

Seminar M6 Patient Safety and Compounding Technologies

Drug Manufacturing and Compounding: A Powerful Tool to Reduce Medication Errors

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Disclosure statement

Conflict of interest: nothing to disclose



Control Question #1

Is the proportion of preparation and administration errors larger than 20% of all medication errors?

YES / NO



Control Question #2

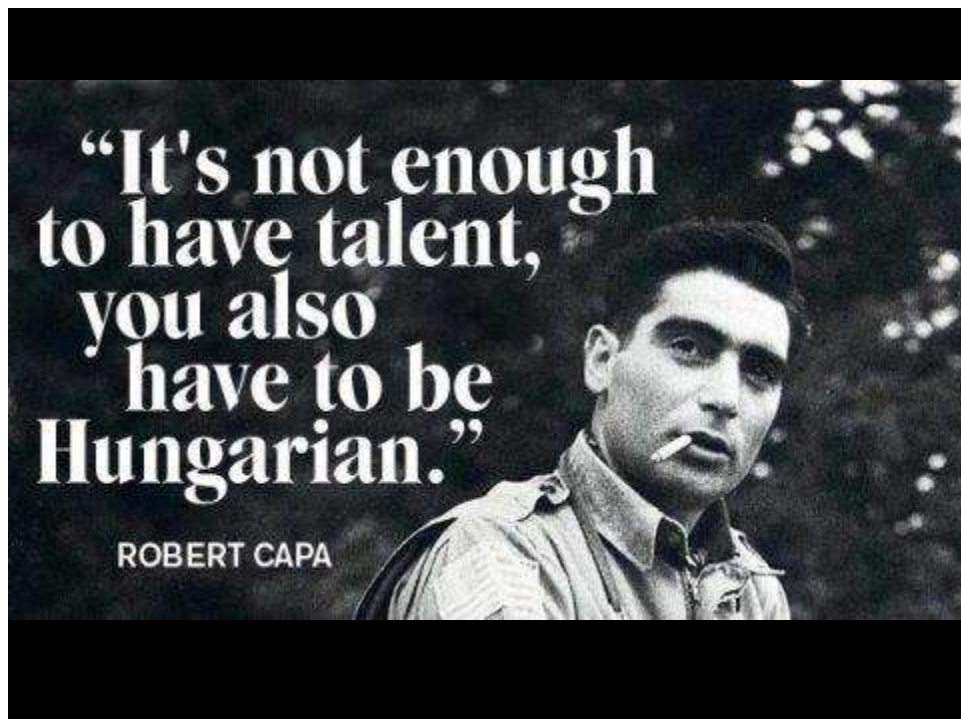
Is moving from ward preparation to pharmacy preparation a proper way to reduce medication errors?

