

Current practice of cytotoxic drug preparation in German pharmacies

Institution

Task



Institution for Statutory Accident Insurance and Prevention in Health and Welfare Services

Funding, Management



Institute of Energy and Environmental Technology e.V.

Organisation, Analysis



Institute of Medical Statistics, Computer Science & Epidemiology

Statistical data evaluation

IfAP

Institute of Applied Pharmacy e.V.

Data processing, Organisation

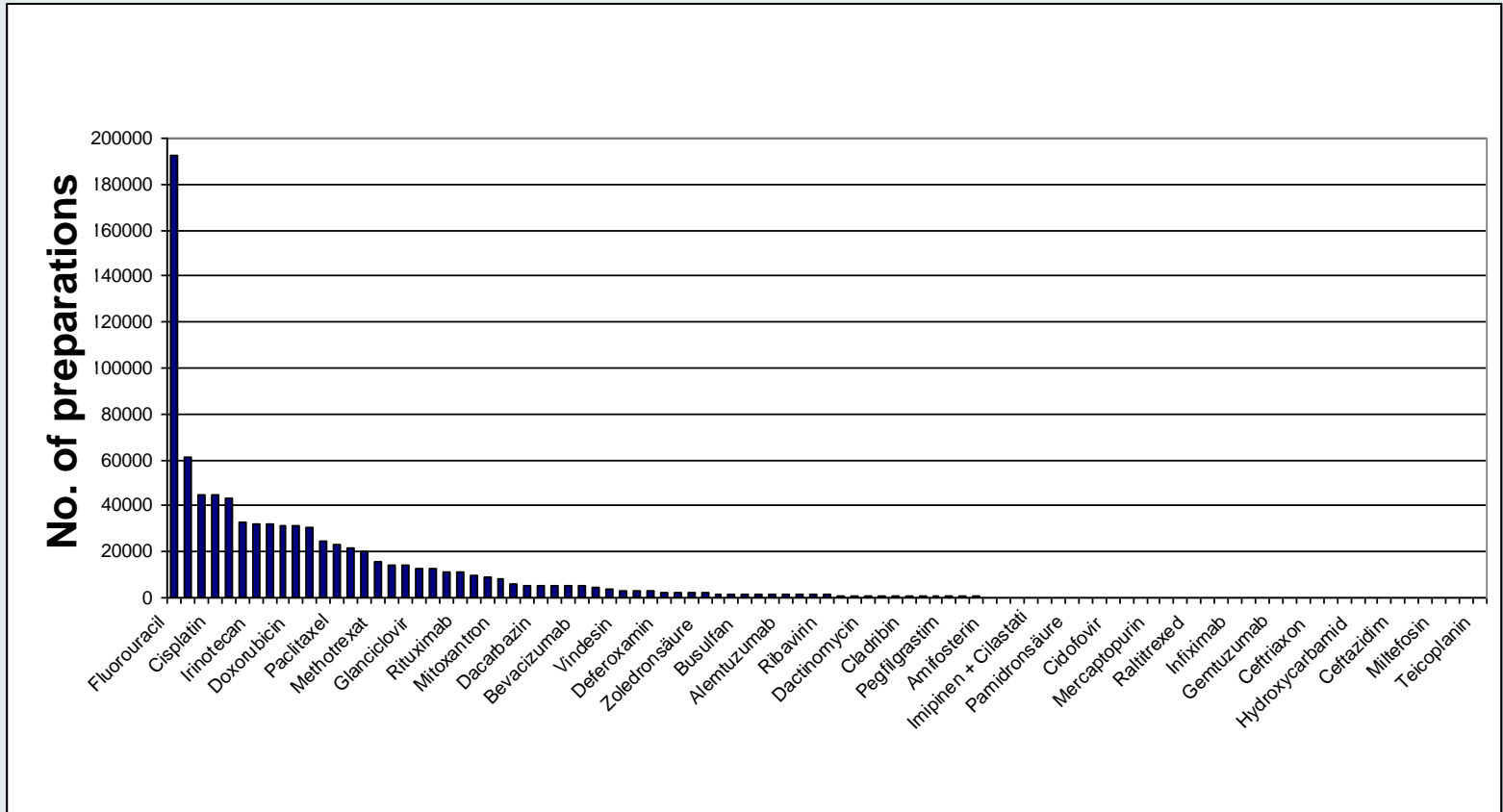
* Monitoring-Effect Study of Wipe Sampling in Pharmacies

Content

- Introduction
- Description of the current practices
- What influences chemical contamination?
- Examples of best practice



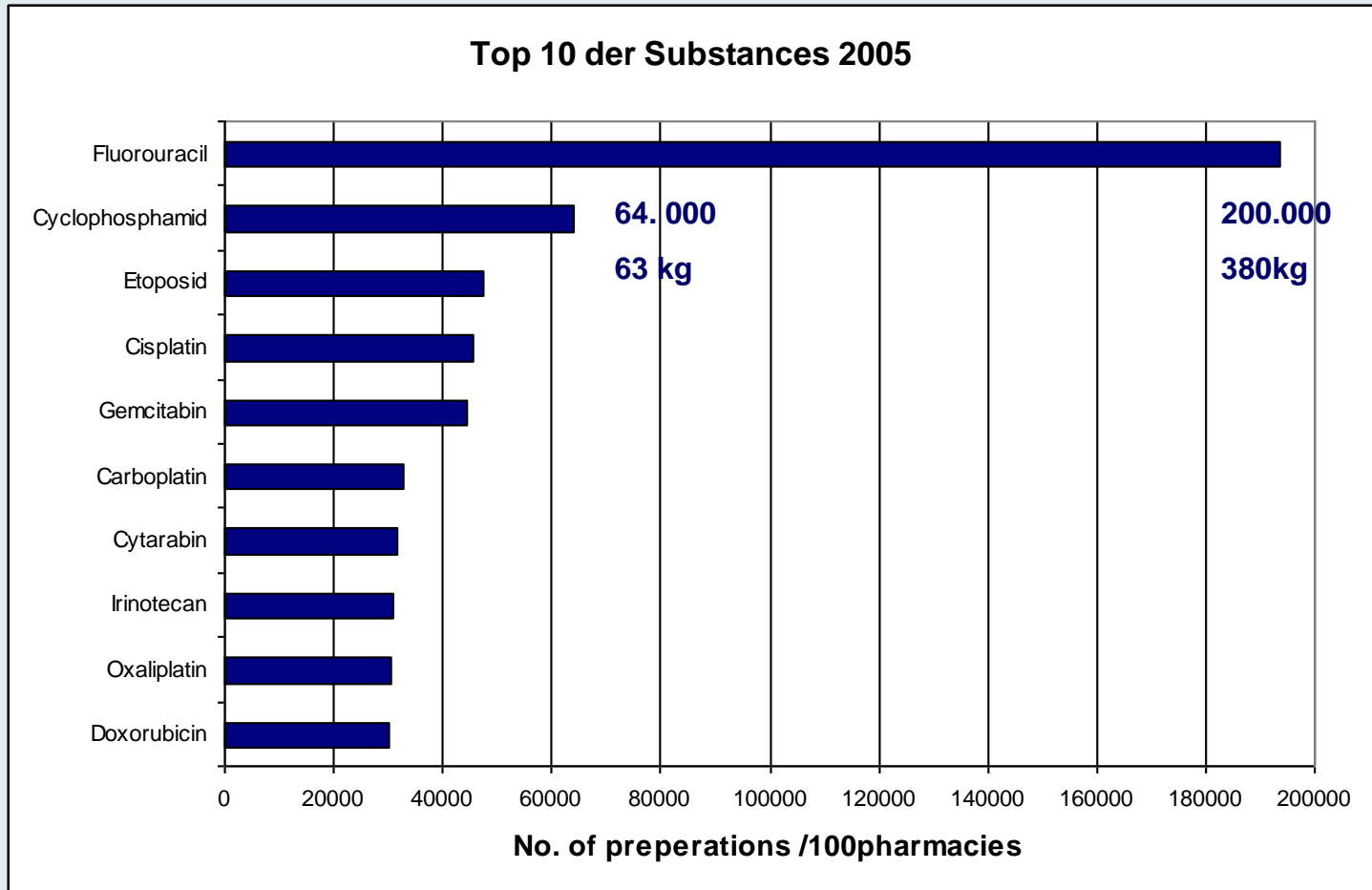
Substances



for 100 German pharmacies



Top 10 Substances



Amount of Substances handled in Germany

Assumption: 800 pharmacies preparing antineoplastic applications in Germany

Rang	Substance	2005		2006
		No. Of preparations	Amount handled [kg]	Amount handled [kg]
1	Fluorouracil	1548224	3025,28	3787,36
2	Cyclophosphamide	510896	505,04	609,28
3	Etoposid	381096	81,6	100,64
4	Cisplatin	363096	24,88	31,28
5	Gemcitabine	356952	589,12	921,6
6	Carboplatin	262160	105,68	154,24
7	Cytarabine	251776	263,2	351,84
8	Irinotecan	247016	47,36	62,4
9	Oxaliplatin	245120	31,84	42,4
10	Doxorubicine	242200	18,72	258,8

