Management of Peritoneal Surface Malignancy

Irkutsk, Sibiria

9 -11 Aug 2017

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Как сделать ГИИХ безопасной для пациентов и персонала

Курт ван дер Шпеетен, д.м.н.
Иркутск, 09.08.2017

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BIOMEDISCH ONDERZOEKSINSTITUUT

- Exposure to Chemotherapeutic Agents
- Exposure to Surgical Smoke
- Рекомендации по безопасности проведения ГИИХ

Exposure to Chemotherapy

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Exposure to Chemotherapeutic Agents

Workers potentially exposed hazardous drugs during HIPEC

- Operating room personnel
- Physicians, anaesthesiologists, surgeons

But also

- Shipping and receiving personnel
- Pharmacists and pharmacy technicians
- Nursing personnel
- Environmental services personnel
- Laboratory personnel

Exposure to Chemotherapeutic Agents

The risk of Chemotherapy

Evolution of Guidelines on Hazardous Drugs

- **American Society of Health-System Pharmacists**
  - **1985, 1990**
  - **2005: Guidelines on Handling Hazardous Drugs**
- **NIOSH (Natl. Institutes of Occupational Safety & Health)**
  - **2004: NIOSH Hazardous Drug Alert**
- **OSHA (Occupational Safety & Health Administration)**
  - **1986**
  - **1995: Controlling Occupational Exposure to Hazardous Drugs**

Exposure to Chemotherapeutic Agents

Workplace exposure has been shown to induce

- health effects such
  - skin rashes,
  - decreased fertility
  - spontaneous abortions
  - congenital malformations
  - leukemia and other cancers

Exposure to Surgical Smoke

Tomita Y et al. Mutagenicity of smoke condensation induced by C02-laser irradation and electrocauterization. Mutat Res. 1981; 89:145

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Exposure to Surgical Smoke

Peritonectomy with high voltage electrocautery generates higher levels of ultrafine smoke particles

S.N. Andréasson [a,*], H. Anundi [b], B. Sahlberg [b], C-G. Ericsson [b], R. Wålinder [b], G. Enlund [a], L. Påhlman [c], H. Mahteme [c]

Table 1
Ultrafine particle/millilitre/hour (pt/ml/h) concentration in personal and stationary sampling.

	PC group ($n = 14$)	Control group ($n = 11$)
Median UFP of PS	8.0×10^2 (5.2×10^2)	2.5×10^2 (3.1×10^2)
Maximum UFP of PS	5.2×10^5 (1.5×10^5)	4.7×10^4 (1.2×10^5)
Cumulative UFP of PS	9.3×10^6 (3.2×10^6)	2.8×10^5 (5.5×10^5)
Median UFP of SS	6.2×10^3 (8.7×10^3)	1.4×10^3 (5.0×10^3)
Maximum UFP of SS	7.7×10^4 (2.0×10^5)	1.4×10^4 (1.8×10^4)
Cumulative UFP of SS	2.6×10^6 (3.5×10^6)	3.9×10^4 (9.5×10^5)

Numbers are medians with interquartile ranges in parentheses.
UFP = ultrafine particles, PS = personal sampling, SS = stationary sampling, and PC = peritoneal carcinomatosis.

TABLE 2: GM and GSD (ng/m^3) of PAH in 40 peritonectomy procedures.

PAH	GM	GSD
Benzo[a]anthracene P/S	0.14/0.14	±2.68/±2.51
Benzo[a]pyrene P/S	0.13/0.16	±2.43/±2.92
Benzo[b]fluoranthene P/S	0.16/0.21	±3.20/±3.83
Benzo[k]fluoranthene P/S	0.14/0.16	±3.14/±3.06
Chrysene/triphenylene P/S	0.15/0.34	±3.31/±6.00
Dibenzo[a,h]anthracene P/S	0.11/0.13	±1.88/±2.95
Indenol[1,2,3-cd]pyrene P/S	0.12/0.12	±2.25/±1.96
Acenaphthene P/S	0.49/6.24	±8.46/±5.64
Acenaphthylene P/S	0.34/14.63	±5.87/±5.71
Anthracene P/S	0.11/0.35	±1.94/±5.40
Benzo[ghi]perylene P/S	0.12/0.16	±2.15/±3.10
Phenanthrene P/S	4.07/6.27	±3.16/±5.17
Fluoranthene P/S	0.19/0.58	±3.99/±7.02
Fluorene P/S	0.90/5.18	±7.07/±6.15
Naphthalene P/S	63.41/178.66	±2.20/±9.32
Pyrene P/S	0.15/0.50	±3.18/±6.84

PAH: polycyclic aromatic hydrocarbon, P: personal sampling, S: stationary sampling, GM: geometric mean, GSD: geometric standard deviation.

