



Linking Inner Context and Innovation Factors: Examining a pharmacy-based intervention through the eyes of pharmacy staff

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ABSTRACT

Introduction: Community pharmacies, as unique and accessible healthcare venues, are ideal locations to implement interventions aiming to improve patient care. However, these interventions may increase workload or disrupt workflow for community pharmacists, technicians, and other staff members, threatening long-term sustainment. There are growing calls from the field of implementation science to design for intervention sustainment and maintenance by maximizing innovation fit. Senior Safe™, an intervention to facilitate safer over-the-counter (OTC) product selection by older adults, serves as a case study to examine the congruence between Innovation Factors and community pharmacy Inner Context constructs and their implications for workload and sustainment.

Methods: Using the Exploration, Preparation, Implementation, Sustainment (EPIS) framework, this qualitative study identified factors surrounding Senior Safe implementation. Semi-structured interviews were conducted with staff from pharmacies where Senior Safe was implemented. Two coders independently analyzed interview transcripts using deductive analysis based on EPIS constructs. Thematic analysis was used to generate three themes that encapsulated innovation fit.

Results: Nineteen pharmacy staff members participated, with the majority reporting no significant change in their workload or workflow due to Senior Safe. Interview feedback supported a pre-existing culture of the healthcare system to engage patients, of leadership commitment to patient safety initiatives, and of an amplified role of pharmacy technicians.

Discussion and Conclusion: Pharmacy staff interviews revealed congruence between Innovation Factors and Inner Context that likely yielded intervention workload neutrality. This study highlighted the importance for researchers to consider maintenance and sustainability when designing and implementing an intervention and the critical influence of culture and leadership support during this process.

1. Introduction

Community pharmacists are considered the most accessible healthcare professionals,¹ making pharmacies prime sites for patient care interventions.² These interventions may be any activity to improve human

health; in community pharmacies, they often take the form of system-level programs aimed at changing patient behavior through education, screening, or assessment.^{2,3} However, even well-intentioned and effective interventions may increase the workload for community pharmacists, technicians, and other staff members.⁴⁻⁶ System-wide changes,

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such as increasing the number of required tasks or increasing the quantity and duration of patient encounters, can make it challenging for pharmacy staff members to keep up with their existing strenuous work demands.^{7,8} This strain puts pharmacy staff at an increased risk of developing occupational fatigue and burnout,^{9–14} which creates a safety concern for pharmacy staff and their patients. Fatigued employees are more likely to make errors that can impact the provision of quality patient care.^{15,16}

Study interventions that increase community pharmacy workload or disrupt workflow often are difficult to sustain long-term.^{17,18} This is because, without participatory incentives or maintenance assistance from the researchers, pharmacy staff may struggle to prioritize these auxiliary duties, even if they offer clinical benefits and improve patient outcomes.^{8,17–19}

One of the goals when designing and implementing an intervention is for the innovation to be sustained after the researchers leave or the funded study ends.^{20–22} Therefore, there is growing emphasis from the field of implementation science to design for sustainment and maintenance.^{23–25} In implementation science, the Exploration, Preparation, Implementation, and Sustainment (EPIS) framework highlights four implementation phases for which the framework is named.²¹ EPIS outlines four constructs that affect intervention implementation—Outer Context, Inner Context, Bridging Factors, and Innovation Factors. Considering and maximizing congruence between Intervention Factors and Inner Context constructs from the Exploration phase and through Implementation can help to ensure long-lasting maintenance.^{21,26,27} Strategies that engage stakeholders, such as participatory design, user-centered design, and community-based participatory research, help researchers to maximize fit and develop sustainable projects that are informed by and meet the needs of the population.^{28–31}

One such intervention is Senior Safe™, a community pharmacy redesign that aids older adults in selecting safer over-the-counter (OTC) products, which warns that “what is familiar is not always safe.”^{32,33} Through a pharmacist expert-curated selection of safer OTCs to treat cough/cold/allergy, sleep, or pain symptoms, Senior Safe helps to support older adult agency when selecting products.³⁴ The intervention also encourages interaction between older adults and pharmacy staff with signage and moving a subset of unsafe products to behind the pharmacy counter. Senior Safe was designed with the input of older adult and pharmacy staff stakeholders.^{30,32} The research team included individuals with expertise in implementation science, human factors, and systems engineering in the community pharmacy context. The intervention was designed to reduce over-the-counter misuse and be embedded into everyday practice in such a way that supports its long-term sustainment while having minimal to no impact on the pharmacy workload.

