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Into Practice

Effectively implementing FDA medication alerts utilizing patient centered medical home clinical pharmacists

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ABSTRACT

FDA medication alerts can be successfully implemented within patient centered medical home (PCMH) clinics utilizing clinical pharmacists.

Targeted selection of high-risk patients from an electronic database allows PCMH pharmacists to prioritize assessments.

Trusting relationships between PCMH clinical pharmacists and primary care providers facilitates high response rates to pharmacist recommendations.

This health system approach led by PCMH pharmacists provides a framework for proactive responses to FDA safety alerts and medication related quality measure improvement.

1. Background

Since 2007, the US Food and Drug Administration's (FDA) correspondence concerning drug safety alerts has increased in volume and complexity.[1] The FDA does not oversee implementation, response, or interventions of these alerts;[2] thus it is up to individual health systems and providers to respond appropriately. Prescribers and pharmacists have the professional responsibility to interpret and respond to FDA drug safety alerts to help ensure patient safety.[2]

In response to these alerts, clinicians are expected to interpret the evidence supporting these warnings to determine the potential impact on their individual patients.[3] Given that primary care physicians (PCPs) already devote substantial time to non-visit related work, responding to drug safety alerts may add to provider burden or not be prioritized.[4] Further, there is a lack of consistency among providers regarding their response to drug safety alerts and communication of these alerts to patients.[5]

As experts on medications and their side effects, pharmacists are uniquely suited to manage drug safety situations. Few studies have highlighted the pharmacist's role in improving medication safety following FDA alerts.[6] Pharmacists may be utilized to disseminate information regarding drug safety warnings and appropriately manage patients exposed to drugs affected by these warnings.[2,7] When pharmacists lack a direct working relationship with the PCPs, recommendations are often provided through letters and faxes, which are associated with low rates of physician acceptance.[8–10] Pharmacists embedded within the patient centered medical home (PCMH) are uniquely positioned to help ensure patient safety in these situations and can play an important role in assisting PCPs with this task.

On August 24, 2011 the FDA issued a safety announcement concerning the antidepressant citalopram and recommended doses should not exceed 40 mg daily or greater than 20 mg daily in specific patient populations (see Table 1) due to increased risk of arrhythmias (torsade de pointes).[11] The FDA revised its recommendations in March 2012 to clarify the previous “contraindication” in certain patients to “discouraged”, given recognition that certain patients may need to continue citalopram use.[11,12]

The citalopram warnings had the potential to have a large impact on clinical practice, because in 2011, citalopram was the most commonly dispensed antidepressant and one of the top 20

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Table 1
Special population citalopram dosing guidelines.[a,b]

Special population	Maximum dose
Patients with congenital QT Syndrome, bradycardia, hypokalemia, hypomagnesemia, recent acute myocardial infarction, uncompensated heart failure, or concomitant use with other medications that prolong the QT interval	Not recommended
Patients with hepatic impairment, older than 60 years of age, who are CYP2C19 poor metabolizers, or taking concomitant cimetidine or other CYP2C19 inhibitors	20 mg

[a] Summary from US FDA Drug Safety Communication.[11]
[b] Summary from US FDA Drug Safety Communication.[12]

most commonly dispensed prescriptions in the United States.[13] Given the number of individuals treated with citalopram, the impact of the FDA alert for citalopram was profound.

With the existence of frequent FDA drug safety alerts, it is important to develop a system for health care organizations to help them proactively assess and manage alerts. This article describes a program that aimed to effectively respond to the citalopram FDA alerts by using a PCMH pharmacist intervention. The goal of the program was to facilitate risk-benefit decision making to ensure patient safety and prevent adverse events.

2. Problem

Following the 2011 FDA alert for citalopram, leadership in the Department of Psychiatry at the health system became concerned about potential unintended consequences associated with the warning, particularly in primary care settings. In busy primary care practices, the ability to accommodate a large volume of visit requests from alarmed patients was limited.

