Implementing ISOPP standards

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ISOPP
International Society of
Oncology Pharmacy Practitioners
www.ISOPP.org

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ISOPP
Standards of Practice

Safe Handling of Cytotoxics

ISOPP GOLDEN STANDARD

= guideline which harmonizes technical with clinical oncology pharmacy

INDEX ISOPP Standard

1. Introduction and Definitions
2. Transport
3. Personnel
4. Education and Training
5. Hierarchic order in protection measures
6. Facilities for sterile cytotoxic reconstitution and personal protective equipment

7. Special Devices
8. Ventilation Tools
9. Non sterile preparations
10. Chemical contamination monitoring
11. Checking procedures
12. Administration of cytotoxic drugs
13. Cleaning procedures
14. Cytotoxic spills, extravasations and other incidents

15. Waste handling and patient excreta
16. Laundry
17. Warning staff of presence of cytotoxic agents
18. Home care
19. Risk management
20. Medicines management
21. Documentation

ISOPP standard

- ✓ Is a HIGH standard
- ✓ Is something to work towards
- ✓ Takes time to implement
- ✓ Takes time to complete
- ✓ Has only 2 goals ,
  1. To improve quality
  2. To improve safety

The biggest
danger
is the one
You don't see

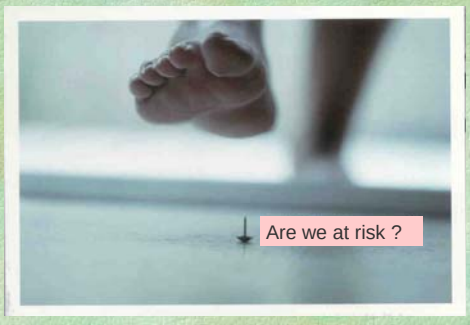
SAFETY FOR THE STAFF

What do we know from patient data ?

Adverse effects of cytotoxics

- Classical cytotoxics are **not tumour specific** :
  and may therefore damage growth and reproduction of normal cells as well.
- Effects are
  - Product and dose related
- Effect on :
  - Bone marrow (suppression), Gastro-intestinal (vomiting/ diarrhea); hair loss
  - Secondary malignity's (5 % of all patients)
  - Gonades : oligospermy, sterility, teratogenicity

What about health professionals ?



SUMMARY OF STUDIES OF ADVERSE REPRODUCTIVE OUTCOMES IN WORKERS EXPOSED TO ANTINEOPLASTIC DRUGS

Year	Author	Population	Birth Defect	Fetal Loss	Other
1992	Skov	Onc Nurses	+	-	+ Ectopic preg.
1993	Stucker	Onc Nurses			+ LBW, - SGA
1993	Saurel-Cubizolles	OR/Onc Nurses			* Ectopic preg.
1995	Shortridge	Onc Nurses			* Menstrual dysf.
1997	Valanis	Pharm + RNs			* Infertility (F); + (M)
1999	Valanis	Rn, Pharm (M+F)		* (F); + (M)	
1999	Peelen	Onc Nurses/Prep	-/*	-	+/* LBW

Source : Melissa McDiarmid; University of Maryland

IARC list

- 5 commonly used cytotoxic drugs are listed in group I, " proven carcinogenic"
  - (e.g. cyclophosphamide, etoposide (comb), alkylating agents,…)
- 4 commonly used cytotoxic drugs are listed in group II A " probably carcinogenic"
  - (e.g. adriamycine, cisplatinum,etoposide, tenoposide.)
- 5 commonly used cytotoxic drugs are listed in group II B " possible carcinogenic"
  - (e.g. bleomycine, dacarbazine,mitomycine,...)

Incidence of Cancer among Nurses Handling Antineoplastic Drugs in Oncology Departments

SITE	OBS	EXP	RR	(95% CI)
All malignant neoplasms (ICD-7 140-205)	14	11.69	1.20	(0.65-2.01)
Lymphatic and heamatopoietic Issues (ICD-7 200-205)	3	0.56	5.37	(1.11-15.7)
NHL (ICD-7 200, 202)	0	0.20	-	-
Hodgkin's disease (ICD-7 201)	1	0.12	8.35	(0.21-46.5)
Multiple myeloma (ICD-7 203)	0	0.05	-	-
Leukemia (ICD-7 204)	2	0.19	10.65	(1.29-38.5)
Mycosis fungoides (ICD-7 205)	0	0.01	-	-