Calculated upon informations of N Pharmacies:

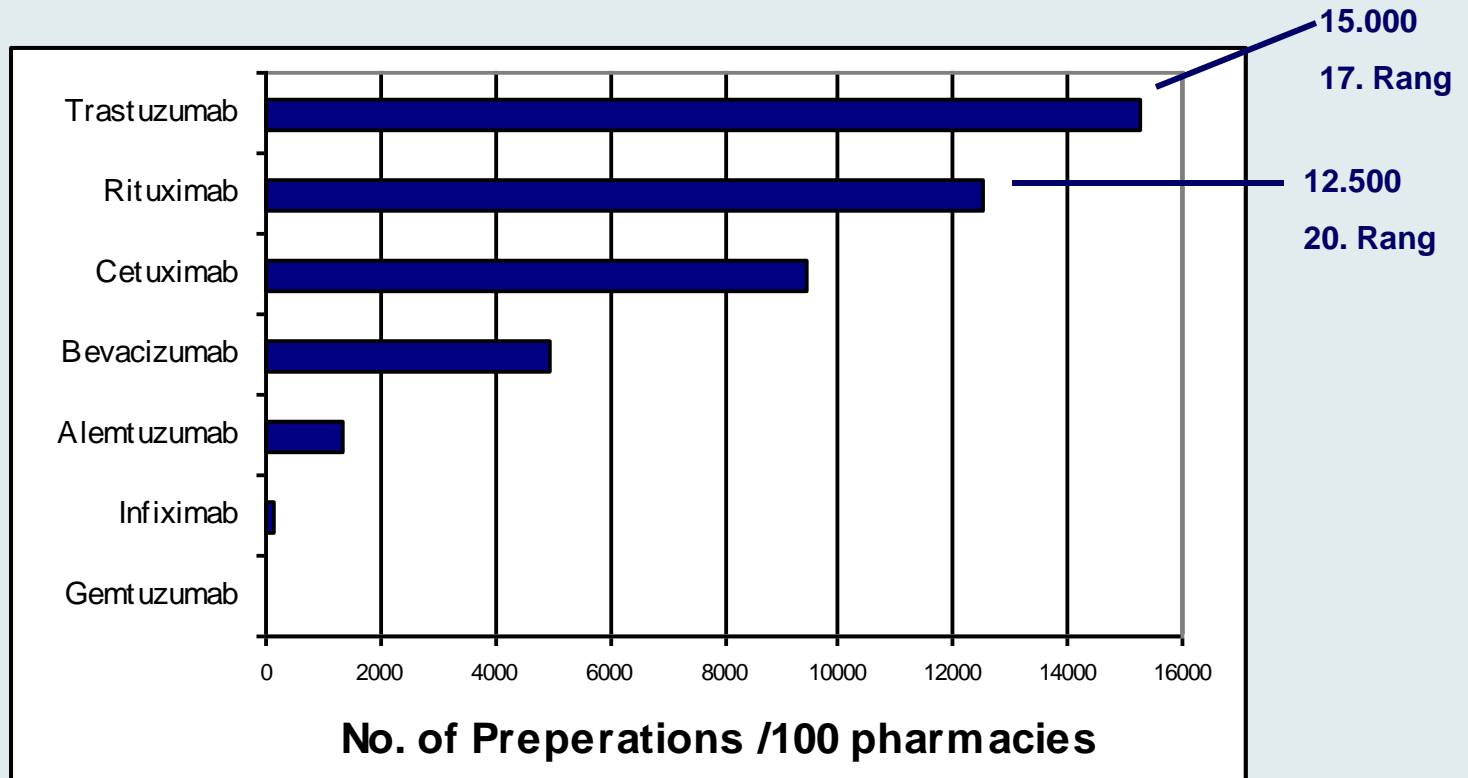
107

111

50



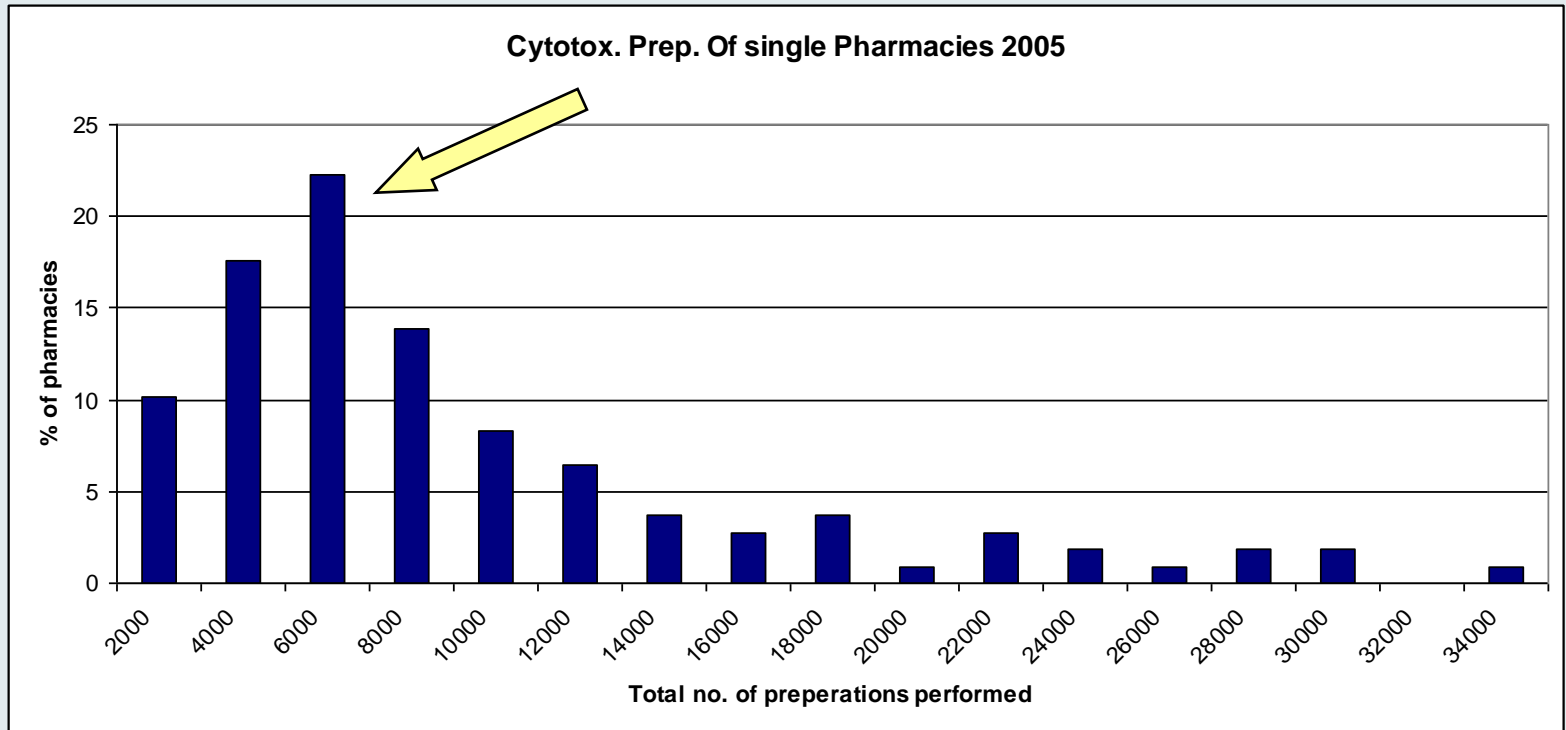
Antibodies



- A total of 44.000 preparations in 100 pharmacies



No. of preparations performed in 2005



- Large variability from **500** to **33.000 preparations** per year
- Almost a $\frac{1}{4}$ performed in between **4000 und 6000** preparations in 2005