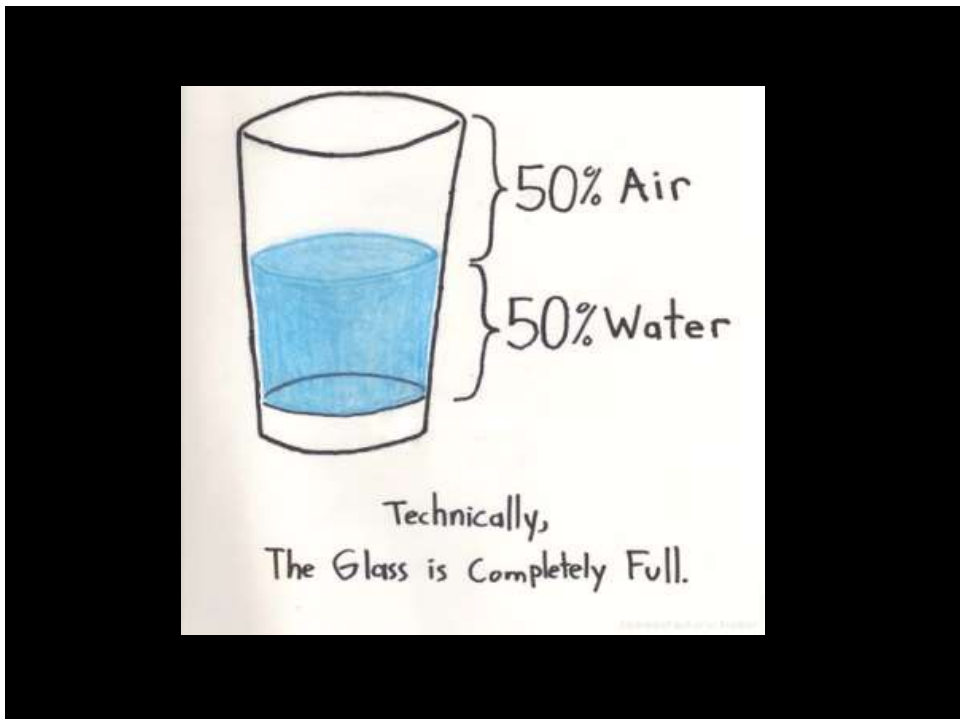
YES / NO



Who am I?

- Hospital pharmacist
- Head of Compounding unit of the Dept. of Pharmacy, Erasmus Medical Centre (Rotterdam, the Netherlands)
- Head of Pharmacy Apotheek A15 (Gorinchem, the Netherlands)
- Board member Dutch Association of Hospital Pharmacists (Drug Manufacturing, Compounding, QC & QA)





Erasmus MC

- Largest Academic Medical Centre in the Netherlands
- Dept. of Pharmacy: 115 FTE
- Three main parts: general hospital, children's hospital & cancer centre
- Compounding activities 2014:
 - Grand total: 200,000 units
 - Children: 130,000 units
 - Adults: 70,000 units
- Drug manufacturing: outsourced completely to Apothek A15 (including QC, QA and logistic aspects)



- *A state of the art* GMP licensed manufacturing facility
- 2000 m² of cleanrooms (GMP class B, C, D)
- Capable of manufacturing every type of product (non-sterile, sterile, aseptic) as well as performing individual and bulk compounding
- Manufacturing necessary but not commercially available drugs for primary care
- Developing new products to ensure regular patient care as well as medication safety
- Production site for Erasmus MC (full scale), University Medical Centre Groningen (full scale) as well as approx. 30 other parties (non-full scale)



What is my intention with you for this afternoon?

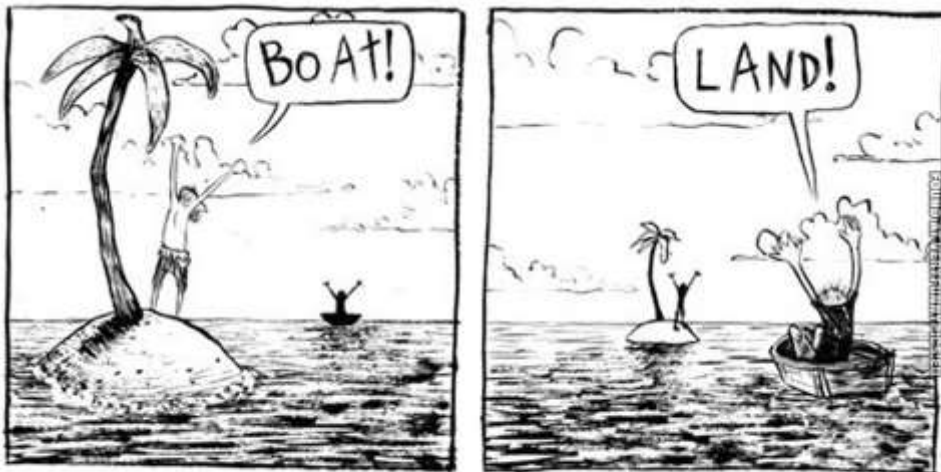




Drug Manufacturing & Compounding

***On a hospital level
is a hard core
necessity!!***





Perspective...

