SAFE HANDLING OF HAZARDOUS DRUGS – QUEBEC INITIATIVES

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Pour l'amour des enfants
Université de Montréal

Unité de Recherche en Pratique Pharmaceutique
URPP

ASSTSAS
Association paritaire pour la santé et la sécurité du travail du secteur affaires sociales

WHO WE ARE

Pharmacy Practice Research Unit

- Research unit of the Pharmacy Department of Sainte-Justine University Health Center
  - Sainte-Justine UHC: 500 beds, mother-child
  - Pharmacy department: ~35 pharmacists, ~35 technicians
  - PPRU: ~ 15 international students/year

Unité de Recherche en Pratique Pharmaceutique
URPP

ASSTSAS

- Joint, non-profit, sector-based association dedicated to promoting occupational health and safety prevention and supporting health and social service sector workers and institutions
  - Consulting services
  - Information, training
  - Research and development activities

ASSTSAS
Association paritaire pour la santé et la sécurité du travail du secteur affaires sociales

Disclosure: *No conflict of interest to disclose*

OVERVIEW

Canadian laws & organizations

Quebec laws & organizations

Quebec guidelines

- Direction québécoise de la cancérologie
- Order of pharmacists of Québec
- ASSTSAS Prevention guide
    - Recommendations
    - Update
    - Compliance to recommendations

Environnemental monitoring

- Canadian studies (literature)
- Quebec studies
- Challenges and perspectives

Biological monitoring

- Planned pilot study
- Challenges and perspectives

CANADIAN LAWS AND ORGANIZATIONS

CANADIAN ORGANIZATIONS

FEDERAL: CANADA

Ministry of Health

↓

Minister of Health

↓

Deputy Minister

↓

Health Canada / Santé Canada

↓

- Public Health Agency of Canada
- Health Products and Food Branch
  - Therapeutic Products Directorate
  - Natural Health Products Directorate

CADTH

Canadian Agency for Drugs and Technology in Health

CANADIAN LAWS

- Criminal code
  - Employer may be accused of employer negligence
- Food and Drug act + regulation
  - Market authorizations, Manufacturing, Advertising, Adverse effects monitoring, etc
- Hazardous products act
  - Hazardous products such as compressed gas, flammable/combustible, poisonous/infectious, corrosive, dangerously reactive (e.g. Acetone)
  - Does not include drugs

QUEBEC LAWS AND ORGANIZATIONS

QUEBEC ORGANIZATIONS

NATIONAL: QUEBEC

Advisory boards

Institut national de santé publique Québec

Institut national d'excellence en santé et en services sociaux Québec

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Ministry Santé et Services sociaux Québec

↓

Minister of Health

↓

Deputy Minister → DIRECTION QUÉBÉCOISE DE CANCÉROLOGIE

↓ Direction de la Santé Publique

↓ Direction des services sociaux

↓ Direction de santé et médecine universitaire

REGIONAL

18 health agencies

LOCAL: districts

Centre de santé et de services sociaux

- CLSC, CHSLD, CPEJ, CR, hospital centers
- Doctors
- Private resources
- Community pharmacies

University HC
Affiliated HC
Integrated networks

QUEBEC LAWS

Québec

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- Civil Code of Québec

- Act respecting health services and social services

- An act respecting occupational health and safety
  - Aims at eliminating hazards for workers
  - Employer must provide a safe work environment
  - Nothing specifically on drugs hazardous to healthcare workers

- An act respecting industrial accidents and occupational diseases
  - Injury compensation, return-to-work protocol

- CSST's For a safe maternity experience program
  - Preventive withdrawal from work, compensation

- *Code des professions*

- Professional laws (eg. Pharmacy Act, Medical Act, Nursing Act, Dentistry Act)

QUEBEC GUIDELINES ON HAZARDOUS DRUGS

Direction québécoise de la cancérologie

2012

CANCER DIRECTORATE

Safe usage of antineoplastic: risks and challenges

- In French
- A team of pharmacists, nurses and oncologists
- 68 pages
- 27 recommandations

Themes

- Treatment plans and prescription
- Drug preparation
- Drug administration
- Practice standards
- Teaching
- Drugs shortages
- Incidents and accidents data

- **For the safe handling and occupational exposure:**
  - Refers mainly to the ASSTSAS guidelines
  - No mention on environmental/biological monitoring

http://publications.msss.gouv.qc.ca/acrobat/f/documentation/2012/12-902-13W.pdf

QUEBEC GUIDELINES ON HAZARDOUS DRUGS

Order of pharmacists of Québec

PHARMACISTS

Order of pharmacists of Québec

ORDRE DES PHARMACIENS DU QUÉBEC
Présent pour vous

- In French
  - In the process of being translated for the rest of Canada

- 3 guidelines on drug preparation

Non-sterile
(with a section on hazardous drugs)

2012

Sterile: non-hazardous drugs

2014

Sterile: hazardous drugs

2014

http://www.opq.org/fr-CA/publications/normes-de-pratique-et-lignes-directrices/

PHARMACISTS

- Inspired by chapter 795 and 797 of the United States Pharmacopeia (USP)

USP<797>

  - USP chapter 800 will be taken into account once published
    - Currently under public review

- Used for professional inspections for hospitals and retail pharmacies (5 year cycle) → mandatory

  - Our center will be inspected in October 2014

- Mostly for pharmacists and pharmacy technicians (but thechnicians are not yet regulated)

  - Has an impact throughout the drug use process

http://www.opq.org/fr-CA/publications/normes-de-pratique-et-lignes-directrices/

PHARMACISTS

Non-sterile preparations

- 84 pages

- Themes
  - Required conditions: workers, procedures, equipments, maintenance
  - Hazardous drug preparations (5 pages)
  - Quality control
  - Patient follow-up
  - Waste management

http://www.opq.org/fr-CA/publications/normes-de-pratique-et-lignes-directrices/

PHARMACISTS

Sterile hazardous drugs preparations

- 116 pages, 46 criteria
- Themes
  - Required conditions: workers, training, procedures, equipments, maintenance, housekeeping
  - Expiry
  - Preparation protocols and registry
  - Patient file
  - Workers' conduct in sterile areas
  - Packaging
  - Receipt and storage
  - Delivery of prepared drugs
  - Drug recall
  - Accidents
  - Wastes
  - Quality insurance

