Dragon, Karen E. (CDC/NIOSH/EID)

From: Laura Beamer [LABeamer@comcast.net]
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To: NIOSH Docket Office (CDC)
Subject: Pregnant oncology workers
Attachments: Chemotherapy Safety.pdf; 29cfr1604.10.pdf; Declared Pregnancy Form_UMich.pdf; TeratogenUpdate_PaternalExposures_60pg161.pdf; Review of Standards of Protection for Pregnant Workers and their Offspring.pdf; 20060926ACOGPositionStatementHB1215-2.pdf; RegGuide8-13_Prenatal_Radiation_Exposure.pdf

The attachments focus on pregnant oncology workers and the administration of therapeutic radiation treatments. Some of the information can be extrapolated to antineoplastic agent administration. Please be certain to consider male oncology care providers seeking to create a pregnancy as well as female workers planning to become pregnant.

An alternative assignment does not necessarily mean transfer to another unit. It can be as simple as not assigning the pregnant/lactating/trying to become a parent healthcare worker to do specific tasks. For example, pregnant workers do not administer antineoplastics, but may monitor patients who are receiving them. Or, pregnant workers are not assigned to the patient that just received radioactive 131-iodine for thyroid cancer.

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Chemotherapy Safety

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1. A hazardous drug that causes teratogenicity has which of the following characteristics?
   a. The ability to cause cancer in animal models, humans, or both
   b. The ability to cause a change or mutation in the genetic material
   c. The ability to cause defects in fetal development or fetal malformation
   d. The ability to cause fertility impairment and adverse reproductive outcomes
2. A plastic face shield should be worn when administering
   a. Oral hydroxyurea.
   b. IV cyclophosphamide.
   c. Intramuscular methotrexate.
   d. Bladder instillation of Bacillus Calmette Gue'rin (BCG).
3. A small amount of chemotherapy splashes on a nurse's skin. What should be the nurse's immediate action?
   a. Wash the affected area with soap and water.
   b. Go to the emergency room or employee health.
   c. Wash the affected area with a 10% bleach solution.
   d. No action is necessary because the exposure was minimal.
4. Which of the following practices results in the greatest risk of releasing a hazardous drug into the environment when priming IV tubing?
   a. Using a dry-spike extension and backflow technique
   b. Using a closed system with a connector attached to the bag before the drug is added
   c. Connecting the tubing to a patient when it is primed with a solution containing a hazardous drug
   d. Spiking an IV bag and priming the tubing before adding a hazardous drug while in a biologic safety cabinet
5. A small spill is defined as
   a. Less than 5 ml or 5 g.
   b. Less than 15 ml or 15 g.
   c. Less than 25 ml or 25 g.
   d. Greater than 150 ml inside a biologic safety cabinet.
6. Which one of the following classes of biologic agents must be handled according to Occupational Safety and Health Administration guidelines for cytotoxic agents?
   a. Interferons
   b. Interleukins
   c. Monoclonal antibodies
   d. Hematopoietic growth factors
7. A patient who completed an infusion of chemotherapy 24 hours ago is incontinent of urine at home. What is the appropriate way for the family to handle contaminated linens?
   a. No special precautions are necessary because the chemotherapy was completed 24 hours ago.
   b. Place linens into the washer separately and wash twice with regular detergent and hot water.
   c. Place linens into the washer with regular household laundry and wash with regular detergent and hot water.
   d. Place all contaminated linens separately in a leak-proof bag and dispose of them in the commercial trash.
8. Education and orientation of nurses related to chemotherapy administration should include
   a. Hands-on experience in the work setting with a mentor.
   b. A test to assess knowledge of chemotherapy administration.
   c. A chemotherapy course based on Oncology Nursing Society (ONS) guidelines six months after orientation.
   d. A chemotherapy course based on the ONS guidelines and hands-on clinical practicum with an evaluation.
9. When a nurse is administering chemotherapy, it splashes into one eye. What should the nurse's first action be?
   a. Go to occupational health.
   b. Go to the emergency room.
   c. Notify the manager or supervisor.
   d. Wash the eye with water for 15 minutes.
10. The nurse's competency related to chemotherapy administration should be evaluated at least
    a. Yearly.
    b. Every two years.
    c. Every two months.
    d. After completion of orientation.
11. What information does a pregnant nurse need to know regarding chemotherapy administration?
    a. Chemotherapy administration during the first trimester represents a risk only to the fetus.
    b. Nurses can administer chemotherapy throughout pregnancy without risk of harm to the fetus from exposure.
    c. Nurses can administer chemotherapy during the last two trimesters of pregnancy without risk of harm to the fetus from exposure.
    d. Chemotherapy administration any time during pregnancy or breastfeeding is a potential exposure risk and should be avoided.

