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Electronic medication complete communication strategy for opioid prescriptions in the emergency department: Rationale and design for a three-arm provider randomized trial

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ABSTRACT

Background: Thousands of people die annually from prescription opioid overdoses; however there are few strategies to ensure patients receive medication risk information at the time of prescribing.
Objectives: To compare the effectiveness of the Emergency Department (ED) Electronic Medication Complete Communication (EMC^2) Opioid Strategy (with and without text messaging) to promote safe medication use and improved patient knowledge as compared to usual care.
Methods: The ED EMC^2 Opioid Strategy consists of 5 automated components to promote safe medication use: 1) physician reminder to counsel, 2) inbox message sent on to the patient's primary care physician, 3) pharmacist message on the prescription to counsel, 4) MedSheet supporting prescription information, and 5) patient-centered Take-Wait-Stop wording of prescription instructions. This strategy will be assessed both with and without the addition of text messages via a three-arm randomized trial. The study will take place at an urban academic ED (annual volume > 85,000) in Chicago, IL. Patients being discharged with a new prescription for hydrocodone-acetaminophen will be enrolled and randomized (based on their prescribing physician). The primary outcome of the study is medication safe use as measured by a *demonstrated* dosing task. Additionally *actual* safe use, patient knowledge and provider counseling will be measured. Implementation fidelity as well as costs will be reported.
Conclusions: The ED EMC^2 Opioid Strategy embeds a risk communication strategy into the electronic health record and promotes medication counseling with minimal workflow disruption. This trial will evaluate the strategy's effectiveness and implementation fidelity as compared to usual care.
Trial registration: This trial is registered on clinicaltrials.gov with identifier NCT02431793.

1. Introduction

The increasing mortality from prescription opioid overdose in the United States has paralleled the rise in opioid prescriptions since the 1990s [1–5]. In 2008, opioid medications were involved in 73.8% of deaths from prescription drug overdose leading to the development of federal interventions to curb abuse [1]. However, analgesic medications including opioids remain the most frequently prescribed drug class in US emergency departments (EDs) [6,7]. The prevalence of painful conditions evaluated in the ED setting necessitates emergency physicians prescribe opioid analgesics at times. Hence, the ED environment presents a challenging dichotomy: emergency physicians may feel criticized for undertreating pain, while simultaneously condemned for over-prescribing opioids and contributing to abuse and addiction [8].

Recent studies also indicate ED discharge processes are inadequate, and patients often leave without the knowledge necessary to care for

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themselves [9]. Communication between patients and providers in the ED can be both affected and hindered by time constraints, unpredicted interruptions, shift changes, overcrowding, and the lack of a preexisting relationship with patients [10–13]. In the context of opioids, this lack of knowledge can have dangerous outcomes, as patients may not know how to take their medication safely, nor be aware of its potential hazards. Our preliminary studies demonstrate patients infrequently recall counseling about opioids, and when counseling occurs it is highly variable [14–17]. For example, in one study of 47 audio-recorded ED visits, the addictive potential of the prescribed opioid was addressed in only one encounter [15].

The Institute of Medicine (IOM) defines the medication use process as encompassing prescribing, dispensing, self-administration and monitoring. In the context of opioids, barriers to safe use may occur at any stage throughout this process. While inadequate counseling may be prevalent at the time of prescribing and dispensing, problems may be compounded beyond the point of care. Even if counseling were to occur at the ED or pharmacy, patients may struggle to recall instructions at the time of self-administration due to pain symptoms, altered sensorium from medications, and unclear labeling may impact interpretation of print instructions. Emergency physicians do not routinely provide post-visit monitoring and primary care providers (PCPs) often are not informed of new ED prescriptions. To support opioid safe use, interventions should take into account the challenges at each of these stages of the medication use process.

With the increasing adoption of electronic health records (EHRs) and mobile technologies, we now have the ability to communicate risk information at multiple time points throughout the medication use continuum while having a minimal impact on workflow. To capitalize on these electronic capabilities, we designed an Emergency Department EHR-based, Medication Complete Communication (EMC^2) Opioid Strategy to 1) support emergency providers in adequately counseling patients at the time of prescribing, 2) automate a mechanism for follow-up to engage additional outpatient providers to reinforce education and confirm understanding, and 3) generate tangible tools to reinforce counseling during self-administration. We designed this intervention based on the goals of both maximizing the quality of communication while also providing a low cost, thus scalable intervention with minimal impact to workflow.