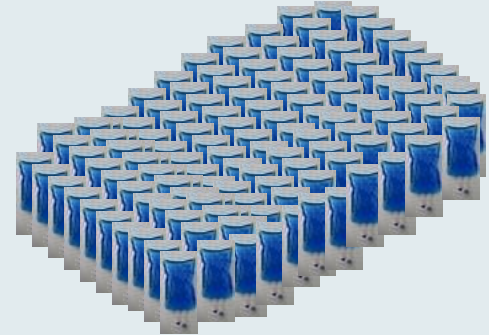
No. of preparations per day



Approx. **2**



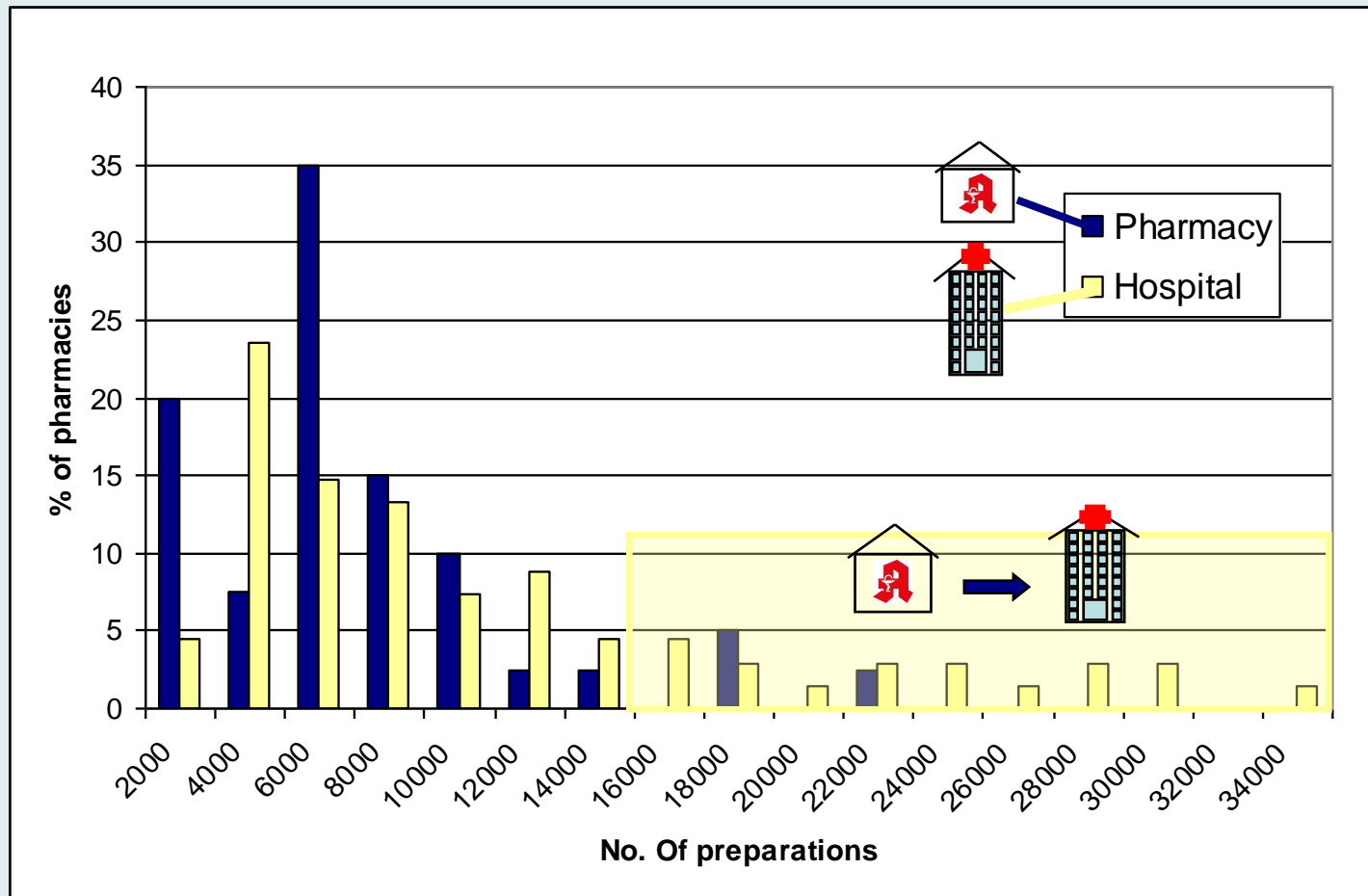
Approx.
130



Almost 1/4 of the pharmacies
prepare in between
16 and 24 applikations per day.



Comparison of public- and hospital pharmacies

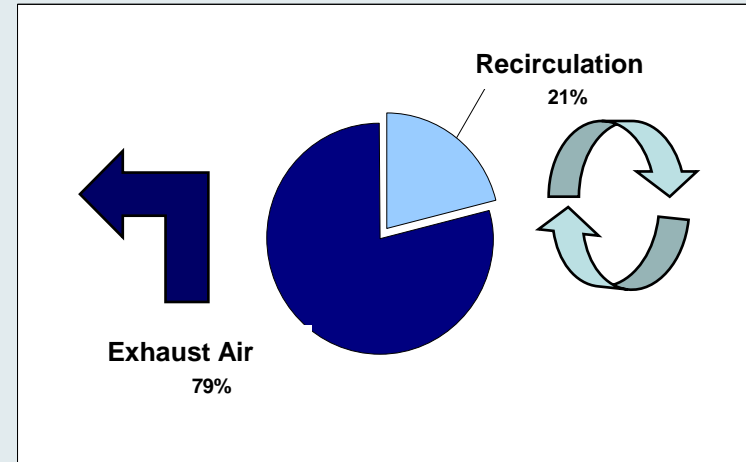
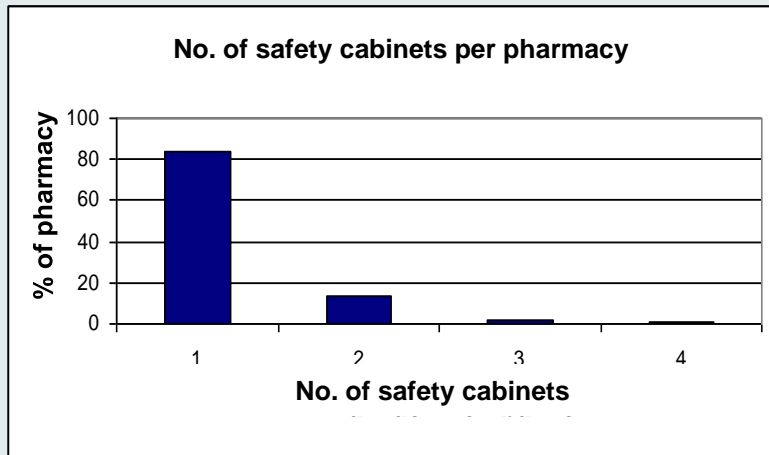




-> approx. 20% have one room only!



Safety cabinets



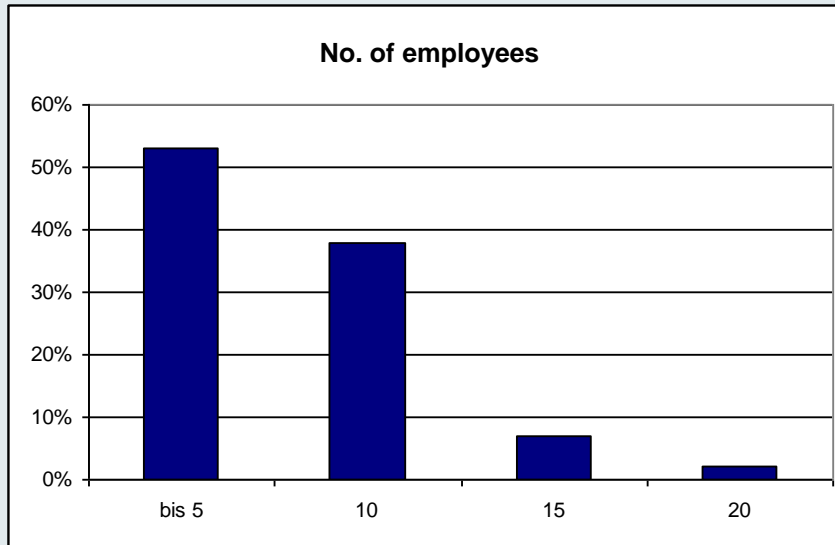
No. of employees

from 2...