http://www.opq.org/fr-CA/publications/normes-de-pratique-et-lignes-directrices/

PHARMACISTS

Sterile hazardous drugs preparations

Monitoring

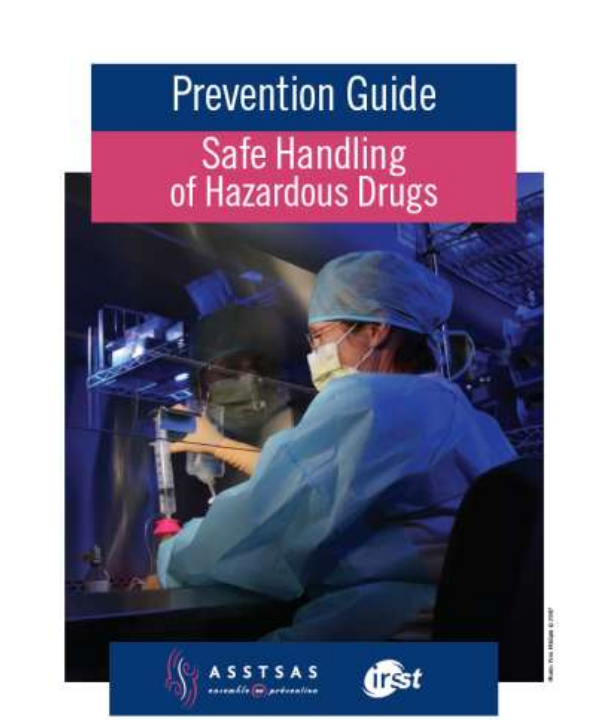
- An environmental surveillance must be put in place
  - Hazardous drugs and microbial contamination
  - Twice per year
  - Results kept in a registry
  - Keep a policy / procedure

- No mention/obligation about biological or medical surveillance

http://www.opq.org/fr-CA/publications/normes-de-pratique-et-lignes-directrices/

QUEBEC GUIDELINES ON HAZARDOUS DRUGS

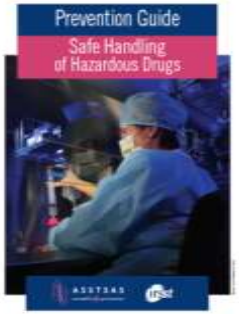
ASSTSAS Prevention guide



2008

ASSTSAS

Prevention guide - Safe handling of hazardous drugs

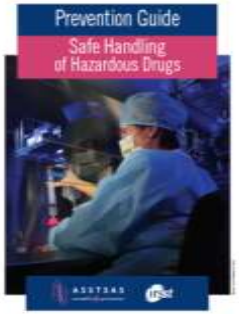


- 2008: update to come
- Multidisciplinary
- Prepublished for consultation
- 158 pages
- 68 main recommendations according to 3 levels
  - *Must* – supported by law, regulation or standard
  - *Should* – measured proposed
  - *May* – measured proposed, but according to circumstances
- Hazardous drugs: antineoplastic vs others

> NIOSH considers that the precautions in its guide apply equally to every drug on its list. The Working Committee believes that **these precautions apply unequivocally to all antineoplastic drugs, regardless of whether they are used in oncology or to treat other conditions** (e.g. methotrexate for arthritis). **However, some precautions could be adapted for other categories (e.g. hormones), based on the specific risks for each category**. Unfortunately, the current documentation did not allow the Committee to prepare (as it would have liked) a list of precautions adapted on the basis of the toxicological characteristics of certain drug classes. **Therefore, the recommendations in this guide are to be considered general recommendations**. It is our hope that updates will allow the development of more targeted recommendations.

http://www.asstsas.qc.ca

ASSTSAS



Prevention guide - Safe handling of hazardous drugs

Guiding principles

- **Protection of human health**
- Scientific rigor (based on the best evidence and knowledge available)
- Prudent practice (no known limits of safe exposure)
- Management

Structure

General recommendation, Followed by Specific recommendations

Confidence rating (evidence)

References

4.1.2 Hazardous Drug Committee — RATING: +++

Establish a Hazardous Drug Committee.

RECOMMENDATIONS

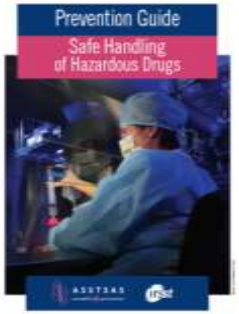
4.1.2.1 This committee should include, at the very least, one representative from each of the following departments and services: occupational health and safety, pharmacy, nursing, hematology-oncology (physician), inhalation therapy, hygiene and sanitation, technical service, risk management.