2. Objective

The aim of this study was to examine the congruence between the Senior Safe Innovation Factors and community pharmacy Inner Context constructs. To accomplish this objective, pharmacy staff members were interviewed after Senior Safe implementation to identify themes surrounding innovation fit, including changes to workload and workflow, and to shed light on the likelihood of long-term sustainment.

3. Methods

3.1. Exploration preparation implementation sustainment (EPIS) implementation framework

The EPIS framework has been widely used across multiple health and public sector settings to facilitate the effective implementation of evidence-based interventions or innovations.²⁷ EPIS details four phases of the implementation process – Exploration, Preparation, Implementation, and Sustainment – that encompass considering emergent

needs, deciding to adopt an evidence-based practice, identifying facilitators and barriers, guiding and planning implementation, and monitoring ongoing impact (see Fig. 1).^{21,26,27}

EPIS also emphasizes the importance of contextual levels and constructs that are instrumental to the implementation process: Outer Context, Inner Context, Bridging Factors, and Innovation Factors. The Outer Context depicts the external environment and macro-level societal, economic, and policy factors outside an organization,³⁵ such as governments, funders, professional associations, and patient advocacy groups. The Inner Context refers to organizational characteristics that shape time, space, resources, and activities,³⁵ and includes culture, leadership, policies, available resources, training, and staffing. Bridging Factors connect relationships between the Outer and Inner Context, namely that Inner Context factors are largely influenced by the external environment and the macro-level systems that govern the organization.²⁷

The final EPIS construct relates to Innovation Factors and details the innovation itself.^{21,27} Innovation Factors include innovation characteristics, intervention developers as well as innovation and organization fit. EPIS emphasizes the “Innovation-Values Fit,” which “posits that implementation of an innovation will be successful to the degree that the innovation matches the mission, values, and service provider tasks and duties of the organization and individuals within the organization” (p. 14).²¹

In this paper, we used EPIS to identify Inner Context and Innovation Factors mentioned during interviews with pharmacy staff members. The factors were used to generate themes surrounding congruence and Innovation-Values Fit that are crucial for Senior Safe sustainment.

3.2. Setting

This study was conducted in partnership with [Affiliation 1], a part of [Affiliation 2] since 2022.³⁶ [Affiliation 2], a leading nonprofit integrated health system in the United States, operates over 1000 care sites and serves nearly 6 million patients yearly. Senior Safe is aligned with the organization’s mission to serve the health needs of individuals, families, and communities.³⁶ Committed to enhancing patient care, [Affiliation 1] has implemented the Senior Safe intervention across 68 of its outpatient community pharmacies in eastern Wisconsin.

Collaborating closely with [Affiliation 1] leadership—including the Manager of Retail Pharmacy Operations and the OTC Category Management Coordinator—the research team was permitted to physically redesign the pharmacy layout and develop new shelf signage. [Affiliation 1] was then responsible for installing Senior Safe using guiding

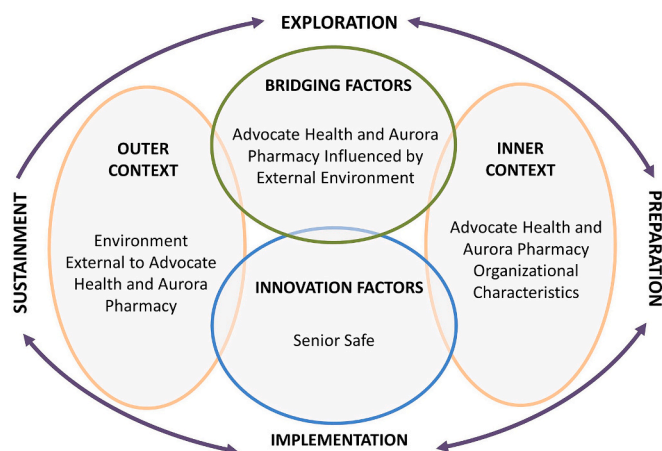


Fig. 1. EPIS Implementation Framework. The four contextual levels of the EPIS Framework—Outer Context, Inner Context, Bridging Factors, and Innovation Factors—were used to code pharmacy staff interviews and generate themes surrounding Innovation-Values Fit.

principles provided by the research team to fit the unique layout and characteristics of each pharmacy. The Manager of Retail Pharmacy Operations and the OTC Category Management Coordinator championed Senior Safe implementation within their organization by supporting data collection and encouraging pharmacy staff participation. The OTC Category Management Coordinator was one of two employees who traveled to every pharmacy to install the shelving displays, demonstrating organizational commitment to Senior Safe.