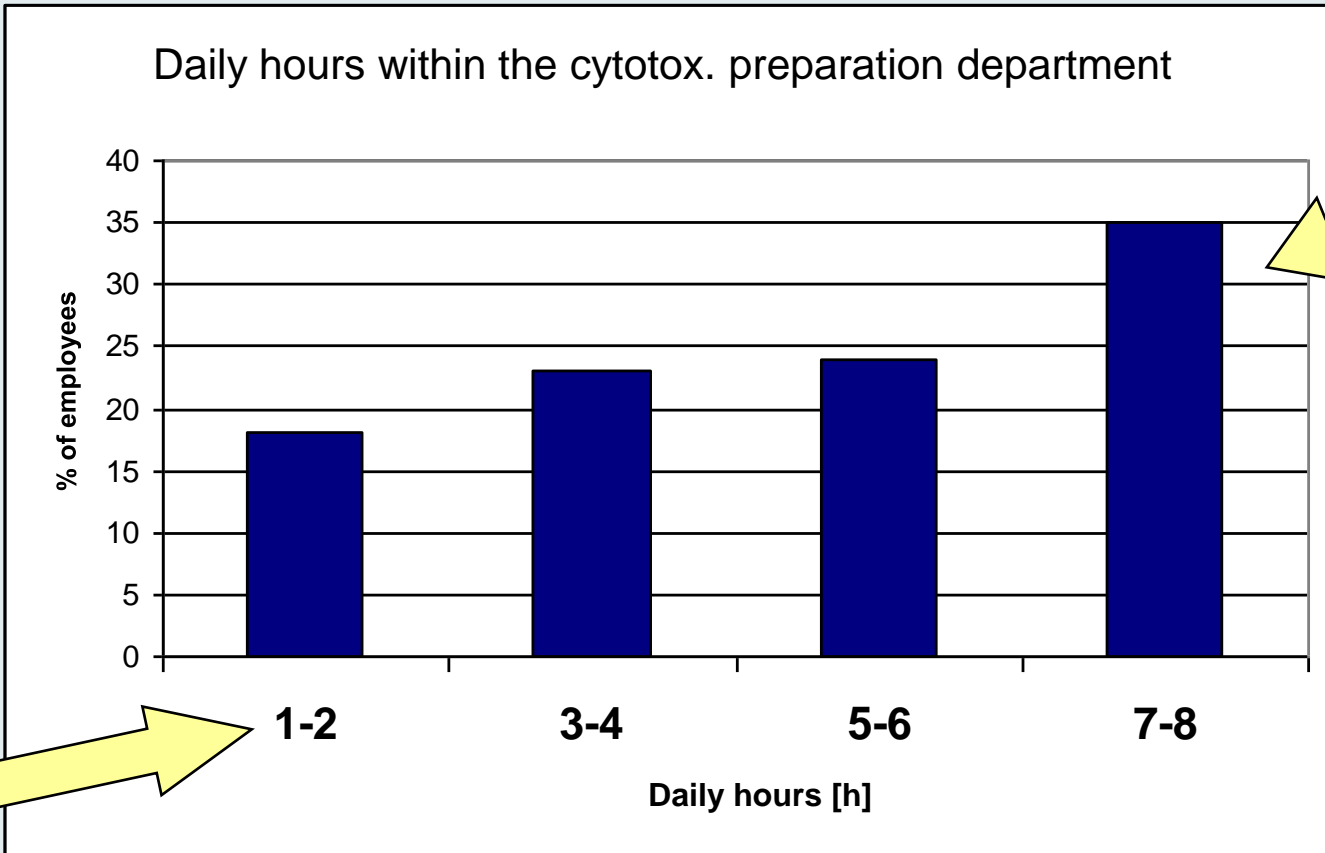
...up to 20

No. of employees



- Approx. 630 /100 Phramacies
- 801 employees with in the MEWIP-Study
- Approx. 5.000 employees in Germany

Daily hours



- 65% of the pharmacies work with a staff-rotation-system



Large Variability!



Gloves worn at the preparation



10% Simple pair of medical gloves for single use only
(DIN EN 455)



25% Double system of medical Gloves for single use only



30% special protective gloves (DIN EN 374)



26% Double system of A and C

?

9% other

Used inside the workbench

- 100 % use spikes
 - 75 % use spike with an integrated filter
 - 18% use spikes with an automated closure system
- 1,5 % claim to always use PhaSeal[®] - System
- 80 % use always compresses



Used inside the workbench

- 97 % always use an absorbing mat
- 4 % do not collect waste inside the bench

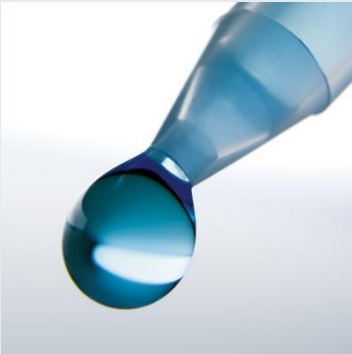


Does cytotoxic waste come back from other departments into the pharmacy?

- Yes in kind of:
- Not administered applications 94%
 - Pumps 52%
 - filled waste bins 25%

To discuss:

Pharmacies = waste-manager for other departments?!



small amounts
Drops <1 ml

Where?

How often?



medium amounts
< 20 ml

Inside the hood/ within the preparation room/ in the pharmacy?

daily/ monthly/ per year/ rarely /never



large amounts
> 20 ml

Notice throughout the study



„Was there an release of large amounts?“

14% Yes

How much ?

Drops → 30-40ml → 250ml

0,1g OxaliPt → → 4g Ifosphamide

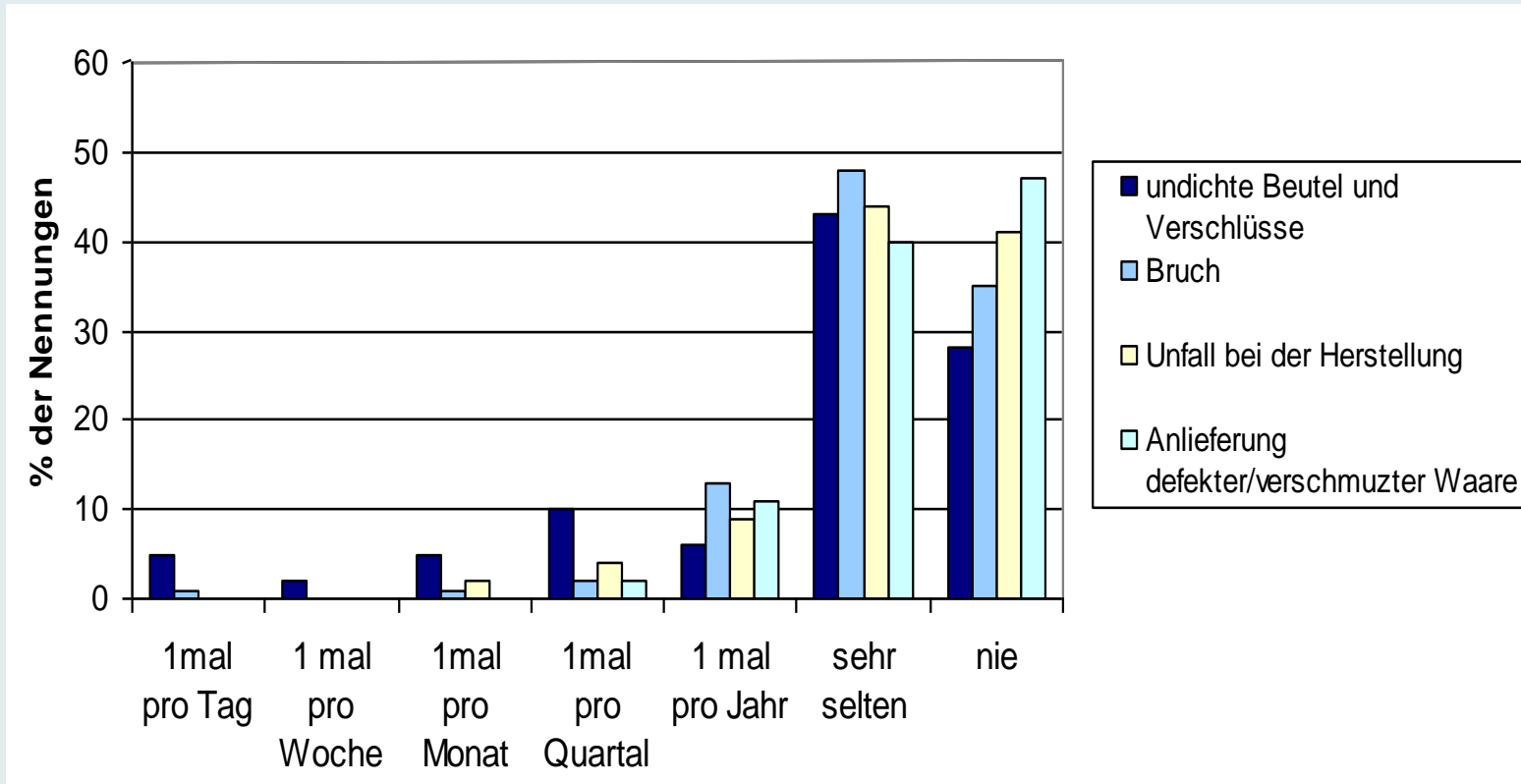


What was the cause?