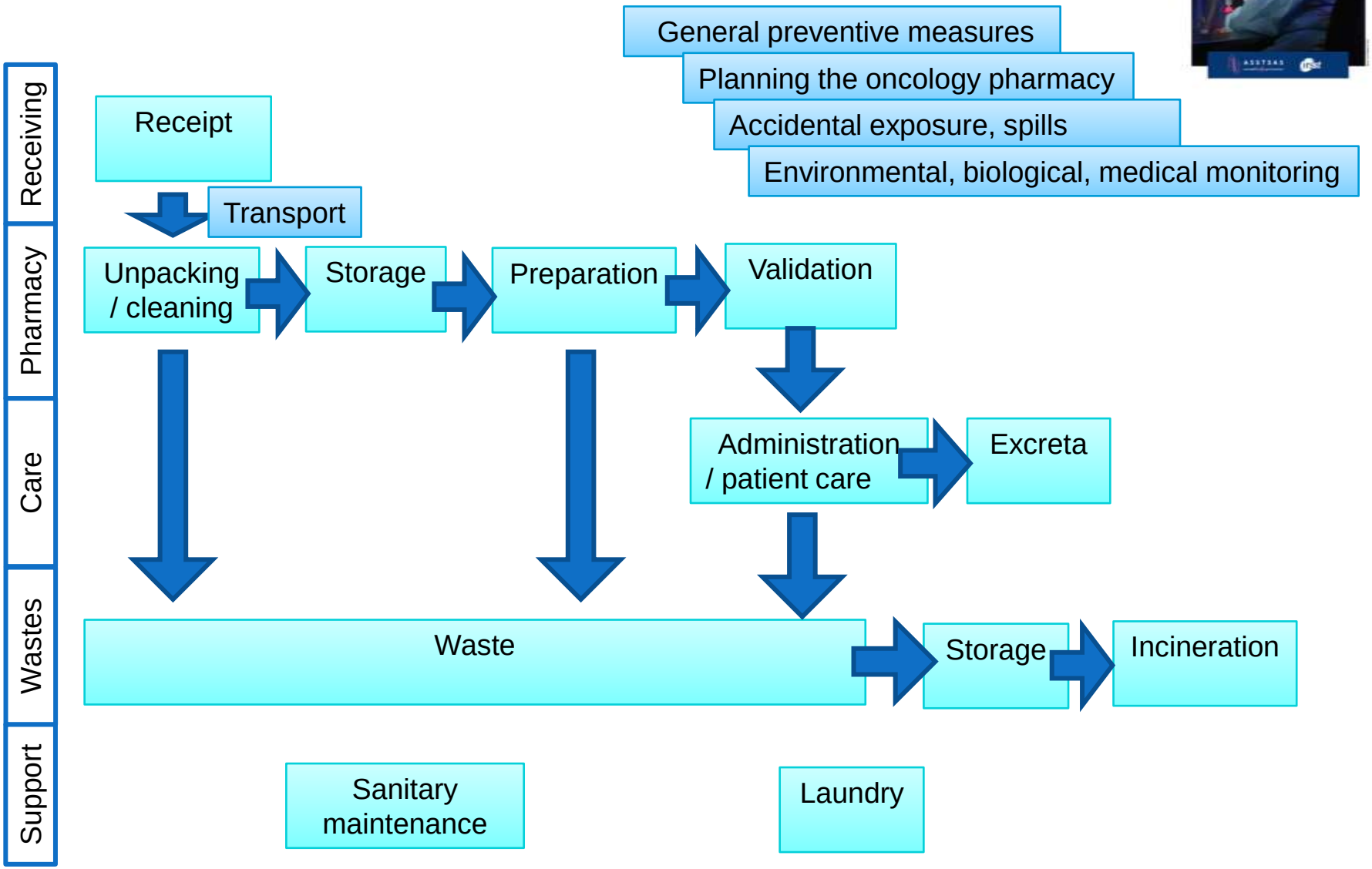
4.1.2.2 This committee should be mandated by the hospital administration to ensure the implementation and follow-up of the Risk Prevention Management Program related to the use of hazardous drugs.

4.1.2.3 This committee should meet at least twice a year to discuss the hazardous drug situation.

http://www.asstsas.qc.ca

Chapters organized according to the drug-use process (*simplified*)





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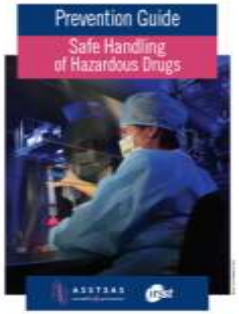

General measures

- Establish a hazardous drug committee
  - Occupational health and safety, pharmacy, nursing, hematology-oncology, inhalation therapy, hygiene and sanitation, technical service, risk management
  - Meeting twice/year
  - Annual self assessment compliance
  - Policies and procedures, list of hazardous drugs

- Establish a continuing education program
  - Assessment tool

- Identification

Cytotoxic

Example of a Caution label used at Sainte-Justine UHC

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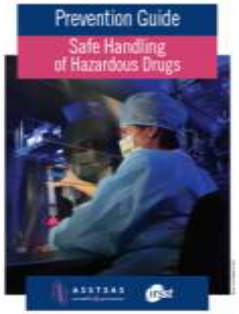


Personnal protection equipment

- In short, the ASSTSAS guide recommends:
  - Gloves and gown always
  - Protective eyewear if risk of splashing
  - + protection if spill or cleaning

- Similar to NIOSH
  - Except 2 gloves for every situation
  - Transport

- Similar to USP
  - Includes sterile requirements such as mask/shoe cover

- Similar to the Order of Pharmacists of Quebec

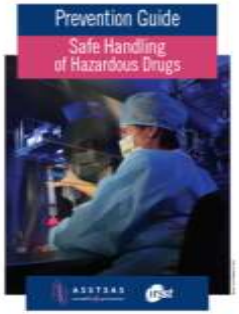
Personnal protection equipments

	Step						
Receiving	Unpacking /Cleaning	2	x	x (ventil.)			
Pharmacy	Storage	1	x				
	Sterile preparations	2	x			x	x
	Non sterile preparations: counting solid oral forms	1	x				
	Non sterile preparations: preparing creams	2	x				
Care	IV, SC, liquid oral administrations	1	x		x (splash.)		
	Solid oral administrations	1	x		x (splash.)		
	Topical administrations	2	x				
	Aerosolized administrations	1	x	x			

Personnal protection equipments

	Step						
Care	Patient care	1	x		x (splash.)		
Wastes	Handling of contaminated bedding on wards	1	x				
Wastes	Waste management (collection, transport)	1	x				
Wastes	Spill or damaged/ broken container	2	x	x	x		x (floor)
Support	Cleaning of sterile preparation room and airlock	1	x			x	x
Support	Cleaning of preparation cabinets (hoods)	2	x	x	x	x	x
Support	Cleaning of other oncology pharmacy rooms and care units	1	x				

Personnal protection equipments



Gloves

- ASTM standard D-6978-05 (chemo)
- Changed every 30 minutes

Gown

- Disposable, lint-free, low permeability fabric
- Adjustable cuffs
- Changed every 3,5 hours
- Ideally, do not reuse

- Face protection

  - Risk of spashing
  - Disposable or non-disposable
  - If protective eyewear (-), use category B goggles + fluid resista

- Respiratory protection

  - Most cases: N95 or N100
  - Vapours: respirator with chemical cartridges
  - Seal-check test before each use
  - French guide: http://www.irsst.qc.ca/-publication-irsst-guide-pratique-de-protection-respiratoire-r-319.html

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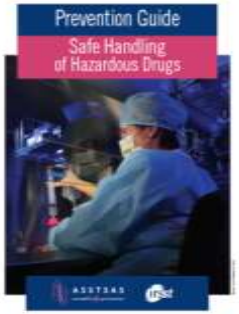

Receiving and transport / Unpacking and storage

- Selection of drugs

- Unpacking and cleaning area at the pharmacy
  - Adequate ventilation, sink, receptacle for waste

- Cleaning procedure
  - Disposable cloth + household detergent

- Separate storage
  - Ventilated cabinet if with other drugs or workstation

- Transport
  - Leakproof plastic bag + rigid leakproof container (labelled)