Answers

Question 1: The correct answer is choice c, the ability to cause defects in fetal development or fetal malformation. Patients receiving chemotherapy and people with occupational exposure to chemotherapy are at risk for this toxicity (Polovich, 2003). Choice a, the ability to cause cancer in animal models, humans, or both, is incorrect. This is the definition of carcinogenicity. Choice b, the ability to cause a change or mutation in the genetic material, is incorrect. This is the

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definition of genotoxicity. Choice d, the ability to cause fertility impairment and adverse reproductive outcomes, also is incorrect. This is the definition of fertility impairment.

Question 2: The correct answer is choice d, bladder instillation of BCG. A plastic face shield or goggles should be worn in any situation where eye, mouth, or nasal splashing or aerosolization is possible, such as with bladder instillation of hazardous drugs (Polovich, 2003). The other choices, a, oral hydroxyurea, b, IV cyclophosphamide, and c, intramuscular methotrexate, are incorrect because they do not pose as great a risk of eye, mouth, or nasal splashing or aerosolization.

Question 3: The correct answer is choice a, wash the affected area with soap and water (Brown et al., 2001; Nevidjon & Sowers, 2000; OSHA, 1995; Polovich, 2003). Choice b, go to the emergency room or employee health, is incorrect because this is the next step after washing with soap and water. Choice c, wash the affected area with a 10% bleach solution, is incorrect. Direct skin exposure to bleach is not a recommended method of cleansing cytotoxic agents from the body. Choice d, no action is necessary because the exposure was minimal, is incorrect because any amount of direct skin exposure requires immediate action.

Question 4: The correct answer is choice c, connecting the tubing to a patient when it is primed with a solution containing a hazardous drug (American Society of Hospital Pharmacists [ASHP], 1990; OSHA, 1995; Polovich, 2003). Choices a, using a dry-spike extension and backflow technique, b, using a closed system with a connector attached to the bag before the drug is added, and d, spiking an IV bag and priming the tubing before adding a hazardous drug while in a biologic safety cabinet, are incorrect. These measures are effective at decreasing the risk of releasing a hazardous drug into the environment when priming IV tubing.

Question 5: The correct answer is choice a, less than 5 ml or 5 g (Brown et al., 2001; OSHA, 2003; Polovich, 2003). Nurses must be able to distinguish between small and large spills because different safety procedures are employed for each. In some facilities, large spills require notification of specially trained individuals. Large spills often require limiting access to the area during the clean-up procedure. Choices b, less than 15 ml or 15 g, and c, less than 25 ml or 25 g, are incorrect. Any spill more than 5 ml or 5 g is classified as a large spill. Choice d, greater than 150 ml inside a biologic safety cabinet, is incorrect because a spill that is greater than 150 ml in volume of solution, diluted or undiluted, needs to be followed by decontamination of the safety cabinet.

Question 6: The correct answer is choice a, interferons. OSHA has identified interferons as hazardous agents, and they must be handled according to OSHA guidelines for cytotoxic agents (Brown et al., 2001; OSHA, 1995). Choices b, interleukins, c, monoclonal antibodies, and d, hematopoietic growth factors, are incorrect. No current evidence suggests that these biologic agents meet any of the current criteria for classification as hazardous: carcinogenicity, genotoxicity, teratogenicity, fertility impairment, or serious organ toxicity at low doses.