2. Methods

2.1. The ED EMC^2 Opioid Strategy

The ED EMC^2 Opioid Strategy is comprised of five automated components that will be triggered for ED patients with a new prescription for an opioid. Fig. 1 details the components. The first three components target providers and occur at the time of prescribing in the ED; the remaining components are provided directly to patients.

I. Prescriber-facing components

1. Provider medication alert. A pop-up window is displayed to the prescribing provider upon signing the opioid prescription in the EHR. This pop-up window reminds the provider to verbally counsel the patient about the medication. The alert does not contain any additional medication information, nor does it require an attestation that counseling occurred to close the alert. This pop-up reoccurs for every new opioid prescription the provider signs.
2. EHR inbox message to PCP. If the patient has an established PCP within the health system noted in the EHR, an alert is sent to the PCP notifying her that her patient received an opioid prescription. The alert is delivered as an EHR inbox message to the individual PCP's EHR account, and is distinct from any other EHR notification messages about the occurrence of the ED visit or test results. The opioid inbox message provides details about the strength and quantity of the opioid prescribed and asks the PCP to provide additional counseling on safe use at the patient's next outpatient visit.
3. Pharmacist request to counsel. An automated request to the dispensing pharmacist to counsel the patient about safe use of opioids is printed on the prescription. The pharmacist prompt is included because although the Omnibus Budget Reconciliation Act of 1990 (OBRA-90) requires pharmacists at a minimum to “offer to discuss” the medication, actual rates of counseling are highly variable (range 8–100%) and pharmacists are less likely to counsel patients on side effects, safe storage and precautions than on directions for medication use [16,18,19].

In the “Special Instructions” field of the prescription, the following text is printed automatically: “Note to Pharmacist: Please counsel the patient about how to safely take the medication.” Although electronic prescriptions for controlled substances may be issued for Schedule II, III, IV and V controlled substances, including opioids, the majority of prescriptions in our health system are issued on tamperproof paper due to e-prescribe security requirements. The notification to the pharmacist is therefore included on the print prescription for this study; there is capability for such text to be included on e-prescriptions under the field of “Special Instructions.”

II. Patient-facing components

4. Plain language MedSheets. We are utilizing the single-page plain language opioid medication information sheet (MedSheet) developed as part of a previous study [20]. MedSheets were designed to provide understandable, actionable information for newly prescribed medications at the point of prescribing and were written at an 8th grade reading level or below. In a follow-up study, different formats of MedSheets were tested with the final version being both preferred by patients and resulting in higher comprehension and recall of drug information when compared to current FDA standard Medication Guides [21] [22]. These sheets, initially designed for use in an internal medicine clinic setting, were further modified for content appropriate to the ED setting. Our preliminary data demonstrated that inclusion of an opioid MedSheet in the discharge instructions increases some aspects of patient knowledge about the medications [23]. As part of the ED EMC^2 Opioid Strategy, an opioid MedSheet is automatically printed with the discharge instructions when the provider signs the order for the opioid prescription.
5. “Take-Wait-Stop” patient centered medication labeling. The Take-Wait-Stop label is an extension of previous work regarding patient centered medication labeling. In 2007, members of our research team devised the Universal Medication Schedule (UMS) to standardize and simplify medication regimens to support safe and effective prescription medication use [24]. The IOM and U.S. Pharmacopeia (USP) favorably reviewed the UMS. Further, the UMS was recommended as a standard of care when the state of California passed legislation declaring it a best practice for drug labeling [24,25]. Multiple efficacy trials demonstrate the value of the UMS in improving patients' understanding of medication dose and frequency [26–29]. One limitation of these studies is the focus only on medications prescribed with fixed dosing intervals, rather than medications prescribed to be taken “as needed” (a.k.a. ‘PRN’; abbreviation for the Latin pro re nata, meaning ‘as the circumstance arises’), including many pain medications.

The Take-Wait-Stop label design includes explicit, deconstructed instructions along with simplified text, numeric characters instead of words (e.g., “1 pill” instead of “one pill”) and “carriage returns” to place each part of the instructions on separate lines [28]. Additionally, to convey the maximum daily dosage to patients in plain language, the