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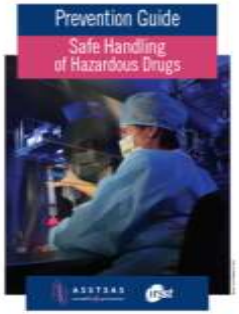
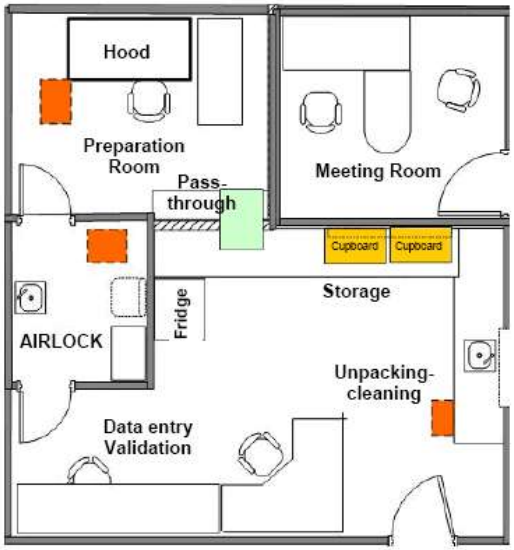


Oncology pharmacy layout

- Order of pharmacists Norm for compounding requirements
- Dedicated zones



- Calibration/maintenance/cleaning of equipment (eg. BSCs)
- Limit comings and goings
  (eg. compounding check by cameras)

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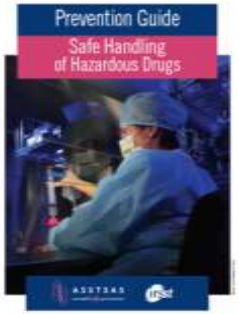
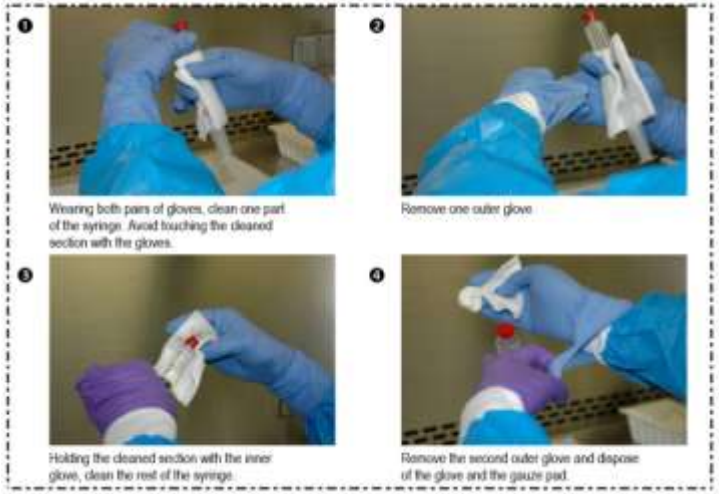


Drug preparation

- Order of pharmacists Norm for compounding requirements
- Avoid overfiling, use Luer-Lock syringes

- Priming at the pharmacy

- Clean compounded products



- Avoid using automated equipments
- Prepare doses ready to administer

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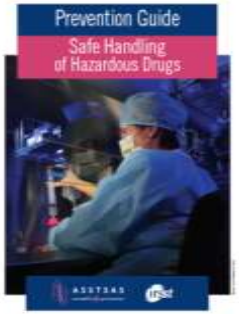

Administration of drugs

- Rooms with limited access
- Choice of easy to clean materials

- Check for leaks
- Use absorbent pads on surfaces or gauzes

- Have procedures for:
  - Extravasations
  - Administrations: IV, SC, IM, oral, topical, vesical, IP, intrathecal, aerosolization (eg. Pentamidine and Ribavirin)

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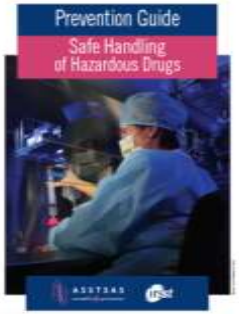

Waste management, accidental exposure, spills

- Policies and procedures
  - Waste = eveything in contact with the drug
  - Appropriate containers; in every area, avoid overfilling

  - At home: provide receptacles and teach patients about what to do at home (eg. transport)

- Accidental exposure
  - Accident/incident report sheet, kept in employee's file
- Spill
  - Trained team, spill kits
  - Annual simulation exercise

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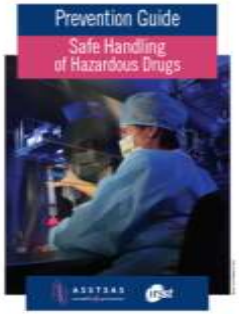

Hygiene / Patient care / Laundry

- Develop a program
  - Frequency
  - Eg, in the oncology pharmacy:
    - Daily: Work surfaces and traffic areas
    - Monthly: ceiling, walls, windows, outside of equipments
  - Products
    - Detergent and water for most situations
    - Sodium hypochlorite 2.4%/water/sodium thiosulfate if extensive

- Patient excreta/vomitus
  - Consider hazardous for the next 48 hours (or more)

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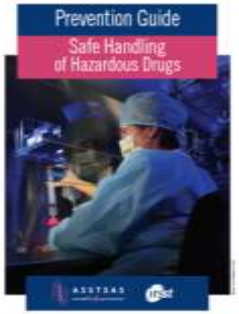

Monitoring

- **Environmental monitoring**
  - Should plan regular monitoring activities
    - Annually or a the time of major changes

Now 2/year according to the Order of Pharmacists of Québec

- **Biological and Medical monitoring**
  - Not recommended
    - Does not allow the effective prevention of health problems related to exposure
  - Record accidental exposures → Mandatory
  - Precautionary reassignment of pregnant/nursing worker → Immediate
  - Precautionary reassignment prior to conception→ no recommendation

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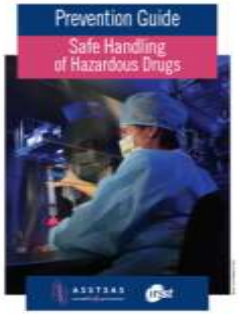

Update process

- Review of the literature 2007-current
  - > 400 documents found
- Evidence reviewed to suggest additions/deletions
- Multidisciplinary committee on hazardous drugs will review the key literature and suggested additions
- Additional studies may be conducted to provide recommendations
  - An audit was conducted on healthcare units from 10 hospitals in 2014