At the time of the interviews, Senior Safe was implemented in 10 test locations for approximately one month as part of a larger randomized control trial to assess the effectiveness of the intervention on patient behaviors.^{32,33} Seven locations were traditional pharmacies, and three were remote dispensing sites. The remote dispensing sites did not have pharmacists physically on the property, but they were accessible via telecommunication.

3.3. Senior safe

Senior Safe and its Innovation Factors have been described in-depth in previous publications.^{32,33} To summarize, Senior Safe was designed and tailored to [Affiliation 1] via two stakeholder groups of pharmacy staff (i.e., pharmacists and technicians) and a third stakeholder group comprised of ethnically and racially diverse older adult patients.^{32,33} Stakeholders discussed what they believed to be most beneficial for the innovation conceptualization, gave feedback on designs, and strategized how to manage potential barriers and facilitators to implementation. Senior Safe was piloted in four [Affiliation 1] community pharmacies prior to the larger effectiveness trial and widespread implementation.

Senior Safe aims to reduce older adults' cognitive burden in differentiating between safe and unsafe OTC products, as well as promote older adult communication with pharmacy staff.³² Senior Safe categorizes OTC products for pain, sleep, and cough, cold, and allergy based on their safety for older adult patients.³⁴ OTC product categorization, along with human factors engineering principles, served as the basis for modifying layouts and placing new banners and signs. OTC products with particularly high levels of risk for older adults, specifically when used chronically, were relocated behind the pharmacy counter and replaced on the OTC shelves with signs informing patients the product had moved "behind-the-counter."

Aware of potential workload changes for pharmacy staff, the study team conducted interviews to explore the congruence between Innovation Factors and Inner Context, identifying themes that indicated the likelihood of Senior Safe's long-term sustainment.

3.4. Data recruitment and collection

The study team aimed to recruit two pharmacy staff members (any combination of pharmacists or technicians) from each of the 10 [Affiliation 1] sites that implemented Senior Safe between June and September 2022. Semi-structured interviews lasting approximately 60 min were conducted virtually via a web-based platform and audio recorded. The semi-structured interview guide (see Supplement 1) aimed to elicit descriptions of the respondents' role in OTC medication selections, as well as how Senior Safe was implemented in their pharmacy. Questions probed for facilitators and barriers to Senior Safe's long-term use (including changes to workload and workflow) and general perceptions about its current and long-term usefulness to help older adults make safer OTC selections. All interviews were completed by one study team member (JS). Participants received \$40 for their participation in the interviews in the form of virtual gift cards. This study received ethical approval by the [Affiliation 3] Institutional Review Board prior to data collection.

3.5. Data analysis

The qualitative thematic analysis was conducted using NVivo 20

following the methodology of Braun and Clarke, using a codebook approach (2019).^{37–39} The interview audio was transcribed verbatim. Two study team members (JM and TW) read the transcripts to generate initial ideas. They developed a codebook based on two EPIS constructs—Inner Context and Innovation Factors (codebook Supplement 2). Examples of Inner Construct codes included general pharmacy practice and tasks surrounding OTC consultations, role delegation and responsibilities, safety culture, and leadership support. Examples of Innovation Factors codes included the use and perceptions of Senior Safe overall, its impact on workload and workflow, as well as specific components such as signage, classification of safe/unsafe products, relocation of products behind-the-counter, and interactions with older adults using the intervention. JM and TW used this codebook to synchronously code one interview transcript and build coding consensus. Then, the two researchers independently coded the remaining interviews using deductive analysis, as well as made memos for additional patterns, themes, or categories that emerged.^{40,41} JM reviewed the coding and identified areas of discordance between the reviewers. JM and TW met to discuss discordance until 100% agreement was met. Following the coding, TW aggregated the codes into themes that explored the congruence between Innovation Factors and Inner Context.^{17,18} Themes were presented and reviewed by the entire research team to ensure face validity and clarify names and definitions. Exemplar quotes were chosen to represent themes in the final manuscript.