From Skov, et al: Br.J.Int.Med. 1992,49:860

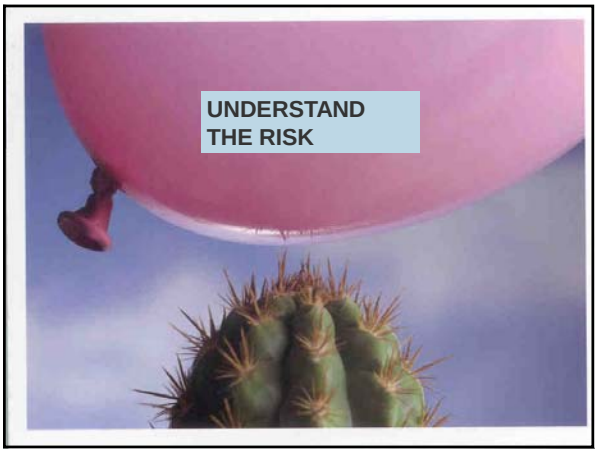
Evaluation of early DNA damage in healthcare workers handling antineoplastic drugs
Ursini, Cavallo, Colombi & all

- Int Arch Occup Environ Health 2006 Nov;80(2) 134-140

- Environmental monitoring detected CP, 5FU and IF in high levels of contamination in day hospital unit
- Biological monitoring measured detectable levels of alfa-fluoro-beta-alanine in 3 nurses
- Comet assay showed an increase on exfoliated buccal cells of mean Tail Moment in day hospital nurses

Genotoxicity Assessment in Oncology Nurses Handling Antineoplastic Drugs.
Rekhadevi, Sailaja, Chandrasekhar

- MUTAGENESIS 2007 NOV.22(6): 395-401
- Urinary cyclophosphamide used as marker for drug absorption was measured in the urine of the nurses.
- DNA damage observed in lymphocytes of exposed nurses was significantly higher than the controls.
- Similarly, a significant increase in micronuclei (MN) frequency with peripheral blood lymphocytes and buccal cells was observed in exposed nurses compared to controls ($P<0.05$)
- Multiple regression analysis showed that occupational exposure and age had a significant effect on mean comet tail length as well as on frequency of MN.



Sources of contamination

- External contamination of drug vials
  - Production and packaging
- Drug **preparation**
  - Preparation techniques (spills – leakage)
- Drug **administration**
  - Administration techniques (spills - leakage)
- Patient excreta
- Waste

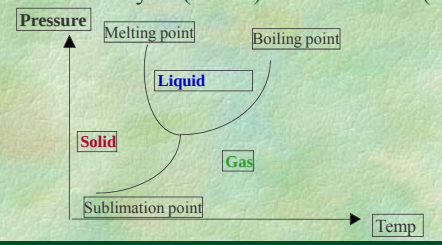
Pure product
High conc

1° Dilution

2° Dilution

Pure, 1° & 2° Dilution

- Research in the Institut für Umwelttechnologie und Umweltanlytic (IUTA) Prof. Schmidt (1998)

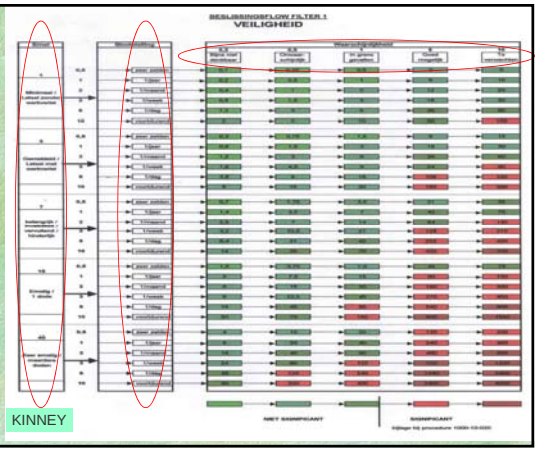


The presence of a product in gaseous state depends on pressure and temperature.

Research of Opiolka and Schmidt

	cyclofosfamide		5 -fluorouracil	
	time in sec		time in sec	
diameter in µm	20°C	40°C	20°C	40°C
1	29	10	137	50
5	722	256	3400	1200
10	2900	1000	13700	4760
50	72200	25600	340000	120000
100	290000	100000	1370000	476000
500	7220000	2560000	34000000	12000000
1000	29000000	10000000	137000000	47600000

RISK ANALYSIS 1



KINNEY

Risk Analysis 2

- **Biological effect monitoring (BEM)**
  - Ames test
  - Chromosomal aberrations (CA)
  - Sister chromatid exchanges (SCE)
- **Environmental Monitoring (EM)**
  - Measures the presence/release of the drug in the environment
- **Biological Monitoring (BM)**
  - Assessment of uptake of the drug in the body of the worker
  - Estimation of health-risk for the worker