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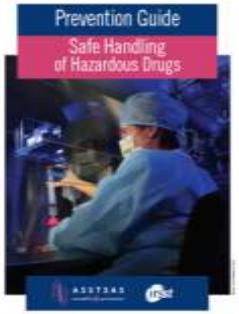

Update – thoughts

- New section on long-term care facilities?
- Personnal protection equipment with compounded products, eg. Blister packs in retail pharmacies?
  - USP800
- Wall contamination?
- Closed-system drug transfer devices: cost/efficacy?
- Update biological monitoring recommendations?
- Precautionary reassignment?
- Youtube videos to illustrate some recommendations
  - Workers education

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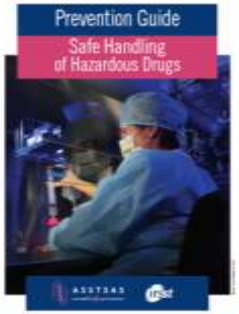
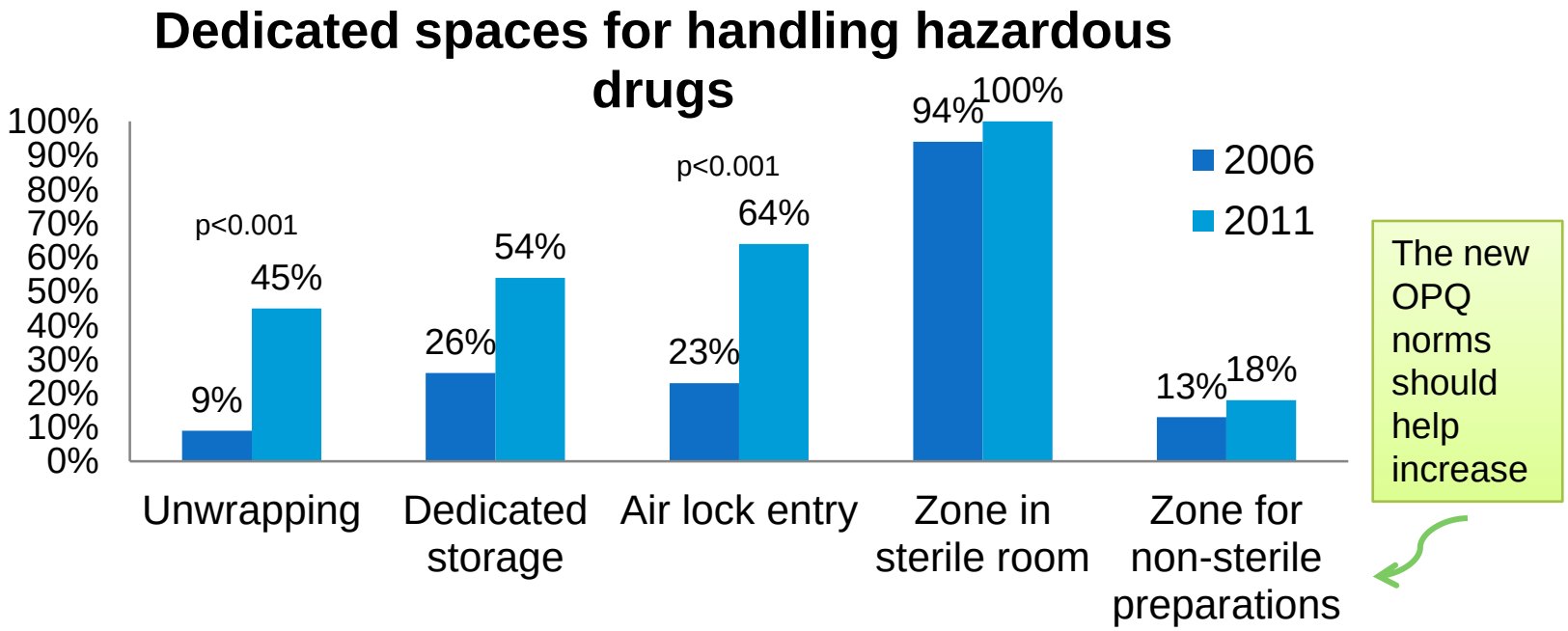


Compliance to the recommendations

- Surveys
- 2006: 53 centers
- 2011: 33 centers

Increase in the mean number of **dedicated** spaces per pharmacy: 3.6 to 5.1



Merger D, Tanguay C, Bussières JF. Circuit des médicaments dangereux en établissement de santé. Québec Pharmacie 2013;13-8.