Main Advantages

- Raising medication safety
- Raising quality levels, true specialisation & centralisation
- More time for nurses at the bed side of the patient (instead of performing pharmaceutical work)
- Minimising overall costs



Necessity for Drug Manufacturing

- Therapeutically necessary, but not commercially available products
- Production problems with commercial products (temporarily / permanently)
- Investigator initiated drug research
- Medication safety (reducing medication errors)
- Service products (making things easier for nurses and patients)
- Individual needs of patients



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Medication Errors (%)

• Prescription	20
• Referral / rewriting	17
• Distribution	10
• Compounding /preparation	5
• Administration	45
• Other	3

Data from CMR = Dutch Registry of Medication Errors



Preparation & Administration

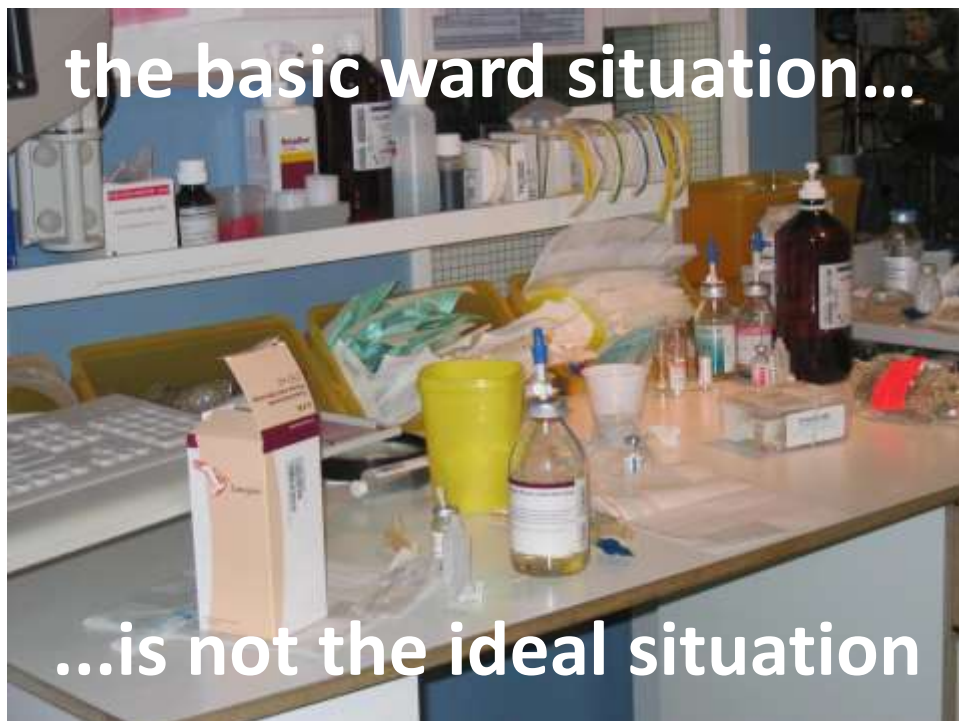
Account for approximately 50% of all medication errors!

Preparation:

- Wrong dose due to incorrect calculation
- Wrong dilution (concentration, infusion fluid)
- Microbiological contamination
- Wrong labelling

Administration:

- Wrong patient
- Wrong drug
- Wrong dosage form



Quality of products: Ranking

- Preparation on the ward
- Preparation in the pharmacy
- Preparation to stock
- Commercially available products

improvement



Prevention of errors

- **Product**
 - Ready to Use (RTU)
 - Ready to Administer (RTA)
- **Process**
 - Centralized compounding
 - Process help for ward preparation



Prevention of errors

- **Product**
Ready to Use (RTU)
Ready to Administer (RTA)



- **Process**
Centralized compounding
Process help for ward preparation



Product level: RTU & RTA

Ready to Use (RTU)



Ready to Administer (RTA)



RTU

- Ready To Use
- Standard dosage
- Prepared dose by the pharmacy
- Commercially available dosages



RTU availability: commercial



RTU availability: Pharmacy prepared

- Norepinephrine 50 mg = 50 ml
- Morphine 50 mg = 50 ml
- Midazolam (2)50 mg = 50 ml
- Furosemide 250 mg = 50 ml
- Heparine 25,000 IE = 50 ml
- Many electrolyte solutions
- Ropivacaine – Sufentanil
- etc



Evident advantages....

