Engineering Resilient Community Pharmacies: A Protocol for Exploring an Integrative Approach to Medication Safety

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Abstract

Background: The increase of people with complex chronic health conditions is stressing the U.S. healthcare delivery system. Community pharmacies play a role in ensuring patients' safe medication use for chronic care management, but their efforts are undermined by volatile work demands and other system barriers.

Objective: This study seeks to conceptualize, design, implement, and test a MedSafeMapTM for the community pharmacy setting to enhance pharmacists' and technicians' abilities to either avoid, or to quickly identify and recover from, medication errors before patient safety is endangered.

Methods: Aim 1: Four rounds of observations within the six pharmacy sites will be conducted to parse out areas MedSafeMap could address. Two rounds of interviews with a different one pharmacist and technician from each of the sites will be used to expand upon areas of interest identified during the observations. Aim 2: Focus groups with pharmacists and technicians will aid in the design of MedSafeMap components. Simulation-based research will be utilized to test MedSafeMap components with standardized patients in complex care managament scenarios. Aim 3: MedSafeMap will be implemented into pharmacies. Observations using WOMBAT for time and motion study will aid in understanding how MedSafeMap impacts pharmacy staff workflow.

Results: As of November 15th, 2024, all six pharmacy sites have been recruited and three of four rounds of observations have been completed. Interviews have been conducted with 12 pharmacists and 11 technicians from the study sites. Preparations for Aim 2 are in the works as Aim 1 analysis continues.

Conclusions: The MedSafeMap is an innovative approach that will be used by pharmacists and pharmacy technicians to better navigate the complex tasks in the pharmacy, and to facilitate communication with both patients and clinicians, while safely providing medications to complex patients with chronic health conditions.

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Keywords: Medication Safety; Community Pharmacies; Provider Status; Pharmacy Intervention; Participatory Design; Stakeholder Groups; Resilience; Safety I/Safety II

Introduction

Over 100 million Americans have multiple chronic conditions[1] that contribute to more than one million adverse drug events (ADEs) annually, prompting four million people to seek medical care and costing the U.S. healthcare system over $8 billion per year.[2,3] Healthcare spending for patients with multiple chronic conditions is up to 20 times higher than for patients with no chronic conditions. That is, Americans with five or more chronic conditions comprise 12% of the population but 41% of total healthcare spending, averaging 20 physician visits per year and using up to 50 times more prescription medications.[1] Challenges with managing multiple chronic conditions has a direct impact on healthcare utilization with such patients representing a quarter of all hospital admissions annually, with a third of all patients having at least one emergency department visit every year.[1] Despite these health consequences, efforts to improve medication safety for complex patients in outpatient settings have not been allocated the appropriate resources to be effective.

Community pharmacists are recognized as the champions of medication safety, not only through dispensing tasks but also by their expanding role in chronic care management (CCM).[4] CCM can include managing health problems and goals, medications, other providers, and community services that patients have and need. In many states, CCM also encompasses ordering and interpreting tests for chronic conditions, such as diabetes,[4] through collaborative practice agreements with providers, and ensuring patients receive appropriate screenings and immunizations. Such expanded practice was facilitated by the COVID-19 pandemic due to pharmacists being one of the few healthcare professionals providing face-to-face care and assuming clinical responsibilities when primary care physicians and nurses were managing COVID-19 emergencies.[5]

Further, community pharmacists play a vital role in medically underserved communities,[6] such as in locations with too few primary care providers, high poverty or a high elderly population. Patients in these areas face difficulty or delays in getting basic health care because of long travel distances to providers, long wait times for appointments, or no providers who can serve uninsured or underinsured patients. As a result, pharmacists are considered accessible primary care practitioners, seeing patients five to eight times more frequently than do primary care physicians.[7] Numerous studies have demonstrated the ability of pharmacists to address medication non-adherence,[8] support naloxone provision and opioid safety counseling,[9] provide pain management and palliative care,[10] improve diabetes and cardiovascular outcomes,[11] and improve vaccination rates in medically underserved communities.[12,13]

However, the abilities of community pharmacists to fill this gap are constrained by a work system that is unsustainable and essentially broken.[14] Pharmacies adhere to product-based reimbursement contracts with pharmacy benefit managers, incentivizing pharmacy staff to fill more prescriptions. As a result, for over a decade, pharmacists have reported high workload and burnout, with opaque corporate performance metrics based on prescription volume and customer service,[14] rather than on safety or clinical outcomes. COVID-19 exacerbated pharmacists' workload strain by adding testing and vaccinations to a system that is chronically understaffed and stretched beyond capacity. With pharmacist burnout rates at an all-time high, a call for action to improve pharmacist work systems is

critical to prevent a complete collapse in America's pharmacy system. Pharmacists across the United States have been executing a series of walkouts since September 2023 to improve harsh-working conditions and preventable errors in care.[15] In Walgreens alone, 600 employees across 20 stores have participated in walkouts, resulting in multi-day disruptions to workflow and patient care.[15] The purpose of these walkouts is to shed light on the need for a solution to improve the working conditions of pharmacy staff.

Juxtaposed to this era of pharmacists' unmanaged workload, there is a push for them to do more, as evidenced by the introduction of "provider status".[16] Provider status will allow pharmacists who provide services such as CCM, comprehensive medication management, and immunizations to receive reimbursement for such clinical services, in addition to product-based dispensing services.[17] This provides a timely opportunity for pharmacists to envision innovative designs to improve medication safety for their patients. To reimagine community pharmacies as an accessible destination for CCM, we must recognize the increased complexity of the community pharmacy work system. Similar to the increase in pharmacy staff responsibility related to the COVID-19 response, adding additional clinical services with the addition of reimbursement has potential implications for the quality and safety of pharmacist education, business practices, and dispensing. Opening up avenues for reimbursement that is not product based allows for stronger sustainability of expanded services and greater impact in their patient care practices, which can potentially fill a critical gap in Wisconsin, where two-thirds of its counties are medically underserved.[12,13]