4. Results

Respondents included 19 pharmacy staff members—six pharmacists and 13 technicians—from seven pharmacies and three remote-dispensing sites where Senior Safe was implemented. Respondents were predominantly white (89.4%), female (78.9%), and not Hispanic or Latino (89.4%), with an average of 14.5 years of experience working in a pharmacy.

Most respondents ($n = 17$, 89.4%) stated that the Senior Safe did not add to their workload, pressure other duties, or disrupt workflow and task transition. The two respondents indicating that Senior Safe did increase workload were from the same pharmacy, but the increase resulted from taking longer to find relocated products and not from the quantity or duration of patient consultations.

Thematic analysis of the pharmacy staff interviews yielded three representative themes related to the congruence between Inner Context and Senior Safe Innovation Factors. To support each theme, three exemplar quotes are provided.

4.1. Theme 1: culture to engage patients

Interviews with pharmacy staff identified Inner Context pharmacy culture that existed prior to Senior Safe implementation. Numerous respondents (both technicians and pharmacists) indicated a cultural norm and expectation to engage and greet patients when they entered the pharmacy (see Table 1). They cited that they wanted to provide a personalized and welcoming experience for patients. An additional factor facilitating patient engagement was that the physical pharmacy space was often so small that it was difficult to not notice someone walking through the door.

The cultural norm to greet patients aligned with Senior Safe's goal to facilitate communication between patients and pharmacy staff regarding OTC safety. Senior Safe Innovation Factors included signage that encouraged older adults to talk to pharmacy staff and, in some locations, relocated OTC products closer to the pharmacy counter so that staff could see if an older adult patient was looking for a product and offer assistance. The introduction of Senior Safe did not drastically change workload because staff were already engaging patients before they reached the counter. Intervention implementation did not generate new tasks that were out of the scope of normal practice.

Table 1
Culture to Engage Patients.

Quote	Respondent	EPIS Construct(s)
We try to say hello to everybody that enters the pharmacy. And if they are looking at the shelves for more than a minute, I'll ask them if they need help finding something...You know, we just have a general policy that we need to greet everyone as they come in and ask them what can we do for them.	Pharmacist 1	Inner Context Culture, policies, and procedures
If somebody is hanging out in the pharmacy looking at products, we'll always reach out and ask if there's anything that we can help them with. And that's been going on before the Senior Safe program, so it's just not really something that changed.	Pharmacist 2	Inner Context Initiating patient encounters Innovation Factors Change to work tasks
Well, usually, since we are so small, we always greet our patients and ask them if they always need help at the over-the-counter area or if they're looking for something...We do that all the time here.	Technician 8	Inner Context Physical environment

4.2. Theme 2: leadership support for patient safety initiatives

Respondent interviews identified strong Inner Context leadership support for patient safety (see Table 2). Pharmacy staff indicated that leadership was very supportive of initiatives that enhanced the patient experience, including those that improved patient safety. Pharmacy technicians also emphasized that their pharmacists and pharmacy managers were supportive of initiatives that improved patient safety.

Congruence between Senior Safe Innovation Factors and Inner Context leadership support was essential for implementation of a patient safety intervention. The installation of modified layouts, new signs, and relocating products, as well as pharmacy staff training, required assistance from the OTC Category Management Coordinator and demonstrated Innovation-Values Fit. Senior Safe also did not notably exacerbate workload for pharmacy staff because the organization dedicated time and resources for regional leadership to print, install, and maintain the intervention. Without this buy-in from leadership,

Table 2
Leadership Support for Patient Safety Initiatives.

Quote	Respondent	EPIS Construct(s)
I think [leadership] supports. I think they help to make sure that we have sufficient help and, you know, to use that workload and add that patient interaction is really important to them.	Pharmacist 5	Inner Context Leadership supports through resources
[Leadership] support [OTC consultations] for the most part, you know, they'll come say they want us to have interactions with the patients I've had some of the upper management-type people before say, they want us to have direct contact with the patients, not make them feel that they're going to some big box store.	Pharmacist 3	Inner Context Leadership supports through culture and policy
As techs, we're not pharmacists, so we do look to them for leadership. So, when they have a clear understanding of what's going on and they're knowledgeable not only in the clinical aspect but also in [Senior Safe], we're already a team, and we bounce off of each other and rely on each other. But when the leadership has that additional knowledge, it really helps us out.	Technician 8	Inner Context Pharmacist leadership supports technicians through knowledge Innovation Factors Training

intervention maintenance (including moving items or updating OTC signage) would require the front-line staff to add intervention maintenance into their existing workload.

