Advancing Facilitated Implementation in Primary Care:

Interactions Between Context, Adaptations, and Outcomes

By

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Abstract

With over 440 million office visits annually, improvements in primary care can improve the lives and care of nearly every person in the US. Research into the process of improving healthcare and aligning clinical practice with evidence has produced a multitude of theories, measures, and frameworks. These research tools are useful for capturing and understanding how change happens in healthcare, and they have been aided numerous improvement efforts within and beyond healthcare. We can retrospectively understand why changes did or did not work using these theories, models, and frameworks, but the people actively improving primary care need practical, real-time, and evidence-based tools to help them reach improvement goals. To equip these healthcare leaders with the toolkit they need for safe and patient-centered improvements, we must generate and interpret research evidence for direct practical applications. To reach this lofty goal we must first understand actionable relationships between the people, systems, and processes in improvement projects, and package that research evidence into tools designed with and for practitioners.

In this dissertation, we leveraged knowledge from three fields, implementation science, human factors, and quality improvement, to understand changes in primary care clinics. We studied implementation data from 30 primary care clinics across the state of Wisconsin working with facilitators to implement new urinary incontinence screening and treatment processes. Using qualitative and quantitative methods, we explored the process of change in these clinics. Meetings between these clinics and facilitators were qualitatively analyzed to understand each clinic's unique context and the customizations they made to their screening and treatment

process. Quantitative data capturing the clinic context, preparedness for change, and engagement during the implementation project were analyzed to further understand the fundamental relationships that drive outcomes. Our results include 7 relationship groupings that capture reasons for and processes of making context-specific adaptations to interventions. Further, we identified measurable implementation differences between clinics and tested a new pragmatic tool to track engagement over time. These findings will inform future implementations of research evidence in primary care and the development of practical tools to support health system improvement efforts.

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1.0 INTRODUCTION

1.1 Problem Statement

Though many approaches for improving healthcare and implementing new, evidence-based practices are known, none are universally effective (Oxman et al., 1995; Powell, Beidas, et al., 2017; Wensing et al., 2010). Adapting evidence-based practices to the unique contexts of each healthcare system is critical to successful implementation (Damschroder et al., 2009; G. Moore et al., 2021; Movsisyan et al., 2019). This means for each new implementation project at each site, context must be thoroughly understood, strategies must be planned, and evidence-based practices must be adapted for local needs (Fernandez et al., 2019; Wensing et al., 2011). These tasks to tailor implementation to local context require significant time and expertise (Fernandez et al., 2019; Powell, Beidas, et al., 2017). The human resources and expertise necessary to facilitate tailored implementation are typically not available within implementation sites, and using an external implementation facilitator makes an implementation project more than twice as likely to lead to successful adoption of the new evidence compared to control groups without facilitation (Baskerville et al., 2012). Yet, even with the help of a facilitator, implementation efforts sometimes fail to make sustainable evidence-based changes to clinical practice (Baskerville et al., 2012; Jaén et al., 2010; Liddy et al., 2015). The variability in the effects of facilitation, the complex nature of healthcare context, and need to adapt evidence-based practices to local needs, are three closely related factors that determine the success of implementation projects. Understanding each of these factors and how they interact is critical to build successful facilitated implementations.

Variability in the effects of facilitation. The facilitation of practice change in primary care is known as practice facilitation and is both effective on average and widely varying across

studies. Practice facilitation has been shown to improve both clinical outcomes such as blood pressure control and clinic capacity for change (Cohen et al., 2016). However, wide variability remains across sites and facilitators, with different studies of practice facilitation showing widely varying effect sizes, and facilitators working with as many as 40 individual practices and as few as one (Baskerville et al., 2012). Yet, practice facilitation is a well-established and widely accepted approach for primary care improvement efforts that focuses on supporting change projects in healthcare and building local capacity for change (AHRQ, 2018). Practice facilitators are external change agents who work with clinics to improve their practices (Kitson et al., 1998). These facilitators' contributions can take many forms from directly completing tasks for clinic staff like data entry, to coaching and training practice team members to complete necessary tasks themselves and develop their own capacity (Walunas et al., 2021). There is evidence that successful facilitation efforts tend to focus on coaching (Stetler et al., 2006), but the ideal set and dose of facilitation activities remains unknown (Baskerville et al., 2012; Liddy et al., 2015). Despite practice facilitation being a well-established implementation strategy in primary care, clinicians lack the time to consistently meet with facilitators and make changes to their care (Liddy et al., 2015; M. McHugh et al., 2018). To ensure widespread and consistent use of implementation strategies like practice facilitation, important details on best practices need to be specified and reported such as the dose, actors, actions, action targets, and temporality of facilitation activities (E. K. Proctor et al., 2013).

Complex nature of healthcare context. Variability in the effects of implementing change in primary care is often related to differences in the context of implementation (Lau et al., 2015; C. R. May et al., 2016). Context is a difficult-to-define concept, especially in healthcare (Nilsen

& Bernhardsson, 2019). Elements of context, also called contextual determinants or barriers and facilitators to implementation, include people, technologies, systems, processes, values, and anything else on the clinic side that might affect the successful implementation of the evidence (Mollon et al., 2009; Ovretveit et al., 2011). This broad definition does not allow for easy operationalization of these concepts in needs assessments seeking to capture critical elements of context (Fernandez et al., 2019; Lewis, Scott, et al., 2018). Instead researchers rely on lengthy frameworks or taxonomies of potential contextual determinants that may impact implementation, and the most critical determinants can still be difficult to identify prospectively (Damschroder et al., 2009; Flottorp et al., 2013; Michie et al., 2005). To improve facilitated implementations in primary care with limited time and resources, the most important determinants to look for and overcome must be identified.

Need to adapt to local needs. The process to achieve a sustainable “fit” between evidence-based practices and local context is known as has been conceptualized in the implementation science literature as tailoring or adaptation (Baker et al., 2015; Chambers et al., 2013; Wiltsey Stirman et al., 2019). Practice facilitators can serve a critical though not yet well specified role in tailoring (Baskerville et al., 2012). Tailoring is generally described as a multi-stage process (Fernandez et al., 2019; Lewis, Scott, et al., 2018; G. Moore et al., 2021; Movsisyan et al., 2019; Wensing et al., 2011), with adaptation referring to the action of changing interventions or strategies to local context (G. Moore et al., 2021; Movsisyan et al., 2019; Wiltsey Stirman et al., 2019). Adaptation of strategies or interventions relies on a facilitator’s ability to balance fidelity to evidence with contextual needs (Harvey & Kitson, 2016; Wiltsey

Stirman et al., 2019), a burdensome design task that can demand multiple meetings between facilitators and clinic teams.

Making intervention adaptations in specific contexts improves implementation outcomes but the relationships between contexts, adaptations, and outcomes are complex, limiting our ability to generate operational guidance for implementors (C. R. May et al., 2016). Documentation of these related implementation concepts has been pursued in implementation science with the help of conceptual frameworks such as PARIHS (Rycroft-Malone, 2004) and i-PARIHS (Harvey & Kitson, 2016). However, little is known about the relationships between context, adaptations, and outcomes that differentiate successful and unsuccessful implementations (Bosch et al., 2007). Capturing these relationships using existing tools for research is cumbersome and unreliable, requiring substantial time and expertise to retrospectively capture the comprehensive data necessary for research purposes (Miller et al., 2021; Powell, Beidas, et al., 2017; Wiltsey Stirman et al., 2019). Developing new pragmatic approaches that reduce the burden of data collection while capturing interrelated contextual factors, adaptations, and outcomes is crucial to generate an evidence-base to guide implementation decisions (Chambers & Norton, 2016). Such approaches would better equip facilitators for implementations in diverse settings and reduce the uncertainty and burden of implementing interventions in complex systems like primary care.

1.2 Useful terminology and definitions from Implementation Science

Implementation science (IS) is a growing field focused on incorporating clinical evidence in regular practice (Eccles & Mittman, 2006; Grol & Grimshaw, 2003; Sales et al., 2019). IS has developed an abundance of useful concepts, models, methods, and frameworks to guide

implementation projects in clinical settings (Curran, 2020; Nilsen, 2015; Tabak et al., 2012). First, an intervention is the evidence-based practice being implemented or improved in a given clinical context (Curran, 2020). Context goes beyond setting, it is the entire circumstance of an implementation comprised of many interacting elements that impact implementation (Craig et al., 2018; G. Moore et al., 2021; Pfadenhauer et al., 2017). Contextual determinants of implementation, sometimes referred to as barriers and facilitators, are the interacting social, organizational, political and other situational elements surrounding the intervention in the local setting where implementation or improvement efforts are occurring (Damschroder et al., 2009; Dixon-Woods, 2014; C. R. May et al., 2016; Pfadenhauer et al., 2017). These determinants are difficult to capture as they interact with and influence implementation in complex ways (Chambers et al., 2013; Damschroder et al., 2009; Lorden et al., 2014). Several taxonomies exist to help with identification and classification of contextual determinants (Damschroder et al., 2009; Flottorp et al., 2013; Michie et al., 2005). Using these taxonomies to identify determinants can help implementors tailor their actions to specific contextual barriers or facilitators (Fernandez et al., 2019; Lewis, Scott, et al., 2018). Tailoring is the process of identifying determinants, then selecting and/or adapting interventions and the strategies used to implement them (Wensing et al., 2011). Implementation strategies are a primary focus of IS; they are the actions taken to encourage uptake and sustainment of an intervention such as, for example, providing an external practice facilitator to support sites in implementing a planned change (Curran, 2020; Kirchner et al., 2020; Lau et al., 2015; Powell et al., 2015). These concepts offer useful framing and vocabulary for research into the challenges of facilitated implementation in primary care.

1.3 Application domain for this dissertation work

Primary care teams are responsible for health management and disease prevention but are not consistently screening for common medical conditions with known treatments, leaving patients without diagnoses and treatment plans. For example, urinary incontinence (UI) is common with over 60% of adult women experiencing UI symptoms (Brown et al., 2020). UI is also treatable through non-surgical means, with behavioral modifications improving symptoms for 64% of patients (Balk et al., 2018). There are common barriers to evidence-based screening for UI and other illnesses in primary care (Brown et al., 2018; Colligan et al., 2020; de Waard et al., 2018; Meissner et al., 2012), for example limited clinician time and limited patient access to preventive care. To overcome these barriers and deliver sustainable, evidence-based practices to the broad network of US primary care clinics, evidence-based implementation approaches are critical (Grimshaw et al., 2004). Understanding best practices for implementation of UI screening and management will help us to implement other, more critical, evidence-based practices in primary care.

Primary care physicians (PCPs) are the first resource for patients with many different health concerns, this task variety and complexity makes primary care difficult to sustainably improve (Crabtree et al., 2011; Holman et al., 2016; Shi, 2012). Despite these challenges, PCPs help patients build their relationship with the health system overall, leading to better health outcomes like reduced mortality (Starfield et al., 2005). Improving primary care, while challenging, is critical to the improvement of the US healthcare system and patient lives. As such, research efforts should support and guide primary care improvements.

Unfortunately, primary care is structurally distant from clinical research. The people who generate clinical evidence (e.g., new drugs, therapies, and processes) are largely disconnected from the users of that evidence (i.e., patients, PCPs, etc.). This gap is not as much physical as it is temporal: It takes 17 years on average for research evidence to be used in regular clinical practice (Balas & Boren, 2000; Morris et al., 2011). The slow infrastructures of academia and its governing bodies make up much of the delay (Balas & Boren, 2000), but implementation of evidence into practice is the critical final step to improving primary care with evidence-based practices (Holtrop et al., 2018).