Surface contamination with cyclophosphamide in preparation areas (ng/cm2)

Description surface	Canada*	USA*	Belgium	Sweden	Germany	Netherlands
Table top cyto preparation/BSC	0.01-2.63	0.05-40.13	0.13-6.61	4.74-15.32	14.02-14.22	0.01-1.16
Floor under BSC	0.05-0.32	0.03-2.40	0.05-0.55	1.79	0.05	0.01-0.03
Floor central preparation room	0.11-0.16	0.01-2.36	0.15-0.31	1.24	1.77	0.01-0.02
Table top not for cyto preparation				0.02	0.03-0.19	0.01-0.36
Floor entrance preparation room				0.52	0.16	0.01-0.02
Floor entrance preparation room/corridor		0.01-0.13	0.14-0.19	0.09		0.01

Data from exposure control, NL

Cyclophosphamide (CP) in urine of technicians preparing cytostatic drugs

Technician	Number of days	Number of urine samples	Number of positive samples	Mean CP (µg/day)
1	13	65	6	0.53
2	8	31	2	0.12
3	8	47	6	0.18
4	16	99	11	0.23
5	16	83	6	0.07
6	8	69	2	0.01
7	8	42	1	0.10
8	8	40	2	0.09
1-8	85	476	36	**0.18**

Data from exposure control

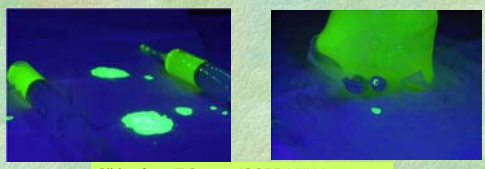
ISOPP recommendation

- Wipe sampling & urine sampling not in routine
- Useful in context of project
- Willing to react

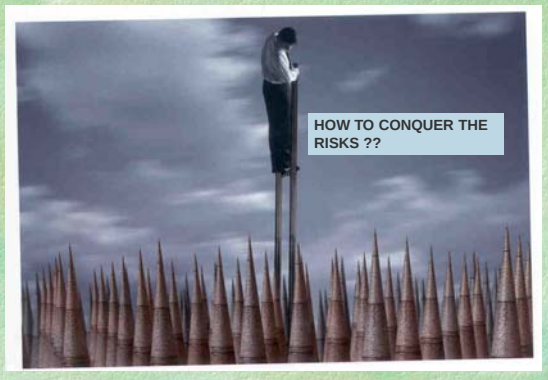
Risk Analysis 3

§ Easy and cheap method of **visualization**
- Using Fluorescence dye
- Using Quinine

» And UV Light



Slides from T.Connor ISOPP VIII Vancouver



Responsibility of the Pharmaceutical Company

- **To deliver to the customer contamination-free drug containers.**
- **Certification of the contamination-free drug containers is strongly advised.**

Staff

EXCLUSION FROM ACTIVITIES
- PREGNANCY
  - REMOVED DIRECT ACTIVITY
  - APPOINTED ANOTHER WARD
- FAMILY PLANNING ????
- REMOVED DIRECT ACTIVITY
  - MALE + FEMALE

Facilities

- ✓ **Centralised** (pharmacy or satellite)
- ✓ **Separate** room
- ✓ **Pressure difference (-)**

Hierarchic Order in Protection

1. REPLACEMENT
2. CLOSED SYSTEM
3. LOCAL AND GENERAL VENTILATION/EXTRACTION
4. PERSONAL PROTECTION TOOL

Most of the guidelines mention only level 4

European council directive

Level 4 protection

- Personal protection
  - Also for non preparing staff (warehouse, waste)
- Proof of resistance
  - Static tests
  - Dynamic tests
- Education and training

Ventilation Tools = level 3

Why isolator & BSC ???

- To prevent from microbiological contamination
- To protect the product

- We have adapted the system for other purposes

- To prevent from chemical contamination
- To protect the manipulator
- BUT IT DOES NOT WORK because they DO NOT PREVEND

35

Closed Systems = level 2 protection

NIOSH

Closed system drug-transfer device =
A device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapour concentrations outside the system

www.cdc.gov/niosh

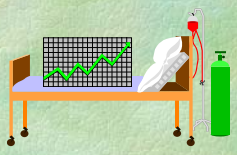
ISOPP = Air tight & leak proof

Closed (MB) = Open systems (CHEM)!!!!

SAFETY FOR THE PATIENT

What can the patient expect ?

