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Primary care workflow process mapping of medication-related activities performed by non-provider staff: A pilot project's approach

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ABSTRACT

Background: A workflow process mapping approach was previously developed to understand the impact of primary care medication use processes on medication safety. The workflow process mapping approach was applied to a pilot project in one primary care practice.

Objectives: The objective of this article is to: (1) exemplify how workflow process mapping was implemented in one primary care practice to characterize medication safety issues (i.e., critical workflow gaps/deviations), (2) discuss the identified critical medication safety workflow gaps and deviations, and (3) summarize the pragmatic, practice-level recommendations developed to enhance practice-level medication safety.

Methods: Four medication-related activities were directly observed, including: (1) medication reconciliation, (2) warfarin medication management, (3) vaccination administration, and (4) medication renewal requests. Observations occurred with registered nurses, medical assistants, and telephone operators. An ideal-state and observed workflow process map was created for each medication-related activity and was compared to identify critical medication safety workflow gaps and deviations. Practice-level recommendations were developed to enhance workflow and medication safety across all medication-related activities.

Results: 111 medication-related observations were recorded over 6-weeks across all 4 workflows (100 observation hours). A total of 17 critical workflow safety gaps, 9 critical workflow step deviations, and 9 workflow sequence deviations were identified. Seventy-six percent of total workflow gaps resulted from inappropriate medication verification. Most workflow step deviations (33%) were due to inappropriate documentation, whereas most sequence deviations (44%) stemmed from inadequate medication verification. Practice-level recommendations to enhance warfarin medication safety were prioritized and implemented prior to the completion of the pilot project.

Conclusion: The results of this workflow mapping pilot project exemplify the need to enhance primary care medication safety for workflows conducted by non-provider staff members in primary care practices. Additionally, this approach can be used to identify opportunities for primary care pharmacist integration, particularly for practices with little or no prior pharmacist involvement.

Introduction

This paper is part of a two-article series. The first article[1] describes a workflow process mapping approach to understand and characterize medication use and safety in primary care practice. This article, the second in the series, describes the application of the workflow process mapping approach to a pilot project conducted in one primary care practice. Throughout this paper, we will use the term "primary care" as meaning office-based primary care.

Primary care medication safety

The majority of medication safety improvement initiatives have occurred in hospital practices[2,3] with guidance from the Joint Commission,[4] the Institute for Healthcare Improvement,[5] and the Agency for Healthcare Research and Quality (AHRQ).[6–8] Very few studies have pursued improvements in primary care medication safety. One study by Galt and colleagues[2] identified several critical opportunities to enhance primary care medication safety. These opportunities included enhancements in medication use processes, patient-staff-provider interactions, and the use of technology to complete medication-related tasks. The results of this study demonstrated that many primary care practices

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today continue to operate with inadequate attention to medication safety, suggesting the need to develop approaches to transform medication safety in ambulatory care practice settings.

In addition to Galt's work, a few other studies have characterized medication safety in primary care.[9–19] These studies have focused on understanding the prevalence of and reasons for medication safety outcomes, such as adverse drug events,[3,9–11] medication errors,[3,12–15,19] and medication discrepancies.[16–18] Various methods have been used to conduct these studies, including retrospective evaluations,[10,12,14,15,19] prospective or retrospective cohort studies,[3,9,11,13,16–18] and stakeholder surveys of primary care prescribers and/or patients.[10] Although these are valuable approaches to advance the awareness of primary care medication safety, they provide minimal understanding into factors that precipitate medication safety events in primary care practices, including provider and staff workflows for medication-related activities.

We developed a workflow process mapping approach[1] to better understand the impact of primary care medication use workflows on medication safety. We applied this approach to a pilot project to characterize and evaluate 4 common medication-related activities conducted in primary care by non-provider staff members. In this paper, we will: (1) exemplify how workflow process mapping was implemented in one primary care practice to characterize medication safety issues (i.e., critical workflow gaps/deviations), (2) discuss the identified critical medication safety workflow gaps and deviations, and (3) summarize the pragmatic, practice-level recommendations developed to enhance practice-level medication safety.

Methods

Practice site description

Our workflow process mapping approach[1] was tested within a family and internal medicine primary care practice located in eastern Connecticut. At the time the pilot project was conducted, the practice employed 1 full-time-equivalent (FTE) physician, 2 FTE mid-level providers (1 physician assistant and 1 nurse practitioner), and 2 part-time physicians. Approximately 7000 patients were attributed to the practice across all providers. The core non-provider staff consisted of 2 registered nurses (RNs), 4 medical assistants (MAs), and 4 telephone operators (TOs). The routine responsibilities of the RNs included addressing telephone calls relating to clinical patient care needs, conducting therapeutic drug monitoring for patients prescribed warfarin by their primary care provider (in collaboration with the primary care providers), and administering vaccinations. MAs completed patient intake and other rooming tasks for each primary care visit, including medication reconciliation. The TOs triaged all incoming calls to the office, many of which are medication renewal requests from patients/caregivers or community pharmacies. The practice also employed a part-time (0.2 FTE) clinical pharmacist who offered various medication management services based on provider referrals. The practice was a clinical rotation site for medical and pharmacy students on a sporadic basis.

Workflow process mapping phases

Details regarding the workflow process mapping approach discussed in this paper have been described previously.[1] Below, we discuss an overview of the workflow process mapping phases used to conduct the pilot project. For details regarding each phase, refer to the first paper within this two-article series.

PHASE 1: Planning

A. Institutional Review Board approval. This pilot project was approved through the University of Conncticut Institutional Review Board.