This opportunity to adopt new services and create coordinated care models can present a significant medication safety challenge. Community pharmacists' heroic response to COVID-19 demands created work systems that increased stress and negatively impacted their ability to ensure safe use of medications they dispense.[18] Pharmacist provider status can lead to sustainable and collaborative programs that holistically address complex patients' chronic care conditions. However, doing so without prospectively considering and testing for unintended consequences may negatively transform the community pharmacy work system, threatening the very medication safety strategies on which pharmacists have come to rely. The consequence of this reality is synergistic: high workload demands contribute to medication errors and ADEs, leading to pharmacists experiencing "learned helplessness" and lack of resiliency (or the ability to adapt to unpredictable work situations) in the face of these ADEs.[19-22]

Approaches to Medication Safety

Many medication safety studies strive for "zero harm"[23-25] by focusing on "what went wrong" in the face of undesired outcomes, referred to as a Safety-I approach.[26] The traditional harm-reduction approach has been to conduct root cause analyses of errors and understand the contributing factors that led to the error, in order to reduce their incidence or mitigate their harm. A number of strategies have been encouraged based on this approach, including those developed and tested in our previous studies,[27,28] but the end result is frequently more constraints in a complex system that limits workers' ability to adapt. Such strategies end up limiting the capacity to adapt to practice demands and make the system more brittle, which can unintentionally lead to other medication safety hazards. Further, stacking isolated interventions does not lead to fundamental changes to the approach to medication safety. It is not surprising that little progress on substantive improvement has occurred in medication safety in the outpatient community pharmacy setting.[29]

Medication safety must be considered in a new way that encompasses Safety-II, the "what went right" approach. Safety-II[30] is based on resilience engineering, which focuses on understanding how resilient performance is achieved – creating a work system that will attend to unexpected threats while also responding to opportunities.[31] Instead of framing safety as a linear failure-based model, we need to broaden the scope of inquiry to recognize the complexity and inherent variability in modern systems such as community pharmacies. Further, we need to shift beyond an exclusive

consideration of ADEs and failures to also understand and strengthen a work system's abilities to continuously create safety in everyday practice.[32] This goal is achieved by focusing on the abilities of a work system to: absorb significant stress before a disruption impacts safety, return to normal operations as quickly as possible and, importantly, adapt to undesirable situations. A system with adaptive capacity can anticipate disruptions and reorganize workflows using alternative paths to maintain successful work and minimize disruptions.[33] An example of Safety-I and Safety-II approaches can be found in Table 1.

Table 1. Examples of Safety-I and safety-II Approaches

Safety-I Example	**Safety-II Example**
Checklists can decrease risk by imposing a structured process, but may be counterproductive	When a checklist restricts an unexpected situation
• A checklist can be completed by rote, rather than thoughtfully • A checklist may install a false sense of security when there is an assumption that all important items are contained in the checklist • Current conditions may be different from the conditions under which the checklist was conceived • The ability for workers to adapt to new conditions is lost	• Workers double-check facts against each other • Workers are open and honest about explaining why they wish to deviate from the checklist • There is a healthy skepticism about deviating from the checklist • Workers ask for constructive criticism, ensuring that they are taking the best possible novel approach • Workers embrace team members from other work systems for their "outside the box" thinking

The Patient Safety Learning Laboratory: ENRICH

Despite numerous calls, there has not been a systematic engineering approach towards outpatient medication safety within community pharmacies. Previous PSLLs have evaluated the physical environment, socio-technological factors, and clinical workflow within inpatient and clinical settings but not within the outpatient community pharmacy settings.[34] This project, informed by resilience engineering, will address the challenges common in community pharmacies to achieve safe medication use in community-dwelling complex patients with multiple chronic conditions. The goal is to evolve from Safety-I approach to a combined Safety-I and Safety-II approach. The resulting outcome, the Engineering Resilient Community Pharmacies (ENRICH) Patient Safety Learning Laboratory (PSLL), is expected to gain knowledge of strategies for building resilience capacity in community pharmacy work systems in conducting CCM. PSLLs encompass a systematic engineering approach to allow cross-disciplinary professionals to evaluate clinical processes and approaches towards improvements in patient safety.[34]

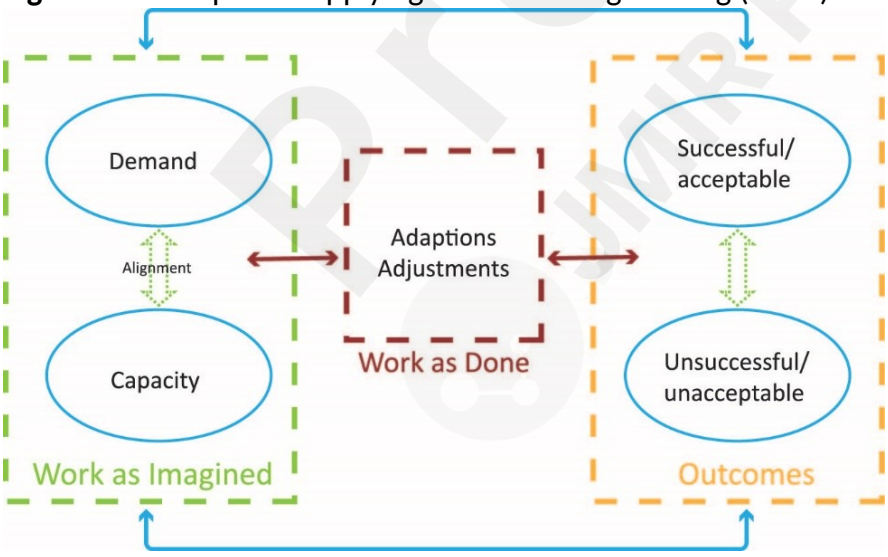
Our long-term goal is to position the ENRICH PSLL as the premier center for medication and patient safety and CCM in community pharmacies. Despite our prior work, a current gap exists in the systematic application and evaluation of human factors and health systems engineering approaches to improve medication safety and staff work life in community pharmacies. Our PSLL, which is led by experts in human factors and health systems engineering, represents a foundational step towards the creation of a center to promote and normalize a Safety-I/Safety-II approach in pharmacy systems research. Our PSLL will include a focus on the use of the principles of dissemination and

implementation research to enhance the potential for sustainability of improvements resulting from patient safety innovations. In addition, this PSLL is designed to generate ideas for future research projects and examine the implications and outcomes related to pharmacist "provider status," which can serve to expand CCM to support complex patients living in medically underserved areas. The PSLL resulting from this study represents the beginning of a new paradigm, unprecedented in the pharmacy setting, for improving medication safety for community-dwelling patients with complex chronic disease.

