

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 |
| AHRQ Funding Amount: | \$1,199,370 |

Summary: Every year, approximately 150,000 infants—1-3 percent of all births in the United States—are born with some form of physical or neurological birth defect. In its 2000 publication, *Envisioning the National Healthcare Quality Report*, The Institute of Medicine identified prevention of birth defects as one of six national priorities for the health care system. 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. Studies have also shown that the concurrent use of contraception with such medications can prevent associated birth defects. Unfortunately, when prescribing potentially teratogenic medications that may disturb the growth or development of the embryo, clinicians rarely counsel women about contraception. Due to this issue, approximately 6 percent of pregnant women are exposed to medications that may increase the risk of birth defects.

This project developed and evaluated 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 conducted a series of focus groups with clinicians and patients from academic and community-based practices in order to find out what information regarding birth defects would be most useful to primary care clinicians and their patients. Data from the focus group discussions were used to refine a multi-faceted clinical decision support (CDS) system that was installed within existing electronic medical records (EMRs) in ambulatory care clinics in Pennsylvania.

The impact of the CDS system was evaluated using a cluster-randomized trial. Data from the following sources were collected to inform the study: 1) data abstracted from the 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. The data were used to test the hypotheses that clinicians in the CDS intervention group prescribed fewer teratogenic medications, were more likely to prescribe contraception when prescribing a teratogenic medication, had more patients report satisfaction with the counseling they received, and reported more satisfaction with the CDS they received.

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. **(Achieved)**

2011 Activities: Data analysis and manuscript writing were the primary focuses for the research team. During the analysis of the EMR data, the team found that the CDS system was not turned off at the end of the study and that an extra year of data was available for analysis. Dr. Schwarz received approval from the internal review board to access the additional year of data and the analysis was expanded to include an additional year of CDS alerts. Multi-level models with random effects were developed to address clustering by physician and patient. Patient visits were excluded if the patient saw physicians from both the intervention and control groups. Analyses were adjusted for visit characteristics to control for baseline imbalances. Additional analyses were conducted regarding provider perceptions of counseling patients on contraceptives as well as patient and provider perceptions of CDS.

Dr. Schwarz used a 1-year no cost-extension to allow time to analyze the additional year of data that was generated from the CDS system. As last self-reported in the AHRQ Research Reporting System, project progress and activities was mostly on track, and the project budget spending was roughly on target. The project was completed in August 2011.

Impact and Findings: Three types of barriers to contraceptive counseling were identified during the clinician focus groups: patient, provider, and health system barriers. At the provider level, barriers included limited awareness of pregnancy risk; lack of knowledge, training, or comfort providing contraception; beliefs about certain contraceptive methods; a perceived patient responsibility for initiating discussions; a need for skilled personnel to place certain contraceptive methods; and a lack of communication with subspecialists. Health system-level challenges regarding contraceptive counseling included lack of insurance or family planning coverage; limits on provider time; limited access to providers trained to fit or insert contraceptive devices; competing medical priorities for patients and providers; visit type; case mix; and lack of a clinical care system to remind providers.

Evaluation of the CDS system indicated that multi-faceted CDS and streamlined clinical alerts were both associated with slight increases in family planning services, however there was no difference in the relative improvement between the two arms ($p=0.87$). The multi-faceted CDS group reported a greater increase in the number of times they counseled women about the risks of medication use during pregnancy. The streamlined CDS group reported greater clinician satisfaction with CDS usability ($p=0.03$). Of note, to avoid alert fatigue, the CDS system was designed such that providers were alerted only once after prescribing a potentially teratogenic medication. An unintended consequence of this design was identified in the analysis; 13 percent of providers responded to the alerts by prescribing an alternate medication that was also a potentially teratogenic medication, however, by design a second alert was not generated in these situations. Overall, the CDS showed potential to improve provision of family planning services but further system refinements are necessary.

Target Population: Women*: Pregnancy

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

* This target population is one of AHRQ's priority populations.