Pumps were out of order, overpressure, faulty/ damaged perfusion bags, breakage, Spike slipped out of vial...



Reasons



Rather often „never“: 40% an accident; 35% breackage

Where?

2%

before entering the
preparation- department



7%

before entering the
preparation- room



43%

before entering
the hood



**48% Do not clean or perform a disinfection of the vials!
(before entering the hood)**

How?



52 %
Wipe



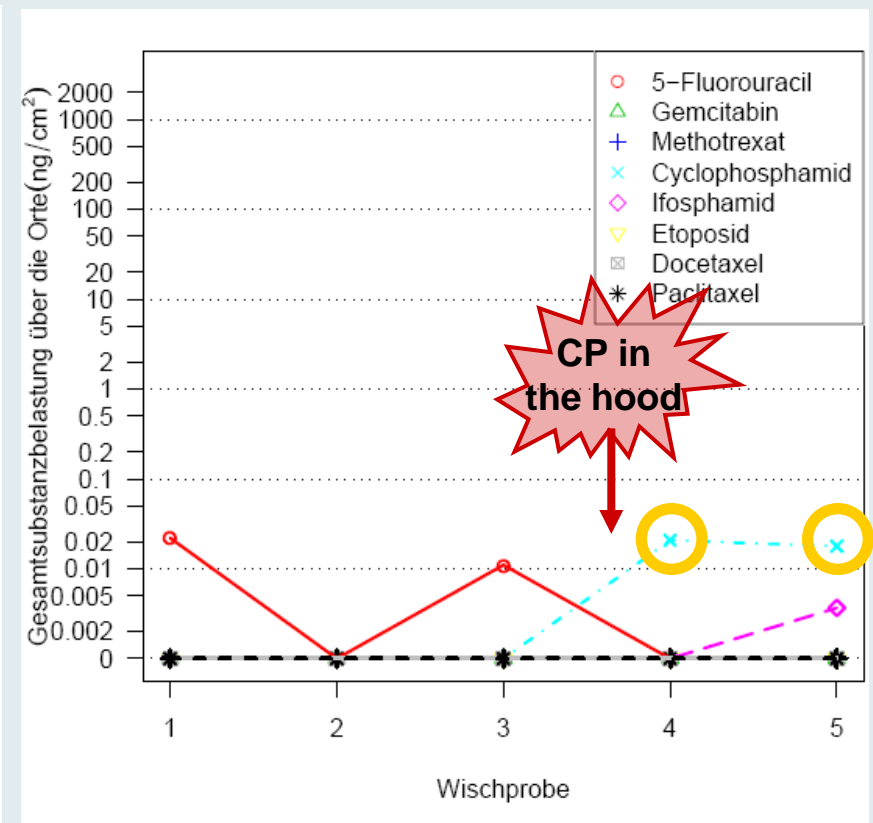
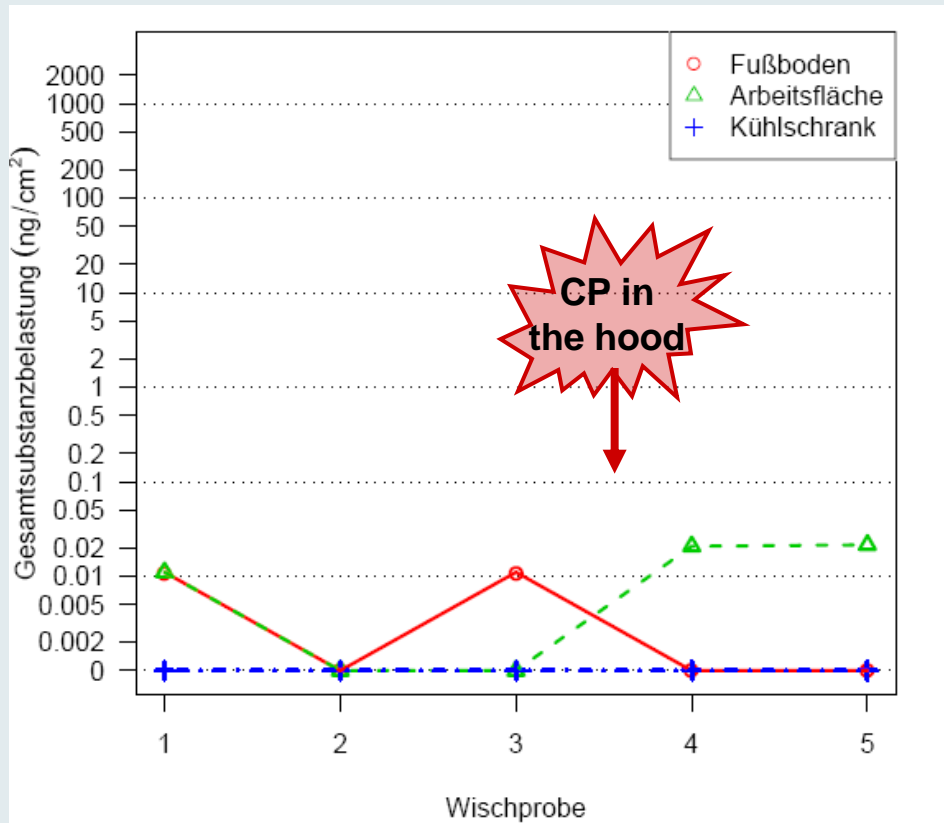
41 %
Spray