EJSO 35 (2009) 780–784

Safety Guidelines for Safe HIPEC

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First of all : the DATA

Table 1
Summary of studies investigating chemotherapy contamination during HIPEC.

	Author	Year	Method	Sample	Chemotherapeutic agent	Method of evaluation	Results
1	Stuart et al. [31]	2002	Open	Urine Gloves Air	Mitomycin – C	High – performance liquid chromatography	No detectable safety hazard to the surgeon or other operating room personnel was documented
2	Schmid et al. [33]	2006	Open	Blood Air Gloves	Mitomycin – C	High – performance liquid chromatography – UV at 360 nm	No detectable risk
3	Guerbet et al. [34]	2007	Open simulation	Air	Oxaliplatin	Inductively Coupled Plasma – Mass Spectometry	No detectable levels – negligible risk of contamination
4	Andreasson et al. [35]	2010	Open	Urine Blood	Oxaliplatin	Inductively Coupled Plasma – Mass Spectometry	No detectable levels of platinum – little or no risk of platinum exposure
5	Konate et al. [36]	2011	Open	Air Surfaces Gloves Urine	Oxaliplatin	Inductively Coupled Plasma – Mass Spectometry	No contamination of healthcare workers operating room was detected
6	Schierl et al. [38]	2012	Open	Surface Gloves	Oxaliplatin	Voltammetric analysis after UV photolysis	Sporadically high platinum concentrations on surfaces on the HIPEC device and operating room floor. Low surface loads are possible.

HIPEC IS SAFE !!!

STEP 1 : prepare the OR and OR staff

- Staff orientation, training, education, and competency assessment
- Training programs to reduce worker risk
- Identifying indicators of exposure or early disease
- Medical monitoring program
- Requirements for Prescribing Chemotherapy
- Requirements for Preparation
- Basic Requisites for Order Processing and Checking of Chemotherapy

STEP 1 : prepare the OR and OR staff

Alternative Duty for

- Pregnancy
- Breast-feeding
- Attempting to conceive or father a child
- Medical and exposure history
  - Assessment and documentation of symptom complaints
  - Physical findings and laboratory values
- immunocompromised

ШАГ 1 : prepare the OR and OR staff

- Warning sign
- No unnecessary entries in the OR
- No entries for ‘vulnerable’ staff

ШАГ 2 : Use of Personal Protective Equipment (PPE)

NIOSH National Institute for Occupational Safety and Health

Personal Protective Equipment for Health Care Workers Who Work with Hazardous Drugs

- Gloves
- Gowns
- Respiratory Protection
  - NIOSH-certified N–95 (no protection against gases and va-pors and little protection against direct liquid splashes)
  - full-facepiece chemical cartridge-type respirator [42 CFR 84; NIOSH 2005]
- Eye and Face Protection
  - face shields in combination with goggles
  - Do not use eye glasses or safety glasses with side shields
- Sleeve, Hair, and Shoe Covers
- PPE Disposal
  - Consider all PPE worn when handling hazardous drugs as being contaminated

ШАГ 2 : Use of Personal Protective Equipment (PPE)

Disposable Personal Protective Equipment (PPE)