1.4 Research Questions

The goal of this research is to explore the roles of context, adaptation, and facilitation in primary care implementation. First, I aim to investigate and describe relationships between contextual determinants and intervention adaptations. Then, I aim to capture the effects of clinic characteristics and facilitation on implementation outcomes. To meet these aims, the research presented in this dissertation answers the following research questions (RQs):

RQ1 – What are the relationships between context and intervention adaptations in facilitated implementations in primary care?

RQ2 – How does engagement with facilitation influence clinic readiness for change across rural and urban settings?

1.5 Contributions

1.5.1 Scientific, Theoretical, and Methodological Contributions

This research work will: (1) establish a foundational understanding of the relationships between contextual determinants of implementation and intervention adaptations, and (2) identify key clinic characteristics and engagement levels that impact implementation outcomes.

By connecting intervention adaptations, clinic context, and outcomes, this work will help to operationalize the theoretical concepts of adaptation and context for real-world implementation decision-making. This work expands on recent efforts to make contextual determinant frameworks more useful for researchers (Damschroder et al., 2022a, 2022b) and the ongoing challenge of identifying the most critical elements of context that will affect implementation outcomes (Bosch et al., 2007; Nilsen & Bernhardsson, 2019).

By examining outcomes differences based on clinic characteristics and engagement with facilitators, this work will clarify the importance of latent contextual factors, like geographical location, and active implementation adaptations, like choosing to hold more meetings with facilitators. Existing implementation theories stress the importance of evaluating outcomes of implementation at different system levels: individuals, organizations, and beyond (Chambers et al., 2013; Glasgow et al., 1999). This work will first examine clinic-level adaptations to interventions and how they relate to the area the clinic is located in. Then I will capture person-level changes by analyzing how individuals' readiness for change, a critical capacity for making sustainable change and outcome of implementation work (Scaccia et al., 2015; Shea et al., 2014), is affected by meetings with facilitators. These analyses will provide a crosswalk between clinic

characteristics, engagement with facilitators, readiness for change, and specific intervention decisions. Similarities or differences found in these analyses between clinics would provide preliminary evidence for studies on the true effects of facilitated implementations and the deterministic nature of clinic context.

1.5.2 Practical Contributions

This dissertation provides insight into the context-driven adaptation of interventions and strategies, guiding future facilitation practice and research. Results from this work will provide a set of resources and processes for facilitators to better plan, execute, and evaluate implementations. These results will expand existing literature on this topic beyond "more is better" (Baskerville et al., 2012) and contextualize the findings of low facilitation engagement in a recent multi-state initiative offering optional facilitation (S. M. McHugh et al., 2022).

This work will establish an initial mapping between contextual determinants and adaptations, an invaluable support for facilitators that support adaptive or complex interventions. Similarly, constructing clinic categories based on contextual, implementation, and outcome factors will support classification and planning in future large-scale implementation efforts.

2.0 LITERATURE REVIEW

To guide my work, I have synthesized the literature relevant to the interactions between context, adaptations, and outcomes in facilitated implementation in primary care. The following specific questions guided this review:

- Literature Question 1: What approaches are used to design or adapt strategies to address contextual barriers to change in primary care practices?
- Literature Question 2: What is practice facilitation and how has it been used in primary care implementations?

2.1 Significance and definitions

It takes 17 years on average for research evidence to be used in regular clinical practice (Balas & Boren, 2000; Morris et al., 2011). The slow infrastructures of academia and government make up much of this delay (Balas & Boren, 2000), but the implementation of tested, evidence-based interventions into practice is the critical final stage. Failures in the implementation stage are the reason why many evidence-based interventions are not yet used in practice (Griffith et al., 1999; Klein & Knight, 2005).

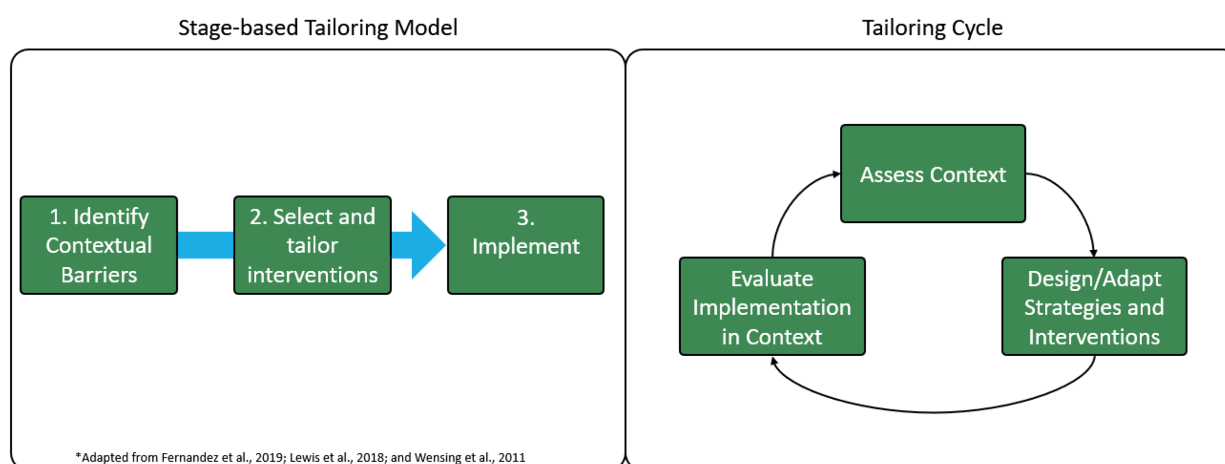
Implementation science (IS) is the study of strategies to encourage clinical evidence uptake in regular clinical practice (Eccles & Mittman, 2006; Grol & Grimshaw, 2003; Sales et al., 2019). Strategies are the actions taken to help healthcare professionals use clinical evidence (e.g., educational workshops) (Curran, 2020; Eccles & Mittman, 2006; Powell et al., 2015). The context of a clinic impacts the effectiveness of these strategies and the outcomes of the implementation. Contextual determinants, or barriers and facilitators, are components of context

(Damschroder et al., 2009). An intervention is the evidence that an implementor is bringing to a clinic, though it is sometimes referred to as an innovation, change, or evidence-based practice. Finally, because intervention efficacy and effectiveness are evaluated in different contexts, some customization of the intervention and/or the strategies used for implementation is usually necessary to make the intervention "fit" (Chambers et al., 2013; Wensing et al., 2011). These processes of customization are called intervention tailoring and implementation strategy tailoring respectively (Baker et al., 2015; Wensing et al., 2011). For the purposes of this research I will define tailoring inclusively, as complementarity between strategies and interventions is critical for implementation success, and because strategies are themselves interventions (Grimshaw et al., 2004), thus separation of the two is unadvisable. In this document, for simplicity, I will use the term, adaptation, in alignment with the proposed tailoring cycle and with the logic model presented by Kirk and colleagues (Kirk et al., 2020). As shown in Figure 2.1, I will define adaptation as a part of the tailoring process.

The process of tailoring and adapting interventions to local context is generally conceptualized as a series of three primary stages: identifying contextual barriers, designing or selecting interventions to overcome these barriers, and implementing the interventions (Fernandez et al., 2019; Lewis, Scott, et al., 2018; Wensing et al., 2011). In the subsequent literature review I will discuss the methods used for each of these stages. However, for the research presented in this dissertation, considering best practices from other fields, a reconceptualization of this linear sequential model is necessary (see figure 2.1). My reconceptualized model builds on established from human factors engineering including the systems engineering initiative for patient safety (SEIPS 2.0) (Holden et al., 2013), from

implementation science including the exploration preparation implementation sustainment (EPIS) model (Movsisyan et al., 2019), and from quality improvement including based on plan-do-study-act (PDSA) (Deming, 1986), to augment existing models and methods for tailoring (Fernandez et al., 2019; Lewis, Scott, et al., 2018; Powell, Beidas, et al., 2017; Wensing et al., 2011).

Figure 2.1. Reconceptualizing Tailoring: From tailoring phases to a tailoring cycle.



Reconceptualizing tailoring from a linear to an iterative process is critical and expands on recent literature in the field moving towards cyclical and iterative designs (Bosch et al., 2007; Glasgow et al., 2020; C. R. May et al., 2016; Movsisyan et al., 2019). Outside of implementation science, iteration and adaptations are explicitly linked as testing, adaptation, and retesting are fundamental to the design of many research frameworks (Carayon, 2019; Deming, 1986; Donabedian, 1966; Holden et al., 2013). Using a cyclical approach similar to PDSA in quality improvement (Deming, 1986) or the model for improvement in healthcare (Langley et al., 2009), encourages continuous effort towards more optimal integrations of interventions and systems. The phases in the tailoring cycle are: assess contest, design or adapt strategies, and evaluate the

implementation in context. Ideally, these phases will be more rapidly carried out and iterated than other cyclical approaches in implementation science (Glasgow et al., 2020; Movsisyan et al., 2019). Promoting adaptability is an implementation strategy that will benefit from this reconceptualization (Powell et al., 2015). By considering adaptability as the ability to carry out tailoring cycles and improve the fit between intervention and context (Chambers et al., 2013), this strategy becomes explicitly repeatable and connects it to another expert-recommended strategy taken from classic quality improvement approaches: conducting small cyclical tests of change (Powell et al., 2015).

2.2 Why Primary Care as a Domain of Application?

With over 440 million office visits annually (Santo & Okeyode, 2018), improvements in primary care can equitably improve the lives and health of nearly every person in the US (Phillips & Bazemore, 2010). However, despite recent equity-focused healthcare improvements, disparities in care are still present and in some cases have widened (Boonyasai et al., 2022). While it is difficult to make sustainable changes in primary care (Crabtree et al., 2011), this is the “front door” of the healthcare system and the first stop for many patient concerns (Starfield et al., 2005). The primary care environment is uniquely tasked with building positive and equitable long-term relationships between patients and care teams (Carayon et al., 2020), while delivering high-quality, evidence-based care (Balas, 1998; Braithwaite et al., 2014; National Academies of Sciences, Engineering, and Medicine et al., 2018). Overcoming challenges in primary care to make this system work better for patients and clinicians is a daunting and crucial engineering challenge.

2.3 Literature Question 1: What approaches are used to design or adapt strategies to address contextual barriers to change in primary care practices?

2.3.1 Contextual barriers to change

Contextual determinants, barriers and facilitators of implementation, include people, technologies, systems, processes, values, and anything else on the clinic side that might affect the successful implementation of the evidence (Mollon et al., 2009; Ovretveit et al., 2011). While contextual facilitators may be leveraged to overcome barriers (Aarons et al., 2011a; Chambers et al., 2013), focusing on barriers to implementation is pragmatic for implementors with limited time and resources. Several highly-cited frameworks have been developed to support identification of barriers to implementation including the Consolidated Framework for Implementation Research (CFIR; Damschroder et al., 2009), the Theoretical Domains Framework (TDF) (Michie et al., 2005), and the Tailored Implementation for Chronic Diseases (TICD) Checklist (Flottorp et al., 2013). The CFIR combined many lists of contextual determinants of implementation into a list of 39 determinants organized into five domains: intervention characteristics, outer setting, inner setting, characteristics of the individuals involved, and the process of implementation (Damschroder et al., 2009). The TDF has over 100 determinants across 12 domains collected and refined by an interdisciplinary group of experts (Michie et al., 2005). Finally the TICD Checklist was developed through a systematic review of existing checklists for implementors and includes 57 determinants across 7 domains: guideline factors, individual health professional factors, patient factors, professional interactions,

incentives and resources, capacity for organizational change, and social, political, and legal factors (Flottorp et al., 2013).