Standard preparation steps using glass ampoules



RTA

- Ready To Administer
- Syringes, examples
 - Anticoagulants
 - Vaccines
- Prepared in the pharmacy



RTA preparation in the pharmacy

- | | |
|--|---|
| <ul style="list-style-type: none"> • Infusion pumps <ul style="list-style-type: none"> – Elastomer pumps – Cartridges – ... | <ul style="list-style-type: none"> • Syringes <ul style="list-style-type: none"> – Manuel – ... – Smartfiller® – Rapid Fill® – ... – Robotics |
|--|---|





Stock preparation in the Pharmacy





Smartfiller®, Dept. Of Pharmacy of Leiden University Hospital



Future.....

- Robotics?
- Several examples
- Advantages: based on “safety issues”
- Cost effectiveness is paramount



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Prevention of errors

- **Product**
Ready to Use (RTU)
Ready to Administer (RTA)



- **Process**
Centralized compounding
Process help for ward preparation



Process

Basic problems during ward preparation:

- Calculations
- Hand hygiene
- Control by second nurse

Basic problems during administration:

- Patient identification
- Hand hygiene
- Control by second nurse



Example

Remiphentanyl

For neonatal intubation

1 mcg/kg
Dilution 100 times!
(0.1 ml/kg)



On the other hand...

Morphine

Pharmacy prepared

0.5 mg/mL
50 ml



Best Practices in the Netherlands

Moving from ward to pharmacy compounding:

- 'Veiligheid op recept' project 2007 ZMC/VuMC *
- 'Feniks' project 2010 MUMC **

Basic results:

- Decrease in (severe) medication errors during compounding
- Decrease in microbiological contamination during compounding
- More nurse time for direct patient care
- More awareness and concentration during administration

* PW Wetenschappelijk Platform. 2007;1(4):78-83

** <http://www.eahp.eu/press-room/feniks-project>



Implementation of the process of decreasing ward preparation

Decrease compounding on the ward

Process management (up close and personal)

Ask yourself:

- Is it actually necessary to administer the drug parenterally?
- Can the IV product be supplied in an easier to use (less handling) form (RTU / RTA)?
- Who is capable to actually perform the compounding?
- Are the relevant staff members in charge of the compounding properly trained?
-



Implementation & Ongoing Concern

Decrease compounding on the ward

Process management (up close and personal)

- ...
- Use as much as possible readily available, in stock, products
- Focus your logistics on RTU & RTA
- Large numbers? Centralise preparation!
- Complex handling? Centralise preparation!



Necessary needs for ward preparation

Some things will stay on the ward and as a consequence you will need to have:

- Up to date and easily accessible *drug database*
- Up to date and easily accessible *protocols*
- Up to date and easily accessible *instructions*
- Etc
- Adequate facilities
- Well trained personnel



Training and Education

The pharmacy will not take over 100%
of all compounding

And thus **training and instruction** of
ward personal is critical!



Explaining the Risks

Critical areas

- Connections
- Open ampoule
- Open syringe
- Needle



Instructions for preparation on the ward



1. handboek raadplegen



2. desinfectie werkblad met alcohol 70%



3. klaarleggen



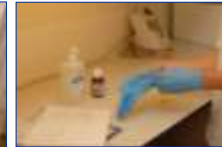
4. etiket schrijven



5. controle



6. handdesinfectie met handalcohol, handen droogwrijven



7. handschoenen



8. desinfectie aanprikpunt



9. bereiding



10. etiket plakken



11. toediencontrole



Summary

- Preparation and administration errors make up 50% of all medication errors
- In order to minimise these types of medication errors, there are several options to possibly consider (product & process level)
 - ✓ RTU & RTA
 - ✓ Centralised compounding
 - ✓ Process support on the ward
- Choices depend on the local situation and in general a combination of the options will be necessary



Acknowledgments

- Paul le Brun – Apotheek Haagse Ziekenhuizen (The Hague)
- Sjoukje Troost – Maxima Medisch Centrum (Veldhoven)



Q & A



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YES !!!