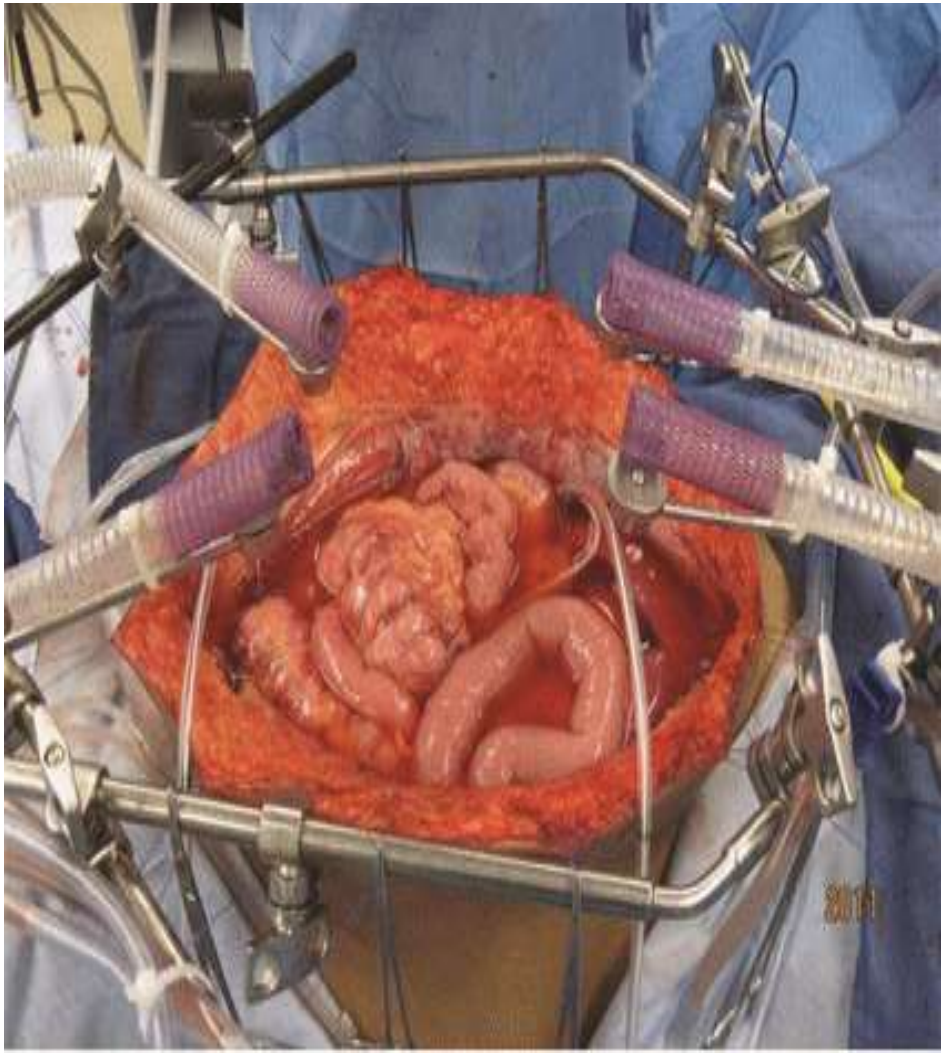
- Double pair of gloves (nitrile ou vinyl) changed every 30 minutes,
- Special gown
- NIOSH-certified N–95 mask changed every 2 hours
- Safety glasses
- Charlotte

ШАГ 2 : применение личного защитного Equipment

Eye Protection	
Use: Potential for splashing, such as administration in the operating room, intravesicularadministration, working above eye level, or when cleaning spills	**Section:** Goggles are needed to provide protection against splashing to the eyes. Eyeglasses or safety glasses with side shields are not sufficient protection (NIOSH, 2008).
Face Protection	
Use: Face shields used to protect against splashing	**Section:** Use face shield in combination with goggles to provide full protection against splashing to the eyes and face.
Head and Hair Cover	
Use: Used for protection from HD particulate or microbial contamination in clean rooms and other sensitive areas (NIOSH, 2008)	**Section:** Constructed of coated materials
Shoe Covers	
Use: Wear shoe covers when compounding HDs. Remove shoe covers when exiting the compounding room (NIOSH, 2008). Wear a second pair of shoe covers when entering the compounding area (USP, 2016).	
Sleeve Covers	
Use: Provide protection from HD residue on arms that come in contact with surfaces of the BSC (NIOSH, 2008	**Section:** Select disposable sleeve covers made of polyethylene-coated polypropylene or other laminate materials.

ASHP—American Society of Health-System Pharmacists; ASTM—American Society for Testing and Materials; BSC—biologic safety cabinet; C-PEC—containment primary engineering control; HD—hazardous drug; HIPEC—hyperthermic intraperitoneal chemotherapy; NIOSH—National Institute for Occupational Safety and Health; ONS—Oncology Nursing Society; PEC—primary engineering control; PPE—personal protective equipment; USP—U.S. Pharmacopeial Convention