3. Personal context

Health system leadership approached Ambulatory Care Services about creating a systematic, yet individualized, approach to assess dose changes for PCMH patients. In the absence of an existing operational process to respond to FDA warnings, Ambulatory Care Services leadership appointed the Director of Pharmacy Innovations to develop a standardized health system-wide approach for addressing citalopram safety alerts. Working with ambulatory care leadership, an interdisciplinary workforce was identified to ensure medication safety. This study was exempt from IRB review since it was a quality improvement project.

4. Organizational context

Across the health system, 10 PCMH clinical pharmacists, or a total of 4.3 full time equivalents, divided clinic time between primary care sites based on patient volume. Strong relationships between medical providers and PCMH clinical pharmacists existed due to established collaborative practice in disease management and quality improvement efforts. Already having the clinical pharmacists embedded in all of the PCMH primary care clinics provided an existing platform to implement this system-wide safety initiative.

However, the citalopram warning posed a challenge to PCMH clinical pharmacists because it required review of a high volume of patients in a short time period. At the time of the initiative, health system PCMH clinics were undergoing a transition to a new electronic medical record system. As a result, resources to automate aspects of the manual data collection for this unexpected safety initiative were limited. Given that the PCMH clinical pharmacists were already working with a high volume of patients with chronic conditions and for overall medication management, and PCMH clinical pharmacist time is a valuable resource for clinics, student pharmacists were employed as part of the response to the citalopram warning. PCMH clinical pharmacists had a longstanding relationship with the College of Pharmacy, training fourth year pharmacy students during clinical rotations and teaching in the classroom. Six second-year students were trained to participate in this safety initiative. The Director of Pharmacy Innovations supervised the student team. Supervision included an initial analysis of agreement with test cases to ensure assessment consistency among students and quality equivalent to pharmacist reviews. Periodic quality assurance checks of student work were also performed. The purpose of the student team was to assess patients on potentially risky doses of citalopram and assist PCMH clinical pharmacists in devising recommendations for providers.

5. Solution

Thirteen PCMH clinics that included a clinical pharmacist as part of the patient care team participated in this safety initiative. A list of patients in the clinics taking citalopram was generated using a health system database query from the electronic medical record in an excel format. Adult patients prescribed over 40 mg of citalopram of any age and patients older than 60 years prescribed over 20 mg citalopram were identified. In total, 305 patients were assessed by the pharmacy student team. Ninety patients were excluded prior to pharmacist assessment. Of the 90 excluded patients: eight died before assessment from unrelated causes; 19 were no longer clinic patients at assessment; two patients had a recent psychiatry referral; and 61 decreased dose or stopped medication before assessment. The remaining 215 patients were referred to PCMH clinical pharmacists for further assessment (see Table 2).

A Citalopram Safety Assessment Form was developed to assess each patient's potential risk factors using data from the electronic medical record. Six trained pharmacy students performed initial reviews of each patient using the form, identifying any risks to continuing the current citalopram regimen. Once the forms were completed, the student team leader collected the forms and distributed them to the PCMH clinical pharmacist at each clinic (see

Table 2
Intervention summary.

Patients assessed from electronic medical record database query[a]	$n=215$	70.5%
Pharmacists recommended medication changes or PCP follow-up	$n=113$	52.6%
PCP response rate to pharmacist recommendations	$n=93$	82.3%
PCP agreed medication changes were required	$n=69$	61.1%
Patients contacted by LPN for medication changes	$n=66$	95.7%
Patients agreed to medication change	$n=60$	90.9%
Medication change was dose reduction	$n=43$	71.7%
Medication change was switch to new medication	$n=17$	28.3%
Patients with follow-up appointment with PCP and/or pharmacist[b]	$n=54$	90.3%

[a] Of the 305 patients selected, 8 died before assessment from unrelated causes, 19 were no longer clinic patients at assessment, 2 patients had a recent psychiatry referral and 61 decreased dose or stopped medication before assessment.
[b] Of the 6 patients who did not have a recorded follow-up after medication change: 1 switched to an outside PCP, 2 agreed to contact PCP if follow-up was desired but this was never done, 1 stopped citalopram before follow-up due to resolved depression, and 2 had weekly follow-up with clinic providers other than the PCP.