7 %
Dipp

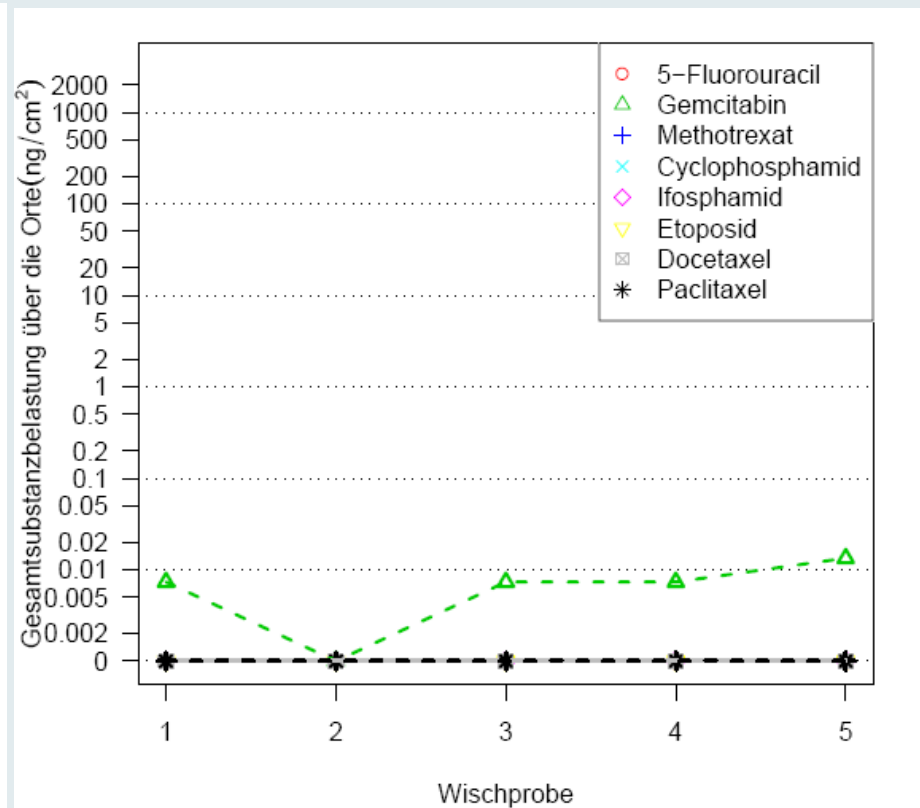
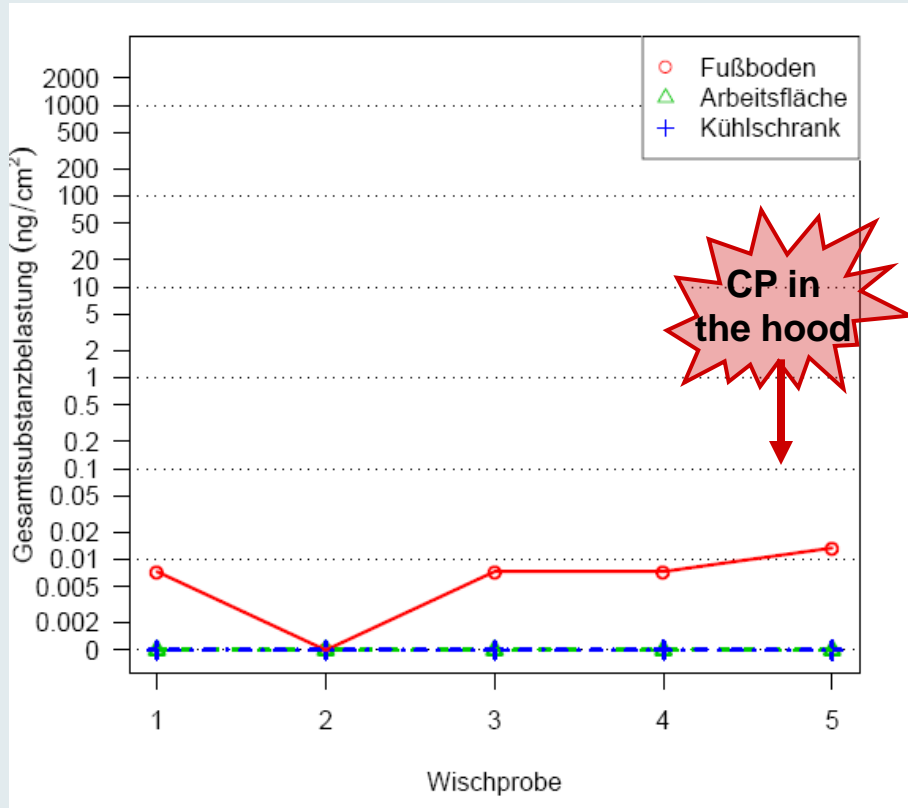
What influences the level of contamination?

1. Accidents?



What influences the level of contamination?

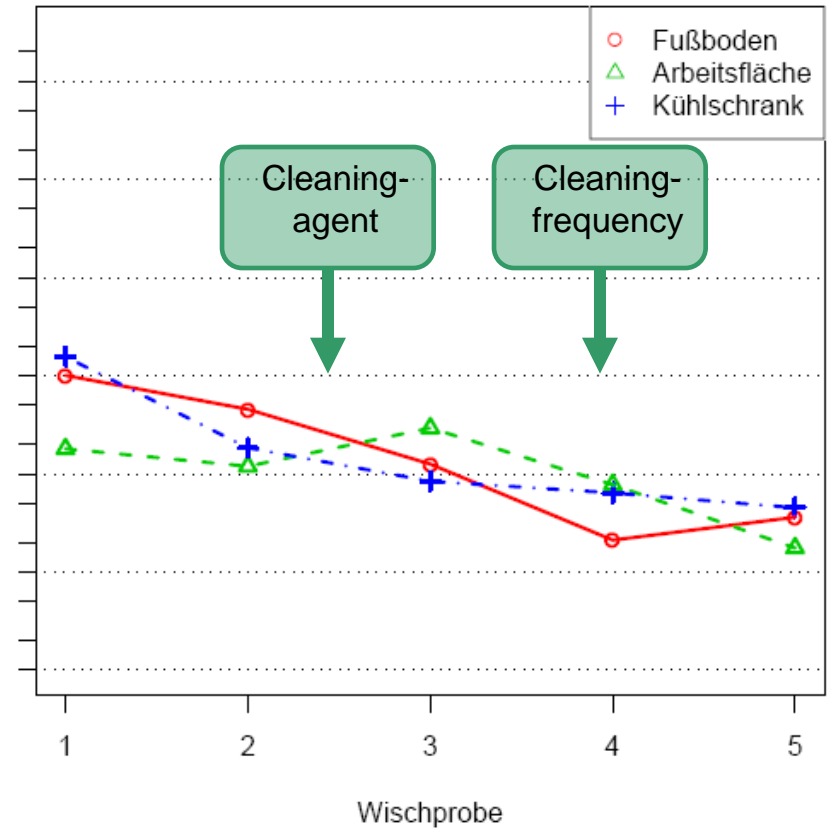
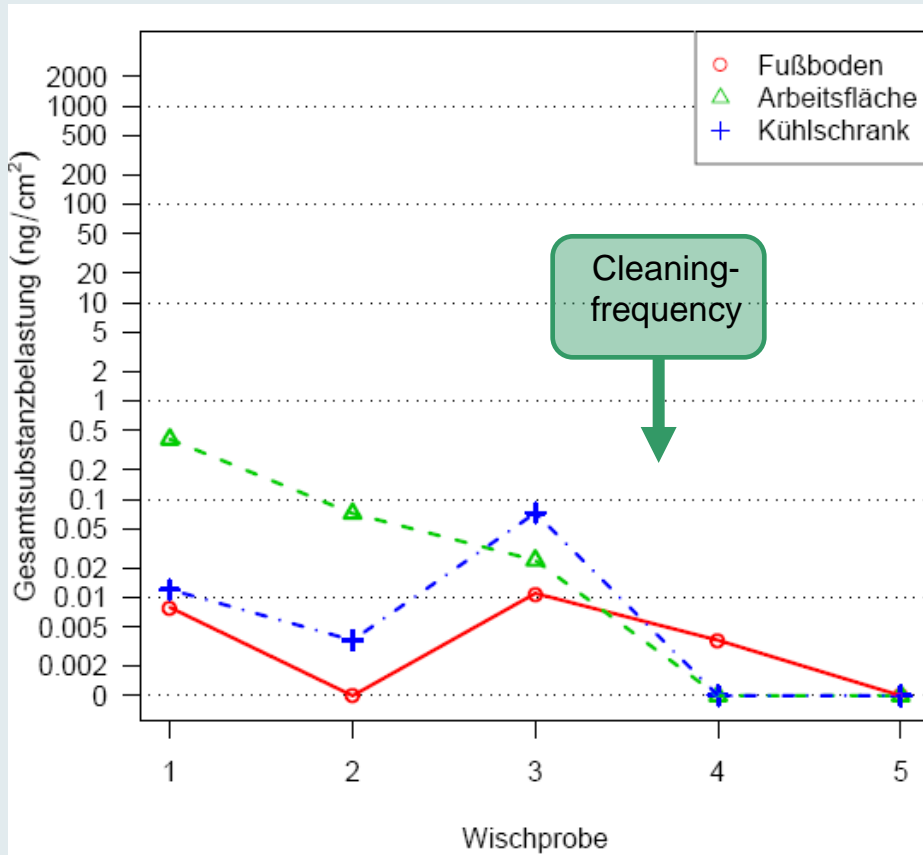
1. Accidents?



→ No spread of contamination!

What influences the level of contamination?