- ***CORRECT* COMPOSITION**
- **STERILITY *OF THE PRODUCT***
- ***CORRECT* ADMINISTRATION**



Correct composition ?

- If possible use pre- authorized protocols
- Do not use of abbreviations
- Check always with 2 persons
- Check on
  - clinical aspects
  - Technical aspects
  - Validate before you go live !

- Clinical checks
  - Chemotherapy regimen, patient profile, BSA, dose calculation, premeds, lab values
- Preparation checks
  - Check of the calculations
  - Assembly of raw materials, preparation, finished product, LABELS
- Validation
  - Product (Microbiological, physiochemical stability)
  - Cross contamination (Operator technique, containment devices)
  - Computer program

BSA = body surface area

Administration

- Careful selection of devices
- Checking on correct patients
- Checking on correct route of administration (IR ⇔ IV)
- Checking on extravasation (before and during)

Importance of sterility ?

- Endangered population
- Due to therapy (chemo and/or radiotherapy), patients has a compromised immune system.
- More needed then for TPN patients
- No microbial effects on short term

Microbial growth in cytotoxics - Irene Kramer

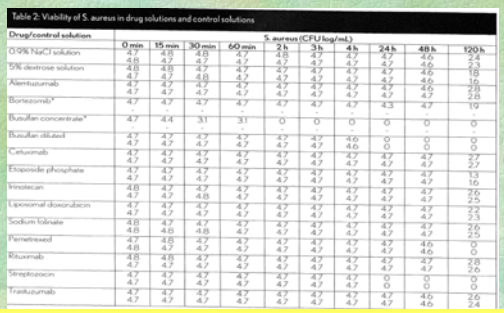
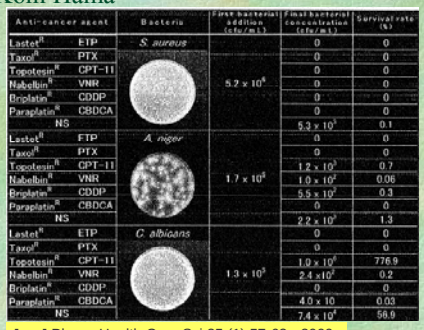


Table 2: Viability of S. aureus in drug solutions and control solutions

Drug/control solution	S. aureus (CFU log/mL)									
	0 min	15 min	30 min	60 min	2 h	3 h	4 h	24 h	48 h	120 h
0.9% NaCl solution	4.7	4.8	4.8	4.7	4.8	4.7	4.7	4.7	4.6	2.4
5% dextrose solution	4.8	4.7	4.7	4.7	4.7	4.7	4.7	4.7	4.6	2.3
Alemtuzumab	4.7	4.7	4.8	4.7	4.7	4.7	4.7	4.7	4.6	1.6
Bortezomib*	4.7	4.7	4.7	4.7	4.7	4.7	4.7	4.7	4.6	2.8
Busulfan concentrate*	4.7	4.7	4.7	4.7	4.7	4.7	4.7	4.7	4.7	2.8
Busulfan diluted	4.7	4.4	3.1	3.1	0	0	0	0	0	0
Cetuximab	4.7	4.7	4.7	4.7	4.7	4.7	4.6	0	0	0
Etoposide phosphate	4.7	4.7	4.7	4.7	4.7	4.7	4.7	4.7	4.7	2.7
Irinotecan	4.7	4.7	4.7	4.7	4.7	4.7	4.7	4.7	4.7	1.3
Liposomal doxorubicin	4.8	4.7	4.8	4.7	4.7	4.7	4.7	4.7	4.7	1.6
Sodium folinate	4.7	4.7	4.8	4.7	4.7	4.7	4.7	4.7	4.7	2.5
Pemetrexed	4.8	4.8	4.8	4.7	4.7	4.7	4.7	4.7	4.7	2.3
Rituximab	4.7	4.8	4.7	4.7	4.7	4.7	4.7	4.7	4.7	2.5
Streptozocin	4.8	4.7	4.7	4.7	4.7	4.7	4.7	4.6	4.6	0
Trastuzumab	4.7	4.7	4.7	4.7	4.7	4.7	4.7	4.7	4.7	2.8
	4.7	4.7	4.7	4.7	4.7	4.7	4.7	0	0	0
	4.7	4.7	4.7	4.7	4.7	4.7	4.7	4.7	4.6	2.6