B. Establishment of a workflow mapping team. The pilot project workflow mapping team consisted of: (1) two researchers (KMS, MAS.) from the University of Conne School of Pharmacy, (2) three doctoral-level student pharmacists, and (3) the primary care practice's medical director. The university-based researchers were responsible for project oversight, including workflow mapping methods development, data collection, and data analysis. The student pharmacists were responsible for project implementation, data collection, and data analysis. The practice medical director oversaw observations of all medication-related activities within the practice and provided insight into the selection of the medication-related activities, workflow observation methods, and interpretation of observational findings.

C. Selection of medication-related activities. The study researchers and the primary care practice's medical director completed a needs assessment to identify the medication-related activities for observation within the practice. The following were selected: (1) medication reconciliation, (2) office-based warfarin medication management, (3) vaccination administration, and (4) medication renewal requests. These workflows were chosen because they represented the most widely encountered medication-related activities performed within the practice. It is important to note that the practice's non-provider staff members (RNs, MAs, and TOs) routinely perform these workflows; therefore, this project was specifically designed to observe and evaluate non-provider workflows for the 4 medication-related activities described above.

D. Development of ideal-state workflow process maps (Fig. 1). Once the medication-related activities were selected for observation, an ideal-state workflow process map was created for each activity. Ideal-state workflow process maps were created to represent the “idealistic” or exemplary workflow for each medication-related activity based on best practices and published clinical guidelines. To develop the maps, the study researchers first identified the fundamental working steps necessary to complete each medication-related activity, and then sequenced these steps in an order representative of the commonly accepted workflow. The study researchers vetted the ideal workflow process until consensus was built regarding the ideal-state workflow for each medication-related activity. The ideal-state workflow maps became the structure or foundation for the observed workflow process maps, which are described in Phase 3 below.

E. Identification of data collection elements (Table 1). Once the ideal-state workflow process maps were created, the study researchers identified the critical data elements needed to represent each fundamental step in the ideal-state workflow processes. These data elements were used to inform: (1) the data to be collected during observations, and (2) the content and structure of the data collection forms. Table 1 outlines the data elements used for each medication-related activity observed in the pilot project.

F. Development of data collection forms. Development Process: one paper data collection form was developed per medication-related activity to document the workflow observations. We used paper data collection forms to minimize obtrusiveness during in-person observations. Each form captured the: (1) date/time of observation (2) the type (i.e., RN, MA, TO), of primary care non-provider staff member observed, and (3) data elements specific to each workflow (see Table 1).

Revision Process: all data collection forms were tested real-time within the primary care office prior to starting data collection. Four hours of direct workflow observations per medication-related activity were allotted to pilot the data collection forms. The in-office pilot observations focused on the forms’ usability and general formatting in addition to the sequencing and effectiveness of the data elements to capture the workflow observations. Any information collected during the pilot testing was discarded and was not included in the final

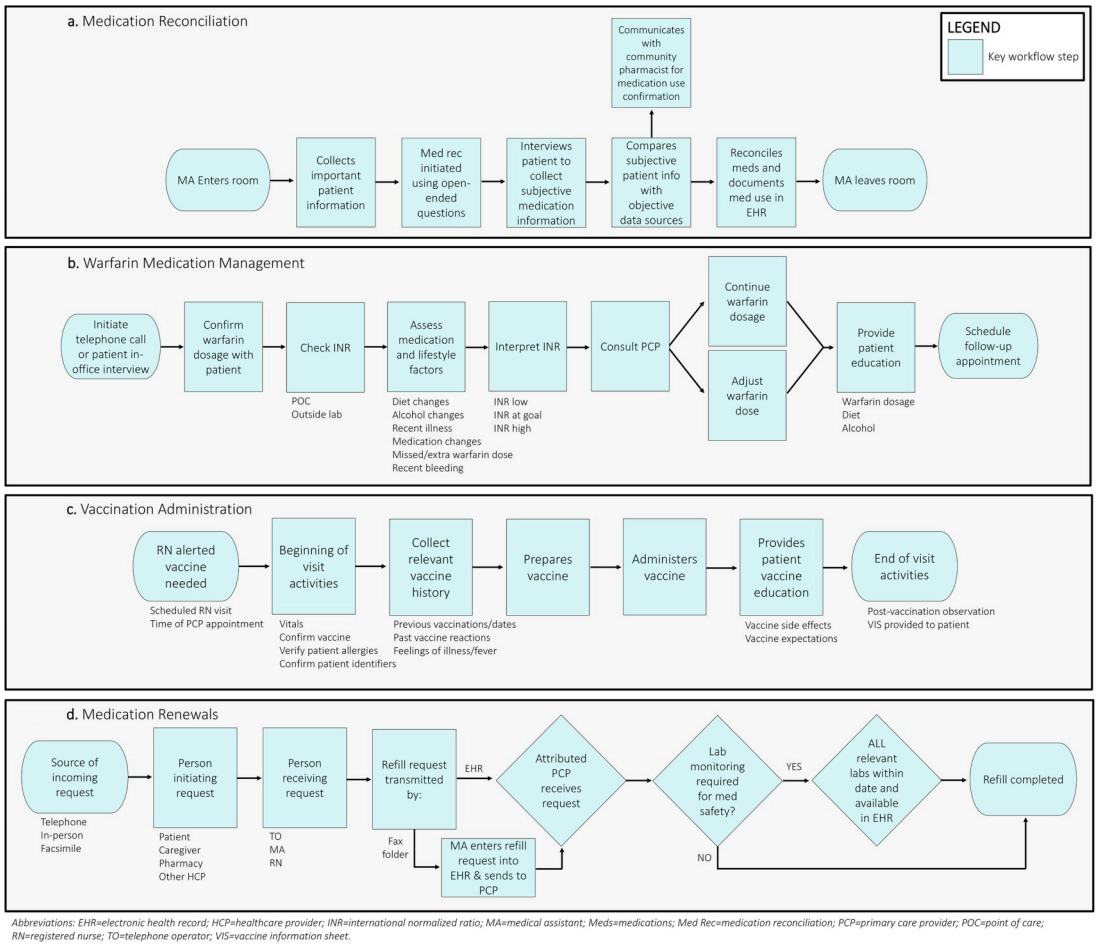

Fig. 1. a.-d. Ideal-state workflow process maps.

workflow evaluation. Minor revisions to the data collection forms were allowed through the first week of the actual data collection period. Approximately 10 h of revision were invested per data collection form.