2.3.2 Approaches to identify contextual barriers

Multiple approaches exist for identifying contextual barriers, and most involve asking stakeholders through interviews, focus groups, or surveys (Flottorp et al., 2013; Huntink et al., 2014; Krause et al., 2014; Moullin et al., 2019). Following data collection, some IS practitioners use a deductive "coding" process to translate findings into standard language using a barrier framework (e.g., the CFIR) (Damschroder et al., 2009; Flottorp et al., 2013; Michie et al., 2005; Vranceanu et al., 2021). After specific barriers are identified, strategies can be selected, adapted, or created developed from the ground up for a specific implementation effort (Wensing et al., 2010, 2011).

2.3.3 Approaches to design and adapt strategies

The process of selecting or designing implementation strategies to address contextual barriers is called tailoring (Baker et al., 2015; Wensing et al., 2011). Strategy frameworks can support tailoring with sets of known strategies (Michie et al., 2013; Powell et al., 2015) that can be mapped to barrier frameworks to guide implementors as they tailor implementations (Michie et al., 2008; Waltz et al., 2019). Additionally, several process models for identifying and addressing barriers can be used to guide the use of the aforementioned methods and frameworks (Fernandez et al., 2019; G. Moore et al., 2021; Movsisyan et al., 2019).

Intervention adaptations are defined in the implementation science literature as changes to interventions to make them "fit" a particular context (Miller et al., 2021; Wiltsey Stirman et

al., 2019). Adaptations, also referred to as modifications, may be planned or unplanned changes to interventions that were developed in or for a context different than the current implementation context (Stirman et al., 2013; Wiltsey Stirman et al., 2019). Adaptations are explicitly not changes to the evidence-based functions of an intervention (Hawe et al., 2004), rather these changes are made in the "adaptable periphery" of an intervention (Damschroder et al., 2009) and concern changes to forms, not functions, of interventions (Hawe et al., 2004; Perez Jolles et al., 2019). Adapted, or tailored, interventions have proven more effective than those without adaptations (Baker et al., 2015), but the best methods to adapt interventions to local context are not yet known (Powell, Beidas, et al., 2017).

Implementation science approaches take an evidence-centered approach to change in primary care and in healthcare more broadly. These approaches use helpful methods and frameworks focused on tailoring to local contexts and transferability to other contexts (Bauer & Kirchner, 2020; Nilsen, 2015). However implementation science approaches, especially approaches for tailoring implementations, generally require significant expertise or familiarity with models and frameworks (Powell, Beidas, et al., 2017).

2.3.4 Complex interventions: Integrating implementation strategies and interventions.

Strategies are designed and adapted, through many approaches, to overcome barriers to implementation of interventions. Implementation research on strategies is a current priority in the field to uncover evidence of best practices for strategy selection and tailoring (Powell et al., 2019). However, caution must be taken when selecting and tailoring an implementation strategy while remaining agnostic about interventions or contextual elements as over-simplification may

occur (Hawe et al., 2004). An implementation strategy is an approach used to increase adoption and sustainability of an intervention (Curran et al., 2012; E. K. Proctor et al., 2013). The unique functional requirements of an intervention (e.g., a screening intervention must include screening questions) directly influence the planning and execution of an implementation (Perez Jolles et al., 2019). However, meeting functional requirements can take many forms (e.g., screening with paper, digital, or verbal surveys) without greatly impacting the implementation of the intervention (Perez Jolles et al., 2019).

The distinction between function and form of interventions also applies to implementation strategies. For example, meeting with a practice facilitator multiple times is a strategy for primary care implementations (Baskerville et al., 2012; Knox et al., 2011). The functions these meetings serve could be training, project management, or any number of other critical elements for successful implementation, but the form of the meeting: in-person, video call, phone call, or email is less consequential than the meeting contents. Establishing evidence for the best functions and forms of practice facilitation will guide decisions on both functions and forms, but if an intervention demands in-person discussions (e.g., sensitive conversations in private areas), the decision-making equation for the strategy is changed.

Building complex interventions requires jointly designing and testing complementary implementation strategies and evidence-based clinical interventions (Campbell, 2000; Eccles et al., 2007; Hawe, 2015). These interventions must be thoroughly trialed, using mixed methods approaches to examine their efficacy within complex systems before larger effectiveness studies (Campbell, 2000). Identification of necessary functions and potential forms can occur through

these trials and will guide, but not determine, their success in diverse contexts (Hawe et al., 2004; Perez Jolles et al., 2019). Centering these complex interventions as the primary focus of implementation research, jointly designing strategies and interventions to best serve unique contexts will be burdensome, but will allow for closer examination and improvement of the complex systems that engulf healthcare (Hawe et al., 2004, 2009). The research presented in this dissertation will examine complex interventions, with attention to the clinical interventions and implementation strategies therein and will seek a greater understanding of the influences that context has on that intervention's effects.

2.3.5 Complementary approaches from other fields

Human Factors (HF), also known as Human Factors and Ergonomics, is the study of how humans interact with technologies, environments, and everything else in the world around them (M. Sanders & McCormick, 1998). This field offers many approaches to improve the quality and safety of healthcare systems (Karsh et al., 2006; Xie & Carayon, 2015), for this review we focus on those relating to sociotechnical systems (STS) and design. STS theory underpins the idea of work systems, or systems of people and things that interact to produce work (Alter, 2013; Pasmore, 1988). STS approaches generally rely on in-depth analyses (e.g., work system analyses) to identify problems in specific work systems (Carayon et al., 2006; Musuuza et al., 2019; Werner et al., 2021). These analyses can inform or co-occur with design processes to create solutions to the identified problems (Robertson et al., 2012). To ensure acceptability of the designed solutions, user-centered design and participatory design approaches focus on eventual users of the solutions and may even involve them in the process as designers to brainstorm,

design, and redesign solutions (Bowie et al., 2015; Gerhart et al., 2015; Sanders, 2002; Sanders & Stappers, 2008). Participatory design approaches are already being used in healthcare settings (Clemensen et al., 2017). Following design, approaches such as usability testing can be used for evaluation and improvement of the design (Bastien, 2010; Cheng et al., 2020).

HF approaches can capture interacting system elements that form barriers and give deliberate focus on users and their needs during design processes. However, HF practitioners often rely on process models from other fields (e.g., PDSA) to guide their improvement projects beyond identification of issues (Hignett et al., 2015). Additionally, the solutions produced by these HF approaches have limited transferability to new contexts because they are created for a specific system with unique barriers or facilitators.

Quality improvement (QI) similarly takes a pragmatic approach to problem-solving; starting by identifying local issues and then focusing on problem-solving (Batalden & Davidoff, 2007; Sollecito & Johnson, 2013). Classic QI approaches are often organized into toolkits like the “7 new management and planning tools” (Mizuno, 1988), or the “7 quality control tools” that focuses on quantitative process improvement (Ishikawa, 1984). The approaches in these toolkits can be used together to form a process that guides users through barrier identification, interconnections between barriers, and prioritization of issues to address (Anjard, 1995).

QI also give us the popular “Plan-Do-Study/Check-Act” or PDSA model to guide improvement projects (Deming, 1986). PDSA has many adapted versions such as “FOCUS-PDCA” and the “Model for Improvement,” these expansions generally add steps to guide proper use of PDSA cycles in practice (e.g., Find a process to improve) (James, 1992; Langley et al.,

2009). Apart from specific process improvements, a goal of PDSA projects in healthcare is to facilitate continuous improvement capabilities (Batalden & Stoltz, 1995).

QI approaches to identifying and overcoming barriers to change have been used extensively in healthcare, likely due to their practicality and approachability (Ahmed et al., 2019; Anjard, 1995; Antonacci et al., 2018; Bakhai et al., 2019; Brassard & Ritter, 2009; Hartkopf et al., 2020). While these approaches are "simple" and well-known in healthcare (Batalden & Davidoff, 2007; IHI, 2021), a review found that only 3% of studies in healthcare environments correctly use PDSA cycles (Taylor et al., 2014). Additionally, several studies have found that QI approaches can struggle to sustain positive impacts in primary care with staff turnover and other challenges (Crabtree et al., 2011; Shortell et al., 1998; Baron et al., 2020).

2.4 Literature Question 2: What is practice facilitation and how has it been used in primary care implementations?

2.4.1 Practice Facilitation Definition

Practice facilitation (PF) is an effective and widely used collection of implementation strategies for implementing evidence-based interventions, but definitions of the approach vary (Baskerville et al., 2012; Ciolino et al., 2018; Halladay et al., 2020; Jaén et al., 2010; Knox et al., 2011). This strategy involves facilitators supporting practices to change or improve their processes and patient or clinician outcomes (Knox et al., 2011). Practice facilitation is closely tied to adaptation with the program manual for practice coaching defining the goal of facilitators as "… help physicians and quality improvement teams develop the skills they need to adapt clinical evidence to the specific circumstance of their practice environment" (DeWalt et al.,

2010). This lack of specificity leads to different facilitators or PF studies yielding widely different results, despite being effective on average (Baskerville et al., 2012). At the most fundamental level, facilitators collaborate with health care professionals and this collaboration will benefit from intentional design and specification.

2.4.2 Practice Facilitation in Primary Care

Practice Facilitation has been used extensively in primary care implementation as a way to develop a capacity for continuous improvement (AHRQ, 2018). EvidenceNOW, a nationwide research initiative led by the Agencies for Healthcare Research and Quality (AHRQ), has led the advancement of practice facilitation approaches in primary care clinics in projects focused on many health conditions (Hemler et al., 2018). EvidenceNOW studies have used practice facilitation in implementation and improvement projects focused on heart disease, alcohol use, and currently, urinary incontinence (AHRQ, 2022). These studies have shown the criticality of facilitation and tailoring in primary care implementations (S. M. McHugh et al., 2022; Perry et al., 2022).

EvidenceNOW studies using facilitation in primary care have also worked to refine the definition and requirements of practice facilitators. While specific actions facilitators completed vary, the “Practice facilitation spectrum” defines the most common types of activities performed based on Walunas and colleagues’ (2021) evaluation of a multi-state implementation study. The practice facilitation spectrum organizes tasks into five ordinal categories: (1) doing tasks, (2) managing projects, (3) consulting, (4) training, and (5) coaching (Walunas et al., 2021). That study found better implementation outcomes in practices that used more coaching strategies.

Enhancing the specification of practice facilitation, as an implementation strategy, requires a better understanding of not only the actions facilitators use from the practice facilitation spectrum (Walunas et al., 2021), but also a better understanding of the targets, temporality, and dose of these actions (E. K. Proctor et al., 2013). Standards for specifying implementation strategies have been developed for implementation researchers and they include determining the actor, action, action target (i.e., recipient), temporality, dose, outcomes, and justification (E. K. Proctor et al., 2013). Specifying the many actions that practice facilitators deliver is critical, but there is currently mixed evidence to support this specification. For example, the proper dosage and temporality of practice facilitation remains unknown and incalculable (Baskerville et al., 2012; Gold et al., 2019; Liddy et al., 2015; S. M. McHugh et al., 2022), making implementation efforts that use this strategy difficult to plan and allocate resources for.