Methods & Design

The methods used for this project have demonstrated success with other healthcare practitioners and in other patient safety studies.[27,28] The Concepts for Applying Resilience Engineering (CARE) model guides our data collection, analysis, and interpretation (Figure 1). Resilience is the ability for the community pharmacy work system to adjust its functioning prior to, during, and following sentinel or unexpected events, and thereby sustain operations under both expected and unexpected conditions.[35] It assumes that variability in the environment creates the need for adjustment. Work as Imagined (WAI) is conceptualized as the intended, or imagined, alignment between demands of the system (prescription volume, patient acuity) and the capacity to meet those demands. Demand and capacity can never completely align because of the complex nature of the system – there will always be unforeseen demands that require workers to adjust in situ. In addition, workers do not simply comply with protocol but naturally adapt and innovate as part of taking control over their environment. In the CARE model, Work as Done (WAD) refers to the adjustments and the natural variability in how tasks are conducted. Predicting acceptable (what goes right) and unacceptable (what goes wrong) outcomes depends on an understanding of WAD in different demand and capacity circumstances. In this project, we will be using the concepts of WAI and WAD to identify the gap in how pharmacy staff plan their approaches to patient care and how they are able to actually fulfill their responsibilities.

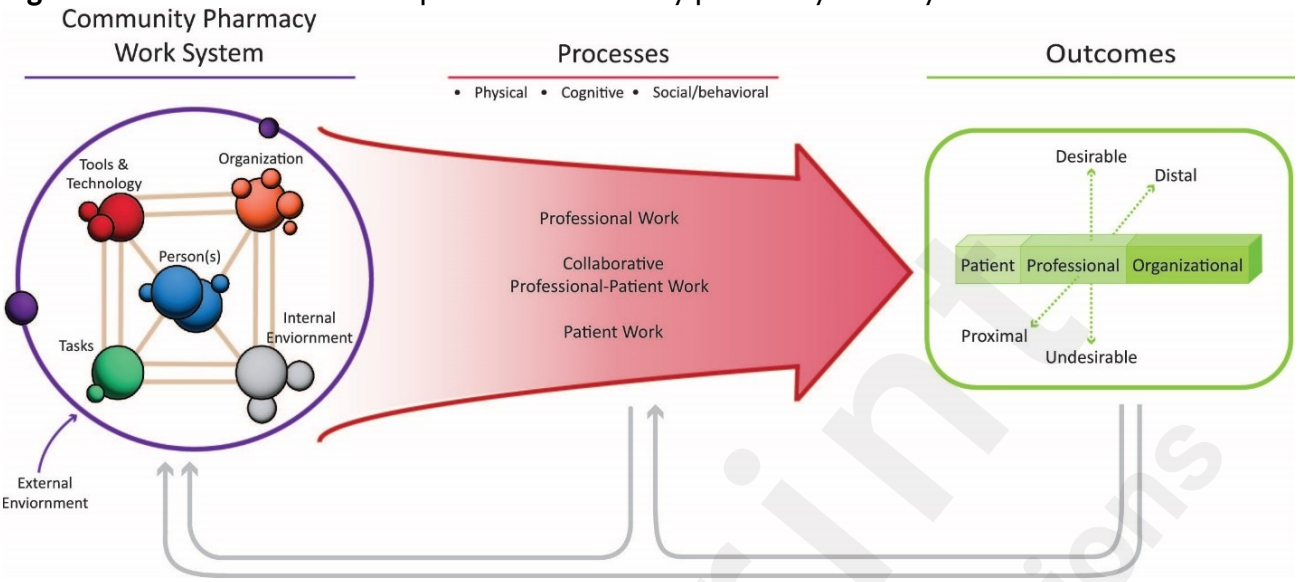
Figure 1. Concepts for Applying Resilience Engineering (CARE) model



Since resilience also applies to the organizational level, and to adaptations in complex systems, it is essential to ensure that characteristics and adaptations of the entire work system are captured. To operationalize the discrete facets of the work system, we have used Systems Engineering Initiative for Patient Safety (SEIPS) 2.0, a human-factors engineering model to improve patient outcomes (Figure 2). The SEIPS model has framed the design and analysis of many safety studies, including research we conducted in community pharmacies.[28,36-38] The CARE and SEIPS models work well in tandem because both models contain feedback loops and account for the interconnectedness of

work system components. In Figure 2, “professional work” references both pharmacists and technicians. Patient work includes the work of the patient and their caregiver, which is essential to CCM.

Figure 2. SEIPS 2.0 model[39] adapted for community pharmacy work system



Ethics Approval

All human subjects research described will be reviewed and approved by the University of Wisconsin – Madison Institutional Review Board. Aim 1 has been approved (study ID: 2023-1100), and all other aims will be reviewed and approved before beginning any human subjects research.

Study Sites

To ensure a complete understanding of the problems and implementation strategies of varied community pharmacy work systems, we will partner with three pharmacy organizations.

1. Advocate Health is the 10th largest non-for-profit, integrated health system in the U.S. with 70 community pharmacies that are geographically dispersed throughout urban and rural Wisconsin and Illinois.
2. UW Health is the integrated health system of the University of Wisconsin – Madison, with twelve outpatient pharmacies.
3. Boscobel and Center Pharmacies are located in rural Southwest Wisconsin and are independently owned.