G. Creation of a data collection observation schedule. Direct observations were scheduled to occur over 6 weeks until 100 h were completed across all medication-related activities. An observation schedule was created to organize observation times across all medication-related activities within the practice. The schedule was structured so that each RN, MA, or TO was observed for no more than 4 h at one time, and no more than 4 h in one week. Four medical assistants (100% of practice MAs), 2 registered nurses (100% of practice RNs), and 4 telephone operators (100% of practice TOs) consented to be observed throughout the data collection period, and were incorporated into the observation schedule. Each practice staff member was scheduled for an equal amount of observation hours and on varying days of the week over the data collection period in order to accurately capture "normal" workflow performance.

PHASE 2: Collecting Data

A. Data collection training. Three doctoral-level student pharmacists (observers) performed the direct workflow observations. Prior to initiating real-time data collection, the study researchers trained each observer on how to: (1) perform the workflow observations using the methods described in Tables 2, and (2) use the data collection instruments. Training consisted of detailed walk-throughs of the data collection process and use of the data collection forms using hypothetical workflow scenarios for each medication-related activity. Additionally, the pilot observations used to test the data collection forms (see Step "F" above in Phase 1) were also an opportunity for the observers to ask the clarifying questions regarding observation methods prior to real-time data collection.

B. Data collection/observation process (Table 2). Table 2 describes the specific methods used to complete observations of each medication-related activity. The observers were unable to address questions from RNs, MAs, and TOs about observed patient encounters, in addition to patient questions. For workflows that required direct patient-staff observations, (i.e., medication reconciliation, warfarin medication management, and vaccination administration), the observers obtained verbal consent from the patient prior to commencing observation and data collection. Patient-specific data was not collected for any of the workflows; however, in order to retrospectively capture the outcome of the medication renewal requests, a coding system was used to link the observation with the patient record in the EHR. Only aggregate, de-identified information was analyzed.

PHASE 3: Analyzing Data

A. Data organization and interpretation. After data collection was complete, information from the paper data collection forms was entered into a Microsoft Office Excel spreadsheet for ease of interpretation and analysis. One spreadsheet was created for each medication-related activity. Columns within the spreadsheets were labeled using the data elements found on the data collection forms so that information could be easily transferred and summarized. The spreadsheets captured whether or not each data collection element was observed during each individual observation. Additionally, the spreadsheets organized the sequence in which the fundamental

Table 1
a.-c. Data Collection Elements for Each Medication-Related Activity Observed in the Pilot Project.

1a. Medication Reconciliation

Data Element Theme	Workflow Step	Data Elements
Pertinent Workflow Details	Identifies medication reconciliation data sources	• EHR medication list; patient/family/caregiver interview; patient Rx list/pill bottles; discharge summary
Beginning of Observation Activities	Verifies medication-related information Initiates medication reconciliation by:	• Existing medication allergies/intolerances/ADEs/SE; pharmacy preferences • Asking patient for at-home medication history using open-ended questions • Reading and comparing MR data sources listed above
Core Workflow Actions	Reconciles medication list	*1. Asks patient about:* • At-home medication use (Rx/OTC/CAM) according to medications listed in practice's EHR and from other MR data sources • Additional medications not in EHR or previously mentioned • Additional medication-related information, including: – Medication problem(s) or effectiveness – New medication allergies/intolerances/ADEs/SE – Updates in pharmacy preferences – Missing medication information – Changes in medication dosages – Past medication experiences/failures – Medication beliefs – New or changed medications prescribed by non-PCP – Patient requests for medication refills
	Documents medication change, discrepancy, or problem in EHR	New/missing medication; missing medication information; changes in medication dosages; stopped/discontinued medication
End of Observation Actions/Follow-up	Leaves room	MR process finished/unfinished
	Communicates medication discrepancies or important medication-related information with PCP	Yes/No

1b. Warfarin Medication Management

Data Element Theme	**Workflow Step**	**Data Elements**
Pertinent Workflow Details	Patient encounter type	• In-office patient appointment (POC testing) • Telephonic patient encounter (e.g., follow-up re: INR laboratory result)
Beginning of Observation Activities	INR lab is drawn/interpreted	• POC visit: INR lab is drawn in-person using POC device. • Telephonic visit: RN locates recently drawn lab in within EHR laboratory module.
Core Workflow Actions	Previous warfarin dosage is verified with patient	Yes/No
	Verifies medication/lifestyle factors that can affect INR	*1. Asks patient about:* • Changes in prescription and non-prescription therapy since last warfarin medication management visit • Recently missed/extra warfarin doses • Changes in diet, particularly with regards to vitamin K intake • Changes in alcohol intake/illicit drugs • Recent illnesses and use of antibiotics • Recent bleeding episodes or signs/symptoms of bleeding
	Interprets INR value	*1. Compares INR to-date to patient's INR goal to determine whether INR is:* • Therapeutic (i.e., within patient's goal INR range) • Sub-therapeutic (i.e., below patient's goal INR range) • Supra-therapeutic (i.e., above patient's goal INR range)
	Adjusts INR accordingly	Consults primary care provider for plan to continue or change patients' current warfarin dosage based on INR value to-date and relevant lifestyle changes
	Provides patient education	*1. Educates patient regarding:* • Dosage continuation/changes • Modifications to diet, alcohol intake (if applicable) • Modifications to concurrently administered medications (if applicable) • Next warfarin medication management appointment
End of Observation Actions/Follow-up	Follow-up warfarin management appointment is scheduled	Yes/No