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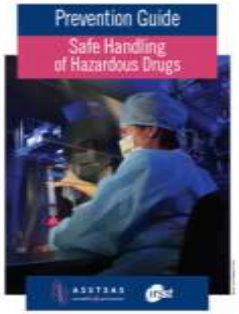
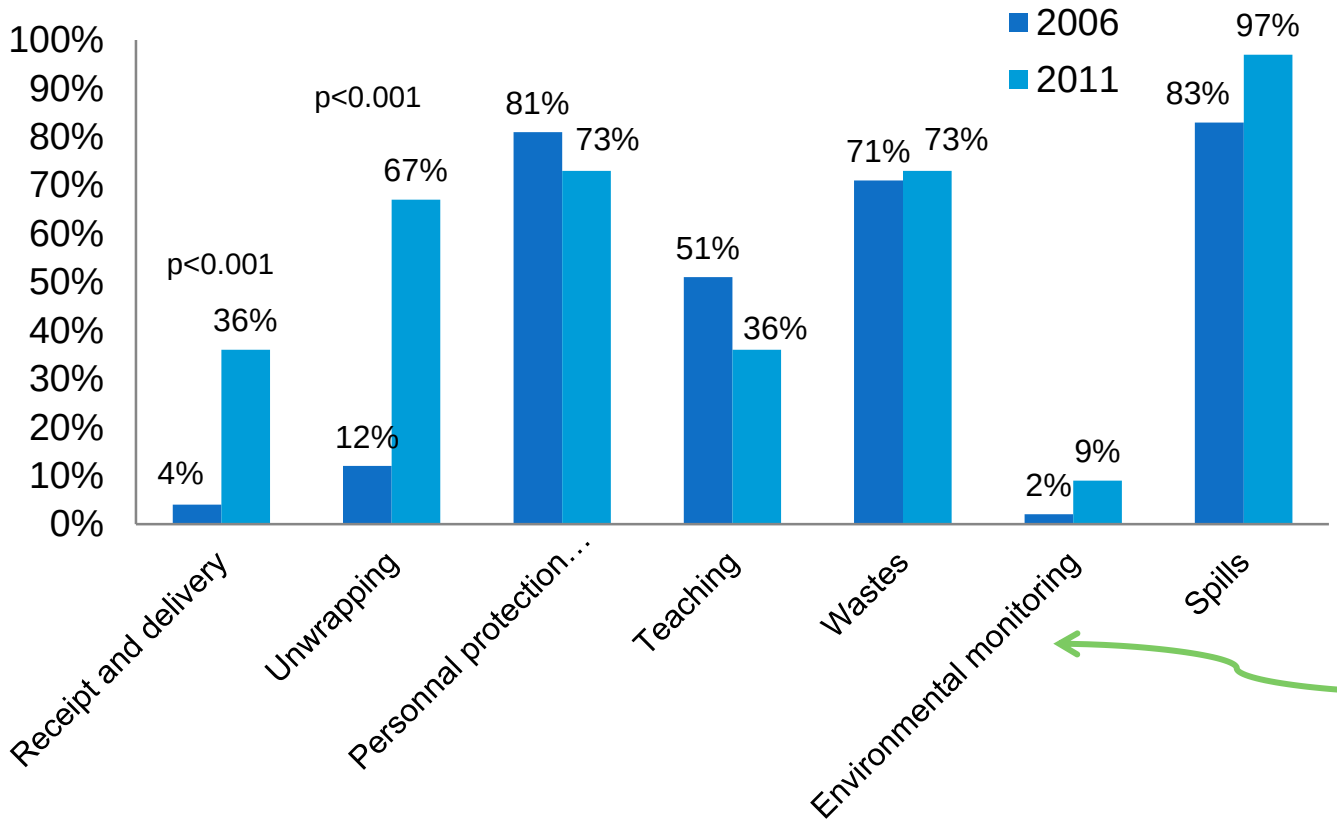


Compliance to the recommendations

Policies and procedures (pharmacy)



The new OPQ norms should help increase

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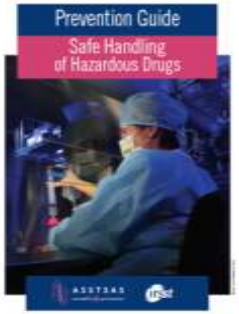
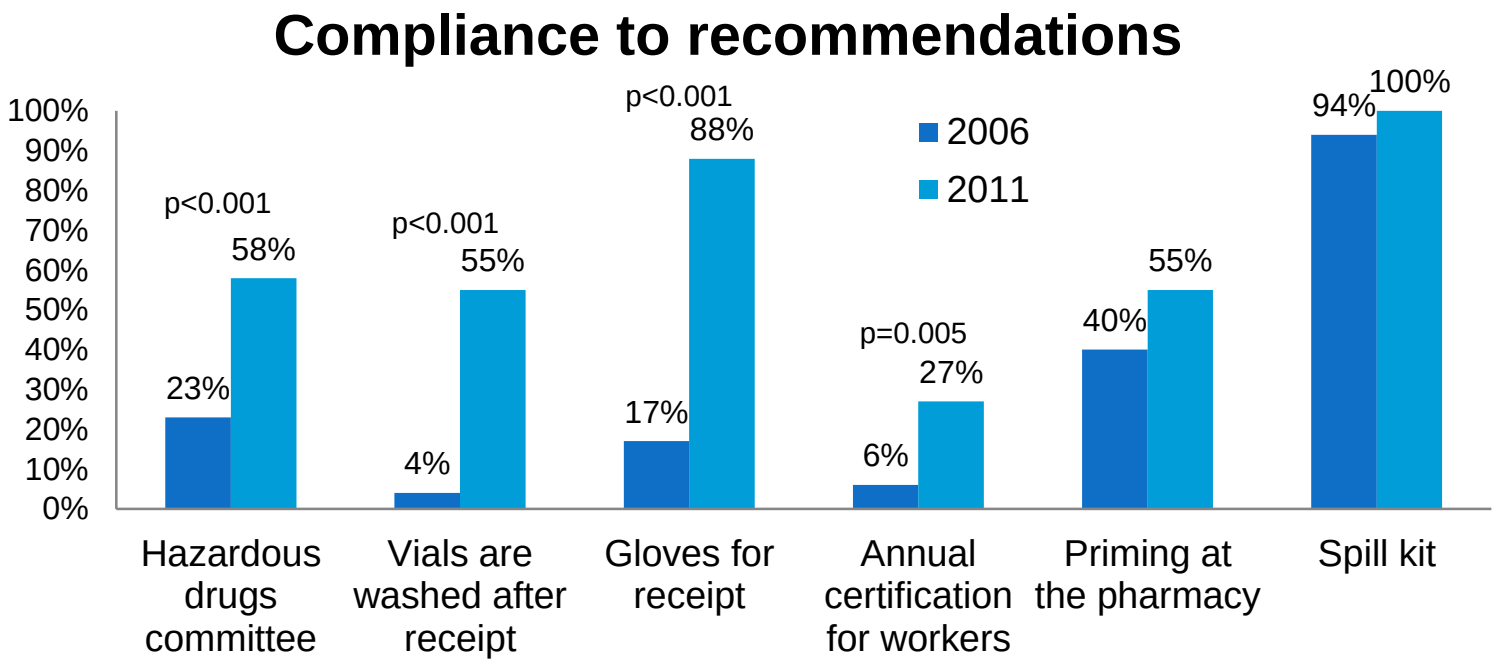


Compliance to the recommendations

Increase in the mean global conformity: 52% to 69%



ENVIRONNEMENTAL MONITORING

CANADIAN STUDIES

Canadian studies in the literature

- British Columbia (Hon et al. J Occup Environ Hyg 2013;10(7):374-83)
- British Columbia (Chu et al. J Oncol Pharm Pract 2012;18(1):46-51)
- British Columbia (Hon et al. Saf Health Work 2011;2(3):273-81)
- British Columbia (Hon et al. Can J Hosp Pharm 2011;64(5):327-32)
- Alberta (Bigelow et al. J Oncol Pharm Pract 2009;15(3):157-60)
- Alberta (Schulz et al. J Oncol Pharm Pract 2005;11(3):101-9)
- USA and Central Canada (Connor et al. Am J Health Syst Pharm 1999;56(14):1427-32)