Within each of these organizations, two pharmacies will participate that serve ethnically diverse populations and people in medically underserved areas that have high area deprivation indices based on income, education, employment, and housing quality, for a total of six pharmacy sites. In addition, all pharmacies will have at least read-only access to the electronic health records of their patients, which may serve as a tool to facilitate CCM.

We will also partner with Fitchburg Family Pharmacy to conduct in-situ simulations, in which we will use simulated complex patient scenarios in a pharmacy itself rather than in training facilities, for the design and development phases (Aim 2) of the project. Fitchburg Family Pharmacy is a medium-sized urban independent pharmacy that provides CCM to a diverse patient population.

Project Aims

Table 2 describes our project structure: starting with problem analysis (Aim 1), continuing with design and development (Aim 2), which will lead to implementation and evaluation (Aim 3). An

expert advisory board, comprised of transdisciplinary stakeholders, will be formed to provide us with high level consultation and content expertise for each of the three project aims. This board includes patients, caregivers, a pharmacy technician researcher, a pharmacy owner, primary care physicians, managers of independent, local, and chain pharmacies, and leaders of pharmacy and medical societies in Wisconsin.

Table 2. Project Structure Guided by the AHRQ RFA 5-Step Methodology

5 Step Methodology	Problem Analysis	Design	Development	Implementation	Evaluation
Aims	*1: Identify and Prioritize*	*2: Prototype and Simulate*		*3: Pilot and Evaluate*	
Methods	• Observations & interviews • Information flow diagraming • Artifact analysis	• Participatory design • Simulation		• Time motion • Pre/post evaluation • Expert evaluation • Surveys and interviews	
Outputs	• Resilience narratives • Functional Resilience Analysis Method diagrams	• Prototypes • Ideal interactions • Detailed design specifications		• Impact of prototypes on process & outcomes • Tools to assess capacity for resilience • Implementation guide	

Aim 1: Identify and Define Design Requirements

To develop effective and sustainable interventions, an in-depth problem analysis of the work system must be conducted. Thus, the goal of this aim is to understand and map work system resilience, including how WAI differs from WAD, how adjustments are created, and how outcomes are generated. Iterative data collection and analysis will allow continual refinement and clarification of the work system.

Observations

In-depth ethnographic observations will be conducted over four visits to each of the six pharmacy observation sites (Table 3). Study team members will debrief after each observation, as well as in-situ as needed, to adjust observation approaches or focus on specific aspects of the workflow. We will complete 24 hours of observations over four days. Observed artifacts that reflect WAI, such as policies and procedures, memory aids, and cognitive tools, will also be collected and recorded. Full descriptive field notes will be produced immediately after each observational session. Data will be collected concurrently at each setting, and researchers will work across all settings so that comparisons between the settings can inform ongoing data collection strategies.

Table 3. Observations at the Pharmacy Sites

High-Level Observation Questions
1. What contributes to variability in demand and capacity? **2.** What misalignment occurs between demand and capacity, and why? **3.** What pressures, problems, or goals are pharmacists and technicians responding to when they create new ways to achieve outcomes? **4.** How and under what circumstances do adjustments or adaptations lead to successful and unsuccessful outcomes?

Visit 1: Exploratory Evaluation	Visits 2-4: Observations
• Observe the pharmacy environment holistically • Identify staff roles and responsibilities, processes, and procedures, flows of information and communication, coordinating mechanisms, and supporting tools and technology • Identify interest areas for more precise and targeted observations in subsequent stages	• Observe the pharmacy staff • In-depth observations of important processes such as shift change handoffs and medication reconciliation for patients during hospital discharge, as processes critical to providing CCM • Short, structured, discussions and facilitated reflection from staff on aspects of the CARE model and using the SEIPS model components

Interviews

Semi-structured interviews will be separately conducted with two pharmacists and two technicians from each of the six pharmacy locations to explore and follow up on issues from the prior observation stages to identify processes or areas for additional observation. Questions will focus on how people do their work and how they manage tricky situations, with probes about variability, adaptations, problems, and challenges. Interviews will be audio recorded and transcribed for analysis with participants' consent.

Data Analysis

Data Analysis will proceed in three stages. First, a combined deductive-inductive approach will be used to thematically analyze the observation and interview data. A coding scheme will be developed based on elements of the SEIPS model, as well as important themes in the data not captured by the model (see Table 4). Categories will be developed by constantly refining the coding scheme, and comparisons will be made between different respondents, different pharmacies, and different processes.

Table 4. Aim 1 Observation and Interview Coding Scheme

Levels	Comparison of WAD and WAI
Teams of Pharmacists & Technicians	• Interpersonal communication, including verbal and nonverbal • Teamwork skills, including leadership and situation awareness
Technology	• Usability, flexibility, adjustability, and adaptability
Internal Environment	• Interruptions and distractions • Lighting • Physical ergonomics of workspace • Crowding and disorganization
Tasks	• Task demands/workload • Contextual changes, including situation deviations from normal or expected • Production pressure

Organization	• Complexity, uncertainty, and risk • Information flow, including quantity and pacing • Culture and climate • Policies and procedures • Incentives and disincentives

Second, guided by the CARE model, we will expand on the SEIPS coding scheme to construct Functional Resilience Analysis Method (FRAM) models[40,41] to visualize WAD, and to articulate the discrepancies between WAI and WAD. FRAM models allow all activities within selected processes to be visualized to show how they relate to each other and how they interact, based on 6 aspects: (1) input, (2) output, (3) pre-condition, (4) resources, (5) time, and (6) control, demonstrating the system's complexity.[42] Each process within the community pharmacy is linked, which allows the study of variability of each process. That variability can produce amplified and unpredicted outcomes (either acceptable or unacceptable).[40,41]

Third, the themes generated by the deductive-inductive approach and the FRAM models will be used to create resilience narratives describing trajectories of activity linking misalignments of demand and capacity, adjustments, adaptations, and outcomes. The narratives will focus on how adjustments and adaptations (WAD) mediate between pressures caused by misalignments of demand and capacity, and outcomes.