1c. Vaccination Administration

Data Element Theme	**Workflow Step**	**Data Elements**
Pertinent Workflow Details	Patient encounter type	• Scheduled appointment with RN for vaccination • "Warm handoff" between PCP and RN for vaccination at the end of a scheduled appointment with PCP
Beginning of Observation Activities	Confirms important vaccine-related information prior to immunization	*1. Verifies the following with the patient and pertinent EHR information:* • Vaccine ordered by PCP for administration • Past vaccination history • Medication/vaccine allergies • Past vaccine adverse reactions • Vaccines received in the last 30 days • Recent fever/illness
Core Workflow Actions	Provides immunization and patient education	*1. Educates the patient regarding:* • Purpose of the vaccine and expected immunity

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Table 1 (*continued*)

1a. Medication Reconciliation		
Data Element Theme	Workflow Step	Data Elements
		• Possible vaccine reactions • What to do if an ADE develops • When next vaccination dosage/booster is due (if applicable) *2. Provides patient with vaccine information sheet*
End of Observation Actions/ Follow-up	Observes patient post-vaccination	Yes/No
	Schedules patient for follow-up vaccination dosage/ booster (if applicable)	Yes/No

1d. Medication Renewals		
Data Element Theme	**Workflow Step**	**Data Elements**
Pertinent Workflow Details	Patient encounter type	• Medication renewal identified during in-office patient appointment • Medication renewal identified during telephonic patient encounter
Beginning of Observation Activities	Medication renewal request initiated by:	Patient/caregiver/community pharmacy/other healthcare professional
	Medication renewal request is communicated by:	• In-person patient request at time of in-office patient appointment • Patient request via telephone communication • Facsimile from community pharmacy or non-PCP physician's office
	Medication renewal request is received by:	TO/MA/RN
Core Workflow Actions	Medication renewal request transmitted to PCP for completion by:	• In-person communication with TO/MA/RN • Telephonic TO-PCP communication with TO/MA/RN • Written note from TO/RN/MA • EHR virtual encounter with TO/MA/RN • PCP facsimile folder (a folder of all incoming faxes addressed to PCP for completion)
	Medication renewal request transmitted by:	TO/MA/RN
	Is medication monitoring recommended per relevant clinical practice guidelines to ensure medication safety?	Yes/No
	Are the results of relevant laboratory tests/vital exams/ procedures available in EHR at the time the medication renewal request is addressed?	Yes/No
End of Observation Actions/ Follow-up	Medication renewal request addressed	*Outcome (check all that apply):* • Electronic/faxed prescription sent to community pharmacy • Hardcopy prescription printed for patient to pick-up at PCP office • Medication renewal denied • Laboratory test/vital examination ordered for patient to complete

Abbreviations: ADE = adverse drug event; CAM = complementary alternative medicine; EHR = electronic health record; MR = medication reconciliation; OTC = over-the-counter; POC = point of care; PCP = primary care provider; Rx = prescription; SE = side effect.

workflow steps occurred for each observation.

Next, the study researchers analyzed how often and in what sequence each key workflow step occurred for each individual encounter. These individual analyses were then compared across all observations for each medication-related activity to determine the most commonly performed workflow sequence, including the frequencies at which each step was performed. The purpose of this approach was to develop a gestalt understanding of the overall practice-level workflow process for each medication-related activity across all involved staff members.

B. Observed workflow process maps (Fig. 2). An observed (or current-state) workflow process map was created for each medication-related activity to represent the observed workflow process according to the analysis outlined above. The observed workflow map was compared to the ideal-state workflow process maps for each medication-related activity to identify differences or discrepancies in workflow steps and sequencing.

Identified medication safety discrepancies were further classified based on context, and included medication safety workflow gaps, medication safety workflow step deviations, and medication safety workflow sequence deviations. *Medication safety **workflow gaps*** are workflow steps that were not routinely observed (or were omitted) during the observation process, but were determined to be a fundamental step in the ideal-state workflow. *Medication safety **workflow step deviations*** are defined as new or unanticipated workflow steps that were observed, but were not anticipated to occur in the ideal-state. *Medication safety **workflow sequence deviations*** are observed workflow sequences that diverge or differ from what is expected to occur in the ideal-state. We defined a workflow gap or deviation to be critical (i.e., could precipitate a medication safety event) if it occurred in ≥20% of total observations per medication-related activity. Critical workflow gaps and deviations are depicted on the observed workflow maps using color-coding and sequence deviation arrows. Calculated observation frequencies were applied to each critical workflow process gap or deviation to represent the rates at which they occurred. Fig. 2 demonstrates the observed workflow process maps with identified critical medication safety workflow gaps and deviations for the 4 observed medication-related activities.

C. Categorization of Critical Workflow Gaps and Deviations. The study researchers discussed all identified critical workflow gaps and deviations to determine the context in which they occurred. Across all medication-related activities, 3 common categories were identified, including non-provider staff: (1) data verification, (2) data documentation, and (3) patient communication. In other words, omitted/inadequate data verification, data collection, and staff-patient communication were determined to be common precipitators of medication safety concerns across all observed medication-related activities.