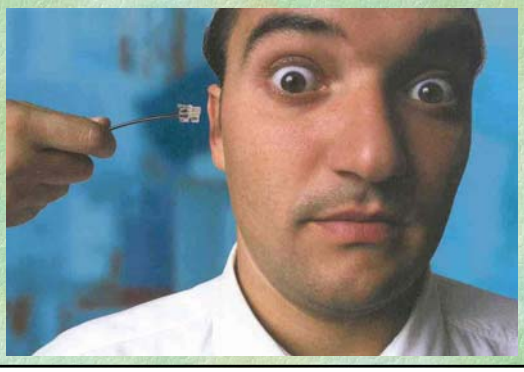
Eur J Hosp Pharm,Vol 1,Nr 1 1991 // J Oncol Pharm Practice Vol 4, Nr 1 1998// EJHP Scienve Vol 13, 2007/2

Microbial growth in cytotoxics – Kohi Hama


Anti-cancer agent		Bacteria	First bacterial addition (cfu/mL)	Final bacterial concentration (cfu/mL)	Survival rate (%)
Lastet®	ETP	*S. aureus*	5.2×10^6	0	0
Taxol®	PTX			0	0
Topotesin®	CPT-11			0	0
Nabelbin®	VNR			0	0
Briplatin®	CDDP			0	0
Paraplatin®	CBDCA			0	0
NS				5.3×10^5	0.1
Lastet®	ETP	*A. niger*	1.7×10^5	0	0
Taxol®	PTX			0	0
Topotesin®	CPT-11			1.2×10^3	0.7
Nabelbin®	VNR			1.0×10^2	0.06
Briplatin®	CDDP			5.5×10^2	0.3
Paraplatin®	CBDCA			0	0
NS				2.2×10^2	1.3
Lastet®	ETP	*C. albicans*	1.3×10^5	0	0
Taxol®	PTX			0	0
Topotesin®	CPT-11			1.0×10^3	776.9
Nabelbin®	VNR			2.4×10^2	0.2
Briplatin®	CDDP			0	0
Paraplatin®	CBDCA			4.0 x 10	0.03
NS				7.4×10^4	56.9

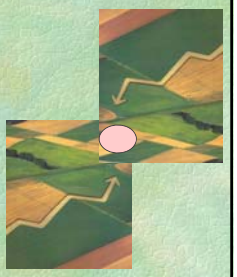
Jpn J Pharm Health Care Sci 35 (1) 57-63 - 2009

Education – Training



Facilities

- **Centralised**
- **Separate room**
- **Qualification of the room**
  - **~ type preparation**
  - **~ type of equipment**



... USP 797 / PIC'S norm

Ventilation Tools


isolator


BSC Type II


BSC Type III

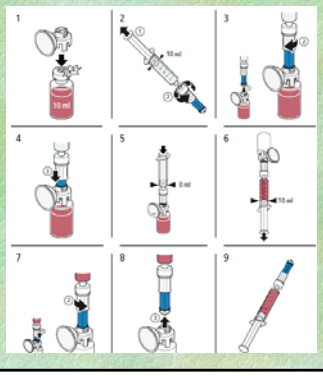

= to BSC Type III

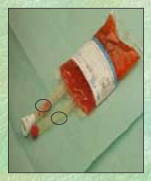
How we implemented this ?

To meet the 2° order in prevention (EU directive)

PhaSeal

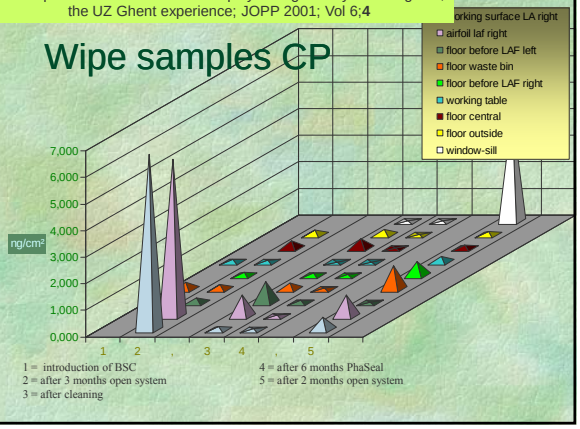
PhaSeal in practice





How to protect environment and employees against cytotoxic agents, the UZ Ghent experience; JOPP 2001; Vol 6;**4**

Wipe samples CP



How to protect environment and employees against cytotoxic agents, the UZ Ghent experience; JOPP 2001; Vol 6;**4**

