NIOSH Hazardous Drugs List Update

Larry Reed and Tom Connor, NIOSH

Public Meeting -- August 28, 2007

Purpose

To obtain and discuss comments on the definition of hazardous drugs and the proposed updated list of drugs.

- Welcome and introductions

CDC Workplace Safety and Health

National Institute for Occupational Safety and Health NIOSH

NIOSH HAZARDOUS DRUGS LIST UPDATE
Agenda

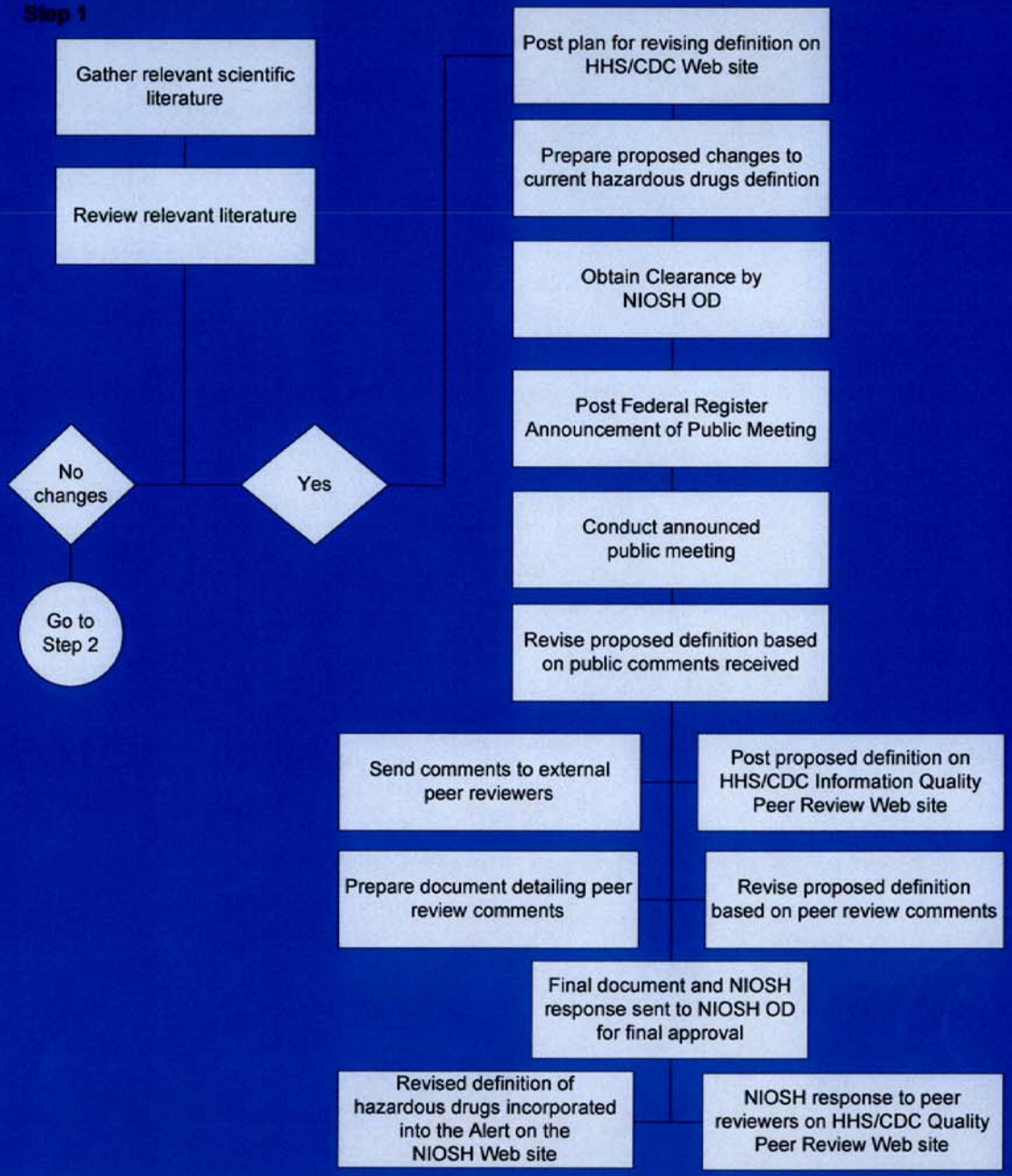
9:00 – 9:15 am	Welcoming remarks and introductions
9:15 – 10:00 am	NIOSH presentation on the process for updating the definition and list of Hazardous Drugs
10:00 – 10:30 am	Questions and presentations by public about the definition
10:30 – 10:45 am	Break
10:45 – 11:30 am	Questions and presentations by public about the list
11:30 – 12:45 pm	Lunch
12:45 – 2:15 pm	Questions and presentations by public about the list
2:15 – 2:30 pm	Break
2:30 – 4:00 pm	Questions and presentations by public about the list
4:00 – 5:00 pm	NIOSH closing remarks and plan/timeframe for finalizing definition and list
5:00 pm	Adjourn