QUEBEC STUDIES

Studies by the Pharmacy Practice Research Unit (since 2004)

- 2 studies in community pharmacies
  - 2009: 8 pharmacies (Bulletin d'information toxicologique 2010:26(3):15-9)
  - 2012: 20 pharmacies (J Am Pharm Assoc 2013;53:423-6)
- 4 studies in hospital pharmacies only
- 1 study in an outpatient clinic

- 4 studies in hospital pharmacies + healthcare units
  - 2014: 50 hospitals in Quebec + Canada (Analysis underway)
  - 2013: 36 hospitals (J Occup Environ Hyg doi 10.1080/15459624.2014.949725
  - 2012: 33 hospitals (Int Arch Occup Environ Health 2014;87:307-13)
  - 2008-2010: 25 hospitals (Can J Hosp Pharm 2012;65(6):428-35)

ENVIRONMENTAL MONITORING IN QUÉBEC

Institut national de santé publique Québec

Method was developped by the INSPQ

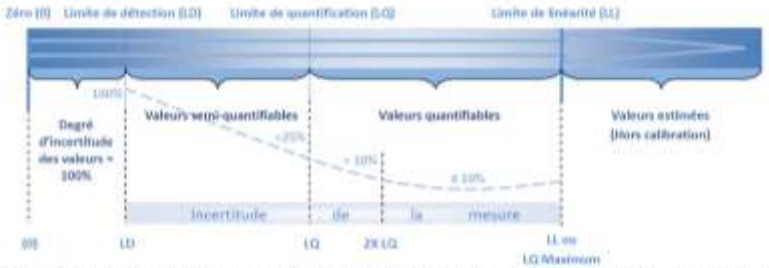
- Cyclophosphamide, ifosfamide and methotrexate
- UPLC-MSMS

	Limit for cyclophosphamide (ng/cm²)			
	2008-2010	2012	2013	2014
Limit of detection	0.0015	0.0018	0.0018	0.00036
Limit of quantification	0.0050	0.060	0.060	0.00121

Uncertainty of measure:
If <LOD, a value of LOD/2 was used
If <LOQ, a value of LOQ/2 was used

Commission directive 2009/90/CE of 31 July 2009. Article 5.
Appl Occup Environ Hyg 1990;5(1):46–51

Figure 1. *Incertitude de la mesure*



La figure 1. montre la variation de l'incertitude d'un résultat en fonction de sa concentration. Les résultats qui se situent entrent 2X LQ et la LL (valeurs quantifiables) comportent une incertitude d'environ 10% ou moins. De la LQ à la LD, l'incertitude sur la mesure croît de manière exponentielle, passant d'approximativement 25% à 100%.

ENVIRONMENTAL MONITORING IN QUÉBEC

6 pharmacy sites

6 healthcare unit sites

Shipment reception counter	Front grille of the hood	Service hatch or post-preparation validation
Storage shelf or bin	Floor in front of the hood	Tray for drug delivery
Storage shelf or bin	Arm rest	Outpatient clinic counter
Counter for priming or validation	Patient room counter	Exterior surface of drug container

ENVIRONMENTAL MONITORING IN QUÉBEC

ASSTSAS guide

	2008-2010	2012	2013	2014
Participating hospitals (n)	25	33	36	50
Samples (n)	259	363	422	-
Cyclophosphamide Positive samples (%) 75th percentile (ng/cm²)	52% 0.0440	40% 0.0094	47% 0.0084	-
Ifosfamide Positive samples (%) 75th percentile (ng/cm²)	20% < LOD	18% < LOD	18% < LOD	-
Methotrexate Positive samples (%) 75th percentile (ng/cm²)	3% < LOD	5% < LOD	3% < LOD	-

Cyclophosphamide is a good marker for environmental contamination.
The proportion of positive samples remains ± constant over the years.
The concentration found on surfaces is reduced over the years.

ENVIRONMENTAL MONITORING IN QUÉBEC

- Similar contamination in pharmacy and patient care areas

- 4 sites have >50% positive samples over the years

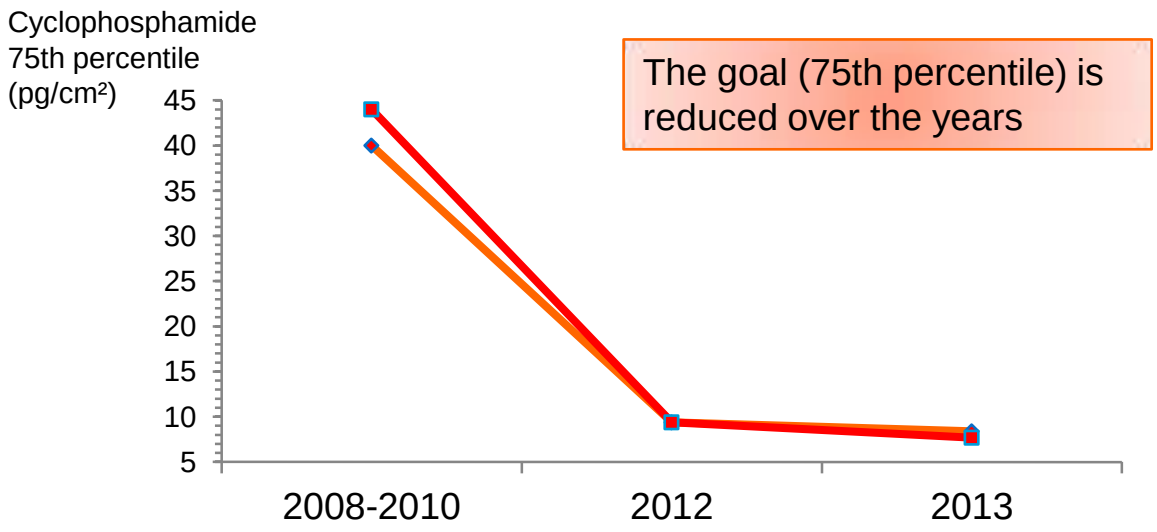
  - Front grille inside the hood
  - Floor in front of the hood

  - Arm rest
  - Outpatient clinic counter

ENVIRONMENTAL MONITORING IN QUÉBEC

And then, what happens?