2. Cleaning?

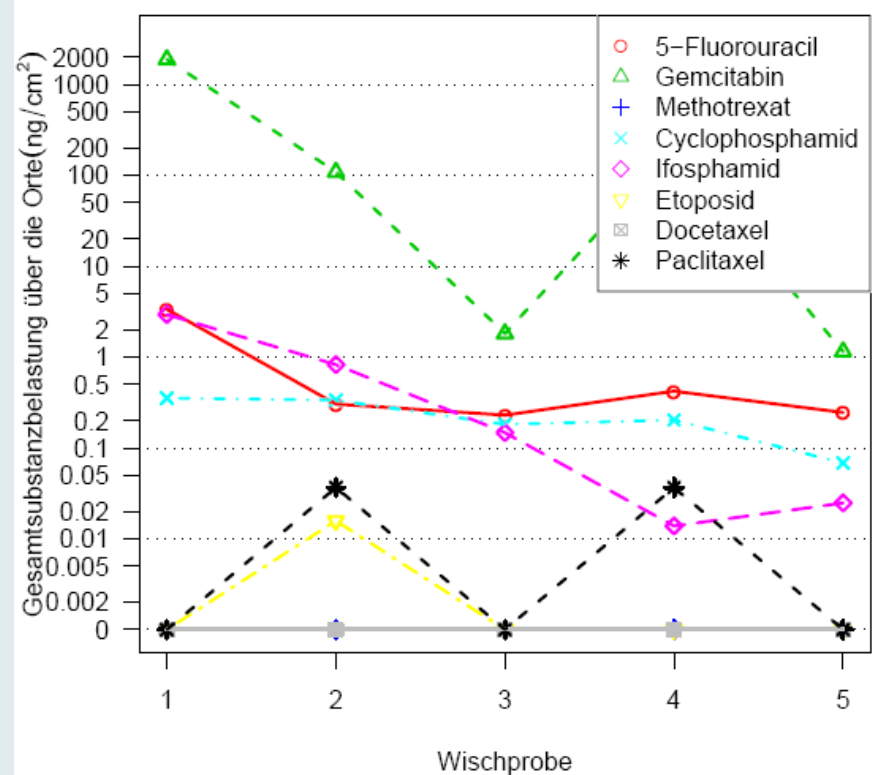
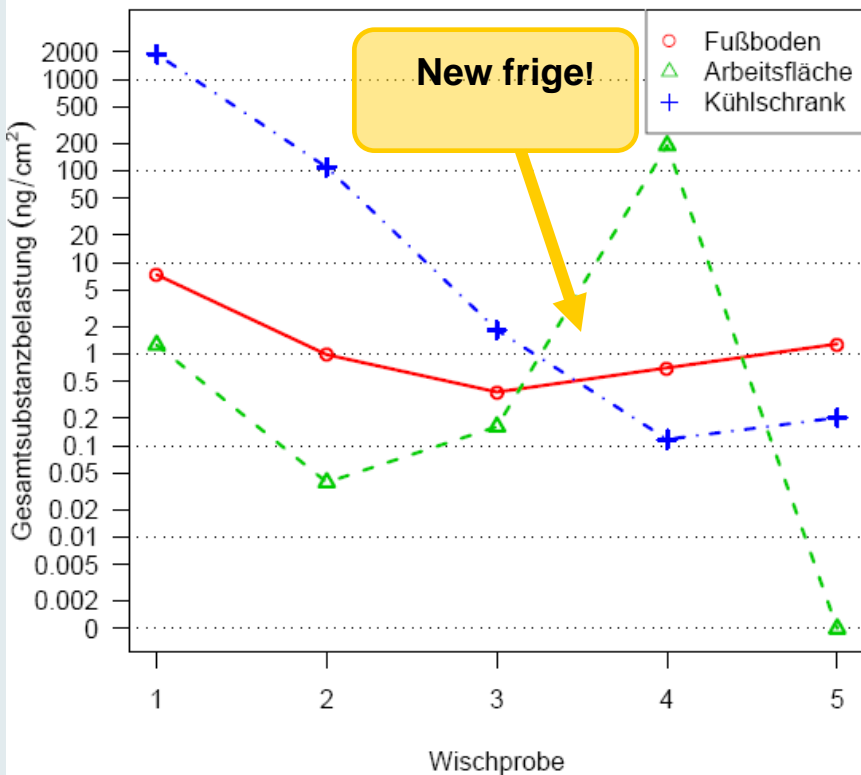


Cleaning

- Procedures to remove contamination, not to wide spread leftovers.
- cloths for single use only
- use of aggressive chemicals?
- consider formation of depots



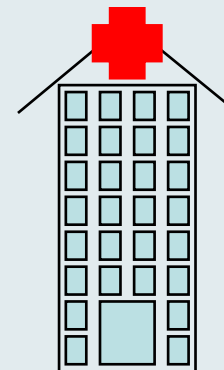
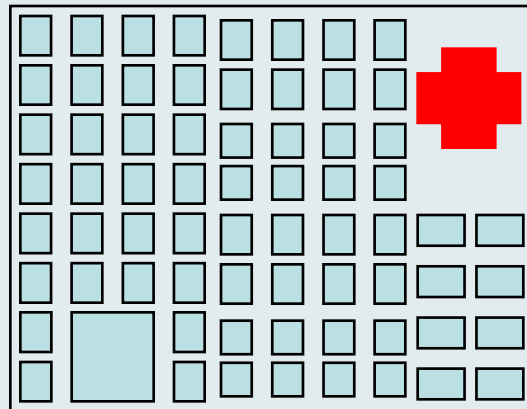
What influences the level of contamination?



What shall we do?

Introduction of 3 „best practice“ Pharmacies

- small public pharmacy
- university hospital pharmacy
- average hospital pharmacy