3.0 RESEARCH OVERVIEW

The research work presented in this dissertation addresses gaps in the literature on facilitated implementation in primary care. To contextualize the research presented in this dissertation, this chapter provides a brief background on the researcher's worldview and the parent study that provided data collection opportunities in primary care settings for this research. Additionally, this chapter offers a summary for the conceptual foundations and methodological approaches for the research studies presented in chapters 4 and 5. The first research study uses a multimethod qualitative design to characterize relationships between the primary care context and adaptations to interventions. The second study uses a comparative statistical design to test quantitative hypotheses about directional relationships between measures of implementation context, adaptations, and outcomes.

3.1 Researcher's Worldview

A researcher's beliefs, experiences, and intentions guide the focus and structure of their work, influencing the questions they ask and the answers they seek. As such, it is important to understand the connections between a research's worldview, their theoretical lens, the methods they choose, and the subjects of their work.

As a researcher I believe there is an objective reality in the world, but that reality is not completely knowable. I must acknowledge that humans, including myself, cannot fully represent reality through knowledge, beliefs, or even objective measure. As such, I do not equate human knowledge or experiences to reality. Instead, I acknowledge the limitations of human perceptions and seek multiple perspectives using multiple methods to triangulate and reduce the persistent

gap between the observable and the real. Thereby generating a truer, though still imperfect, picture of reality.

My research paradigm aligns most closely with critical realism. Critical realism offers a framing of the world as real but acknowledges the limitations of our abilities to observe and communicate all that is present around us. For research, critical realism encourages the pursuit of causal mechanisms, why things happen, in the real world while maintaining all representations of these mechanisms through empirical measure or personal belief are imperfect and subject to revision to better represent reality. To approach reality with research observations and measures, critical realism directly supports pragmatism in selection of methodologies and the constructions of interdisciplinary research teams (Haigh et al., 2019). This framing of reality, empirical measures of reality, and experiences of reality separate from each other is particularly useful for the study of sociotechnical systems, like primary care clinics.

Primary care clinics help people with a variety of health care needs. However, any explanation of the activities that happen in and around primary care is necessarily incomplete. These clinics are complex systems with observable and unobservable elements; we can never directly observe the mechanisms at play beyond those that people can articulate or measure. These unobservable and unpredictable mechanisms are the reason many improvement efforts in primary care fail (Crabtree et al., 2011; Sturgiss & Clark, 2020).

The only way for us as researchers to begin understanding the mechanisms that underpin complex systems is through examining the combined experiences of many people, the combined results of multiple studies of subsystems (social, technical, monetary, etc.), and the integrative

analyses of immense amounts of data and observation. This aggregative approach unfortunately discounts the experiences of the few and it is therefore critical, in pursuit of equity, to identify groups that warrant a close focus using proxies like location, income, housing status, sexuality, and race, among others. These proxies are imperfect as they can only offer limited representations of research subject. For example, rural populations may be considered "underserved", but certainly not all rural areas present the same barriers to care or societal pressures. In any case, attempting to understand a system as well as possible within existing limitations, pragmatically selecting methods, research problems, and topics, is the best we as researchers can do.

Appreciation of nuance is fundamental in equity-focused research. Equating a person to their identities is a fallacy, as is claiming understanding of a person and the systems they operate within through observation. With limitations of knowledge, time, and funding, we cannot fully understand the nuances of complex systems. The large networks of information, people, technology, and interactions, while extant, are too broad for consideration in a single study or a single research career. This truth guides the scope of the research presented in this dissertation. Focusing on the important and accessible elements of systems which can be observed and measured while contributing to a larger research discussion.

3.2 Parent Study Overview: WI-INTUIT

This dissertation was conducted as part of an ongoing study titled "WI-INTUIT: Improving Nonsurgical Treatment for Urinary Incontinence" which is itself a part of a national EvidenceNOW project funded by the Agency for Health Research and Quality (AHRQ) titled

"Improving Nonsurgical Treatment of Urinary Incontinence among Women in Primary Care" (AHRQ, 2021; Neuner, 2023). This project has three aims. The first is to evaluate the relative utility of two implementation strategies: streamlined practice facilitation (SPF) and partnership building (PB). To achieve this aim, the research team has used a hybrid randomized implementation trial (Curran et al., 2012) to compare the use of a single strategy (SPF) to the use of both strategies (SPF+PB). The second aim is to examine the impact of implementation strategies and contextual determinants on the implementation outcomes for an evidence-based intervention targeting improved screening and treatment for women with UI (UI-Assist). To achieve this aim, the research team will perform a mixed methods process evaluation. The third aim is to assess patient health outcomes associated with the screening and treatment intervention (UI-Assist). This aim will be achieved through qualitative analysis of patient-reported outcome surveys and practice surveys.

3.2.1 Study Setting and Sample

The parent study takes place in Wisconsin, recruiting primary care clinics from across the state. Clinics, rather than patients, were recruited and enrolled in the study as participating sites. 30 primary care clinics from across the state of Wisconsin and one clinic in Minnesota are enrolled in the study. The participating Minnesota clinic is part of an existing health system with several Wisconsin clinics who are collectively participating in the study. To account for shared staff and other organizational overlap between several participating clinics, clusters have been created to ensure that related clinics are similarly randomized in this study.

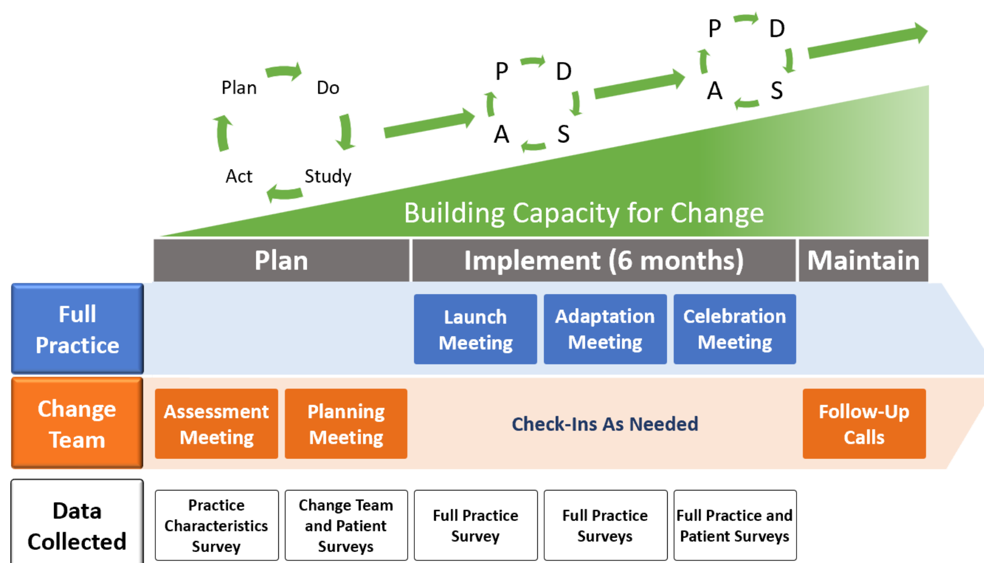
These clinics serve various patient populations in rural and urban areas, though rural and underserved clinics were purposefully oversampled to better understand the unique challenges they face. Participating sites include independent clinics, clinics in health systems or collaboratives, tribal health centers, federally qualified health centers, and residency clinics.

3.2.2 Data Collection

Clinics began participation in a rolling fashion, going through 5 planned meetings with a practice facilitator (LJ, HT, ER, or RP). The first two pre-implementation meetings will involve a subset of clinic staff, designated as the practice change team. The practice change team, serving as local champions for the change effort, first participates in two meetings to plan the implementation and will complete additional surveys and implementation tasks throughout the project. Then, the entire practice including change team members meet with the facilitator for three meetings, launch, midpoint, and celebration. Additional check-ins with the practice facilitator and relevant site staff before, during, and after implementation are scheduled as necessary to support clinics.

Data is being collected at multiple timepoints from each practice. Collection of both qualitative and quantitative data is detailed below. Surveys are collected at regular intervals for participating clinics according to the date they enroll in the project and when they begin implementation. This timeline is outlined in Figure 3.1 below.

Figure 3.1 Project Timeline



As part of the larger research initiative, the research team is collecting meeting transcripts and field notes from each meeting and facilitator check-in. A summary of these and other collected data is shown in Table 3.1. All facilitated meetings and check-ins are semi-structured group interviews, see Appendix 1 for an example of our interview guide for an assessment meeting.

Table 3.1: Summary of Data Collected in Parent Study

Data Type	Description
Qualitative	- Recordings and transcripts of meetings - Field notes and implementation logs - Internal decision-aiding documents - Free response practice surveys - Emails from practices
Quantitative	- Practice Characteristics (e.g., rurality, payer mix) - ORIC Surveys (Shea et al., 2014) - Burnout Surveys

	- Facilitator effort tracking - Additional surveys (from all practice members) - Patient surveys - EHR reports of positive screening and treatments over time. - Intervention Menus (See below)

Intervention components were compiled and structured based on the 5A's: Ask, Advise, Assess, Assist, and Arrange, a model develop through past AHRQ EvidenceNOW studies (AHRQ, 2012). This menu of intervention options for each of the 5A's supports documentation of intervention components for a clinic's UI screening and management workflow. These data, tracked over time, can also be used to capture adaptations to the intervention that occur during implementation (Miller et al., 2021; Wiltsey Stirman et al., 2019). These menus were developed iteratively through weekly multidisciplinary review and refined through application in a pilot study with 10 clinics. A blank template of the final menu can be seen in Appendix 2.

4.2.3 Data Analysis

Proposed analyses for the parent study include comparative analyses of clinics receiving SPF and SPF+PB implementation strategies to understand the relative utility of these strategies. These comparative analyses may include cost analysis of implementation strategies and clinical outcome evaluation between the two randomized groups. Further, the parent study will use a mixed method approach to evaluate the effects of context on the implementation process and implementation strategies. Finally, the WI-INTUIT study will examine the effects of the intervention on patient health outcomes using a mixed methods approach. The final two aims of the parent study, though using similar data to the proposed methods for this dissertation, are

distinct from the research presented in this dissertation. This separation is mainly structural as the analyses presented in this document do not rely on the parent study design or randomization scheme beyond recruitment and data collection. To preserve validity of both the parent study and my research, a senior researcher (ER) and I have committed to maintaining separation between these two bodies of work.

3.3 Study Overview

As discussed above (2.0 Literature Review), practice facilitation (PF) is a widely used approach for implementing research evidence into clinical practice. However, implementations using PF are intentionally non-standardized, instead they are usually adapted, intentionally and unintentionally (Holden et al., 2013), to the unique context of each clinic. To arrive at a well-fitted, sustainable change in a clinic, adaptation of interventions is necessary (Chambers et al., 2013). Unfortunately, little is known about the relationships between contextual factors and adaptations to interventions. Adapted interventions have proven more effective than those without adaptations (Baker et al., 2015), but the best methods to tailor or adapt interventions to local context are not yet known (Powell, Beidas, et al., 2017).

