Harnessing Health Information Technology to Prevent Medication-Induced Birth Defects

Principal Investigator: Schwarz, Eleanor, M.D.
Organization: University of Pittsburgh at Pittsburgh
Mechanism: RFA: HS07-006: Ambulatory Safety and Quality Program: Improving Quality Through Clinician Use of Health Information Technology (IQHIT)
Grant Number: R18 HS 017093
Project Period: September 2007 – September 2011, Including No-Cost Extension
AHRQ Funding Amount: $1,199,370
Summary Status as of: December 2010

Target Population: Women

Summary: Each year, 150,000 infants – one to three percent of all births in the United States – are born with some form of physical or mental birth defect. The Institute of Medicine has identified prevention of birth defects as one of six national priorities. It is estimated that each year, 12 million women in the United States use medications that might increase the risk of birth defects if used during pregnancy. However, studies show that the concurrent use of contraception with such medications can prevent associated birth defects. Unfortunately, when prescribing potentially teratogenic medications, medications that may disturb the growth or development of the embryo, clinicians rarely counsel women about contraception, and approximately six percent of pregnant women are exposed to medications that may increase the risk of birth defects.

This project proposed to develop and rigorously evaluate ways that health information technology (IT) may help doctors counsel women about preventing birth defects that could be caused by the use of certain medications. Dr. Schwarz and her project team began by conducting a series of focus groups with clinicians and patients seen in academic and community-based practices in order to find out what information would be most useful to primary care clinicians and their patients.

Data from the focus group discussions were used to refine the two distinct health IT application interventions: 1) multi-faceted clinical decision support (CDS), and 2) the networked tablet computer’s electronic collection of machine-actionable information about women’s risk of pregnancy. The impact of each of these interventions is being evaluated using a factorial design randomized controlled trial. In the first trial, multi-faceted CDS (intervention) is being compared to streamlined clinical alerts (control). The second trial evaluates whether collecting machine-actionable information about women’s risk of pregnancy using a networked tablet computer (intervention) is superior to the way clinicians usually collect this information (control).

Data from the following sources were collected to inform the study: 1) data abstracted from the electronic medical record (EMR) when clinicians prescribed teratogenic medications; 2) phone interviews conducted with women prescribed medications by study clinicians; and 3) participating clinicians surveyed about their satisfaction with the CDS they received. These data are being used to confirm the hypotheses that clinicians in the intervention groups will prescribe fewer teratogenic medications, be more likely to
prescribe contraception when prescribing a teratogenic medication, have more patients report satisfaction with the counseling they received, and report more satisfaction with the CDS they received. All of the practice sites use the EpicCare EMR system.

This evaluation will provide much-needed information on how health IT can best be harnessed to prevent medication-induced birth defects nationwide. The health IT intervention shown to be most effective will be implemented throughout the University of Pittsburgh Medical Center (UPMC), which supports three million outpatient visits each year.

**Specific Aims:**

- Develop and implement two CDS systems designed to alert ambulatory clinicians to the risk of medication-induced birth defects. *(Achieved)*
- Evaluate the effect of two CDS systems designed to alert ambulatory clinicians to the risk of medication-induced birth defects. *(Ongoing)*

**2010 Activities:** In 2009, decision support was rolled out across UPMC’s outpatient clinics. In 2010, project staff abstracted real-time data from the EMR to assess use of the CDS system and impact on prescription of teratogenic medications and concordant prescription of contraceptives, and collected surveys from study clinics’ clinicians and patients. The data from these sources were merged to permit assessment of the CDS across control and intervention study arms.

Data analysis and manuscript writing were the primary focuses for the research team in 2010. The team assessed the data collected from four focus groups with women of reproductive age, using a grounded theory approach to content analysis, and produced two manuscripts which were published in 2010. In preliminary analyses of the EMR data, two important issues were identified. First, the team found that the CDS system was not activated for participating resident physicians. As a result, study analyses will be adjusted and this limitation will be described in manuscripts. The project team also determined that approximately 13 percent of providers responded to the alerts generated by the CDS system by prescribing an alternate medication that was also potentially teratogenic. As the CDS system was only designed to issue one alert, the clinician was not alerted if the newly prescribed medication was also potentially teratogenic. To respond to this unintended consequence, the team is looking into modifying the system so that physicians will be alerted to any risks that may result from a newly prescribed medication. In 2011, the team will complete further analyses of the EMR data that incorporate information provided by the physician and patient surveys.

**Grantee’s Most Recent Self-Reported Quarterly Status (as of December 2010):** The project is progressing well overall despite the fact that the CDS system was never activated for some participating clinicians. Dr. Schwarz reports that the project is mostly on track and spending is roughly on target.

**Preliminary Impact and Findings:** Three types of barriers to contraception counseling were identified during the clinician focus groups: barriers at the patient, provider, and health system levels. The providers identified patient contraceptive method of preference, outside influences, already on birth control, desire for pregnancy, religion, patient discomfort, and sexual activity confidentiality as patient level barriers to counseling. The bulk of the discussion focused on perception of barriers that providers bring to contraception counseling. At the provider level, barriers included: pregnancy risk; lack of knowledge, training, or comfort; beliefs about certain contraceptive methods; a perceived patient
responsibility for initiating discussions; a need for skilled personnel for certain contraceptive methods; and a lack of communication with subspecialists. Finally, health system level challenges regarding contraceptive counseling included lack of insurance or family planning coverage, limitations on time, access to providers trained to fit or insert contraceptive devices, competing medical priorities, visit type, case mix, and lack of a clinical care system to remind providers.

**Strategic Goal:** Develop and disseminate health IT evidence and evidence-based tools to improve the quality and safety of medication management via the integration and utilization of medication management systems and technologies.

**Business Goal:** Synthesis and Dissemination

* AHRQ Priority Population