

Project Title: Harnessing Health Information Technology to Prevent Medication-Induced Birth Defects

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Organization: University Of Pittsburgh at Pittsburgh

Mechanism: RFA: HS07-006: Ambulatory Safety and Quality Program: Improving Quality through Clinician Use of Health IT (IQHIT)

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Project Period: 09/07 – 08/10

AHRQ Funding Amount: \$1,199,370

Summary Status as of: December 2008

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

Summary: This project was initiated in September 2007 and has completed the first third of the grant period. This project conducts a series of focus groups with clinicians and patients seen in academic and community-based practices to better understand what information about the risk of medication-induced birth defects would be most useful to primary care clinicians and their patients. Data from these discussions are used to refine the two distinct health information technology (IT) application interventions: 1) a multi-faceted decision support, and 2) the network 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 decision support (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). Over the course of a year, data were abstracted from the electronic medical record (EMR) when study clinicians prescribed teratogenic medications, conducted phone interviews with women prescribed medications by participating clinicians, and surveyed participating clinicians about their satisfaction with the decision support they receive. These data are being used to confirm the hypotheses that clinicians in the intervention groups will: 1) prescribe fewer teratogenic medications, 2) be more likely to prescribe contraception when a teratogenic medication is prescribed, 3) have more patients report satisfaction with the counseling they received, and 4) report more satisfaction with the decision support they received. 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 disseminated within the University of Pittsburgh Medical Center (UPMC), which provides 3 million outpatient visits each year.

All of the practice sites have used the EpicCare (Summer 2007) EMR system that has been developed by UPMC through collaboration with the Epic Systems Corporation since 1999. EpicCare, a Certification Commission for Healthcare Information Technology (CCHIT) certified product, supports a patient medication list that is reviewed with each patient encounter. All visit documentation is either typed directly into EpicCare or is dictated, transcribed, and then authenticated online. Results of laboratory testing, imaging studies, and most other tests done in UPMC hospitals are fed directly into the EpicCare system. Transcriptions of most emergency department, inpatient admission, and inpatient discharge notes are automatically filed in EpicCare. UPMC's electronic Medical Archival Record System (MARS) stores additional clinical information from inpatient settings (including all laboratory, imaging, and other test

results, as well as all consult and progress notes dictated about hospitalized patients) with comprehensive outpatient data. MARS also provides additional opportunities for quality and outcomes assessment.

Specific Aims

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

2008 Activities: The project conducted 12 focus groups as of September 2008 (and April 2009). The aim of these focus groups was to: 1) obtain the perspective of women of reproductive age on how they would like their primary care clinicians to provide information about medication-induced birth defects, and 2) understand clinician perspectives on what type of decision support would be most useful. Two abstracts describing this work were accepted for oral presentation at the Organization of Teratologic Information Specialists Annual Meeting in June 2008. A third abstract, titled “Primary care providers’ perspectives on the challenges of contraceptive counseling,” was presented as a poster at the Association of Reproductive Health Professionals and Society of Family Planning 2008 Annual Meeting, held September 19, 2008, in Washington, DC. A manuscript describing some of this work is forthcoming in the journal *Birth Defects Research, Part A*. Project staff continue to develop manuscripts that describe this work in more detail.

Programming of the FAST tablet-PC system to enable assessment of pregnancy intentions and use of contraception has been completed and is “live.” Consent to be randomized was obtained from all clinicians at the community-based practice and most faculty at the university clinic; however, two clinicians who consented subsequently left the clinic practice, leaving 29 faculty participants and the majority of clinical trainees. The 69 consenting clinicians were then randomly assigned to one of four groups.

The decision support system has gone live and “pre-intervention” surveys have been completed by 78 percent of participating clinicians. Dr. Schwarz and Dr. Koren finalized a list of which medications should trigger decision support alerts and provided this list to the individuals responsible for programming the decision support algorithms. Decision support has been programmed in to the system and has gone live at both the General Internal Medicine Faculty practice as well as all three Partners in Health clinics.

The project has begun recruiting patients at four primary care clinics to participate in this project. To date, 2289 women have consented (an average of 18 women recruited per day), 1130 have completed surveys, and an additional 243 will hopefully complete surveys via the Internet or by telephone in the next month. Project staff anticipate beginning to analyze the data in the coming months.

Preliminary Impact and Findings: Themes that emerged from focus groups with women of reproductive age include: 1) A desire to receive information about medication side effects from physicians at the time of prescription; 2) a feeling that pregnancy-related risks (related to medication use or poor maternal health) should be routinely discussed; 3) that women depend on their physicians for information about pregnancy risks because they feel other sources may not be reliable; 4) that women can rarely alert their physicians to the possibility of pregnancy because most do not plan their pregnancies; and 5) that if a clinician thinks a woman should not get pregnant while using a medication, the clinician needs to help the woman avoid pregnancy by providing an effective form of birth control.

Barriers that women identified as preventing them from obtaining desired information about medication risks include: a lack of privacy at the pharmacy, embarrassment at raising the possibility of an unplanned pregnancy, lack of trust in a clinician, and language barriers.

The major themes that emerged from focus groups with primary care clinicians include: 1) desire for accurate information about teratogenic risk that is available in “real time”; 2) difficulty identifying concise sources of teratogenic information on the Internet; 3) concern that hard-copy references may not be up to date; 4) desire for references that provide clinically relevant information about teratogenic risks (such as absolute risks instead of relative risks); 5) belief that decision support with computerized order entry would help them alert women to the possibility of teratogenic risk; 6) concern that few medications have been adequately studied during pregnancy; 7) worry that information about teratogenic risks may lead some women to decide not to use needed medications; 8) concern that raising the possibility of unintended pregnancy may offend some women; 9) perception that few women present requesting preconception counseling; and 10) perception that limited clinical time requires prioritizing acute issues and issues that can be billed for (clinicians cannot currently bill for providing preconception counseling).

Selected Outputs

Two abstracts accepted at the Organization of Teratology Information Specialists 21st Annual Meeting, Monterey, CA; June 28 – July 1, 2008.

Abstract presented at the Society of Family Planning Annual Meeting, Reproductive Health 2008, Washington, DC; September 17 – 20, 2008.

Grantee’s Most Recent Self-Reported Quarterly Status: The project is mostly on track with 80 to 99 percent of its milestones and is generally on time.

Milestones: Progress is mostly on track.

Budget: Spending is roughly on target.