ШАГ 3 : Smoke Evacuator



ШАГ 3 : Smoke Evacuator

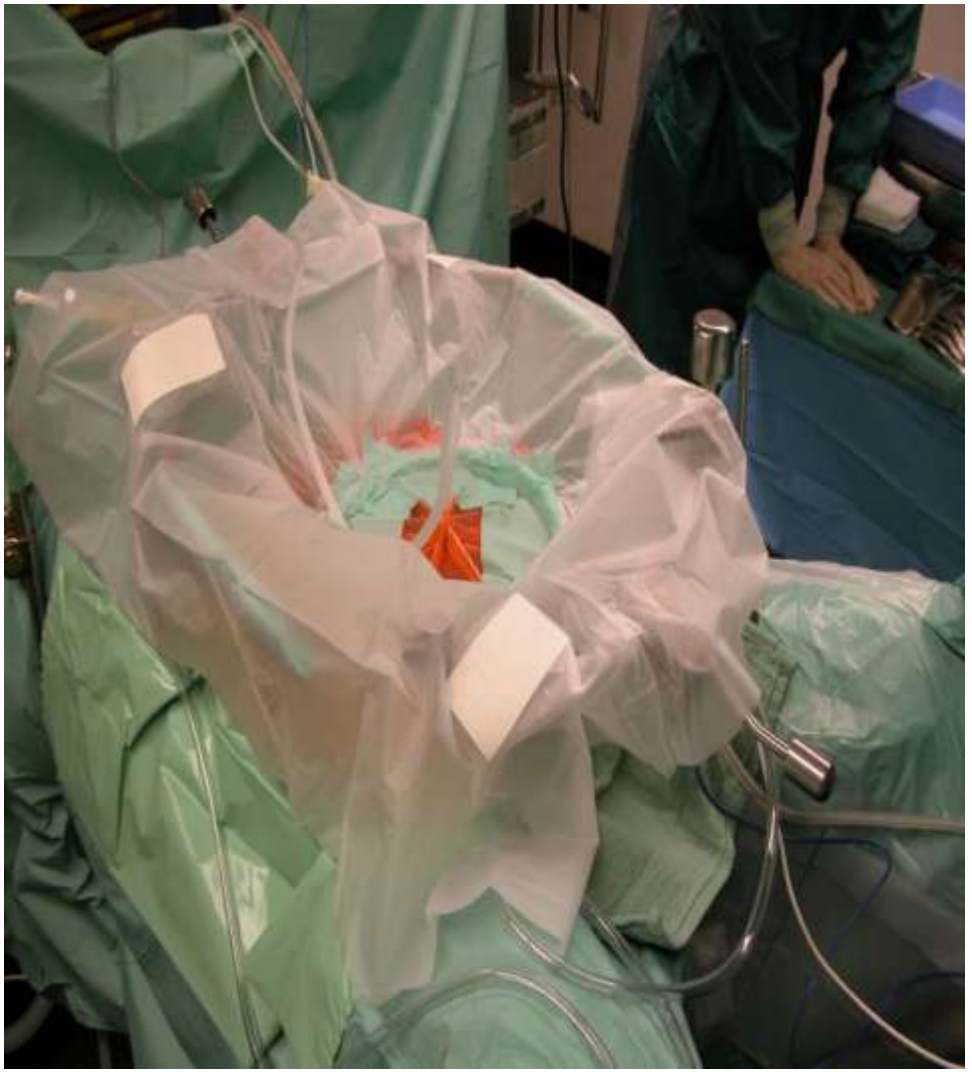
NIOSH/CDC: Work Practices

- The smoke evacuator or room suction hose nozzle inlet must be kept within 2 inches of the surgical site.
- The smoke evacuator should be ON (activated) at all times when airborne particles are produced.
- Health care workers should follow standard precautions.

AORN
GO CLEAR AWARD
Surgical Smoke-Free Recognition Program

ШАГ 4 : Splash Screen

Fig. 1. Intraperitoneal chemotherapy containment instrument. The instrument provides a fixed access portal above the open abdominal incision for the surgeon's double-gloved hand to manually distribute the heated chemotherapy solution. [Color figure can be viewed in the online issue, available at www.interscience.wiley.com.]



ШАГ 5 : Spillage Recovery Sets

ШАГ 6 : Accidental Contact

Measures after accidental contact with cytotoxic agents

- **Eye Contact**
  - Flush the affected eye(s) of clean water or normal saline
  - minimum 15 minutes
- **Skin Contact**
  - Remove any contaminated clothing
  - Wash the affected area with soap and water
  - minimum of 15 minutes
- **Skin Punctures**
  - Wash the puncture site thoroughly with soap and running water
  - 15 minutes.
  - Allow wound to bleed freely
  - Refer to extravasation policy
- **Obtain medical attention**
- **Document exposure in employee's medical record and medical surveillance log**

Выводы

- Be aware of the risks involved
- Involve the nursing unions !!
- EDUCATE yourself, OR staff, ICU staff,..
- Have a protocol at hand and stick to it
- Spillage sets !