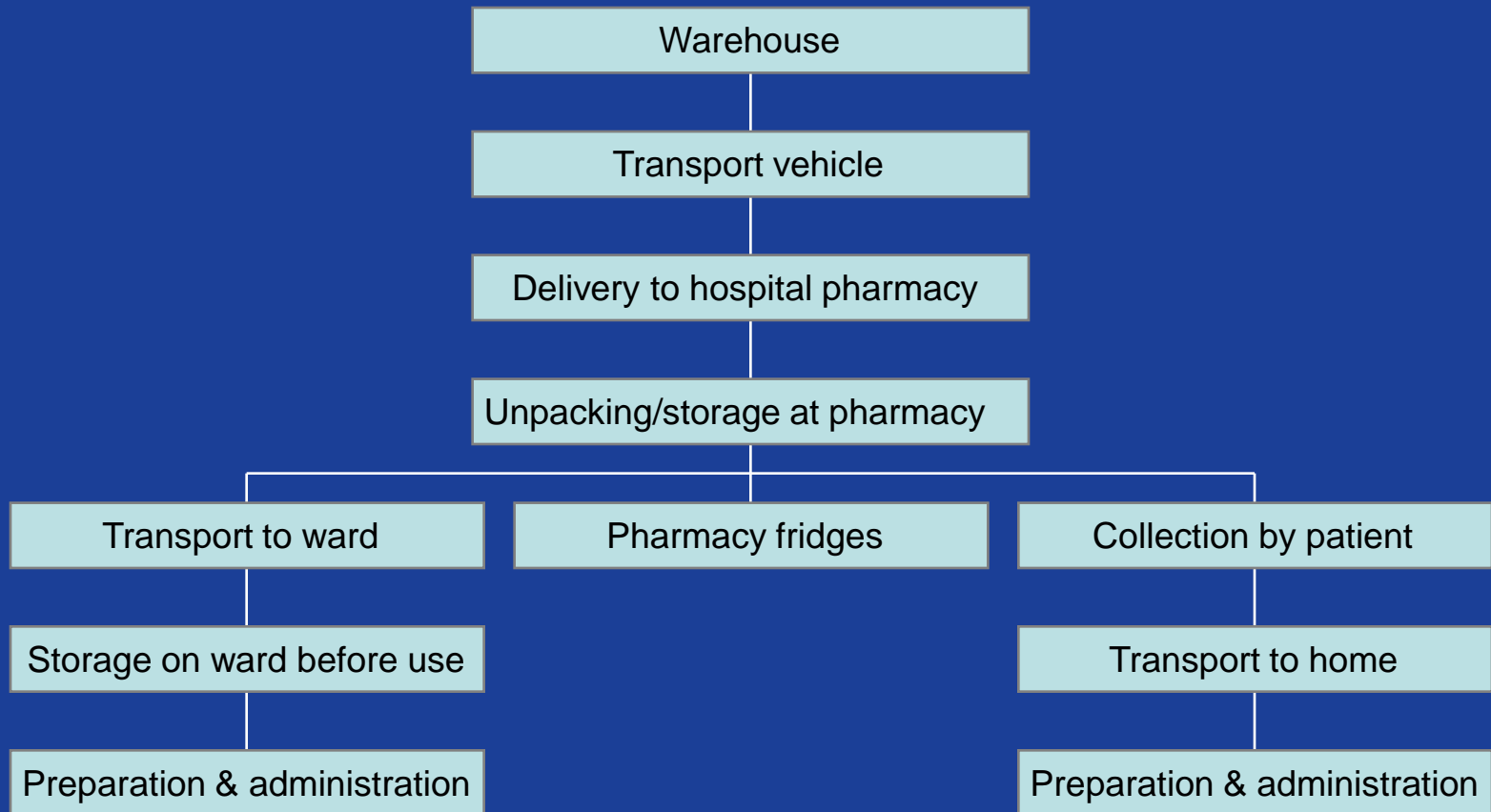
Fridge requirements

- Fridge must be capable of maintaining the contents between 2 and 8° C with the minimum amount of intervention
- Must be monitored using an electronic minimum/maximum thermometer with an accuracy of +/- 0.5° C which should be readable from outside of the unit
- Thermometer calibrated annually
- Temperature taken at least once on a daily basis and recorded into a temperature log
- Ideally fitted with an alarm system