Table 2
Pilot project observation methods for each medication-related activity.

Medication-Related Activity	Primary Care Staff Observed	Observation Criteria		Observation Details[a]
		Inclusion Criteria	*Exclusion Criteria*	
Medication Reconciliation	Medical assistant (MA)	−All medication reconciliation encounters scheduled during each observation period	−Employees of the researcher's university or students enrolled at the university −Patients who declined consent for observation	−Observer stood behind MA during observations −MA documentation/workflow steps completed outside the patient room were observed −Workflow clarification questions were addressed with MA outside of patient visit/room
Warfarin Medication Management Vaccination Administration	Registered nurse (RN)	−All warfarin anticoagulation encounters scheduled during each observation period −All vaccination encounters scheduled during each observation period		−Observer stood behind RN during observation −Workflow clarification questions were addressed outside of patient visit/room −All RN consultations with PCP outside the patient room were observed −Documentation/workflow steps completed outside the patient room were observed
Medication Refills	Telephone operator (TO)	−All medication renewal encounters occurring during each observation period	−Employees of the researcher's university or students enrolled at the university	*Telephonic medication refill request* ***(TO workflow)*** Medical assistant (MA) −Observer sat behind TO and listened to one-way telephone call −Observer watched TO document/triage refill request within the EHR −TO summarized conversation with the observer and dictated what was documented in EHR −Office pharmacist evaluated outcome of refill and available labs in EHR −Workflow clarification questions were addressed with TO after the request was transmitted in EHR *Medication refill request at time of medication reconciliation* ***(MA workflow)*** −Observer stood behind MA during observation −Workflow clarification questions were addressed with MA outside of the patient visit/room −Office pharmacist evaluated outcome of refill and available labs in EHR

Abbreviations: EHR = electronic health record; PCP = primary care provider.

[a] Direct observations were scheduled to occur over 6 weeks until 100 h were completed across all medication-related activities. Each practice staff member (10 total) was scheduled for an equal amount of observation hours and on varying days of the week over the data collection period in order to capture variation in normal workflow performance.

Table 3
Summary of critical workflow gaps and step/sequence deviations identified in pilot project.

	Medication Reconciliation	Warfarin Medication Management	Vaccination Administration	Medication Renewal Requests	Total Observations, Gaps & Deviations (all workflows)
Observations					
Total (n)	29	11	9	62	111
Workflow Gaps					
Total gaps (n)	6	3	8	0	17
Workflow gap details/ categorization	**Data Verification:** *Lack/incomplete verification of …* 1. Med allergies 2. Pharmacy preferences 3. Existing med info in EHR* 4. Med info NOT already in EHR* 5. New or past med-related issues 6. All SIG components for each med (Rx and non-Rx)	**Data Verification:** *Lack/incomplete verification of …* 1. Lifestyle changes since last INR evaluation* **Communication:** Lack/incomplete communication regarding … 2-3 Patient education about warfarin self-management*	**Data Verification:** *Lack/incomplete verification of …* 1. Vaccine for administration 2. Patient identity 3. Patient allergies 4. Past vaccine reactions 5. Vaccination history 6. Vaccines received in past 30 days 7. Recent illness/sickness **Communication:** *Lack/incomplete communication regarding …* 8. Patient education about vaccine received/possible ADRs*	N/A	–
Workflow Step Deviations					
Total step deviations (n)	8	1	0	0	9
Workflow step deviation details/categorization	**Data Documentation:** *Inappropriate or incomplete documentation within EHR regarding …* 1. Discontinuation of med(s) within EHR without objective verification[a] 2. Documentation of med change, discrepancy, or problem without objective verification[a] 3. Problem entering new medication into EHR* **Communication** *Inappropriate communication regarding …* 4. Medication pronunciation Miscellaneous 5. Insufficient time to complete MR 6-8 Other (3)*	**Communication:** *Inappropriate communication regarding …* 1. Consultation with PharmD student for warfarin dosage treatment plan*	N/A	N/A	–
Workflow Sequence Deviations					
Total sequence deviations (n)	3	2	1	3	9

(*continued on next page*)

Table 3 (*continued*)

	Medication Reconciliation	Warfarin Medication Management	Vaccination Administration	Medication Renewal Requests	Total Observations, Gaps & Deviations (all workflows)
Workflow sequence deviation details/ categorization	**Data Verification:** *Inappropriate approach used to …* 1-2 Initiate MR process* **Miscellaneous** 3. Insufficient time to complete MR	**Data Verification:** *Workflow sequence does not include verification of …* 1. Lifestyle changes since last INR evaluation* **Communication:** *Lack of communication …* 2. Between RN and PCP for warfarin dosage adjustment plan*	**Data Verification:** *Workflow sequence does not include verification of the following prior to preparing the vaccine for administration …* 1. Vaccine to administer, patient identity, patient allergies, past vaccine reactions, vaccination history, vaccines received in past 30 days, recent illness/ sickness*	**Data Communication:** *Inappropriate communication method regarding …* 1. Transmission of med renewal request to PCP for completion* **Data Documentation:** *Inaccurate/inappropriate documentation within EHR regarding …* 2. Med renewal request recipient (i.e., prescriber)* 3. Up-to-date laboratory/vital information within the EHR at time of med refill*	–
Total Gaps & Deviations (each workflow)	17	6	9	3	**35**

MR = medication reconciliation; EHR = electronic health record; med = medication; info = information; SIG = *signetur*; Rx = prescription; INR = international normalized ratio; ADR = adverse drug reaction; PCP = primary care provider.

*See observed workflow process maps (Fig. 2) for each medication-related activity for details.

