

There has been an increase in the number of female Veterans receiving care at Veterans Health Administration (VHA) facilities,¹ and many of these female Veterans are of childbearing age. Nearly half of pregnancies in the United States are unplanned, and women of childbearing age are at risk of receiving medications that increase the potential for birth defects or pregnancy loss. The Joint Commission (JC) requires patient-specific information to be readily accessible to those involved in the medication management and the monitoring of high-risk or high-alert drugs, including medications that carry a higher risk for adverse outcomes.

The current version of the VHA's Veterans Health Information Systems and Technology Architecture (Vista) and Computerized Patient Record System (CPRS) software does not provide any information to the provider that a particular medication is teratogenic. Teratogens are drugs (including medications), chemicals, or other exposures, like radiation, that can interfere with normal embryonic/fetal development and thus, may lead to birth defects or pregnancy loss. In addition, there is a group of medications that pose a potential risk to breastfed infants. The requested enhancements will provide a notification or alert to prevent inadvertent prescribing of teratogenic medications to patients who are pregnant or at risk for pregnancy and inadvertent prescribing of medications of potential risk to breastfed infants for patients who are lactating.

The notification or alert will prompt the provider to consider whether to initiate or continue a medication for a patient who is pregnant or lactating and will provide an opportunity for counseling and consideration of appropriate therapeutic alternatives for female patients who are pregnant, lactating, or of childbearing potential. For the purposes of this document and all efforts related to the T Drugs project, the term "High Risk Medication" is defined as any medication that is a known or potential teratogen or poses a risk to a breastfed infant.

Since 1979, the Food and Drug Administration (FDA) has used a five-category system (Pregnancy Categories A, B, C, D, X, see Exhibit 1.3.2) for classifying medications based upon their teratogenic potential. Each category is defined by the presence or absence of data, the source of the data (animal and/or human) and the results of the studies (positive findings or negative). Some categories (D and X) also include consideration of the drug's benefits to the mother as well as the potential risks to the fetus. Category A and B medications are generally considered safe to use during pregnancy based on no evidence of increased pregnancy loss, birth defects, or growth abnormalities in adequate and well controlled human studies and/or animal studies. Medications receive a Category C if animal studies showed an increased risk for either pregnancy loss or birth defects. Based on the severity, frequency, and consistency of abnormal findings and the dose at which they occurred, animal studies may raise different levels of concern about embryofetal risk in humans. Category D drugs are known human teratogens; however, only some pregnancies exposed to these medications result in miscarriage or a fetus with birth defects. Some category D medications (e.g. anti-seizure drugs) offer great benefit to pregnant women who need them, and sometimes this benefit outweighs the increased risk of birth defects to the fetus. Category X medications are contraindicated in women who are or may become pregnant, because the risk of use during pregnancy always outweighs the clinical benefit to the mother.

The Joint Commission (JC) requires that patient-specific information to be readily accessible to those involved in the medication management. Included in the information needed about the patient includes pregnancy and lactation status. In addition, the JC requires monitoring of high-risk or high-alert drugs, including medications that carry a higher risk for adverse outcomes. It is up to the hospital to determine which medications are high-risk or high-alert drugs.

The Office of Information (OI) Health Data & Informatics Patient Safety Office has reviewed this request and assigned it a patient safety score of 46. Requests with a score of 24 or higher present a significant risk for an adverse event to occur and are to be addressed in the first available software release. CPRS provides the ordering provider with order checks, notifications and alerts. An order check is a component of CPRS that reviews orders as they are placed to see if they meet certain defined criteria that might cause the clinician placing the order to change or cancel the order or provide additional counseling to the patient (e.g., duplicate orders, drug-drug/diet/lab test interactions, etc.). Notifications are messages that alert, provide information, or prompt the clinician to act on a clinical event, such as a critical lab value. Notifications are displayed on the bottom of the Patient Selection screen for a predetermined amount of time. Currently, there are no order checks, notifications or alerts for High Risk Medications.

As currently configured, the Women's Health (WV) application provides the ability to document if a patient is pregnant (see documentation in the WV technical notes). The Radiology application provides a prompt to the provider when the order is placed asking if the patient is pregnant at the time of the order. Pregnancy status is also printed on the Radiology request. There is no sharing of information entered into the WV and Radiology applications.

There is no national Clinical Reminder for pregnancy and lactation. The information contained in the WV and Radiology applications and local Clinical Reminders is not presented to the prescribing clinician during the medication ordering process, nor with the Pharmacist when the order is finished. Women are at the greatest risk for harmful effects of potentially teratogenic medications during the first trimester when they may not even be aware of the fact that they are pregnant. Ideally, it would be important to identify women who plan to get pregnant or are at risk of becoming pregnant so that appropriate counseling and medication adjustments could be made in advance. Neither CPRS nor VistA provides support for identification of women who may become pregnant.