PF strategies, as part of interventions, have been adapted for many different contexts but many specific adaptations are difficult to track and identify. Methods for tracking specific adaptations have been proposed, (Miller et al., 2021; J. D. Smith et al., 2022; Wiltsey Stirman et al., 2019), but these approaches are time-intensive and difficult to use for proactive planning. Specific adaptations to PF interventions, like changes in the amount or regularity of meetings between facilitators and clinic stakeholders are much easier to track, but these adaptations have

shown mixed effects on implementation success (Liddy et al., 2015; Parchman et al., 2013). There is a need to identify and understand the mechanisms that connect clinic characteristics and contextual factors (e.g., clinic location, number of staff, etc.) to adaptations (e.g., changing owner of clinical tasks). Further, connecting context and adaptations to implementation and clinical outcomes is critical for planning and decision-making (Bodenheimer & Sinsky, 2014; Glasgow et al., 2019; E. Proctor et al., 2011; E. K. Proctor et al., 2013). By identifying the mechanisms that connect certain contextual factors to adaptations and to outcomes, we can determine which adaptations should be encouraged or discouraged for successful implementation.

Ideally, proactive adaptation of interventions based on measurable contextual factors would save facilitators and primary care clinics time for other critical tasks (Liddy et al., 2015; S. M. McHugh et al., 2022; Powell, Beidas, et al., 2017). These adaptations could reduce or even eliminate the need for regularly scheduled meetings with facilitators, allowing for shifts to an appointment model of facilitation (S. M. McHugh et al., 2022; Ye et al., 2020). This assertion relies on the appropriateness of the proactively suggested adaptations and other impacts of less facilitator presence (Baskerville et al., 2012; E. Proctor et al., 2011; Walunas et al., 2021).

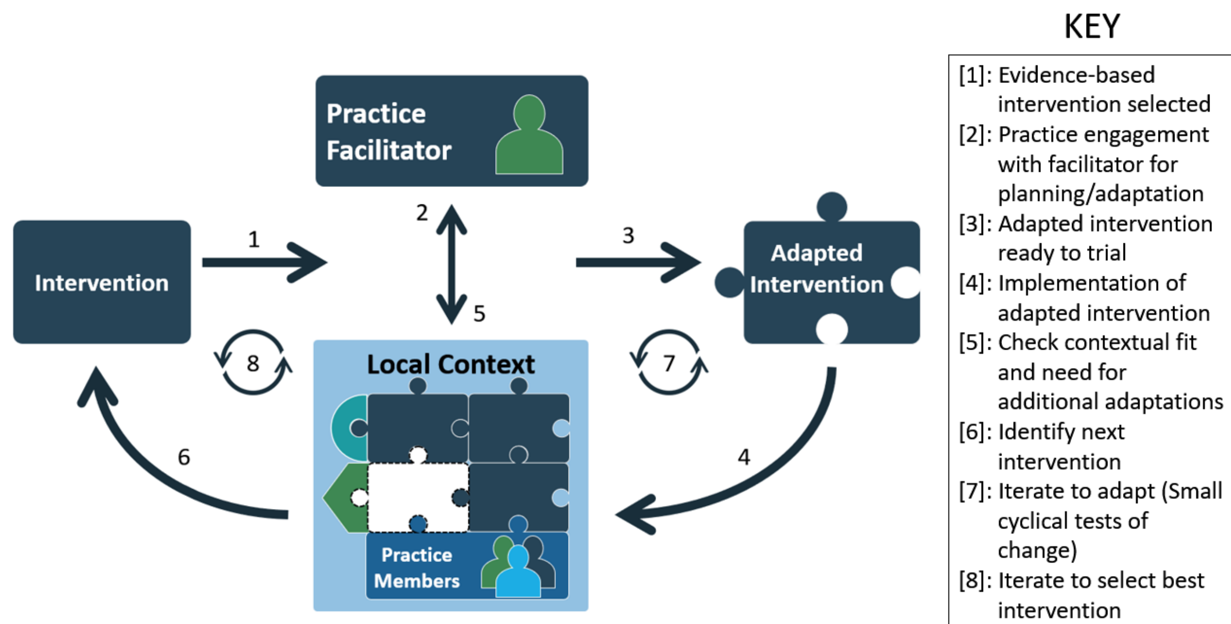
Sending an external facilitator into a specific primary care clinic to support implementation provides an ideal setting for an intervention to be adapted to fit in that context. However, the specific strategies used by facilitators and the dose, or intensity of successful PF implementations in the literature vary (Baskerville et al., 2012). Additionally, interventions adapted to local context have proven more effective (Baker et al., 2015), but the best methods to

adapt during implementation are not yet known and existing methods are not practical (Powell, Beidas, et al., 2017). Streamlining practice facilitation can reduce the burden on clinics and practice facilitators, but it is critical to identify and retain the core strategies of PF for each practice (Perez Jolles et al., 2019).

3.4 Conceptual Framework

The conceptual framework proposed below advances implementation science, human factors, and quality improvement by incorporating elements from a range of models, frameworks and definitions. First, the use of practice facilitators to deliver evidence-based practices (i.e., interventions) to practices and guide adaptation comes from the practice facilitation literature (AHRQ, 2018; Baskerville et al., 2012; DeWalt et al., 2010; Knox et al., 2011) (see figure 3.2 [1], [2], and [3]). Then the iterative proposed testing, evaluating, and adaptation of interventions (see figure 3.2 [4], [5], [3], and [7] builds on adaptations in work systems (Carayon, 2019; Holden et al., 2013), improvement cycles (Deming, 1986; Langley et al., 2009), and directly ties to the reconceptualization of tailoring (see figure 2.1). Finally, this conceptual framework extends to the search process for new interventions to be adapted and implemented locally (see figure 3.2 [6], [8], and [1]).

Figure 3.2: Conceptual Model of Facilitator Engagement and Intervention



Adaptation

Interventions and implementation strategies are adapted to fit local context by practice facilitators and local implementation teams in clinics. The research in this dissertation investigates the nature and necessity of practice facilitator engagement in primary care improvement efforts, and as catalysts for adaptation and tailoring. Past research suggests that facilitators serve a critical role in implementation and facilitated implementations are nearly 3 times more likely to encourage adoption of interventions (Baskerville et al., 2012). Further, facilitated implementations that tailored interventions to local context had greater effects (Baskerville et al., 2012), agreeing with the findings of a systematic review that found variable but positive effects of tailoring on implementation success (Baker et al., 2015).

This dissertation conceptualizes practice facilitation strategies and a UI screening and management intervention (UI-Assist) as interventions comprised of components. Several of these

components are inherent to the structure of PF or UI-Assist and are thus non-negotiable, e.g., patients must be asked about UI to be considered "screened." Other components are configurable and can be tailored to best meet the practices' needs, e.g., facilitators might meet virtually or in-person. This notion of configural components builds on "core functions and forms" (Perez Jolles et al., 2019) and "adaptable periphery" (Damschroder et al., 2009) as discussed above, adding in explicit options to aid in the decision-making involved with tailoring.

Through the studies presented in this dissertation, practice facilitation will be advanced and improved while building on previous literature, which has established the main "activities" a facilitator may perform (Walunas et al., 2021). The "practice facilitation spectrum" (Walunas et al., 2021) describes five activity types a practice facilitator may perform. To expand on this, I have worked with my research team to specify the specific strategies from the ERIC taxonomy that may be performed by facilitators in our study as part of two strategy bundles described in section 4.2. Additional implementation strategies that extend and augment the efforts of practice facilitators will be captured using the Expert Recommendations for Implementing Change (ERIC) (Powell et al., 2015).

Adaptations of interventions are used to improve the fit of the intervention in a specific local clinic context (Chambers et al., 2013; Wiltsey Stirman et al., 2019). Primary care clinics have certain characteristics that do not change frequently or significantly such as rurality and payer mix. I hypothesize that clinics with similar characteristics and contextual determinants may arrive at similarly adapted interventions and implementation outcomes.

3.5 Research Questions

To explore the complex relationships between primary care clinic context, interventions, and adaptations, I have two core research questions:

RQ1 – What are the relationships between CFIR determinants and intervention adaptations in facilitated implementations in primary care?

To answer this question, I will capture and jointly analyze contextual determinants with associated intervention components and adaptations in a multi-site implementation study.

RQ2 – How does engagement with facilitation influence clinic readiness for change across rural and urban settings?

To answer this question, I will collect clinic-level data including geographical location and measures of engagement with facilitators. I will use statistical analyses to examine clinics, grouped by their characteristics and engagement with facilitation, on clinic readiness for change.

3.6 Study Design

To answer my research questions, I led the analyses summarized in Table 3.2 below. These analyses rely on data collected as part of the parent study.

Table 3.2: Summary of Data Collection and Analyses

Research Question	Data Collected* (*collected as part of the parent study)	Data Analysis Methods
RQ1	- Intervention Menus (See Appendix 2) - Transcripts of facilitated meetings.	- Deductive Content analysis (Elo & Kyngäs, 2008; Hsieh & Shannon, 2005) - Code Mapping (Saldaña, 2013)

RQ2	- Practice Characteristics (e.g., rurality, payer mix) - Clinic Rural and Urban groupings (Health Innovation Program, 2020) - Organizational Readiness Surveys (Shea et al., 2014) - Facilitator effort tracking - Practice Assessment of Change Engagement	- Independent t tests - Mann-Whitney U Tests (Wilcoxon sign-rank tests) - Correlation Analysis

4.0 Why We Adapt: Understanding How Context Shapes Intervention Adaptations in Facilitated Implementations in Primary Care

RQ1: What are the relationships between CFIR determinants and intervention adaptations in facilitated implementations in primary care?

The following research is presented in manuscript format aligned with the requirements of the Implementation Science Communications journal.

4.1 Background

Evidence-based interventions that have been adapted to address contextual barriers to implementation are more than twice as effective as those without adaptation (Baker et al., 2015). Adaptations, also referred to as modifications, may be planned or unplanned changes to interventions that were developed in or for a context different than the current implementation context (Stirman et al., 2013; Wiltsey Stirman et al., 2019). Existing methods to capture adaptations and related contextual barriers are time-intensive and burdensome for implementation stakeholders (Damschroder et al., 2009; Miller et al., 2021; Nilsen & Bernhardsson, 2019; Stirman et al., 2013). Developing pragmatic, low-burden methods to interpret adaptations and their relationships with context are a crucial step towards proactive adaptation guidance across contexts (Chambers & Norton, 2016).

Contextual determinants, or barriers and facilitators, of implementation, include people, technologies, systems, processes, values, and anything else on the clinic side that might affect the

successful implementation of interventions (Mollon et al., 2009; Ovretveit et al., 2011). Interventions with evidence to their effectiveness may still see varied outcomes when implemented in new and different contexts (Bauer & Kirchner, 2020; Lau et al., 2015; C. R. May et al., 2016). Frameworks and taxonomies, such as CFIR 2.0 allow us to retrospectively identify the contextual elements that impacted an implementation effort (Damschroder et al., 2009; Flottorp et al., 2013; Michie et al., 2005). Understanding contextual elements and adapting interventions accordingly is crucial to improving the ultimate effectiveness of an intervention in a given context (Baker et al., 2015; Powell, Beidas, et al., 2017).

Adaptations are explicitly not changes to the evidence-based functions of an intervention (Hawe et al., 2004), rather these changes are made in the "adaptable periphery" of an intervention (Damschroder et al., 2009) and concern changes to forms, not functions, of interventions (Hawe et al., 2004; Perez Jolles et al., 2019). Implementing multicomponent interventions in complex contexts may require many different adaptations to achieve desired implementation outcomes such as sustainability (Baumann et al., 2017; Chambers et al., 2013; J. N. Roscoe et al., 2019).