4.3. Theme 3: amplifying the role of pharmacy technicians

As shown in Table 3, the Inner Context policies regarding pharmacy technician roles and responsibilities were important for Senior Safe implementation. Interview respondents reported that, even prior to Senior Safe, it was the pharmacy technicians who often initiated contact with the patient. Pharmacy technicians were trained in organizational policies and federal regulations stating that pharmacists were the only staff members permitted to provide clinical care. Pharmacy technicians would triage patient questions, answer if able (e.g., location of product), then engage and hand-off the patient to the pharmacist (e.g., therapeutic recommendation). In the case of remote-dispensing locations where the pharmacist supervises off-site, pharmacy technicians would contact the pharmacist for a video-call consultation.

As part of Senior Safe's implementation, the research team provided training to pharmacy staff on the components of the intervention and the justification behind OTCs as "safe" or "unsafe" for older adults. Pharmacy technicians stated that this training, in addition to the color-coded display, supported their agency to recognize unsafe OTCs when brought to the counter for purchase. Even if an older adult didn't have a question, technicians felt knowledgeable to briefly engage the patient in an explanation of the initiative and transition to the pharmacist for a full consultation.

Senior Safe aligned with current practices for pharmacy technicians

Table 3
Amplifying the Role of Pharmacy Technicians.

Quote	Respondent	EPIS Construct(s)
I guess if anything, it was more shocking to me to see what was considered unsafe...I wouldn't have thought that some of those products were considered unsafe for the elderly... Just like the Unisom, the diphenhydramine, I think, like the Benadryl...I've also taken it since I've been a child for allergies. So it's just weird to kind of think about that this could be harmful like as I'm going on in my adult life.	Technician 2	Inner Context Technician knowledge and experiences Innovation Factor Training Product categorization
When I go out there to help now, I show them which one is safe and not. The stickers help. For example, we have a lot of older people coming in for pain medications over the counter. And so, I had one patient come up to me and ask me for an over-the-counter medication. So I went out there and directed them and showed them, actually, I pointed out some of the stickers for them, which ones were safe and not safe. And so I think that helped them a lot too, whatever medication that they wanted. So that's usually how it goes. We go up there and show them which one they said was safe and not safe, and they choose which one, you know, they want.	Technician 4	Inner Context Technician tasks and workflow Patient and technician interaction Innovation Factor Product categorization and signage
We have a regular patient that would come in a lot, and he would buy stuff to help him sleep. I noticed one time, he was buying the Nyquil one. And I never even paid that much attention to it, I guess or all the signs. And I was like, "hey, why don't you talk to a pharmacist about this really quick," you know? "Maybe there's something that could work a little better for you."	Technician 3	Inner Context Technician, patient, and pharmacist interactions Innovation Factor Product categorization and signage

to triage patient interactions and engage the pharmacist. Senior Safe did not change workload for pharmacy staff because it aligned with technicians' current responsibilities and amplified their roles in promoting a culture of medication safety—engaging patients when they enter the store, helping them make better OTC decisions at the shelves by pointing to safer products, identifying potentially unsafe products, and triaging pharmacist counseling. The responsibility to use and implement the intervention wasn't solely on the pharmacist and, by design, elevated technicians to work at the top of their legal authority.

5. Discussion

Three themes exemplified the congruence between [Affiliation 1] Inner Context and Innovation Factors: pre-existing culture to greet patients, local leadership support for patient safety initiatives, and amplifying the role of pharmacy technicians. These aligned with the EPIS Framework's recommendation for clear Innovation-Values Fit and the research team's desire to keep the intervention workload neutral and not create additional, non-value-added work burden for the pharmacy staff who would be responsible for maintaining and sustaining Senior Safe.²¹

In 2023, Lehnbohm et al. published a summary of community pharmacy interventions that aimed to improve older adult OTC safety.² Interventions included enhanced pharmacist counseling, student pharmacist counseling, and follow-up phone calls to patients seeking self-care recommendations. The review also cited barriers to helping older adults select safe OTC medications. The most predominant barrier was the pharmacist's limited capacity to expand services, demonstrated by time-and-motion studies from the UK, Australia, and Portugal. In comparison to the other referenced studies, Senior Safe is unique in its design and emphasis on Innovation-Values Fit from conception.

