

Microbial contaminated TPN admixtures

The ‚Mainz case‘ in August 2010



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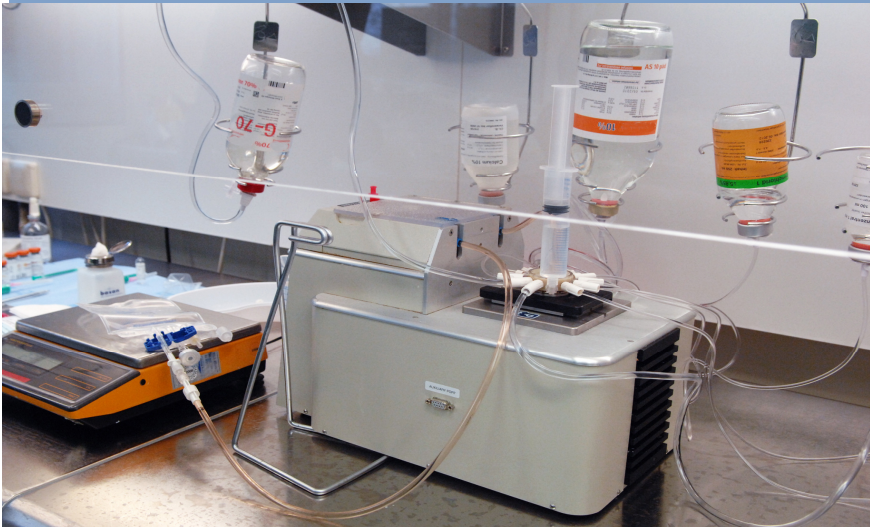
Apotheke, Prof. Dr. Irene Krämer

MAINZ

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Apotheke, Prof. Dr. I. Krämer MAINZ

TPN admixtures for paediatric patients compounded in the pharmacy department

- Individual prescriptions for paediatric intensive care patients (premature newborns, paediatric, IMC)
- On average 20 patients, 24 h supply
- Aqueous admixtures (glucose, amino acids, electrolytes, 7-9 components)
lipid emulsion (lipids, vitamins)
- Prescribing until 12:00
Preparation until 16:00
Administration starting at 17:00



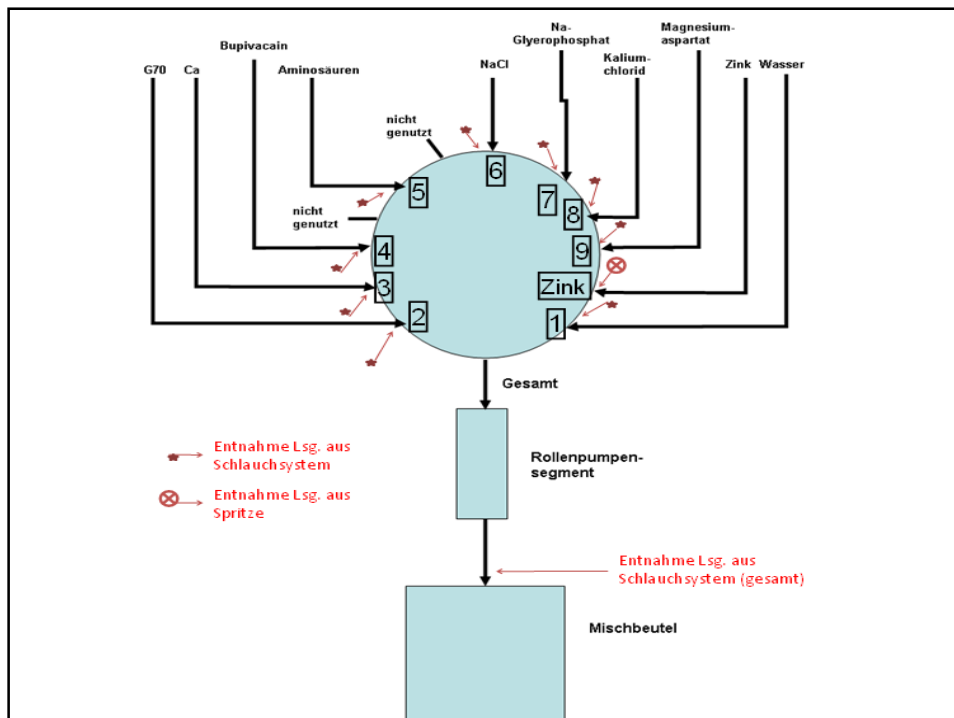
Infusion solution used	Expiration	Batch Nr	Manufacturer
Aqua ad injectabilia Ecoflac 1000ml	31.3.2013	0147A25 1	B. Braun
Glucose 70 % 500 ml	31.2.2013	0125A16 4	B. Braun
Aminopäd 10% 1000ml	31.2.2012	10C0292	Baxter
Natriumchlorid 5,85% 250ml	31.1.2014	221345	Serag Wiessner
Glycerophosphat-Natrium 100ml	31.12.2011	221286	Serag Wiessner
Calciumgluconat 10 % 250ml	31.3.2011	220747	Serag Wiessner
Kaliumchlorid 7,45% 250ml	31.3.2013	221446	Serag Wiessner
Magnesiumaspartat 100ml	31.12.2012	S100707 9	Eigenherstellung, Apotheke Uni-Mz

Origin of bacterial contamination

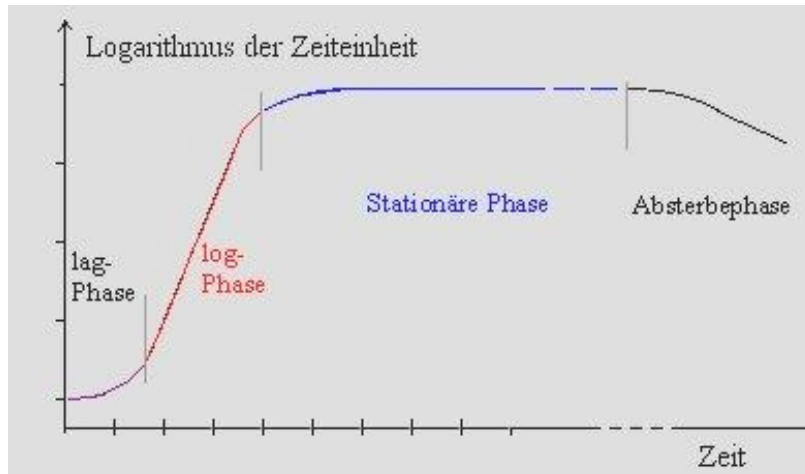
- Contamination during preparation ?
- Contaminated medical devices ?
- Contaminated infusion solution ?

TPN admixtures for paediatric patients

- Information from department of microbiology- blood cultures prepared from dummy solution contaminated – Enterobacter (30.000 bacteria/ml) dummy of lipid emulsions not contaminated
- Information of wards by the pharmacy
- Administration of TPN admixtures stopped
- Blood cultures from all admixtures contaminated with Enterobacter cloacae and Escherichia hermannii
- 2 infusion solutions used were contaminated (amino acid solution, Ca-chlorid solution)



High endotoxin levels in the TPN admixtures (>1100 u/ml)



Environmental monitoring

- Enterobacter not detected (except sink in the changing room)
- Air quality, surfaces, finger prints, media fills within the limits
- Process in accordance with standards
- Only explanation: contaminated infusion solution contaminated during production?
damage during transport?
Good transportation practice???