New pragmatic tools are necessary to capture intervention adaptations as they occur over time due to changing context. Tools like the Framework for Reporting Adaptations and Modifications – Expanded (FRAME) allow us to document adaptations and their local contextual "reasons," but these tools are too burdensome for direct use in implementations where time is limited (Wiltsey Stirman et al., 2019). Pragmatic, low-burden tools would allow for the early

identification of functional adaptations that may impact intervention effectiveness (Perez Jolles et al., 2019).

In this study we developed a pragmatic method of capturing and codifying adaptations, leveraging the structure of the intervention (Holtrop et al., 2022). Menu options of intervention components (e.g., multiple training options in various formats/languages) have been used to proactively customize interventions to stakeholder needs for implementations in education and healthcare (Kilbourne et al., 2007; S. N. Smith et al., 2022). We took a similar approach focused on longitudinal adaptation tracking rather than proactive assignment, capturing relevant intervention adaptations with configurable intervention menus, a tracking tool developed previously by our team (Parks et al., 2023). Configural intervention menus build on the ideas of core functions and forms (Perez Jolles et al., 2019) and configuration (Holden et al., 2013). The menus are intervention-centered and must be specifically developed for each intervention by experts, but the final configurable menu is low-burden and requires minimal to no specialized training for use in practice (Parks et al., 2023). By using these menus, we are able to track intervention adaptations over time and across contexts.

We operationalized the definition of adaptations to be: changes to an intervention over time to improve fit in contexts (Miller et al., 2021; Wiltsey Stirman et al., 2019). This conceptualization supports pre-/post- comparisons of interventions using tracking tools like configurable intervention menus (Parks et al., 2023). Leveraging the structure of the configurable menus, our team defined two distinct categories of adaptations a priori that capture changes within and between intervention components, building on the concepts of configuration and

intervention specification (Hickey et al., 2017; Holden et al., 2013; E. K. Proctor et al., 2013). This intervention-centered approach to defining and capturing adaptations is designed to help us improve on existing adaptation taxonomies which are limited in their *coverage*, ability to represent all potential intervention adaptations, and their *clarity*, ability to distinguish taxonomy subcategories (Chambers & Norton, 2016; J. N. Roscoe et al., 2019).

Our objectives in this study were to (1) capture intervention adaptations and contextual determinants in a primary care implementation study, and (2) understand the relationships between contextual determinants and intervention adaptations. This study was conducted as part of a statewide initiative titled “WI-INTUIT: Improving Nonsurgical Treatment for Urinary Incontinence” which is itself a part of a national EvidenceNOW project funded by the Agency for Health Research and Quality (AHRQ) (AHRQ, 2021; Neuner, 2023). This hybrid implementation effectiveness trial enrolled over 30 primary care clinics from across the state of Wisconsin to study the implementation and effectiveness of an evidence-based intervention targeting improved screening and treatment for women with Urinary Incontinence (UI).

4.2 Methods

4.2.1 Developing Intervention Menus

Our multidisciplinary research team with expertise in primary care medicine, urogynecology, clinical operations, and implementation science, iteratively developed an intervention menu to guide and track adaptations over time. This intervention menu is structured around the 5A’s (ask, advise, assess, assist, arrange) to capture changes to the specific screening and treatment intervention being implemented in the parent study (AHRQ, 2012; Dosh, 2005).

The intervention menu was trialed and refined by the research team and facilitators over the course of 5 introductory meetings with clinics. The menu contains 13 questions corresponding to intervention components, each with multiple possible response options that can be selected to represent the intervention as observed by a facilitator for each site following each observation (See Appendix 2). Additionally, facilitators were encouraged to add relevant notes to accompany component question responses.

The intervention menu tool leverages the 5 A's as well as the concept of configuration from systems engineering (Dosh, 2005; Holden et al., 2013; Parks et al., 2023). Configuration refers to the interacting people, technology, or other system components that most prominently impact system performance (Holden et al., 2013). By projecting the possible configurations of work in primary care settings for each stage of the 5 A's model, we were able to generate the set of intervention components that defined a configuration. Using this tool, we assessed intervention components using simple questions (e.g., Who gives the survey to the patient?) and defined intervention configurations as the set of responses to question. Changes to the intervention configuration over time were defined as intervention adaptations.

4.2.2 Data Collection

Table 1: Clinic Characteristics

Clinic ID #	Cluster ID[δ]	Rural / Urban Grouping*	Clinic Type	Clinic Size (FTE)
1		Urban	Independent Practice	8
2		Rural	Independent Practice	10
3	A	Rural	FQHC	15

4	A	Rural	FQHC	35
5	B	Rural	Non-Academic Health System Affiliated	15
6	B	Rural	Non-Academic Health System Affiliated	120
7	B	Rural	Non-Academic Health System Affiliated	12
8	B	Rural	Non-Academic Health System Affiliated	13
9	B	Rural	Non-Academic Health System Affiliated	16
10		Urban	Independent Practice	47
11		Urban	Independent Practice	17
12		Urban	Independent Practice	4
13		Urban	Independent Practice	2
14		Urban	Non-Academic Health System Affiliated	3
15		Rural	Non-Academic Health System Affiliated	4

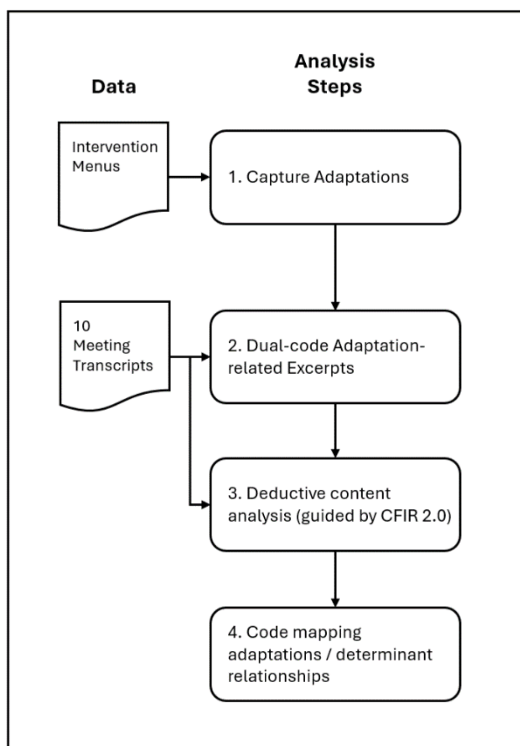
[δ] Several clinics participated jointly in this project as members of existing integrated health systems.
*Clinic rural/urban groupings were designated using each clinic's ZIP code and an existing statewide classification of rural and urban areas (Health Innovation Program, 2020).

During a larger parent study, the Wisconsin Improving Nonsurgical Treatment of Urinary Incontinence (WI-INTUIT) Study, a facilitator and notetaker met with 15 clinics (see Table 1) for 3 recorded meetings over the course of about 5 months. The purpose of these 3 meetings with each clinic were to (1) design an intervention collaboratively with clinic representatives, (2) introduce the planned changes to the full clinic staff, and (3) to assess the implementation effort and identify any areas of improvement, respectively. These meetings were generally held virtually using video teleconferencing software, apart from two meetings that were held in-person in clinic meeting rooms. Additional check-in meetings with facilitators were available to clinics and especially encouraged before the second meeting where the "kickoffs" for the full staff occurred. These meetings were not the first or last contacts between the study facilitators

and clinic representatives, this subset was selected to capture the early to middle phases of implementation where most adaptations are theorized to occur (Aarons et al., 2011b, 2012; Chamberlain et al., 2011; Moullin et al., 2019). Following each meeting, facilitators and notetakers led a debrief conversation without clinic team members to gather action items, finalize notes, and document the current intervention details in the intervention menu. Debriefs generally lasted 15 to 30 minutes and were also recorded.

Recorded meetings were transcribed using a professional transcription service. All meeting data and data collected during the debrief discussions were stored on secure servers and data will be deleted following the completion of parent study analyses.

Figure 1: Summary of our Analysis Process



4.2.3 Adaptation Identification

For this initial, intermediary step, we operationalized the definition of intervention adaptations as an intervention **reconfiguration**, or a change from one configuration of intervention components to another over time (Holden et al., 2013). We used intervention menus to track intervention configurations following each facilitation encounter and compared configurations longitudinally to identify reconfigurations. However, as additional changes to interventions could occur that did not alter the presence or form of intervention components, thus not meeting the criteria of reconfiguration as we defined it (E. K. Proctor et al., 2013). To capture these additional adaptations, we defined a **respecification** as a documented change in the execution or function of a given intervention component without a configural change.

Intervention menus from each clinic and each timepoint were collected into a single document and jointly reviewed by two researchers (RP, MM). Using the definitions above, the researchers collaboratively identified adaptations and collected them into a single summary table. As adaptations are changes over time, the first and last meetings included in this study were the two comparison timepoints chosen a priori. Any reconfigurations or respecifications, identified as changes on intervention menus between meetings 1 and 3, were documented in a summary table of all adaptations. Adaptations were described in the general format: "[intervention component] was changed ***from*** [previous form] ***to*** [later form]." For example, an adaptation from EHR to paper patient educational handouts was described as: "The mode of patient educational materials delivery was changed ***from*** digital via the EHR ***to*** on paper."

After adaptations were identified from intervention menus, a deductive excerpt analysis of 10, 1-hour long mid-implementation meeting transcripts was used to identify any transcript excerpts that were relevant to each adaptation (Hsieh & Shannon, 2005). Two researchers (RP, MM) used NVivo to independently identify any relevant excerpts for each adaptation in the corresponding meeting transcript. Excerpts were coded at the multiple-sentence or paragraph level to capture context including interviewer questions. Each adaptation was given an identifier used to associate a coded transcript excerpts with the relevant adaptation(s). Weekly consensus-building discussions with a senior researcher were used to review coded excerpts for disagreements and resolve any coding challenges.

4.2.4 Content Analysis

For this intermediary step, our team performed a deductive content analysis of the same 10, 1-hour long mid-implementation meeting transcripts guided by the Consolidated Framework for Implementation Research (CFIR 2.0) (Damschroder et al., 2022b; Elo & Kyngäs, 2008; Kleinheksel et al., 2020). Our team initially planned to focus this analysis on only contextual barriers in a problem-focused approach. However, based on peer feedback and a review of the literature we revised our approach to include all determinants, both barriers and facilitators (Correa et al., 2020; Damschroder et al., 2022b; C. R. May et al., 2016).

The content analysis was carried out by a primary coder (RP), a secondary coder (MM), and overseen by a senior researcher (ER). Coders met to familiarize themselves with the CFIR 2.0, and to co-code a single transcript to establish shared understanding of the coding framework and software (NVivo 14). After this training period, the primary coder (RP) finished coding all

10 transcripts while the secondary coder dual-coded 30% of transcripts. Coders were instructed to label excerpts no shorter than a sentence with the relevant code and annotate any excerpts that created uncertainty. Weekly consensus building discussions were used to resolve discrepancies in dual-coded transcripts and to address any questions with a senior researcher.