Aim 2: Design and Develop MedSafeMap™

Stakeholder engaged participatory design and simulation-based research will be used in an iterative fashion to design and develop MedSafeMap™, a package of components to optimize pharmacy staff interactions within their work system and with patients and detailed pharmacy design recommendations. Standardized complex patient scenarios will be developed to have both internal validity and fidelity to the real-world pharmacy environment. The goal is to create MedSafeMap components that will ultimately lead to pharmacy staff resilience and optimized patient interactions around CCM.

Participatory Design

Participatory design is an approach to systems design that actively involves all stakeholders at several stages of the innovation process to help ensure that the result meets their needs and is usable.[28] Two stakeholder groups will be used: one group consisting of five community pharmacists and one group consisting of five technicians.

Stakeholder group meetings will be held six times, approximately every 6-8 weeks. The first four meetings will be held with the pharmacists and technicians separately, since they have different work responsibilities, tasks, and concerns. We also want technicians to fully engage in MedSafeMap development without a pharmacist presence imposing a power differential. The resilience narratives and FRAM diagrams developed in Aim 1, which demonstrate variability and resilience potential, will inform the design and development of the MedSafeMap. We will focus on the processes required to conduct CCM for complex patients, including the possibility of a communication tool to support discussion of alternatives, enhanced instructions for patients, and cognitive aids to support memory. The final two meetings will involve MedSafeMap refinement. To do so, we will bring the pharmacist and technician groups together to work collaboratively. Table 5 provides a list of anticipated or possible MedSafeMap components. Completed MedSafeMap components will be peer reviewed by our advisory board to confirm that they will reproduce the experience in a real-world pharmacy. Scenarios will be piloted in the in-situ simulated setting and refined prior to implementation in Aim 3.

Table 5. Current Interactions and potential MedSafeMap Components to Encourage Ideal Interactions

Current Interactions	Potential MedSafeMap Components

• CCM is seen as important but has an impact on workload, which is a barrier to sustained services
• Fragmented information across providers
• Medication information gap (e.g., multiple pharmacies, no diagnoses or lab values)
• Busy retail pharmacies lead to reduced interactions with patients
• Coordination gap between pharmacists and caregivers, patients, and providers
• Technicians limited by traditional roles
• Medication concerns not adequately addressed
  o Limited support and space for shared decision making
	• **Modeling behaviors**
	  o Tactics to overcome communication barriers in pharmacies and engage providers
	  o Patient/family supports to bridge information gap
	• **Information support**
	  o Use technology or low-tech strategies to "push" eligible patients into the pharmacy workflow
	  o Create mechanisms to include caregivers prior to, in appointment, and follow up
	• **Cognitive Aids**
	  o Physical structures to improve pharmacists' and technicians' situation awareness
	  o Supports to address high priority medication needs
	• **Collaborative work support**
	  o Facilitate a "huddle" between pharmacist sand technician to create appointment agenda, anticipate patient challenges, review monitoring needs
	• **Role clarity and cross training**
	  o Empowering technicians as equal partners and health leaders in the community pharmacy

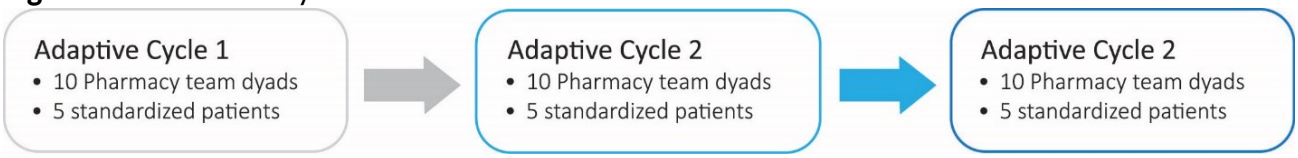
Simulation-Based Research

In situ simulation,[43] or simulation in an actual community pharmacy, will then be conducted to study the ergonomics and physicality of the work setting on performance. In situ simulations also will promote process and MedSafeMap refinement before deployment in actual pharmacies.

The final two stakeholder meetings also will involve three rapid adaptive simulation cycles for MedSafeMap refinement (see Figure 3). Each simulation cycle will include 5 different standardized patients (hired for the study). Each patient will represent one of five different complex CCM scenarios that will include at least two chronic conditions and at least one social determinant of health (e.g., low health literacy patient with diabetes and congestive heart failure who is non-adherent to medications). Staffing and equipment, level of complexity, and other critical indicators identified in the participatory design will vary, and allow for comparisons, across the five patient

scenarios. Creating robust and standard scenarios is important to mitigate threats to internal validity. Thus, we will devote considerable time to ensuring that the MedSafeMap may be utilized in different patient cases, and in different community pharmacy settings (i.e., are pharmacy agnostic).

Figure 3. Simulation Cycles



Ten pharmacist/technician dyads will be recruited to participate in each adaptive simulation cycle. In each adaptive cycle, the pharmacy/technician dyad will complete the simulation five times, once for each standardized patient. The process will be replicated for each of the 10 pharmacy dyads resulting 50 simulations per adaptive cycle. At the completion of each cycle, the study team will then utilize the data collected combined with significant reflection and formative evaluation to refine the MedSafeMap that facilitates resilience and encourages adaption by pharmacy staff.

Data Collection

Four wide-angle video cameras will be used to record the simulation from locations that best capture how pharmacy staff interact with the physical space, communicate, and share information, and use artifacts within the work system. In addition, two sets of eye tracking glasses (Tobii Pro Glasses)[44-46] – one each for the pharmacist and the technician – will be deployed to track eye movement in the natural world, which will inform the development of prototypes. Specifically, as pharmacy staff navigate the physical pharmacy space, the glasses collect data that will provide an understanding about which artifacts are most instrumental to performing CCM, factors that influence pharmacy staff and patient decision-making, and workflow. Gaze data will be recorded as pharmacy staff read and review information on prescriptions and prescription profiles on the pharmacy electronic health record, and interact and educate patients.[47,48] Aim 2 will be accomplished in three steps, conceptualized in Table 6.