Question 7: The correct answer is choice b, place linens into the washer separately and wash twice with regular detergent and hot water (ASHP, 1990; Goodman, 2000; OSHA, 1995; Polovich, 2003). Choice a, no special precautions are necessary because the chemotherapy was completed 24 hours ago, is incorrect because 48 hours is considered the standard time for most chemotherapy drugs to be excreted from the system, so the linens still are considered contaminated. Choice c, place linens into the washer with regular household laundry and wash with regular detergent and hot water, is incorrect because contaminated linens should be washed separately from other household laundry. Choice d, place all contaminated linens separately in a leak-proof bag and dispose of them in the commercial trash, also is incorrect. This is an inappropriate method for handling contaminated materials.

Question 8: The correct answer is choice d, a chemotherapy course based on the ONS guidelines and hands-on clinical practicum with an evaluation (Brown et al., 2001). Choices a, hands-on experience in the work setting with a mentor, b, a test to assess knowledge of chemotherapy administration, and c, a chemotherapy course based on the ONS guidelines six months after orientation, all fall short of current ONS guidelines for safe administration of chemotherapeutic agents and do not contain all of the recommended nurse education and orientation components.

Question 9: The correct answer is choice d, wash the eye with water for 15 minutes. The immediate action should be to wash out the eye to prevent or reduce damage from chemotherapy exposure. The eye wash station should be capable of delivering water for 15 minutes. Eyewash facilities should be made available to employees working with cytotoxic agents in the workplace (OSHA, 2003). Choices a, go to occupational health, b, go to the emergency room, and, c, notify the manager or supervisor, are incorrect. Depending on institutional policy, these steps may or may not be recommended. Regardless, these steps should be followed after the eye has been thoroughly irrigated.

Question 10: The correct answer is choice a, yearly. Annual competency of RNs who administer chemotherapy is recommended (ASHP, 1990; Brown et al., 2001). The other choices, b, every two years, c, every two months, and d, after completion of orientation, are incongruent with ONS guidelines.

Question 11: The correct answer is choice d, chemotherapy administration any time during pregnancy or breastfeeding is a potential exposure risk and should be avoided (Brown et al., 2001). OSHA (1995), ASHP (1990), and Brown et al. stated that nurses should consider the risk and make an informed decision about handling chemotherapy while pregnant or breastfeeding. Exposure to chemotherapy during pregnancy can be harmful to the fetus, and many drugs are present in breast milk. Choices a, chemotherapy administration during the first trimester represents a risk only to the fetus, b, nurses can administer chemotherapy throughout pregnancy without risk of harm to the fetus from exposure, and c, nurses can administer chemotherapy during the last two trimesters of pregnancy without risk of harm to the fetus from exposure, are incorrect because chemotherapy administration poses a potential risk to the fetus throughout pregnancy.

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or indirectly any limitation, specification, or discrimination as to sex shall be unlawful unless based upon a bona fide occupational qualification.

§ 1604.8 Relationship of title VII to the Equal Pay Act.

(a) The employee coverage of the prohibitions against discrimination based on sex contained in title VII is coextensive with that of the other prohibitions contained in title VII and is not limited by section 703(h) to those employees covered by the Fair Labor Standards Act.

(b) By virtue of section 703(h), a defense based on the Equal Pay Act may be raised in a proceeding under title VII.

(c) Where such a defense is raised the Commission will give appropriate consideration to the interpretations of the Administrator, Wage and Hour Division, Department of Labor, but will not be bound thereby.

§ 1604.9 Fringe benefits.

(a) "Fringe benefits," as used herein, includes medical, hospital, accident, life insurance and retirement benefits; profit-sharing and bonus plans; leave; and other terms, conditions, and privileges of employment.

(b) It shall be an unlawful employment practice for an employer to discriminate between men and women with regard to fringe benefits.

(c) Where an employer conditions benefits available to employees and their spouses and families on whether the employee is the "head of the household" or "principal wage earner" in the family unit, the benefits tend to be available only to male employees and their families. Due to the fact that such conditioning discriminatorily affects the rights of women employees, and that "head of household" or "principal wage earner" status bears no relationship to job performance, benefits which are so conditioned will be found a prima facie violation of the prohibitions against sex discrimination contained in the act.