4.2.5 Code Mapping

Three members of the research team (RP, MM, ER) carried out code-mapping (Saldaña, 2013) using as inputs the results of the identification of adaptation-related conversation excerpts and of the content analysis guided by CFIR 2.0. Code-mapping is used to identify and organize themes in previously-coded qualitative data (Hurst, 2023; Saldaña, 2013). This inductive and iterative process has been used to reveal connections between codes as they appear in vivo, going beyond pre-existing relationships like those defined in the CFIR (Damschroder et al., 2009; Duncan et al., 2023; Jobin et al., 2019; Lobczowski et al., 2021; Saldaña, 2013). Our code mapping approach focused on the relationships between contextual determinants identified in transcript excerpts and the adaptations associated with those excerpts. First, each relationship between adaptations and co-occurring contextual determinants was reviewed alongside the relevant transcript excerpt and described briefly in a single sentence plain language summary. These descriptions were then refined and grouped into categories of similar descriptions across all clinics. In a final iteration, the categories were further organized into higher order conceptual groups.

4.3 Results

Our analyses produced a set of adaptations, adaptation-related transcript excerpts, transcripts coded for contextual determinants, and groupings of adaptation-determinant relationships generated by code mapping across the sampled clinical implementations.

4.3.1 Adaptations Identification Results

Two researchers reviewed intervention menus for the sampled clinics (n=15) and identified 52 adaptations. Respecifications and reconfigurations to the interventions in each clinic were collected and are summarized below (see Table 3).

Table 2: Summary of Adaptations

Clinic ID #	Cluster ID	Adaptations		
		Total	**Reconfigurations**	**Respecifications**
1		6	3	3
2		7	5	2
3	A	3	1	2
4	A	5	5	0
5	B	1	1	0
6	B	0	0	0
7	B	1	1	0
9	B	0	0	0
10		6	3	3
11		5	5	0
12		6	4	2
13		5	5	0
14		3	3	0
15		4	4	0
	Totals	**52**	**40**	**12**

* Clinic (ID# 8) was included via shared-meeting-transcript data but omitted from analyses due to missing data.

The process of identifying adaptations and related transcript excerpts produced few respecifications (n=12) compared to reconfigurations (n=40) (see Appendix 3). On average, clinics made 3.7 adaptations to their interventions from the planning to mid-implementation phases of their respective implementations. Additionally, several clinics (n=2) did not make any adaptations that could be captured with this process during the study period. Despite sharing meetings, facilitators captured different adaptations between clinics who met jointly with facilitators as a part of a health system or collaborative.

4.3.2 Excerpt Identification Results

Coders identified 100 excerpts across the 10 meeting transcripts relating to the 52 identified adaptations. These excerpts had high intercoder agreement, and any coded excerpts with disagreement were reviewed and revised jointly by the coders to reach agreement on final excerpts prior to content analysis.

4.3.3 Content Analysis Results

The content analysis produced 502 code instances across the 10 transcripts representing 51/76 CFIR determinants across all six CFIR 2.0 domains. Table 2 is a summary of CFIR determinants represented and not represented in this dataset. Determinants not represented in these data may have been present in the clinic contexts but were not discussed explicitly and thus could not be coded in meeting transcripts. The determinants represented in these data were cross-referenced with adaptation-related excerpts and informed the subsequent code-mapping process.

Table 3: Summary of CFIR 2.0 Coded Data

Domains	Represented	Not Represented
Innovation	A. Innovation Source B. Innovation Evidence-Base D. Innovation Adaptability E. Innovation Trialability G. Innovation Design	C. Innovation Relative Advantage F. Innovation Complexity H. Innovation Cost
Outer Setting	A. Critical Incidents B. Local Attitudes C. Local Conditions D. Partnerships & Connections F. Financing G. External Pressure 3. Performance-Measurement Pressure	E. Policies & Laws G. External Pressure 1. Societal Pressure 2. Market Pressure
Inner Setting	A. Structural Characteristics 2. Information Technology Infrastructure 3. Work Infrastructure C. Communications D. Culture 2. Recipient-Centeredness 4. Learning-Centeredness E. Tension for Change F. Compatibility G. Relative Priority H. Incentive Systems I. Mission Alignment J. Available Resources 1. Funding 3. Materials & Equipment K. Access to Knowledge & Information	A. Structural Characteristics 1. Physical Infrastructure B. Relational Connections D. Culture 1. Human Equality-Centeredness 3. Deliverer-Centeredness J. Available Resources 2. Space
Individuals	*Roles Subdomain* G. Other Implementation Support H. Innovation Deliverers I. Innovation Recipients *Characteristics Subdomain*	*Roles Subdomain* A. High-level Leaders B. Mid-level Leaders C. Opinion Leaders D. Implementation Facilitators E. Implementation Leads

	A. Need B. Capability C. Opportunity D. Motivation	F. Implementation Team Members
Implementation Process	A. Teaming B. Assessing Needs 1. Innovation Deliverers 2. Innovation Recipients D. Planning E. Tailoring Strategies F. Engaging 1. Innovation Deliverers 2. Innovation Recipients G. Doing H. Reflecting & Evaluating 2. Innovation I. Adapting	C. Assessing Context H. Reflecting & Evaluating 1. Implementation
Outcomes Addendum	*Anticipated Implementation Outcomes* 3. Sustainability *Actual Implementation Outcomes* 2. Implementation *Innovation Outcomes* 3. Recipient Impacts	*Anticipated Implementation Outcomes* 1. Adoptability 2. Implementability *Actual Implementation Outcomes* 1. Adoption 3. Sustainment *Innovation Outcomes* 1. Key Decision-Maker Impacts 2. Deliverer Impacts

4.3.4 Code Mapping Results

Excerpt coding results were merged with the CFIR 2.0 coded transcripts and CFIR construct codes were associated with adaptations by cooccurrence with adaptation-related excerpts. Adaptations were associated with nearly every CFIR 2.0 determinant (See Appendix 5).

Our research team used code mapping to understand the relationships between CFIR determinants and adaptations. CFIR determinants that were discussed in adaptation transcript excerpts were mapped to the adaptation as documented in the intervention menus. The relationships between CFIR determinants from each excerpt and the associated adaptations were discussed by two coders to generate brief plain language summaries describing how the contextual determinants described in each excerpt relate to the adaptation made. These summaries were iteratively revised, grouped, and regrouped over several meetings to inductively generate 7 groupings (See Table 4). A senior researcher (ER) offered input on summaries and groupings throughout this process.

Table 4: Final Code Mapping Groupings

Code Mapping Groupings	Description	Example Quotes	Count	Frequent CFIR 2.0 Determinants
Context Driving Adaptations				
Developing an Easier to Execute Process	Adapting screening and treatment procedures to simplify process steps and reduce burden or workload.	"…staff were having a hard time remembering… The idea for them that would work best were to just print the screenings and hand it to the patients. So that seems to be working best for all women's physicals 18 years and older."	31	IT Infrastructure, Compatibility, Innovation Deliverer>Opportunity, Assessing Needs
Meeting Patient Needs/Wants	Adapting screening and treatment procedures to meet patient needs and address patient wants	"I would say not that anybody's really wanted to go to or participate in [Community Continence Classes] … I think some are maybe a little bit apprehensive about a	31	Innovation Recipients + Capability/Opportunity/Motivation, Partnerships & Connections, IT Infrastructure, Access to

		group setting or you know for a private issue."		Knowledge & Information
Navigating Referrals/Insurance Coverage	Adapting screening and treatment procedures to overcome challenges with referrals and insurance coverage for treatment.	"Well, I talked to a pharmacist because they didn't approve that medication. They had to do it preoperatively. Oh, sure. So the insurance didn't go through."	18	Partnerships & Connections, Innovation Recipients + Opportunity, Communications
Addressing EHR Limitations/Capabilities	Adapting screening and treatment procedures based on what is possible and not possible in the clinic's EHR	"…if we had the ability for them to use the [EHR] features or things ahead of time to get stuff completed, that it would reduce the nursing staff's burden in documentation."	18	IT Infrastructure, Planning, Innovation Deliverers + Opportunity
Meeting Clinic Needs/Wants	Adapting screening and treatment procedures to meet clinic or health system preferences and priorities	"We try to use as little paper as we can because there's so many forms and pamphlets and things."	6	Compatibility, IT Infrastructure, Tension for Change, Assessing Needs>Innovation Deliverers, Planning, Reflecting & Evaluating>Innovation
Adaptation Process				
Maintaining the New Intervention	Actions are being taken to preserve previous adaptations in the current context	"…when I see somebody coming for follow-up of urinary incontinence, I'll just say, 'Whoever's going to get it, don't forget to do the UA and give them the video.'"	24	IT Infrastructure, Partnerships & Connections, Compatibility, Innovation Deliverers, Innovation

				Recipients, Opportunity
Still Making the Change	Adaptations are ongoing and/or time to completing adaptations has been impacted by contextual factors	“Now that we're doing this, the urinary incontinence screening isn't in our Medicare template. And so we have to remember to actually put it in… the problem is it'll blow into anybody's, but we can just delete it.”	5	Incentive Systems, Innovation Deliverer + Opportunity, Engaging>Innova tion Deliverers

Coders identified two broader conceptual categories that capture the 7 groupings. The first category, “Context Driving Adaptations,” captures the relationship groupings wherein contextual factors inspired, necessitated, disincentivized, or blocked the specific intervention adaptations that were made. The 6 groupings identified in this category capture the contextual influences behind adaptations. The second category, “Adaptation Process” captured instances where context was supporting or challenging the process of maintaining a previously implemented adaptation or the process of making a planned adaptation.

Context Driving Adaptations

Grouping 1: Developing an Easier to Execute Process

This grouping included adaptations that were made to simplify, streamline, or reduce burden of the process intervention on any actor involved. Many adaptations in these data came out of the initial problem solving of clinic team members who implemented a process and then found ways to improve their workflows. For example, one clinic found that the new screening

questions were getting forgotten by MAs amidst other questions that had to ask patients in preventive visits.

> *"When they come in for physicals, we're doing a lot of other things also because they have physicals. I feel like it's getting lost in our flow…" [3]*

This clinic adapted their process to include laminated survey forms to simplify the screening process for MAs and offer a visual reminder.

> *"We have the laminated sheets in our rooms... we just have a stack in our MA room. And if I see that they're coming in for a physical, I'll just grab it on my way to grab the patient and do it." [3]*

Grouping 2: Meeting Patient Needs/Wants

This grouping captures patient-driven adaptations to the screening and treatment intervention. After initial implementation of the new process, patients provided feedback in many ways that influenced adaptations to clinic processes. For example, one clinician noted that some patients felt uncomfortable responding to screening questions about UI, but they adapted their screening process from relying fully on physicians to also include rooming staff as a way to start the conversation and give patients more opportunities to open up.

> *"Sometimes I feel like they don't really want to answer truthfully. So I'm like, "If you don't want to tell me, do you want to just fill out the form and then I'll come back for it?" Because they'll be like, "No, no. I don't leave." But then they turn red or they have their little signs that something's not you know on point." [1]*

Grouping 3: Navigating Referrals/Insurance

This grouping is related to Meeting Patient Needs/Wants, focusing on the last steps of the UI process where patients are connected with treatment and follow-up care for UI. As clinicians

implemented their interventions and began sending more patients out for UI treatment, several noted new challenges and opportunities related to the provision and payment of specialist UI care. Several clinics noted that UI care for their patients at nearby physical therapists or urogynecologists depended significantly on insurance coverage and the wait times patients face. One clinic, after finding particularly reliable PT and urogynecology options that worked for most patients, adapted their process to stop automatically scheduling follow-up visits to treat patients who screened positive for UI and instead offered them a referral as a first step.