NIOSH ALERT

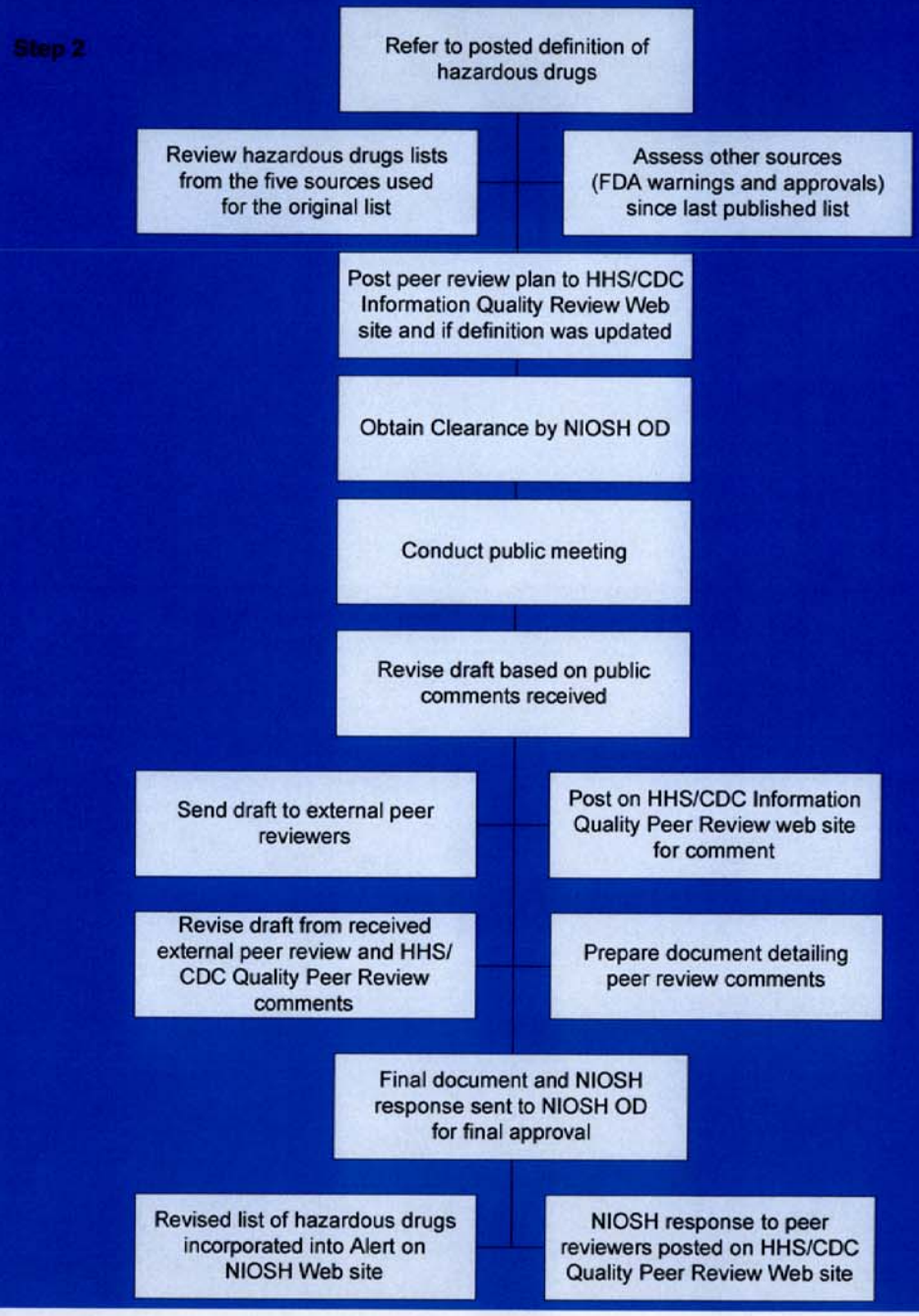
Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