Table 6. Aim 2 Data Collection Procedures

	Step 1	Step 2	Step 3
Tasks	• Record simulations • Document individual and collective behavior	• Introduce MedSafeMap and record simulations • Simulate with 10 pharmacist/technician dyads for each of five different standardized patients	• Conduct individual debrief interviews with the pharmacists and technicians following completion of each simulated scenario
Goal	• Identify patterns of interactions and thought processes	• Reproduce situations identically to increase confidence in the MedSafeMap's ability	• Gain insight into the thoughts and cognitive processes of pharmacists and technicians
Output	• Descriptive account of how community pharmacy staff make decisions or share information	• Explain variation in the outcome of interest	• Understand participants' perceptions of (1) understanding the problem situation, (2)

	• Understanding rare events such as sentinel medication errors		assessing prototype feasibility, (3) evaluating the effect of the prototype, and (4) optimizing the design and implementation of the prototype

Data Analysis

Observational checklists will be used to code participant behavior recorded on the videos, thereby assessing MedSafeMap feasibility and effectiveness. The recordings from the wide-angle video cameras and eye tracking glasses will be analyzed for themes between participants and across sites by assessing what areas of interest participants fixate on for extended periods of time. Using gaze duration as a proxy for wearer attention provides insights into which elements of MedSafeMap are influential in shaping pharmacy staff behavior. For example, if one of the components of MedSafeMap includes a technician training to "speak up" when they are concerned that the pharmacist missed a medication related problem, we can respectively code the reactions of the pharmacist and technician based on the videos.[49,50]

Qualitative data from pharmacist and technician stakeholder meetings will be subjected to a rigorous analytic approach.[36,51-54] We will use deductive content analysis, inductive patterns, themes and categories in our data, guided by our theory-based approach.[55] A conceptual coding structure will be created and as each interview transcript is added to the analysis, passages will be classified according to existing codes, and codes will be added as needed. Inductive content analysis will also be conducted to determine unanticipated work system characteristics that may facilitate or inhibit resilience.

Aim 3: Implement and Pilot Test MedSafeMap

Although simulation-based research can have high internal validity by controlling the highly standardized scenarios that will be developed in Aim 2, it is critical to implement and evaluate MedSafeMap "in real life" where WAD diverges from WAI and to address external validity concerning pharmacy work systems relevant to CCM. With this approach, we can determine if changes in performance can be attributed to MedSafeMap rather than other external (e.g., regulatory changes) or internal elements (e.g., updates to electronic health records), and how such elements can affect MedSafeMap performance or impact. The six community pharmacies that participated in Aim 1 observations and interviews will implement MedSafeMap for optimal interactions designed in Aim 2.

Implementation and Adaptation

A stepped wedge design[38] will be employed, where the MedSafeMap will be sequentially implemented in two clusters, each cluster comprising of three pharmacies (one pharmacy from each organization) (see Figure 4). The two pharmacies from each organization will be randomized into the two clusters. Each cluster will commence with baseline pre-test data collection and then cross-over from the control condition (pre-implementation) to the intervention condition, where a formative evaluation of MedSafeMap and the strategies from the Implementation Guide will be conducted. This evaluation will be performed for each cluster 4 months into its implementation

period to consider "what might be missing, what sociotechnical factors had not been considered and to identify 'bugs and glitches' that still need to be addressed."[56] The evaluation will include one day of observations by shadowing pharmacy staff and may involve short discussions and facilitated reflection from staff at each of the three pharmacies in Cluster 1. Those observations will be brought back to the research team and advisory board to identify opportunities to improve MedSafeMap. Following the formative evaluation in Cluster 1, we will refine and improve MedSafeMap and implementation strategies to mitigate vulnerabilities or unintended consequences that may expose patients to new harms or further the work burden of pharmacists and technicians. The adapted MedSafeMap and implementation strategies will be deployed for Cluster 2, which will also undergo a similar evaluation. It is possible that minor adaptations will be made, if necessary, before subjecting the cluster to a post-test evaluation.[57]

Figure 4. Stepped Wedge Design and Data Collection Methods

Cluster 1	Pre-test Time & Motion Study	Implementation	Formative Evaluation Ethnographic Observation	Adapted Intervention	Post-test Time & Motion Study Pharmacy Data Interviews			
Cluster 2				Pre-test Time & Motion Study	Implementation	Formative Evaluation Ethnographic Observation	Adapted Intervention	Post-test Time & Motion Study Pharmacy Data Interviews

Evaluation

We will use a sequential explanatory design in which the initial data is quantitative (time and motion study, work volume) and complemented by qualitative data (interviews, medication error reporting). This mixed-methods approach will allow the research team to understand variables individually and determine which ones will require further analysis. In line with the CARE and SEIPS 2.0 models, we will collect and analyze data that reflect workflow and care processes, and the perspectives of pharmacists and technicians.

Time and Motion Study

Our evaluation goal is to examine the impact of MedSafeMap on pharmacists' and technicians' ability to be resilient – that is, to successfully attend to unexpected threats while also responding to opportunities,[31] such as CCM. To do so, we must understand clinical work processes and the way that care is delivered to patients. We anticipate that MedSafeMap will impact the way that pharmacists and technicians perform their work and the ways in which they engage each other and their patients. Time and motion studies have been used to measure clinical workflow related factors, including time task distributions, frequency of multitasking and interruptions, and who completes tasks with a goal of improving efficiency.[58,59]

We will conduct observations before and after the adapted MedSafeMap. Using the observational data collected in Aim 1, we will develop a pharmacy work task classification (see Table 7). The classifications will be incorporated in the Work Observation Method by Activity Timing (WOMBAT) program to allow for the consistent recording of observational data.[60,61] WOMBAT allows observers to time the start and end of tasks, and to record multiple simultaneous tasks using the multitasking function. If an external factor appears to cause a pharmacist or technician to stop performing one task and start another task, an "interruption" can be recorded.