[a] Objective information source examples: communication with primary care provider or non-PCP prescriber, community pharmacy administrative claims, hospital discharge summary, etc.

Results

Summary of observation frequencies

One hundred hours (111 encounters) of direct observation occurred over 6 weeks across all 4 workflows. The TOs were observed most often (50/100 h). The MAs and RNs were observed at (24/100 h) and (26/100 h), respectively.

The workflow with the greatest number of observation encounters was medication renewal requests (62/111 encounters, 56% total encounters). The medication reconciliation and warfarin medication management workflows had 29 and 11 observation encounters (26% and 10% of total encounters, respectively.) The vaccination administration workflow resulted in the least number of direct observations (9/111 encounters, 8% total encounters).

Summary of identified workflow gaps and deviations (Table 3)

Across the 4 workflows, a greater number of critical workflow gaps (n = 17) were identified, compared to sequence deviations (n = 9) or step deviations (n = 9) (total gaps/deviations = 35). Table 3 summarizes the number of workflow gaps and deviations identified across all 4 medication-related activities based on the categories discussed in "Phase 3: Categorization of Critical Workflow Gaps and Deviations."

Practice-level workflow enhancement recommendations (Table 4)

Pragmatic, practice-level recommendations to enhance workflow safety were developed for each observed medication-related activity. We presented these recommendations to the practice's medical director, in addition to a summary of the identified critical medication safety workflow gaps and deviations. The purpose of this discussion was to prioritize opportunities for medication-related workflow enhancement within the practice. The recommendations found in Table 4 pertaining to warfarin medication management were selected as top-priority, and were implemented prior to the completion of the project. Recommendations relating to the other 3 medication-related activities were marked for future implementation beyond the timeframe of the pilot project given competing, internal practice priorities.