(d) It shall be an unlawful employment practice for an employer to make available benefits for the wives and families of male employees where the same benefits are not made available for the husbands and families of female employees; or to make available benefits for the wives of male employees which are not made available for female employees; or to make available benefits to the husbands of female employees which are not made available for male employees. An example of such an unlawful employment practice is a situation in which wives of male employees receive maternity benefits while female employees receive no such benefits.

(e) It shall not be a defense under title VIII to a charge of sex discrimination in benefits that the cost of such benefits is greater with respect to one sex than the other.

(f) It shall be an unlawful employment practice for an employer to have a pension or retirement plan which establishes different optional or compulsory retirement ages based on sex, or which differentiates in benefits on the basis of sex. A statement of the General Counsel of September 13, 1968, providing for a phasing out of differentials with regard to optional retirement age for certain incumbent employees is hereby withdrawn.

§ 1604.10 Employment policies relating to pregnancy and childbirth.

(a) A written or unwritten employment policy or practice which excludes from employment applicants or employees because of pregnancy, childbirth or related medical conditions is in prima facie violation of title VII.

(b) Disabilities caused or contributed to by pregnancy, childbirth, or related medical conditions, for all job-related purposes, shall be treated the same as disabilities caused or contributed to by other medical conditions, under any health or disability insurance or sick leave plan available in connection with employment. Written or unwritten employment policies and practices involving matters such as the commencement and duration of leave, the availability of extensions, the accrual of seniority and other benefits and privileges, reinstatement, and payment under any health or disability insurance or sick leave plan, formal or informal, shall be applied to disability due to pregnancy, childbirth or related medical conditions on the same terms

and conditions as they are applied to other disabilities. Health insurance benefits for abortion, except where the life of the mother would be endangered if the fetus were carried to term or where medical complications have arisen from an abortion, are not required to be paid by an employer; nothing herein, however, precludes an employer from providing abortion benefits or otherwise affects bargaining agreements in regard to abortion.

(c) Where the termination of an employee who is temporarily disabled is caused by an employment policy under which insufficient or no leave is available, such a termination violates the Act if it has a disparate impact on employees of one sex and is not justified by business necessity.

(d)(1) Any fringe benefit program, or fund, or insurance program which is in effect on October 31, 1978, which does not treat women affected by pregnancy, childbirth, or related medical conditions the same as other persons not so affected but similar in their ability or inability to work, must be in compliance with the provisions of §1604.10(b) by April 29, 1979. In order to come into compliance with the provisions of 1604.10(b), there can be no reduction of benefits or compensation which were in effect on October 31, 1978, before October 31, 1979 or the expiration of a collective bargaining agreement in effect on October 31, 1978, whichever is later.

(2) Any fringe benefit program implemented after October 31, 1978, must comply with the provisions of §1604.10(b) upon implementation.

[44 FR 23805, Apr. 20, 1979]

§1604.11 Sexual harassment.

(a) Harassment on the basis of sex is a violation of section 703 of title VII.[1] Unwelcome sexual advances, requests for sexual favors, and other verbal or physical conduct of a sexual nature constitute sexual harassment when (1) submission to such conduct is made either explicitly or implicitly a term or condition of an individual's employment, (2) submission to or rejection of such conduct by an individual is used as the basis for employment decisions affecting such individual, or (3) such conduct has the purpose or effect of unreasonably interfering with an individual's work performance or creating an intimidating, hostile, or offensive working environment.

(b) In determining whether alleged conduct constitutes sexual harassment, the Commission will look at the record as a whole and at the totality of the circumstances, such as the nature of the sexual advances and the context in which the alleged incidents occurred. The determination of the legality of a particular action will be made from the facts, on a case by case basis.

(c) [Reserved]

(d) With respect to conduct between fellow employees, an employer is responsible for acts of sexual harassment in the workplace where the employer (or its agents or supervisory employees) knows or should have known of the conduct, unless it can show that it took immediate and appropriate corrective action.

(e) An employer may also be responsible for the acts of non-employees, with respect to sexual harassment of employees in the workplace, where the employer (or its agents or supervisory employees) knows or should have known of the conduct and fails to take immediate and appropriate corrective action. In reviewing these cases the Commission will consider the extent of the employer's control and any other legal responsibility which the employer may have with respect to the conduct of such non-employees.