Process to Review & Update the Definition of Hazardous Drugs

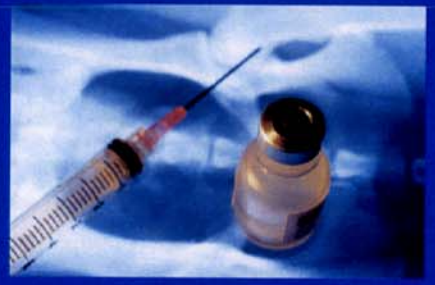


Process to Review & Update the List of Hazardous Drugs

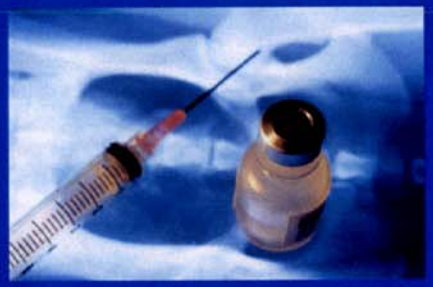


NIOSH Hazardous Drug Group

- Thomas Connor
- Barbara MacKenzie
- Jim O'Callaghan
- Larry Reed
- Doug Trout



Panel of Expert Reviewers



- Caroline Freeman (OSHA)
- Melissa McDiarmid (U Maryland)
- Bruce Naumann (Merck & Co, Inc.)
- Marty Polovich (ONS)
- Cynthia Reilley (ASHP)
- Chuck Schwartz (Pfizer Global Environment, Health, and Safety/PhRMA)
- Debora Van der Sluis (Genentech/BIO)
- S. Leigh Verbois (FDA)
- Katie Slavin (ANA)
- Vernon Wilkes (VHA)

Current NIOSH Definition of Hazardous Drugs

- Carcinogenicity
- Teratogenicity or other developmental toxicity ††
- Reproductive toxicity ††
- Organ toxicity at low doses ††
- Genotoxicity ‡ ‡
- Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria.

Current NIOSH Definition of Hazardous Drugs

†† All drugs have toxic side effects, but some exhibit toxicity at low doses. The level of toxicity reflects a continuum from relatively nontoxic to production of toxic effects in patients at low doses (for example, a few milligrams or less). For example, a daily therapeutic dose of 10 mg/day or a dose of 1 mg/kg per day in laboratory animals that produces serious organ toxicity, developmental toxicity, or reproductive toxicity has been used by the pharmaceutical industry to develop occupational exposure limits (OELs) of less than 10 µg/m3 after applying appropriate uncertainty factors [Sargent and Kirk 1988; Naumann and Sargent 1997; Sargent et al. 2002]. OELs in this range are typically established for potent or toxic drugs in the pharmaceutical industry. Under all circumstances, an evaluation of all available data should be conducted to protect health care workers.

‡‡In evaluating mutagenicity for potentially hazardous drugs, responses from multiple test systems are needed before precautions can be required for handling such agents. The EPA evaluations include the type of cells affected and in vitro versus in vivo testing [51 Fed. Reg. 34006–34012 (1986)].

Current NIOSH List of Hazardous Drugs

- Based on 6 criteria in definition
- 136 Drugs
- 89 Antineoplastics (AHFS)
- Others
  - Antivirals
  - Immunosuppressants
  - Hormonal agents
  - Monoclonal antibodies

Current NIOSH List of Hazardous Drugs

- The NIH Clinical Center, Bethesda, MD (Revised 8/2002)
- The Johns Hopkins Hospital, Baltimore, MD (Revised 9/2002)
- The Northside Hospital, Atlanta, GA (Revised 8/2002)
- The University of Michigan Hospitals and Health Centers, Ann Arbor, MI (Revised 2/2003)
- PhRMA (2004)

Current FDA Warning for Cytotoxic Anticancer Drugs

"Procedures for proper handling and disposal of anticancer drugs should be considered. Several guidelines on this subject have been published. There is no general agreement that all of the procedures recommended in the guidelines are necessary or appropriate."

Update to the NIOSH List of Hazardous Drugs (2007)

- All new FDA drug approvals since 2004
- All new FDA drug warnings since 2004
- Current NIH list of hazardous drugs

Drugs Reviewed for 2007 Update

Based on these three sources:

- 62 Drugs fit the NIOSH definition of a hazardous drug
- 87 Drugs do not fit the NIOSH definition of a hazardous drug

Summary of Process for Updating List of Hazardous Drugs

1) NIOSH review group

2) Public comment
   a) Public meeting (8/28)
   b) NIOSH docket (closes 9/20)

3) External peer review panel

4) NIOSH finalizes updated list of hazardous drugs

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CDC Workplace Safety and Health

NIOSH National Institute for Occupational Safety and Health