Fridge checks

- QC daily manual checks of fridge temps
- Computer system monitoring
 - Tempulogger (3D)
- Covers approximately 30 fridges
- Alarm system actuates if above or below 0–15° C for more than 1 hour
- Attached to home computer of principal pharmacist QC – on call pharmacist
- Locking up procedure – manual check 5.30pm

Supply chain



Potential pitfalls



- Potential during process to remain out of fridge for anything up to 8 hours!
- Definite concerns about lengths of time pharmaceuticals are stored above recommended range
- Need to consider practical measures that can be implemented to reduce this amount of time

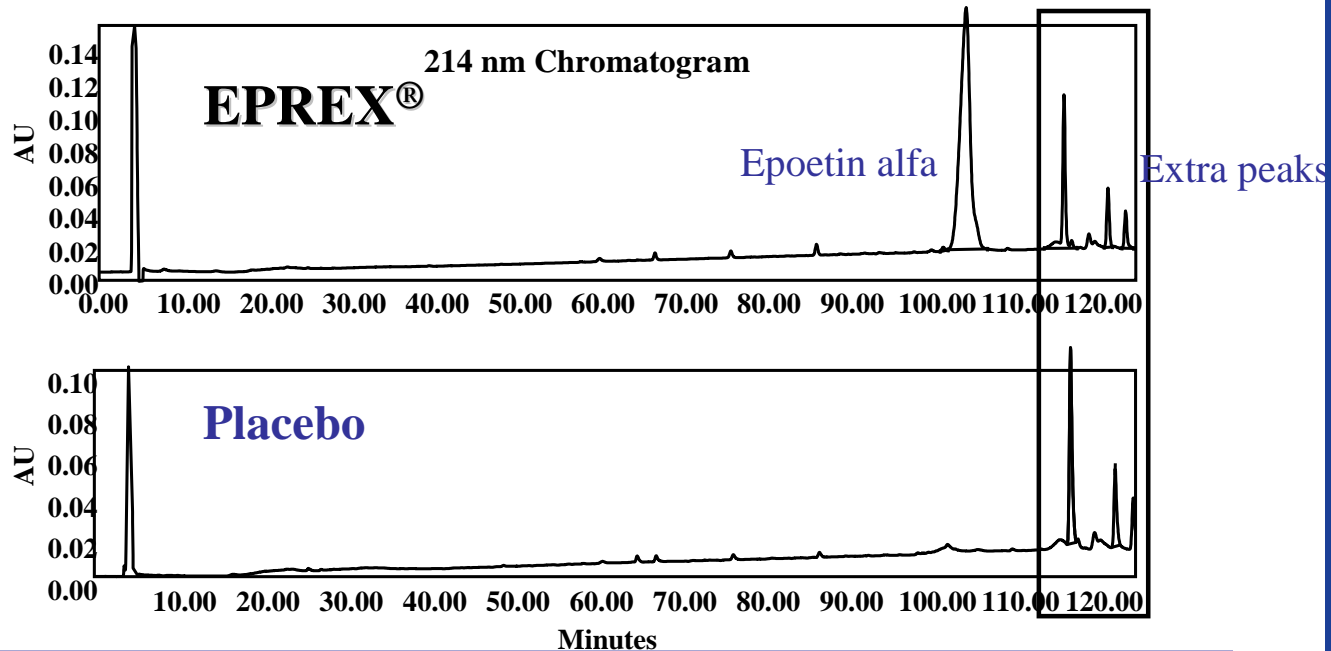
Storage

- Adherence to the container
 - Reduces effectiveness x3 or x4
- Reduced by adding HSA
 - Eg filgrastim, erythropoietin, interferon
- Some products are only stable in plastic syringes, eg erythropoietin, somatropin
- Others are stable in glass, polyvinyl chloride and polypropylene, eg aldesleukin

Prefilled syringes

- G-CSF is stable for up to 7 days in Becton Dickinson (B-D) syringes
- Erythropoietin is stable for up to 14 days
- Aldesleukin is recommended to be stored in PVC. Stable for 48 hours when refrigerated
 - So each product is different

EPREX[®] Tween 80 formulation with uncoated rubber stopper



Organic leachates in Tween 80 formulation with uncoated rubber stopper

Light protection

- Many biotech products are sensitive to light
- Dornase alfa is packaged in protective foil
- Alteplase when lyophilized needs to be protected from light but not when in solution
- So pharmacists need to be aware of the specific storage requirements for each product
- Generally – protect from strong light until the product is used