(f) Prevention is the best tool for the elimination of sexual harassment. An employer should take all steps necessary to prevent sexual harassment from occurring, such as affirmatively raising the subject, expressing strong disapproval, developing appropriate sanctions, informing employees of their right to raise and how to raise the issue of harassment under title VII, and developing methods to sensitize all concerned.

(g) Other related practices: Where employment opportunities or benefits are granted because of an individual's submission to the employer's sexual advances or requests for sexual favors,

[1] The principles involved here continue to apply to race, color, religion or national origin.

Declaration of Pregnancy Form RSS-105A

The Declaration of Pregnancy Form RSS-105A provides the formal means by which a pregnant occupational radiation worker voluntarily notifies Radiation Safety Service (RSS) of her choice to authorize the application of federal and/or state radiation dose limits to an embryo/fetus as a condition of her radiation related work at the University of Michigan. A declaration of pregnancy to the Department of Occupational Safety & Environmental Health - Radiation Safety Service can only be made by use of this form. **Complete and submit this form only if you knowingly and voluntarily intend to declare your pregnancy to RSS.**

The choice of whether to declare one's pregnancy is a personal one and is to be an informed one. A pregnant occupational radiation worker needs to be cognizant of information supplied by the NRC, the University of Michigan-Radiation Policy Committee (RPC) and RSS as to the potential health effects from radiation to herself and to an embryo/fetus. RSS supplies written instructional material discussing such potential effects and will assist the pregnant worker in understanding the material contained therein so as to allow her to make an informed choice.

Revocation, Expiration and Lapse of Declarations of Pregnancy

Revocation: A declared pregnant worker may voluntarily revoke her declaration of pregnancy at any time and for any reason without explanation. This can be done whether or not pregnancy has concluded. However, revocations can only be made through the submission to RSS of a signed and dated Revocation of Declaration of Pregnancy Form (RSS- 105B) to RSS. Revocation forms are available from RSS.

Expiration: A declaration of pregnancy automatically expires when the associated condition of pregnancy actually ceases or upon termination of employment as an occupational radiation worker with the University of Michigan. A declared pregnant worker should provide RSS with a signed and dated written notice of the expiration of the declaration of pregnancy. This can be done by completing and submitting a Pregnancy Declaration Expiration Form (RSS-105C).

Lapse: RSS reserves the option to deem that a declaration of pregnancy has lapsed and no longer is in effect on the earlier of either: 1) 60 days after the estimated date of delivery designated by the declarant on the form of declaration; or 2) one year after the date of receipt of the declaration form at RSS offices.

Limitations

The Declaration of Pregnancy Form (RSS-105A), the Revocation of Declaration of Pregnancy Form (RSS-105B) and the Pregnancy Declaration Expiration Form (RSS-105C) serve the sole purpose of providing the means of election and choice in compliance with NRC dose limit rules and regulations. It does not serve as actual or

implied notice to any other department or unit within the University of Michigan regarding the declarant's physical status or condition.

Privacy

The information contained in the Declaration of Pregnancy Form (RSS-105A), the Revocation of Declaration of Pregnancy Form (RSS-105B) and the Pregnancy Declaration Expiration Form (RSS-105C) constitutes a record subject to the confidentiality provisions of applicable federal and/or state privacy laws and becomes part of the declarant's confidential record with RSS.

Issuance of Dosimeter

If you declare your pregnancy, you will be issued dosimeters and receive reports of results periodically to help monitor the dose to the fetus during the course of your pregnancy. In most instances, those dosimeters will be in addition to dosimeters you may already be receiving. A fetal monitor dosimeter usually will have a monthly wear period and, upon completion of each wear period, it will be exchanged with a replacement. You may elect to either: 1) arrange to personally collect fetal monitor dosimeters and corresponding reports at RSS offices at the start of each wear period; 2) have the fetal monitor dosimeters and reports delivered directly to you at your work address by campus mail; or 3) have the fetal monitor dosimeters and reports delivered in the usual manner to the contact person designated for the dosimeter series assigned to the authorized user or facility where you work. You will continue to receive other dosimeters that you get routinely to monitor your own dose, if any, in the usual manner through your dosimetry series contact person.