Urine test results

	Date	Person	Function	0 - 24 hour µg	24 - 48 hour µg
PhaSeal	22/04/99 – 23/04/99	1	Tech.	Nd	Nd
	30/04/99 – 01/05/99	2	Tech.	**0,6**	Nd
	11/05/99 – 12/05/99	3	Tech.	Nd	Nd
	22/04/99 – 23/04/99	4	Pharm.	Nd	Nd
	27/04/99 – 28/04/99	5	Pharm.	Nd	Nd
	03/05/99 – 04/05/99	6	Pharm.	Nd	Nd
Classical	07/10/99 – 08/10/99	3	Tech.	**2,17**	Nd
	08/10/99 – 09/10/99	7	Tech.	Nd	/
	12/10/99 – 13/10/99	8	Tech.	**17,75**	**0,25**
	14/10/99 – 15/10/99	2	Tech.	Nd	Nd
	15/10/99 – 16/10/99	9	Tech	**1,54**	Nd
	18/10/99 – 19/10/99	10	Pharm.	**0,27**	**0,16**

Closed devices any help for sterility ?

Microbiological challenge of 4 transfer devices compared to needle

- § Evaluation of microbiological resistance / safety
- § In "Worst case" and "Realistic" contamination level
- § Recommendations for daily practice

Microbiological challenge of protective devices for the reconstitution of cytotoxic agents
Letters in Applied Microbiology 47; 2008; 543-548

PhaSeal

CHEMOSPIKE (CODAN)

Clave valve

Securmix

Needle & syringe

DETECTION METHOD = CHEMSCAN

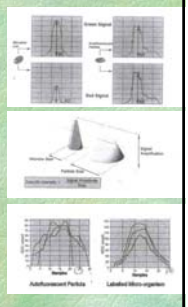
- § Solid Phase Cytometry
  - F Quick (30 min incubation, results in 45 min)
  - F Specific = Detection of fluorescent microorganisms by argon laser scanning
  - F Precise : Counts from 1 micro organism to aborted scan (>30.000)

FLUORESCENCE ?

- § Non-fluorescent substrate chemchrome v6 is taken up by metabolically active cells
- § Substrate is cleaved by intracellular enzymes into green fluorescent carboxyfluourescein which can be retained in intact cells only.

DIFFERENCIATION M.O. ↔ PARTICLES ?

1. COLOR RATIO
   = RATIO HEIGHT SIGNAL FLUORESCENCE IN GREEN LIGHT (500-530 nm) TO ORANGE LIGHT (540-585 nm)
2. SPECIFIC LIGHT INTENSITY
   = RATIO OF SIGNAL AMPLITUDE TO SIZE
3. SHAPE OF SPECTRUM
   (1 → 3 = COMPUTERIZED)
4. VISUAL CONFIRMATION BY EPIFLUORESCENCE MICROSCOPE



CONTAMINATION OF VIAL DOP

- § PSEUDOMONAS AEROGINOSA
- § 40 µL 10^{-4} OVERNIGHT CULTURE
  ==> **4 X 10^{3}** (= R.C.)
- § 40 µL 10^{-2} OVERNIGHT CULTURE
  ==> **4 X 10^{5}** (= W.C.)

WORST CASE SCENARIO

ANOTHER WAY TO REPRESENT

INITIAL Contamination	PhaSeal	Chemo Spike	Clave valve	Securmix
400.000	1 / 46	1 / 24	1 / 6	1 / 15
4000	1 / 40	1 / 24	1 / 7	———

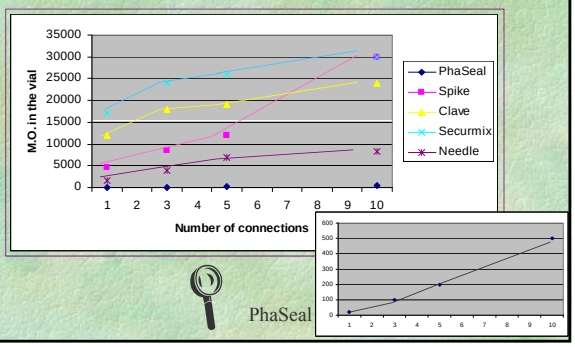
Very good correlation between Worst case and Realistic

CONTAMINATION OF TRANSFER DEVICE with Pseud.Aer.

10 µL 10^{-2} O.N.C. (= W.C.C.)
10 µL 10^{-4} O.N.C. (= R.C.)

1 / 3 / 5 / 10 coupling or needle stick

RESULTS MULTIPLE CONNECTIONS M.O. IN THE VIAL (N = 10) W.C.