Table 7. Pharmacy Work Task Classifications

Work Task Classification	Examples
What – the task being performed	Counseling, communication with prescriber
Where – the physical location where the task is undertaken	Behind desk, office, front of OTC counter

With whom – who the pharmacy staff was with when performing the task	Alone, patient, technician, student
How – any tools used to complete the task	Phone, face to face, computer

Observer Training

Prior to MedSafeMap implementation and baseline data collection, two observers will be trained to use the WOMBAT program. Data collection will begin when simultaneous but independent observations of the same events, such as those seen in Table 7, yield an inter-rater reliability score of at least 85%.[62]

Data Collection

Observations will be purposely scheduled across a variety of weekday shifts to maximize data variability and capture the full pharmacy workday. One observer will shadow a pharmacist equipped with a tablet with the WOMBAT software installed on it, while, at the same time, a similarly-equipped second observer will shadow a technician. In total, two pharmacists and two technicians will be observed at each pharmacy. Observations will be limited to three, two-hour, sessions per day, each separated by a brief break to reduce participant/observer fatigue. During each break, observers will memo any thoughts for future questions or more in-depth observation. The pharmacists and technicians will be observed for 36 hours both pre- and post-implementation, for a total of 72 hours. We estimate observing tasks across 72 hours in each pharmacy,[58] yielding a total of 432 hours across the six participating pharmacies.[60,63]

Data Analysis

To assess changes in pharmacists' and technicians' task time distribution post-implementation, we will calculate the proportion of total observed time in each task category by study period (pre- versus post-implementation) for each pharmacy. The proportions of total observed time where pharmacists completed tasks with technicians or alone and using different information tools will also be calculated for each pharmacy. To assess the extent to which the introduction of MedSafeMap increased opportunities for pharmacists and technicians to engage with patients in CCM, we will examine changes to the time pharmacists and technicians spent in (1) discussions with each other on responding to opportunities (i.e., identifying complex patients who would benefit from CCM) and attend to unexpected threats (i.e., personnel absences) and (2) discussions with patients about medications.[63] Z-tests for proportions will be used to compare the extent of pre- and post-implementation change in the proportion of total observed time for each task category in each pharmacy site. A $p<.05$ significance level will be used, as well as Holm approaches to account for multiple comparisons, with 95% confidence intervals based on the large sample normal approximation.

Pharmacy Reported Data

We anticipate that MedSafeMap will support pharmacists' and technicians' ability to embed CCM and other clinical services into their workflow, which will improve the quality of patient care, ideally without increasing workload. To assess perceived changes in service provision, pharmacists and technicians will be administered a validated subjective workload survey.[64] The number and type of documented medication-related problems during CCM services[65] that are identified and resolved for six months prior to and 12 months following MedSafeMap implementation also will be collected.

Pre/post comparisons of services provided and medication-related problems that they averted will be conducted.

Pharmacist and Technician Evaluation

We also want to gain a more in-depth understanding of how MedSafeMap changed attitudes, behaviors, and performance. It is expected that pharmacists and technicians will feel more resilient after MedSafeMap implementation. That is, they will feel more "capable, facilitated and supported by the organization, to utilize resources to continually adapt and flourish at work, even if/when faced with challenging circumstances."[66] This construct will be represented through the Employee Resilience Scale,[67] a measure of behavioral elements such as learning orientation, proactive posture, positive outlook, network leveraging, and adaptive capacity.

Pharmacists and technicians also are likely to eventually feel a greater sense of shared responsibility and teamwork, which would create an environment that enhances the medication safety of their patients. This construct will be represented through the NASA-developed Cockpit Management Attitudes Questionnaire,[68,69] comprising three scales – Communication and Coordination, Command Responsibility, and Recognition of Stressor Effects – which have application to the pharmacy work system.

Because we are working with a small number of pharmacists and technicians, and because we want to do an in-depth exploration of pharmacy staff attitudes and behaviors, we will adapt the Employee Resilience and Cockpit Management Attitudes Questionnaire items into an interview guide that will include semi-structured probes. Eight months following MedSafeMap implementation, interviews will be conducted using a retrospective pre-/post-test design approach[70,71] by asking, "Compared to before MedSafeMap was implemented, …" This approach is appropriate because it is pragmatic, less time-consuming, eliminates the impact of response-shift bias,[70] and has been used successfully in pharmacy studies.[72,73] Questions will prompt insights into the impact of MedSafeMap on pharmacist and technician resilience, teamwork, and shared responsibility. Interview data will be subjected to the same rigorous qualitative data analysis techniques described in Aim 1.

Outcomes

Study outcomes are targeted to help populations of medication safety researchers and organizational leaders responsible for implementing proven practices. A summary of the anticipated outcomes can be found in Table 8.

Table 8. Outcomes

Aim 1	Aim 2	Aim 3
• Resilience narratives and FRAM models that are context rich and context dependent • Potential to uncover anticipated relationships between variables that can be tested in the subsequent aims to inform the development of the MedSafeMap	• Components of MedSafeMap that support CCM in community pharmacies • MedSafeMap that may include designs that re-align currently-existing tasks, coordinate tasks with different pharmacy staff members, or incorporate new practices • MedSafeMap that may	• Quantitative and qualitative evaluation of the impact of MedSafeMap on community pharmacy processes and outcomes • Toolkit to assess capacity and resilience • Implementation Guide

	include tools to facilitate pharmacist/patient and pharmacist/prescriber collaboration, or tools to provide cognitive support for pharmacists and technicians to anticipate crises or other problems	

Project Duration

The entire duration of the project is projected to be from September 30th, 2023, to August 31st, 2027. Aim 1 was anticipated to end by August 31st, 2024, but data collection has lasted beyond that date. Aim 2 was anticipated to commence September 1st, 2024, but has been postponed due to the extension of Aim 1. Aim 2 will approximately begin December 2024. Aim 3 will begin September 1st, 2025, and last through August 31st, 2026. Participant recruitment is expected to be completed by the conclusion of Aim 3, alongside data collection. Results from varying analyses within the project are anticipated to be disseminated during the project's duration and following its completion. Aim 1 has received IRB approval, and each subsequent Aim will be reviewed by the UW-Madsion Institutional Review Board (IRB) before recruitment begins for each aim.