- Each participating hospital receives their results from the INSPQ
- We gather results and analyse:
  - Overall proportion of positive samples
  - Minimum, median, 75th, 90th percentile and maximum concentration of drugs
  - A new local « goal » is set each year, corresponding to the 75th percentile
- We send each center a personnalized report
  - We highlight every sample site >75th percentile
  - The aim is to maintain the contamination as low as reasonably achievable



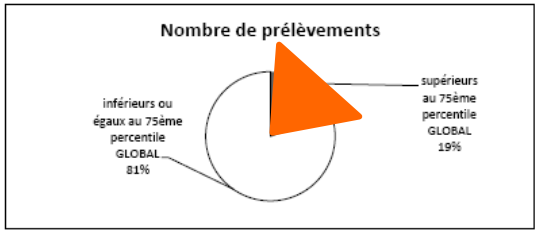
ENVIRONMENTAL MONITORING IN QUÉBEC

Example: center with
7 samples >75th percentile

1) Comparaison des données de votre établissement par rapport au 75ème percentile GLOBAL de contamination[a] mesuré dans l'étude québécoise réalisée en février 2013

Dans l'étude multicentrique québécoise de 2013, le 75ème percentile GLOBAL était de 0,0084 ng/cm² pour le cyclophosphamide et inférieur à la limite de détection (LOD) pour l'ifosfamide et le méthotrexate. Dans votre établissement, veuillez cibler vos actions sur les 7 valeurs de prélèvements de surface supérieures au 75ème percentile GLOBAL de l'étude québécoise 2013. Le nombre maximal de valeurs de prélèvements par établissement est de 36, soit 12 sites de prélèvements pour 3 médicaments dangereux par établissement.

Étude québécoise 2013	Nombre de prélèvements de votre établissement	
Médicament (75ème percentile GLOBAL)	supérieurs au 75ème percentile GLOBAL	inférieurs ou égaux au 75ème percentile GLOBAL
CYCLOPHOSPHAMIDE (0,0084 ng/cm²)	4	8
IFOSFAMIDE (< LOD)	3	9
METHOTREXATE (< LOD)	0	12
TOTAL	7	29



2) Résultats détaillés par site de prélèvement

No prélèvement	Sites de prélèvement	2008 Votre établissement (ng/cm²)	2008 Étude québécoise (n = 25 centres) (ng/cm²) 75ème percentile par site	2012 Votre établissement (ng/cm²)	2012 Étude québécoise (n = 33 centres) (ng/cm²) 75ème percentile par site	2013 Votre établissement (ng/cm²)	2013 Étude québécoise (n = 36 centres) (ng/cm²) 50ème percentile par site	2013 Étude québécoise (n = 36 centres) (ng/cm²) 75ème percentile par site	2013 Étude québécoise (n = 36 centres) (ng/cm²) 100ème percentile par site
CYCLOPHOSPHAMIDE : limite de détection[b] (LOD) en ng/cm²		0,0015		0,0018		0,0018			
1	Comptoir de réception (Pharmacie)	**0,0440**	< LOD	**0,0030**	< LOD	< LOD	< LOD	< LOD	0,1000
2	Tablette d'entreposage (Pharmacie)	**0,0190**	0,0770	**0,3300**	0,0090	**0,0840**	< LOD	0,0066	2,1000
3	Grille frontale de la hotte (Pharmacie)	**0,0560**	0,2300	**0,0750**	0,1800	**0,2100**	0,0165	0,1200	1,3000
4	Plancher devant la hotte (Pharmacie)	**0,0160**	0,0170	**0,1100**	0,0600	**0,2800**	0,0210	0,0578	1,0000
5	[illegible]			< LOD	< LOD	[illegible]	< LOD	0,0030	0,6400
6	[illegible]			< LOD	< LOD	< LOD	< LOD	< LOD	0,0160
7	[illegible]			**0,0030**	0,0030	< LOD	< LOD	0,0030	0,0560
8	[illegible]				0,0030	< LOD	0,0020	0,0030	0,1700
9	[illegible]				0,0800	< LOD	0,0200	0,0430	0,8300
10	[illegible]								
11	[illegible]								
12	[illegible]								

We recommend that corrective measures be applied in priority to these sites

25% « worst » sites are targeted each year

The PPRU follows up with centers and answers their questions

CHALLENGES AND PERSPECTIVES

Participation

- Participation voluntary → Monitoring now mandatory with the Order of Pharmacists of Québec

Costs

- No financial support from the Health Ministry or other
- Discussions ongoing to add other substances, but costs kept at a minimum

Interpretation of results

- The PPRU offers an annual goal for participating centers
- Goals should be local and attainable, as long as no health-based limit is known

Working practices

- Washing vials after they are received seems to have an impact
- Closed-system drug transfer devices work, but are costly
- Work closely with sanitary maintenance
- Education is important!

BIOLOGICAL MONITORING

BIOLOGICAL MONITORING

Prevention

- We are currently doing interventions to promote good pratices and the wear of personnal protective equipments amongst workers

Pilot study underway

- Pharmacists, pharmacy technicians, nurses, doctors (+ controls)
- Cyclophosphamide, ifosfamide, methotrexate, 5-fluorouracil (FBAL)
- 1 measure per participant, at the end of shift
- Participants will fill out an exposure journal
- We chose not to present individual results to participants
    - Pilot study, we want to validate the method and feasibility
    - Health risks unknown
    - Long term risks unknown (eg. insurance)
- We will present global results to the participants and discuss about what could be improved

Will be followed by a multicentric study

CHALLENGES AND PERSPECTIVES

Participation

- Voluntary

Costs

- No financial support

Interpretation of results

- Medical meaning and transmission of individual results?
- Use biological monitoring as an annual snapshot of % of positive workers?

Ethical issues

- Insurance issues?

Working practices

- Regularly train employees on good working practices
- Audit practices
- Highlight the importance of personnal protection equipments
- Work with a multidisciplinary team

SUMMARY

- There are Canadian/Québec laws for workers protection
- There are recent Québec guidelines on the safe handling of hazardous drugs
  - ASSTSAS guide is being updated
- Compliance to these guidelines is improving, but still work to do
- Promote good working pratices and use of PPE
  - Regular training, audits
- Environmental monitoring is now mandatory in Québec pharmacies
  - Constant proportion of positive samples
  - Reduction in the concentration over the years
- No health-based safe exposure limit is known
  - We use the annual canadian 75th percentile, as a local and attainable goal
- Ongoing discussions about biological monitoring

THANK YOU

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