PhaSeal

CONCLUSION CONCERNING MICROBIOLOGICAL CHALLENGE

- § PhaSeal ® significant safer (> 1 to 2 log unit difference) compared to all other systems and needle in multiple handling!
- § The Critical Point is the "Dopping" Phase!
- § Need for validated decontamination proces

Decontamination + Dopping protector

contamination level in the decontamination test

SPECIES	Contaminate with
Staphylococcus Aureus	2X 10^7
Pseudomonas Aeroginosa	4 X 10^7
Candida Albicans	1 X 10^6
Aspergilllus Niger	2 X 10^5

=0 >1 >10 >100 >1000 >10000

	Staph Aur.	Pseud Aer.	Asperg Nig.	Candida Albic.
NO DECONTAMINATION				
ISO Swab (SW)				
Chlorhex 0,5%- ISO 60 Spray (SP)				
H_2O_2 0,125% - ISO 70 Spray				
Chlorhex 0,5%- ISO 60 SP+SW				
H_2O_2 0,125% - ISO 70 SP+SW				
H_2O_2 0,3% - ISO 70 SP+SW				
Chlorhex 2 % - ISO 70 SP+SW		0-1-1-1-0		0-1-1-1-0
Chlorhex 2 % - ISO 70 SP 6 min +SW			0-0-0-0-3	

NEVER ENOUGH MONEY…

What is the cost of safety ?

Economical impact of preparation scenario's for cytotoxics. An observational study EJHP Practice,vol 14 2008/5 ; 37 -42

Key Questions !

- **CHEMICAL / PHYSICAL STABILITY**
  Literature, databases, ….
  ➔ Keep vials longer
- **CRITICAL POINT = STERILITY**
  Validated procedure / devices
  ➔ Keep vials longer
- If legally admitted, the Hospital Pharmacist is the only person who can take the responsibility for keeping punctured vials for longer period.
- He/she must take that decision based his/here local conditions and regulations

Discussion : Conflict of interest by Pharmaceutical Companies

- The recent years more and more research has been done on the chemical / physical stability of cytotoxic drugs after dissolving and in further dilution. Given the conflicting interest, this type of research is done by other parties (academic, hospital pharmacy, …) then the pharmaceutical industry.
- Most of the time, the expiry time is limited to 24 hrs , arguing that the sterility cannot be guaranteed over a longer period.

Scenario 1

- For **scenario 1** we used the drug vials available on the Belgian market and calculated for each preparation the optimum number of vials needed to prepare each dose individually.
- single preparation 187 mg
  ➔1 vial of 100 mg + 1 of 50 mg + 4 of 10 mg

Scenario 2

- For **scenario 2** we calculated the number of different vials needed to prepare the prescribed dosages, cumulated for one day.
- 525 mg scheduled for that day
  ➔5 vials of 100 mg + 3 of 10 mg

Scenario 3

- For **scenario 3** we calculated the number of vials needed, based on the highest volume and/or concentration available on the market and taking into account the maximum expiry date found in the literature.
- stability of cisplatinum = 14 days
  - ➔ Only 100 mg vials are used

- **Scenario 1** = per preparation
  : single preparation 187 mg
  ➔1 vial of 100 mg + 1 of 50 mg + 4 of 10 mg
- **Scenario 2** = per day
  : 525 mg scheduled for that day for 3 patients
  ➔5 vials of 100 mg + 3 of 10 mg
- **Scenario 3** = until end chemical stability or 14 days
  ➔ Only 100 mg vials are used

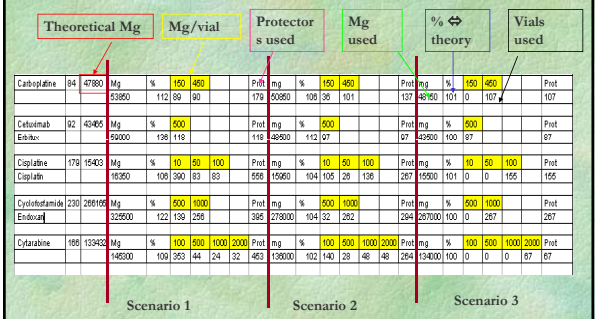
Billing in all 3 scenarios is the same
Government pays based on vials a s close as possible to what the patient received in therapy

Number and products

- In total **3086** preparations are evaluated.
- In the observation period, **39 different products** were used with a top 10 of most used products :

product	number of preparations
FLUOROURACIL	718
CYCLOPHOSPHAMIDE	229
ETOPOSIDE	182
CISPLATINE	178
DOXORUBICINE	177
CYTARABINE	166
GEMCITABINE	151
VINCRISTINE	133
OXALIPLATINE	116
IRINOTECAN	103