Discussion

Interpretation of findings

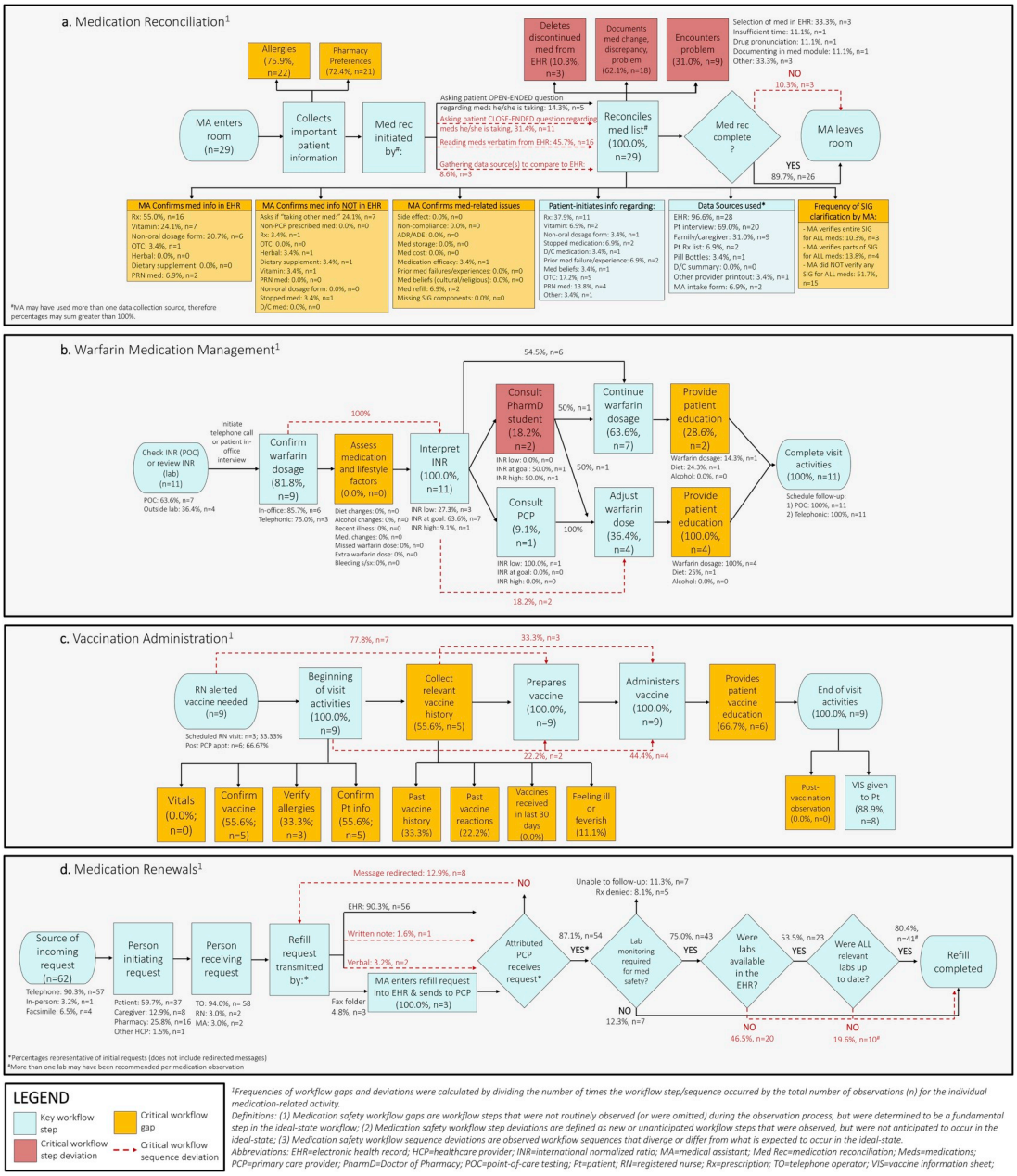
A. Medication reconciliation

The observed medication reconciliation workflow had the greatest number of combined critical medication safety workflow gaps and deviations. Issues with data verification, data documentation, and communication resulted in 17 gaps and deviations total, or 49% of total workflow safety issues across all medication-related activities. The majority of these gaps and deviations (9/17, 53%) were due to issues with data verification. These encounters were commonly influenced by inappropriate MA-patient communication methods during the medication reconciliation process. In 31% of the total medication reconciliation encounters, MAs initiated the medication reconciliation process using close-ended questions, such as "are there any changes in your medications today?" Similarly, in 46% of total encounters, MAs completed medication reconciliation by reading verbatim the medications available within the practice's electronic health record (EHR). These two communication methods are not ideal, as they minimize opportunities for active patient engagement in the medication verification and reconciliation process, which can ultimately lead to the development of an incomplete or incomplete mediation list.

Some of the critical medication safety workflow gaps and deviations were also a result of incomplete or inappropriate documentation within the EHR (3/17, 18%). Many times MAs did not verify patient-reported

Table 4
Recommendations to enhance practice-level medication safety for each medication-related activity.

Medication-Related Activity	Recommendations to Enhance Mediation Safety
Medication Reconciliation	• Development and implementation of a medication reconciliation training program for medical assistants, nurses, and providers to enhance understanding of medication reconciliation "best practices" and to implement a consistent approach to medication reconciliation
Warfarin Medication Management	• Development of an outpatient warfarin management algorithm to increase consistency in prescribing patterns/warfarin management across all office providers • Development and facilitation of an office-wide lunch and learn for providers and staff education regarding considerations in warfarin management • Creation of a 1-page summary on appropriate warfarin management
Vaccination Administration	• Nursing education on the importance of verifying: (1) Relevant historical information including vaccine history/recently administered vaccines, past vaccine reactions, and patient allergies, (2) Vaccine to administer for ALL patients, and (3) patient identify and confirmation of recent/current illnesses prior to vaccine administration
Medication Renewal Requests	• Development of an outpatient medication refill protocol to be used by an office pharmacist to streamline the medication refill process and enhance medication safety



[1]*Frequencies of workflow gaps and deviations were calculated by dividing the number of times the workflow step/sequence occurred by the total number of observations (n) for the individual medication-related activity.*
Definitions: (1) Medication safety workflow gaps are workflow steps that were not routinely observed (or were omitted) during the observation process, but were determined to be a fundamental step in the ideal-state workflow; (2) Medication safety workflow step deviations are defined as new or unanticipated workflow steps that were observed, but were not anticipated to occur in the ideal-state; (3) Medication safety workflow sequence deviations are observed workflow sequences that diverge or differ from what is expected to occur in the ideal-state.
Abbreviations: EHR=electronic health record; HCP=healthcare provider; INR=international normalized ratio; MA=medical assistant; Med Rec=medication reconciliation; Meds=medications; PCP=primary care provider; PharmD=Doctor of Pharmacy; POC=point-of-care testing; Pt=patient; RN=registered nurse; Rx=prescription; TO=telephone operator; VIS=vaccine information sheet;

Fig. 2. a-d. Observed workflow process maps.

data with an objective data source, such as patients' medication prescription vials or community pharmacy dispensing histories. Unless a patient is a reliable and accurate historian, this approach can lead to inaccurate documentation of the patient's medication use within the home, and can inappropriately influence higher-level medication management processes such as medication prescribing and optimization.

B. Warfarin medication management

Although the warfarin medication management workflow had less total critical medication safety gaps and deviations (as compared to medication reconciliation), the identified gaps and deviations for warfarin management were found to have serious safety implications. Sixty seven percent (4/6 total gaps and deviations) were a result of inappropriate RN-patient communication. In all observations (n = 11), the RNs never asked about changes in lifestyle pertaining to warfarin use (e.g., medication adherence, missed warfarin doses, changes in diet) prior to adjusting or continuing warfarin dosages. This step is crucial to safe warfarin use, as lifestyle factors can significantly influence the decision-making process for continuing or modifying warfarin medication regimens. If this information is not verified at the time medication treatment decisions are made, patients can experience clinically significant subtherapeutic or supratherapeutic international normalized ratios (INRs).

Additionally, the RNs rarely provided patient education for warfarin self-management and administration within the home. Communication of changed or continued warfarin dosages and lifestyle modifications is imperative to ensure patients comprehend how to appropriately manage their therapy in-between anticoagulation management appointments and primary care provider visits.

In 73% of total warfarin medication management observations, RNs initiated a medication dosage change without consulting with the primary care provider. This is inappropriate given that the practice currently does not have an established anticoagulation collaborative practice agreement between RNs and primary care providers. This practice can potentially increase the risk of an adverse drug event or medication error if an erroneous dosage adjustment is made without the oversight and approval of the provider.

C. Vaccination administration

8/9 (89%) of the critical medication safety workflow gaps and deviations for the vaccine administration workflow were a result of incomplete data verification. In 7/9 encounters (78%), the RNs prepared the vaccine for administration prior to verifying or collecting important vaccine-related information. Examples of important vaccine-related information include: (1) patient identity, (2) vaccine for administration, (3) patient allergies, and (4) past vaccine reactions/intolerances. Preparing a vaccine for administration prior to verifying or collecting this information is critical to prevent medication waste (if the incorrect vaccine was prepared) and medication safety events, such as vaccine-induced anaphylaxis.

Verification of important vaccine-related information was performed 0%–56% (range) of the time, depending on the specific data element. Comprehensive evaluation of important vaccine-related information should be performed for every vaccination encounter to ensure appropriate, effective, and safety vaccination administration for every patient.

