Apoteket

Preparation of medicinal products – Computer software

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Where do we find preparation of medicinal products?

- Reconstitution of:

  ➢Cytotoxics

  ➢Antibiotics

  ➢Immunoglobulin for infusion

  ➢Clinical trial iv-medication

  ➢TPN

Characteristics for preparation of medicinal products

- Prescriptions with individualized doses

- Always reconstitution of medicinal products into individualized specific patient doses

- Handwritten documentation

- Handwritten labels

- Lots of signatures to document the control procedures

- Lots of possibilities for errors

Ways to prescribe to day?

A computerized system?

- What do we want from a computer system?
- What does the authorities want from the system?
- Can we transform our wishes?
- Can the it-system-makers understand our wishes?
- It is just the pharmacy who wants a system?
- What does the software cost?
- What does the hardware cost?
- Shall we make our own system or by a commercial?

What do we want from a computer system?

- The system should ease all critical steps during prescription and preparation
- The critical steps could be:
  - ➤ Transferring data from the patient journal to the prescription
  - ➤ Reading the prescription
  - ➤ Transferring the data from prescription to production documentation
  - ➤ Productions documentation
  - ➤ Labels
  - ➤ Quality control after production

What do we want from a computer system?

- Better patient safety

- Possibility to order our starting materials

- Possibility to sell our products

- Possibility of different statistics

What does the authorities want from the system?

- The Eudralex is not really a help
- Local rules set by the health authorities
- Validation according to the Eudralex and the GMP rules
- Security for that the system is an improvement in documentation of the preparation
- Easy traceability of errors
- Better patient safety
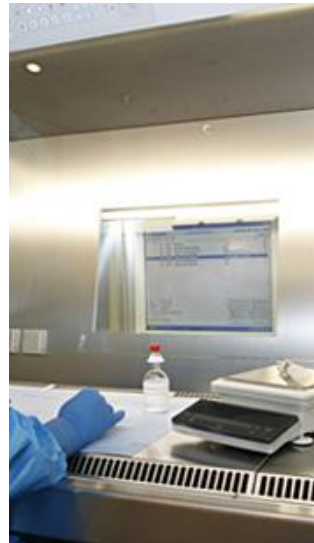
Computer system

Ward

pharmacy

Prescription online

Supply

Release for Preparation

Can we transform and make our wishes understandable?

- Remember!
  - ➢ Computer specialists are not pharmacists
  - ➢ The knowledge of our requirements is very wage
  - ➢ Our knowledge in computer design is zero
  - ➢ What you think is clearly expressed is often not what is understood/heard
  - ➢ What seems smart according to the computer designers might not be what you can use
  - ➢ Many vital details are hard to remember
  - ➢ Risk management is of high priority

Shall we make our own system?

- Advantages:

- Influence on all decisions

- Control of every step

- Easy access to changes

- All our wishes fulfilled ?

Shall we make our own system?

- Disadvantages:

- The design and initiative often is based on the ideas of one person

- Lack of experience in design of computer systems

- No back up support for the system

- Expensive and slow

- Is the system at the end suitable for commercial use?

Servisys

- Danish system
- Only pharmacy
- Based on gravimetric preparation method
- During preparation – operated by two persons
- Documentation of all steps in the preparation
- High security of the preparation
- Not commercial and under development for 12 years

Computerized system for cytotoxic preparation on the market

- Cypro

- Cato

- Cytodose

Cypro

- German system with more than 10 years experience

- Both for prescription and pharmacy

- Based on gravimetric preparation method

- During preparation – operated by one person

- Not possible to switch to volumetric preparation

- Documentation of all steps in the preparation

- High security of the preparation

Cato

- Austrian system
- Both for prescription and pharmacy
- Based on gravimetric preparation metode
- During preparation – operated by one person
- Possible to switch to volumetric preparation
- Documentation of all steps in the preparation
- High security of the preparation

Cytodose

- Norwegian system
- Both for prescription and pharmacy
- Based on volumetric preparation method
- During preparation – no computer documentation
- Before preparation print out of labels and fill-in documentation
- Reduced security to the preparation

What do we get?

- Safe transfer of data from the prescriber to the pharmacy

- Good safe documentation of the preparation for the patient

- Minimization of errors

- Minimization of waste

- Statistics of all sorts

But no

- Minimization of industrial injuries

What does a the software cost?

- Commercial system

- Workstation   EUR 4500
- Additional workstation   EUR   350
- Hotline service and update pr. month

                                                          EUR 70–90

- Education of staff 2 days/person

                                                          EUR 1700

Health Robotics Robot - ROBERTINO

Automation of preparation of medicinal products

- Combination of computer software and mechanical preparation

- Minimization of industrial injuries

- All the preparation advantages exposed by computer software

Automation of preparation of medicinal products

- All the administrative advantages of a computer system

- All the statistical advantages of the computer software

- Minimization of contamination

Robertino from the inside

CytoCare – the future?

Computer system and automation of preparation

- Limits in the gravimetric preparation due to weighing range

- Accept of precision range of doses

- Vulnerability during breakdown

System validation

- No EU requirements
- Requirements are different from county to country
- Check up with your authorities
- Negotiate with the company selling the software
- If no local rules – ask your colleagues from in and out of the country
- Decide if you need rules in your country
- Make your own validation
- Be flexible – remember you cannot get it all.

Shall we provide our self with a computer system?

Yes of course!!

The advantages of

- ➢ Better documentation
- ➢ Minimization of errors
- ➢ Safe transfer of data
- ➢ Automatic pricing
- ➢ Statistics of all sort
- ➢ Etc

Surely overrules the disadvantages!!!

The workload after having a computer system and a robot.