Number of used drug vials



Results : Difference in drug costs over a period of 2 months

	Scenario 1	Scenario 2	Scenario 3
Financial value (Euro) of used drug vials	836198	785079	738329
Difference in Euro compared to scenario 3	97869	46750	
%	+ 13 %	+ 6 %	

Results : Number & cost of Protector

Table 5	Scenario 1		Scenario 2		Scenario 3	
Protector Type	Number	Cost	Number	Cost	Number	Cost
Total p14	272	1523	258	1445	211	1181
Total p21	4119	20183	2632	12897	1695	8306
Total p50	2459	14508	1337	7888	1123	6626
Total	6850	36214	4227	22230	3029	16113
%		+ 125 %		+ 40 %		

Results : Total cost difference

Table 6	Scenario 1	Scenario 2	Scenario 3
product	836198	785079	738329
protector	36214	22230	16113
total	872412	807309	754442
Difference with scenario 3 (Euro)	117970	52867	
Difference in % with scenario 3	+ 15,6%	+ 7,0 %	

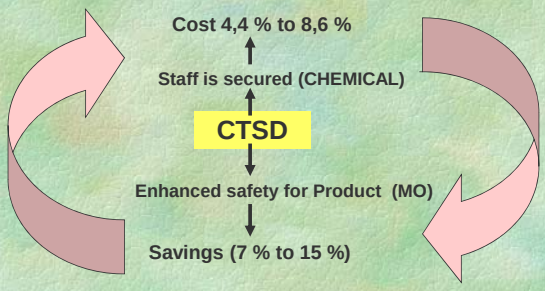
Discussion : % costs due to PhaSeal

§ Approx 50 % of the costs = Protectors

§ Approx 50 % of the costs = Injector + Connector

➔ COST = 4,4 % and 8,6 % OF DRUG COST

What is the cost of safety ?



Other factors to consider !

✓ Negotiation with pharmaceutical / generic companies about "off patent" drugs (Up to > 50 – 60 % discount)

✓ In some countries submitted for approval of reimbursement

✓ What is the cost of "in case off" …eg human harm, to appear in court, bad publicity, ….

Implementation in general

1/ Start with simple easy to change things

2/ Centralize your preparations

3/ Use closed devices to ensure safety for the staff and the patient.

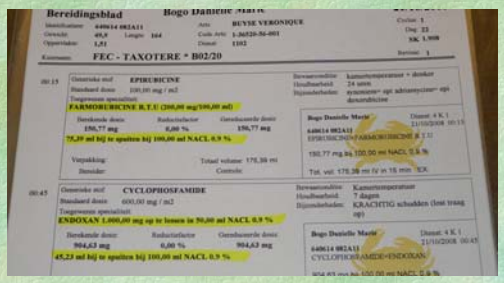
4/ Work on a better "clean environment"

5/ Validate you working procedures

6/ Use beyond the "magical" 24 Hours limit up to the last droplet according to the chemical - physical stability

7/ Safe money to invest further into safety and service.

Documented & electronic prescription and label



Centralised preparation in Pharmacy

Separated room with neg pressure

Personal protection (level 4)

BSC type 2 B 2 (level 3)

External exhaust

Closed system (level 2)

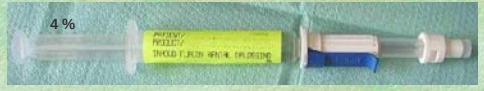
Cleaning & decontamination of vials

Dopping of the protector

Storage of dissolved product or restfractions

Preparation with PhaSeal

Preparation forms



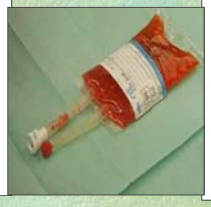
Controlling the preparation

Near Future :
•Multispec
• laser resonance spectometry

Secure and seal before transport

Transport to the ward

C.A.S. infusion lines

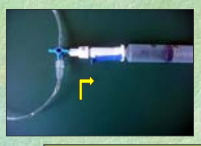


Closed system of administration

DRY connection technique for intravenous administration of cytotoxics

Single Bolus

IV line



Bladder instillation

Intrathecal injection

ISOPP safety standard

- ✓ **> 10.000 copies have already been distributed in 22 different countries around the world**
- ✓ **Audit tool is next project of ISOP standards committee**
- ✓ **Join ISSOP, the only world wide organisation of oncology pharmacists**
- ✓ **www.isopp.org**

To end with …

IF YOU UNDERSTAND THE RISKS ….. YOU CAN COPE WITH THEM