Senior Safe implementation may be challenging in pharmacies that do not share the same Inner Context and organizational characteristics. For example, Senior Safe implementation and sustainment may be more difficult in larger community pharmacies, where pharmacy staff may have difficulties seeing and engaging patients in the OTC aisles. In a 2019 study, pharmacy staff cited a barrier to providing OTC recommendations was the aisles being located physically far away from the pharmacy.³⁰

Another organizational characteristic to consider is leadership buy-in. Senior Safe sustainment would be difficult in an organization with limited support and would likely face a lack of ownership or commitment to maintaining the intervention after the research ends. This is exemplified in the literature, which notes that sustaining community-pharmacy-based interventions is often challenging without incentives to reimburse and motivate staff.^{17,18}

A final organizational characteristic that may impact Senior Safe adoption is the pharmacy culture and the relationship between pharmacists and technicians. Within this study, pharmacy technicians were encouraged to engage patients, triage OTC consultations, and involve the pharmacist. Previous studies have emphasized the importance of equitable partnerships for pharmacy technicians, pharmacists, and their organizations.⁴² Organizations in which technicians have low job satisfaction and minimal supervisor or coworker support may face struggles in maintaining an intervention that relies on technician involvement.

As evident by these potential Senior Safe challenges, the central limitation of this study is the lack of broad generalizability. Senior Safe was implemented in a variety of pharmacies from one midwestern health system and received full organizational support and buy-in. As part of a larger [Affiliation 2] system, [Affiliation 1] had the ability to prioritize the patient experience and safety and may have worried less about the implication of Senior Safe to reduce sales of unsafe products like traditional retail establishments. Additionally, the qualitative interviews were limited to the perspectives of employees for whom Senior Safe was chosen for initial testing, indicating the potential for selection

bias. Pharmacists may have also self-selected to work in an organizational culture such as [Affiliation 1] because of its commitment to patient safety.

Amidst these limitations, however, the study demonstrated the value of considering innovation fit and sustainability from intervention conception. This study leveraged the EPIS framework to examine congruence between Inner Context and Innovation Factors. The potential challenges for other organizations to implement and adopt Senior Safe emphasize the need for tailored and adapted context-specific interventions. Organizations intending to implement interventions in community pharmacies should employ Implementation Science principles to ensure intervention success.^{21,26,27}

Future research will further examine Senior Safe sustainability, including intervention fidelity and pharmacy staff's beliefs about program effectiveness. Research activities are currently underway to monitor OTC sales after Senior Safe implementation, distribute a sustainability questionnaire to all health system pharmacy staff, and leverage immediate and 3-month post-intervention photographs to determine intervention drift over time. Such research will additionally confirm whether innovation-fit can help approximate or predict long-term intervention sustainability.

6. Conclusion

This study highlighted the importance for researchers to prioritize maintenance and sustainability when designing and implementing an intervention. That is, the goal of an intervention is never "just" effectiveness. Research teams may achieve this by designing interventions with end-users through strategies such as user-centered design, co-design, or participatory design. Additionally, this study emphasized the critical influence of a patient safety culture and leadership support during this process. Therefore, attaining broad, continued, and active commitment from leadership and aligning Innovation Factors with organizational culture when developing or adapting an intervention is often integral to the likelihood of sustainability.

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Availability of data

The data underlying this article cannot be shared publicly for the privacy of individuals that participated in the study. Deidentified may be shared on reasonable request to the corresponding author.

CRedit authorship contribution statement

Taylor L. Watterson: Writing – original draft, Methodology, Investigation, Formal analysis, Conceptualization. **Jukrin Moon:** Writing – review & editing, Validation, Investigation, Formal analysis, Conceptualization. **Jamie A. Stone:** Writing – review & editing, Project administration, Data curation, Conceptualization. **Aaron M. Gilson:** Writing – review & editing, Conceptualization. **Maria E. Berbakov:** Writing – review & editing, Conceptualization. **Emily L. Hoffins:** Writing – review & editing. **Jason S. Chladek:** Writing – review & editing. **Elin C. Lehnbohm:** Writing – review & editing. **Stephanie M. Resendiz:** Writing – review & editing. **Shiyang Mai:** Writing – review & editing. **Kenneth D. Walker:** Writing – review & editing. **Joel D.**

Gollhardt: Writing – review & editing. **Michelle A. Chui:** Writing – review & editing, Supervision, Resources, Funding acquisition, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.rcsop.2024.100486>.

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