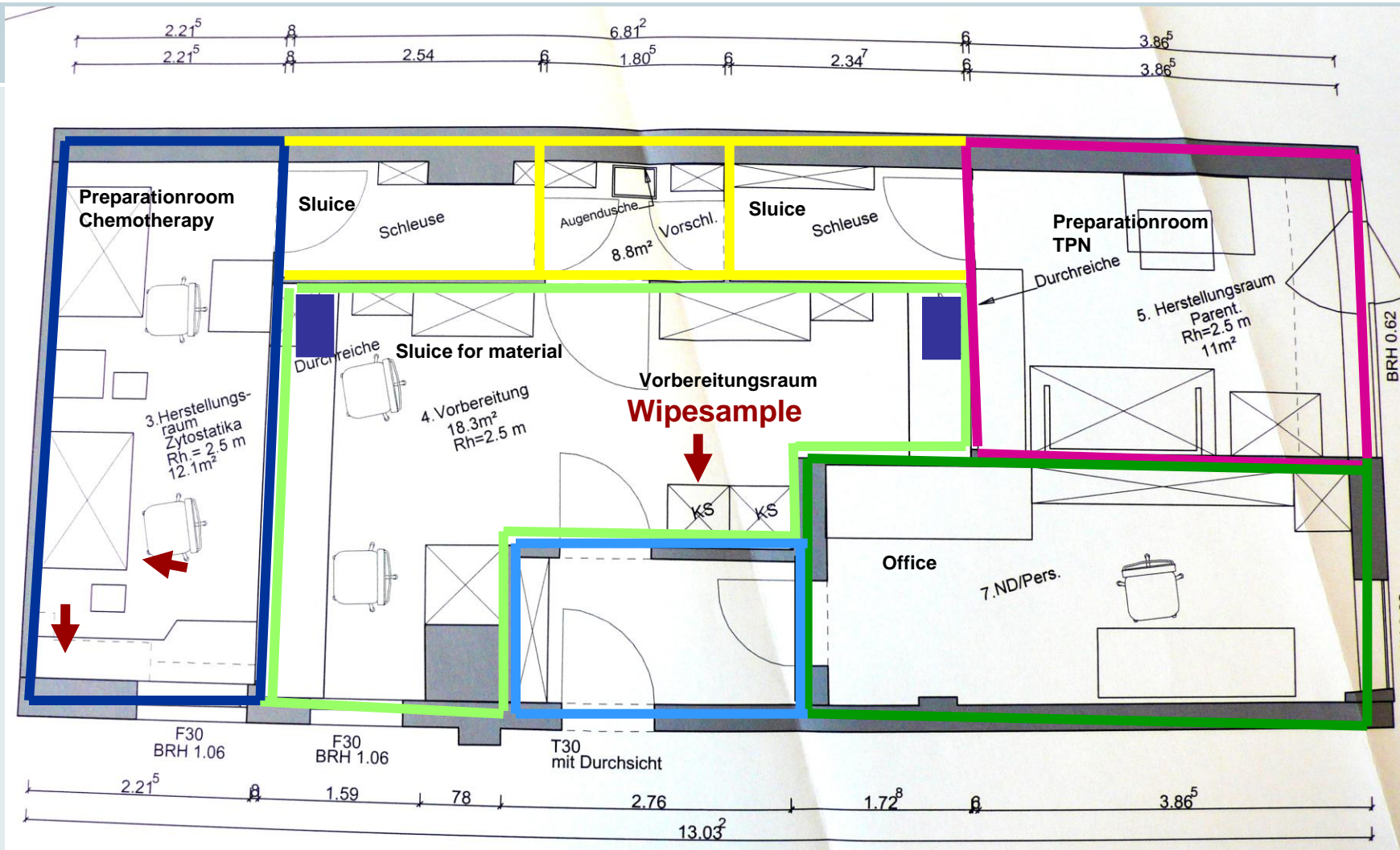
small public pharmacy



-Total of 27 employees

-5 Employees for the sterile preparation department

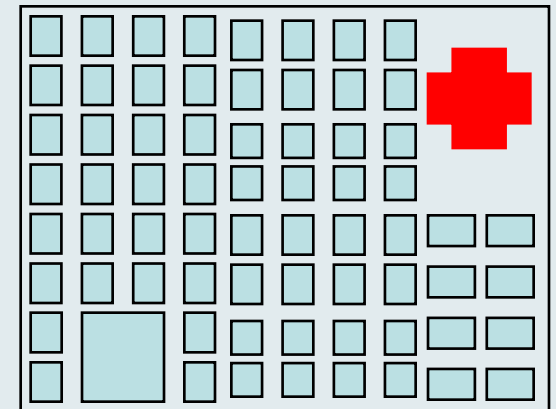
-4.200 chemotherapy preparations 2005



Approx. 65 m² for sterile preparation

University hospital pharmacy

- Total of 40 employees
- Two part-time pharmacist
- two full-time and one half-time technician
- 23.000 Chemotherapy preparation 2005
- > Some impressions of the facility



merchandise management, logistic



aseptic preparation



TPN-Preparation



Lab, Quality- control



pre-preparation room



Central chemotherapy preparation

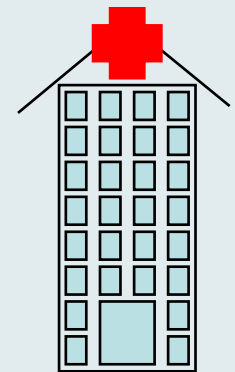


preparation-room

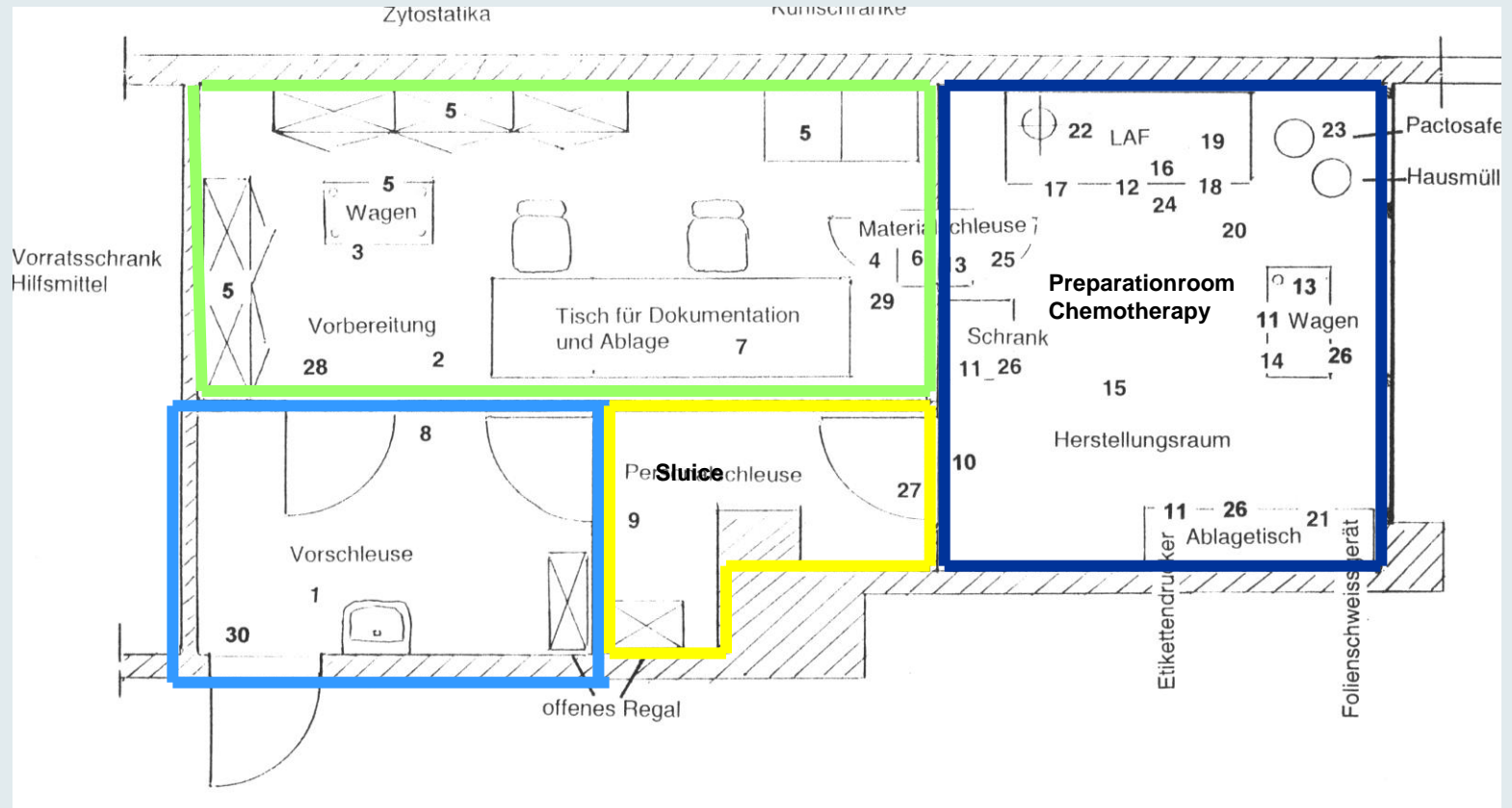


average hospital pharmacy

- **pharmacy of a rather small hospital**
- **BUT they supply 4 other hospitals and 6 ambulant chemotherapy centers!**
- **5 persons performing chemotherapy preparation**
two part-time, 3 temporary (approx 1h per day)
- **5.000 chemotherapy preparations 2005**



Examples of „Best Practice“



What do they do?



- General good general terms and conditions
 - space, money, man-power ...



- Besides the “usual” standards like

- centralizes preparation
- preparation in hoods
- usage of spikes
- four-eye-principle
- ...



What do they do?

General assumption: **Vials are contaminated.**

- separate receipt of cytotoxic goods
- With gloves!



What do they do?

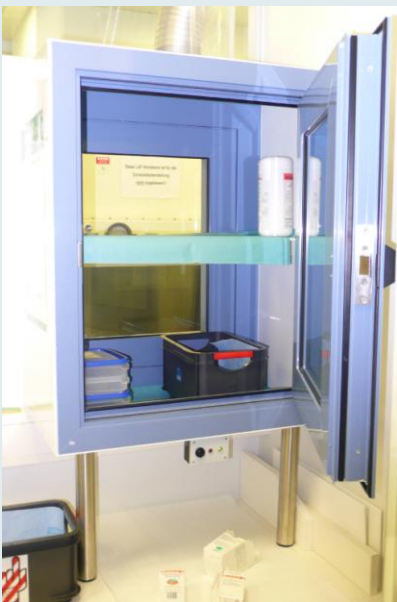
General assumption: vials are contaminated

- **All vials are cleaned before usage!**



What do they do?

- Transportation of vials and applications with boxes or trays only!



What do they do?

- Usage of absorbent pads
 - On work- tops, trays, inside cupboards...



What do they do?

- All kinds of waste is handled with care,
- packed or sealed in plastic bags,
- But only waste containing larger amounts are deposited separately.



Not only alertness for the release of contamination but special achievements to prevent wide spreading!



What do they do?

General procedures:

- One pair of gloves for one task.
- Regular training, revalidation.
- Weekly meetings, reflections of the week.
- Frequent improvement of QM guidelines.
- Practice the usage of spill- kits
- ...

What shall I do?

- Even the best facility is no guarantee for “cleanness”.
- Neither are small facilities always “dirty”.
- The attitude of the staff is very important.
- It's a process of steady improvement.

Thank you!

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