Results

As of November 22nd, 2024, all six pharmacy sites have been recruited and three of four rounds of observations have been completed. The first and second round of interviews with 12 different pharmacists and 12 different technicians from the study sites have been conducted. Preparations for Aim 2 are in the works as Aim 1 analysis continues. Aim 2 materials have been submitted to the IRB for review as of November 21st, 2024. Recruitment for Aim 2 will begin once it has received approval from the IRB.

Discussion

The prevailing Safety-I approach for improving medication safety has emphasized retrospective incident analysis, reactive measures targeted at past problems, human error as an explanation, and control of work through procedural compliance and outcome monitoring.[74] This approach has proven to be insufficient and frustratingly slow at achieving "zero harm" in outpatient settings, and specifically the community pharmacy.[75] Such a lack of success stems from investigating medication errors through root cause analysis, which assumes a shortsighted linear cause-and-effect model, rather than a complex model.[76] Finally, importantly, these approaches create a negative psychological impact on staff by creating a culture of blame.[31,77,78]

Strengths

This study will be the first to operationalize resilience engineering to include a Safety-II approach to medication safety in community pharmacies. The vast majority of safety studies involving community pharmacies assume a linear work process, which limits understanding of community pharmacies as complex work systems. Our research demonstrates that work is not conducted

linearly, but rather is comprised of interdependent processes.[79] The use of the innovative FRAM model will provide a robust model to map multiple processes and their variability, which can inform co-design of potential solutions.[40,80,81]

This project will prioritize and emphasize the role of pharmacy technicians as critical members of the community pharmacy work system. Expedited during the COVID-19 pandemic, technicians are increasingly being recognized for their willingness to assume new roles and adapt to changing environments.[82] Technicians have proven themselves effective in collecting patient medication histories,[83] administrative functions associated with vaccinations, and even providing immunizations to patients.[84]

Provider Status, a new legal designation authorizing Medicaid reimbursement to pharmacists' services, presents both a timely opportunity to evaluate how increased or broadening responsibilities can be adopted while improving quality of care and medication safety. Legal endorsement to "stretch professional boundaries and envision innovative designs"[56] is the perfect circumstance in which to move the needle on outpatient medication safety through the design of the next generation of community pharmacies. Pharmacists and technicians, depleted by the unrelenting workload and additional responsibilities from COVID-19, find the Safety-II approach to be attractive.[75] Safety-II also better represents and supports a culture of safety because it accurately portrays the constant variability of pharmacy work, the need for adjustment, and the importance of flexible adaptation in producing outcomes.

Introducing and utilizing a Safety-II approach will provide the test bed, tools, metrics, and frameworks to build the ENRICH PSLL. This new paradigm of approaching CCM with resilience engineering methodologies to improve quality in community pharmacies could then be disseminated to and adopted by medication safety researchers around the country.

Limitations

Participant bias caused by sensitivity to researcher's presence is a recognized risk in qualitative observational studies but can be minimized by ensuring that observers have frequent presence in the research setting, which can lead to habituation to their presence, researcher's sensitivity to and respect for pharmacy staff' concerns, and their ability to build relationships and trust. Risk of measurement bias will be reduced by having two researchers collecting data only after achieving a satisfactory inter-rater reliability rate, ensuring that differences in interpretation can be identified, discussed, and resolved before full data collection is accomplished.

We will use one simulation site, despite being aware that community pharmacies have very different work systems. We also know that using multiple simulation sites would increase the generalizability of findings and enable comparison between sites. However, utilizing simulations to evaluate prototypes that focus on workflow changes related to CCM is unprecedented in community pharmacies, so we want to begin with a single setting to ensure a robust infrastructure to evaluate such simulations. To expand our understanding beyond the single work system exemplified by the simulation site, we will seek input from advisory board members who will provide feedback on the feasibility of implementing MedSafeMap in their diverse community pharmacy settings.

Conclusion

Community pharmacies have experienced a great deal of change in the last decade alone. With an increase in responsibilities due to the pandemic, as well as changes to the healthcare structure that increases their workload, pharmacy staff are becoming increasingly burnt out. Coupled with high turnover rates and understaffing concerns, there is an unprecedented risk of safety errors and

resulting patient harm. To allow staff to take on these responsibilities as CCM providers, we must find a way to manage the workload and optimize resources. We are in a unique position to provide support directly to the pharmacies and give them a voice to influence change in the pharmacy work system. Through this PSLL, we can rethink the current safety approaches and develop an improved work system for medication safety, resulting in improved work conditions for pharmacy staff and increased patient care.

Acknowledgements

Authors' contributions

MC and JF initiated the project as co-principal investigators of the study and jointly supervised the writing of this protocol. AG, JS, and EL contributed to the conceptualization of the research study. JS managed and coordinated research activity. MC, MB, AG, JS, and JF drafted the initial manuscript. MB collected and organized the relevant data for publication. MB and EH updated proposed models and created new graphics. All authors contributed to the revision process. All authors read and approved the final version of the manuscript.

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Abbreviations

ADE: Adverse drug event
CCM: Chronic Care Management
CARE: Concepts for Applying Resilience Engineering
ENRICH: Engineering Resilient Community Pharmacies
FRAM: Functional Resilience Analysis MethodPSLL: Patient Safety Learning Laboratory
SEIPS: Systems Engineering Initiative for Patient Safety
WAD: Work as done
WAI: Work as imagined

Conflict of Interest

MC is a co-owner of Fitchburg Family Pharmacy, which serves as the simulation site for this project. MC will not receive any payment for the use of the pharmacy for this project. The other authors declare no competing interests.

Availability of data and materials

Data is not yet available for this study. Future data will be made available in adherence with the NIH Data Management and Sharing policy.

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Supplementary Files

Existing Peer-Review Reports from Funding Agencies (for protocols/proposals only)s

Existing Peer-Review Reports.
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