D.Medication renewals

No critical medication safety gaps or workflow step deviations were identified for the medication renewal request workflow; however, 3 critical medication safety workflow sequence deviations were noted. Sixty-seven percent (2/3 encounters) were attributed to inappropriate documentation, and 33% were a result of inadequate RN-patient communication.

Seventy-five percent of total medication renewal encounters were attributed to a medication that required monitoring (per recommended clinical guidelines) of one or more laboratory values or vital signs. Forty-seven percent of these medication renewal requests did not have appropriate laboratory/vital information available within the EHR at the time the prescriber addressed the renewal request. For the 53% of medication renewal requests that had all pertinent laboratory/vital data available within the EHR, 20% of the requests contained one or more out-of-date laboratory/vital test. Although we did not directly observe prescriber workflows, there is a medication safety concern if prescribers refill these medications without reviewing current laboratory/vital test results. Additionally, the TOs sometimes alerted the prescriber of a medication renewal using a written note or verbal notification without documenting the request in the EHR. This is not ideal, as this approach can increase the risk of the prescriber forgetting to complete the medication renewal since it is not within the medication renewal EHR inbox, which can potentially extend the length of time the patient may be without their medication at home.

In 13% of the total medication renewal encounters, the initial renewal request transmitted within the EHR required redirection to the appropriate recipient, in this case, prescriber. Although seemingly a small percentage of the total incoming medication renewal requests, this inefficient workflow can significantly slow down the time it takes for the patient to receive their medication from the pharmacy by as much as 1 week.

Workflow Mapping Implementation Challenges

A few challenges were encountered in the implementation of the workflow process mapping pilot project. One of the largest challenges was preventing observed non-provider staff members from altering their normal workflow during observations (i.e., Hawthorne Effect).[20] When the observers recognized an alteration in workflow, they alerted the observed non-provider staff members of the change in workflow. This alteration in staff behavior could have impacted our findings by masking potential workflow safety concerns that would have normally been present. In future studies, researchers should consider using a triangulated approach to data collection by supplementing direct observations with practice staff and leadership surveys, questionnaires, semi-structured interviews, and/or focus groups.[21,22]

Additionally, we found it difficult to ensure an equal amount of time was allotted to observe each individual RN, MA, or TO across all medication-related activities. When we created our workflow observation schedule prior to the start of data collection, we scheduled the 100 observation hours evenly across the 3 types of staff members; however, unanticipated barriers within the practice prevented this from occurring, including: (1) day-of RN, MA, or TO shift changes; (2) high frequency of staff vacation, personal, and/or sick days, and (3) MA and RN cross-coverage of staffing responsibilities within the practice's outpatient primary care and specialty offices. These barriers were most common with the practice's RN and MA schedules, and were a major reason why approximately 50% of observations occurred with the practice's TOs. Given this challenge, it is possible that greater workflow variation exists for the workflows performed by the RNs and MAs, but was unable to be observed. Extending the observation timeframe or increasing the flexibility to reschedule observation times could help overcome this issue in future studies. This was not possible in our study, however, given that our data collection period was restricted to a 6-week timeframe.

Limitations

There are a few limitations of this pilot project that are important to note. First, we were limited to a 6-week timeframe for data collection and observation purposes. This limited our abilities to reschedule observations with practice staff when needed, as noted above under “Workflow Mapping Implementation Challenges.” Additionally, this

hindered our ability to follow-through with implementing all of the medication safety improvement recommendations prior to the completion of the pilot project. This project was also conducted within one primary care practice. Therefore, the types of workflow gaps and deviations identified in this pilot may not be representative of all practices. Researchers or clinicians looking to utilize this approach in the future may consider using a multi-site model to strengthen our understanding of the workflow safety issues occurring in practice today. Additionally, the observed workflow process maps developed in this pilot are representative of the pilot project practice's specific RN, MA, and TO workflows for the 4 medication-related activities. Therefore, future studies should consider that observed workflow process maps may vary depending on each practice's characteristics, and may not be identical to the results identified in this pilot project. Lastly, the scope of this project was to characterize the landscape pertaining to primary care medication safety by identifying critical medication safety workflow gaps and deviations. Future research should explore the use of workflow process mapping to identify system-level factors that contribute to the development of medication workflow gaps and deviations. This approach could provide insight into specific opportunities for practice-level process redesign to improve safety for medication-related activities in primary care.

Implications for practice

Workflow process mapping of medication-related activities can determine opportunities for primary care pharmacist integration. Primary care clinical pharmacists can utilize their expertise and training to collaborate with primary care clinicians and leaders to: (1) develop training curriculum to educate staff and providers on the appropriate approaches to complete medication-related activities, and (2) develop workflow-specific algorithms or protocols to ensure consistency in workflow execution across all staff/providers. While the medication safety improvement recommendations developed in this pilot project may be rudimentary for advanced or highly integrated primary care practices, these recommendations are exemplary of pragmatic strategies for pharmacists to improve primary care medication safety. This may be especially applicable for practices with minimal pharmacist integration.

Conclusion

The results of this workflow mapping pilot project exemplify the need to enhance primary care medication safety at the practice-level. Opportunities exist to streamline workflows relating to data verification, data documentation, and staff-patient communication for 4 common medication-related activities in primary care, including: (1) medication reconciliation, (2) warfarin medication management, (3) vaccination administration, and (4) medication renewal requests. Additionally, this approach can be used to identify opportunities for primary care pharmacist integration, particularly for practices with little or no prior pharmacist involvement.

Declaration of interest

Conflicts of interest

None.

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