> *"And then if they're positive [for UI], you know it's either a mix, an urge, and we discuss it, then I offer them the physical therapy or the urogynecology… if they're older and they're on medications already because I have patients that I already [started] on oral medications, then I offered physical therapy and gynecology." [12]*

Grouping 4: EHR Limitations/Capabilities

This grouping includes cases where the EHR's functions or structure at a clinic drove adaptations to their interventions. For example, several clinics attempted to use the EHR to distribute materials as a part of the intervention but after testing this process and identifying barriers within the EHR, they adapted their intervention to use paper forms instead. In other cases, clinics initially used paper surveys and patient information only until EHR systems could be updated to include this information, allowing them to adapt their intervention away from using paper. One clinic found a function that allowed them to "mainstream" UI questions that had always been difficult to access in their EHR, allowing them to discard longer paper surveys in favor of an easier process.

> *"I think since the question is already in [EHR system], the one we wanted to use, it's just a couple of clicks and it's mainstreamed and quick and easy to actually do the documentation. So that's going really good." [15]*

Grouping 5: Meeting Clinic Wants/Needs

This final grouping gathered instances when clinic context including clinic team preferences, other clinic projects, and broader health system initiatives influenced adaptations to their UI screening and treatment process. In efforts to drive improvement in statewide quality measures related to the new UI screening and treatment process, the cluster of 5 clinics that jointly participated in the study [clinic numbers 5-9] added a measurement and reporting step to their processes to breed healthy competition between sites.

> *"We have our [state] community measures that we're constantly working on for quality. And so one thing we could do would be we send out monthly emails with how the sites are doing… And so maybe we add that to the monthly email because the nurses do get competitive about that. And so that would be a good solution." [5,6,7,8,9]*

Category 2: Adaptation Process

Grouping 6: Maintaining the New Process

This grouping captured the relationships between context and adapted interventions after the adaptations have been made. Following most adaptations, clinics discussed the ways the new process functioned in their context and did not mention the ways that context motivated the adaptation originally. In some cases, contextual factors such as limited time caused clinic team members to forget the new process or revert to previous versions of their process, negating the adaptations made. For example, one clinic adapted their screening process to rely on a form

attached to clipboards which patients filled out in the lobby, but this new process was not yet routine forefront desk staff.

> *"A lot of my patients haven't been getting those top sheets on their clipboard. So I've noticed that in the last week or so, we've been missing. So we can just make sure that they're getting them. Otherwise, I think it's going okay." [10]*

Grouping 7: Still Making the Change

This grouping includes relationships between CFIR determinants and adaptations that are ongoing as of the last meeting in our dataset. These relations occurred when clinics either rolled out adaptations in stages (e.g., starting with physicals before expanding to all visits) or when the adaptation itself revealed new opportunities or challenges that the clinics are still working on. For example, one clinic made a several changes to their UI screening using the EHR in physicals before providers realized it had added steps to their UI management in Medicare annual wellness visits.

> *"I have it automatically imported in my women age 40 to 65 template or just my under but we haven't really played around with our Medicare note template yet. And so I have found that when I pull in my Medicare template, I have to take the time to create a little paragraph that says like urinary incontinence screening, and then I have to manually bring in the questionnaire." [11]*

4.4 Discussion

In this qualitative study we examined the complex relationships between context and intervention adaptations and developed a useful typology for these relationships. We engaged multiple data sources and analysis approaches to capture adaptations holistically while limiting burden to implementation facilitators, our primary data collectors. The results of this study include a novel adaptation tracking approach, a new way to define adaptations centered in

systems science, and a typology of relationships between context and adaptations of interventions in primary care. This study found that adaptations can be related to context through context driving adaptations and context impacting the process and work of adapting interventions.

4.4.1 Intervention Menus

The field of implementation science has identified a need for clear and transferable documentation of intervention adaptations (Chambers, 2023; Chambers & Norton, 2016; Holtrop et al., 2022; Perez Jolles et al., 2019; E. K. Proctor et al., 2013). While many adaptation frameworks and taxonomies have been established in the literature (Miller et al., 2021; G. Moore et al., 2021; R. D. Roscoe et al., 2019; Stirman et al., 2013; Wiltsey Stirman et al., 2019), these approaches use a thorough and time-intensive approach to documenting all possible adaptations to both interventions and contexts relying on the expertise and training of users. Our team identified a need for a pragmatic and intervention-centered approach to capturing adaptations rapidly and as they occur during implementation projects (Parks et al., 2023).

This study is the first demonstration of menu-based interventions that support tracking of longitudinal changes, adaptations, to the configuration of intervention components. Intervention menus inherently pre-specify the structure and granularity of adaptations, guiding our analyses and distinguishing two types of adaptations: reconfigurations and respecifications. Used in conjunction with intervention menus, these adaptation types were easily identifiable and can be used to track fidelity of interventions continuously, allowing for evaluation of implementations' responsiveness to context. However, our menus built on previous work identifying the

fundamental 5 A's structure of primary care screening and treatment processes (Dosh, 2005). Development of menus for interventions focused on other clinical processes should be preceded by similarly detailed study of the workflows that are being established or targeted for change. Future work should include the development of further intervention menus and evaluation of this configural approach to intervention adaptation tracking.

4.4.2 Relating Adaptations and Context

Using the CFIR 2.0, we deductively analyzed transcript data to identify the contextual determinants of implementations across 15 practices. This analysis captured the context of primary care clinics during implementation and how those clinics were responding to the recently introduced intervention. We engaged clinic team members, clinicians and staff, only and did not analyze patient data. However, clinic team members regularly referenced their interactions and experiences with patients in facilitated conversations. These vicarious patient data are biased through clinic perspectives but did capture some of the patient-side reasons for adaptations clinics made to their interventions. By capturing these data we are contributing to the research knowledge of everyday primary care operations and how primary care clinic contexts respond to change (Chreim, 2010; King et al., 2009; Linzer, 2009; Tomoaia-Cotisel et al., 2013). Future work on primary care context during periods of change should complement these results with direct engagement of patients and other stakeholders.

Our team jointly analyzed intervention menu and coded CFIR data to understand the relationships between adaptations and context, arriving at a set of groupings and categories for these relationships. This framework can be used to document relationships between context and

adaptations to similar interventions and expanded to be applicable across other interventions and contexts. Future work will expand and refine this framework as a tool to organize and understand adaptation-context relationships.

The framework presented in this study characterizes two ways context relates to adaptation: context driving adaptations and context impacting the adaptation process. Existing research frameworks related to adaptation have been optimized to comprehensively capture instances of context driving adaptations (Kirk et al., 2020; Miller et al., 2021; J. E. Moore et al., 2013; Wiltsey Stirman et al., 2019). However, our inductive approach in this study with access to longitudinal adaptation data revealed a novel category of relationships that occur after context has motivated an adaptation. This category, adaptation process, captures the relationships between context and adaptations that occur while adaptations are being made and maintained (See "Implementing Adaptations" in Table 3). These relationships are outside the scope of previous frameworks but are crucial to capture when characterizing the causes and effects of adaptations. Future work to examine causal and longitudinal interactions between adaptations and contextual factors is crucial to developing the logic chain from intervention adaptations to implementation and clinical outcomes.

Limitations

Our team selected the CFIR 2.0 as a framework to help us analyze and describe primary care clinic contexts (Damschroder et al., 2009, 2022a, 2022b). This framework of over 70 determinants and sub-determinants is comprehensive but presented a difficult learning curve and limited the speed of content analysis for all coders. Further, the complexity of a primary care

clinic context can never be fully captured, even with over 70 codes, when viewed through the lens of a single meeting transcript. However, this framework is deeply connected to literature and will support the translatability and generalizability of our findings. Our team encourages the continued refinement of the CFIR and the identification of pragmatic and effective tools for qualitative coding.

As a secondary analysis, this study was limited by the scope of available implementation data. The sample of clinics in this study does not represent all possible contexts and they do not serve all relevant patient populations. Identification of contextual determinants present at each site was limited by the length and content of transcribed meetings. Intervention adaptation identification was limited by the intervention details captured in the brief and intermittent meetings between clinics and facilitators. These limitations directly informed the design of our study and the selection of methods to ensure trustworthiness and rigor in these analyses.

Rigor

Despite limitations in our data, we took steps to ensure the quality of this work, by focusing on credibility, transferability, and dependability in the design of my research procedures (Creswell, 2009; Devers, 1999). Throughout the entire research study and analyses, a detailed audit trail was kept, and additional strategies were used throughout data collection and analysis to ensure trustworthiness (Creswell, 2009; Tobin & Begley, 2004). Facilitators reviewed adaptations and contextual factors with clinic team members multiple times during the study during regularly scheduled meetings (Birt et al., 2016; Devers, 1999). The completion of intervention menus leveraged investigator triangulation with facilitators and notetakers present in

each meetings reviewing their notes in debriefs to agree on menu selections and final facilitation notes (Flick et al., 2004). Finally, regular meetings with an expert in qualitative methods from outside of the study team were used as peer debriefing to review analysis decisions and discuss best practices (Creswell, 2009).

5.0 Practical Facilitation in Primary Care: Measuring Key Variables in an EvidenceNOW Implementation Trial

RQ2 – How does engagement with facilitation influence clinic readiness for change across rural and urban settings?

The following study is presented according to the manuscript guidelines of the IISE Transactions on Healthcare Systems Engineering journal.

5.1 Introduction

With over 440 million office visits annually (Santo & Okeyode, 2018), interventions in primary care can equitably improve the lives and health of nearly every person in the US (Phillips & Bazemore, 2010). The context of each individual primary care clinic impacts the implementation of evidence-based interventions in complex ways (Mollon et al., 2009; Ovretveit et al., 2011). Practice facilitation is one effective approach to customizing and implementing interventions to address the unique needs of clinics (Baskerville et al., 2012; Halladay et al., 2020; Jaén et al., 2010; Knox et al., 2011). Understanding the relationships between clinic contextual factors, interventions, and implementation methods is crucial to achieving desired patient and clinical outcomes.

Contextual determinants of implementation include people, technologies, systems, processes, values, and other factors that act as barriers and facilitators to the successful implementation of the evidence in clinics (Mollon et al., 2009; Ovretveit et al., 2011). While various contextual facilitators and barriers may impact outcomes (Aarons et al., 2011a;

Chambers et al., 2013), addressing the most impactful and readily measurable determinants first is pragmatic for implementors with limited time and resources (Powell et al., 2019). For example, rural and urban contexts generally differ in implementation and patient outcomes (Baumann et al., 2017; Khoong et al., 2014). Understanding fundamental differences across rural and urban clinic contexts would allow for implementors to properly allocate and adapt resources preemptively. Examining the effects of key contextual determinants is crucial to establishing context-driven implementation decision-making and achieving effective improvements in outcomes across diverse clinical settings.

Practice facilitation (PF) is a collection of strategies for implementing evidence-based interventions that has been used extensively in primary care (AHRQ, 2018; Baskerville et al., 2012; Ciolino et al., 2018; Halladay et al., 2020; Jaén et al., 2010; Knox et al., 2011). Implementations using PF have been most effective when facilitators support practices as a coach to change their processes and achieve better patient or clinician outcomes (Knox et al., 2011; Walunas et al., 2021). However, the approaches to implementation with PF vary widely in their dose, quality, and intensity, which result in different and unreconcilable outcomes across studies (Walunas et al., 2021).

Specifying process measures of practice facilitation a priori is crucial to comparing PF across projects and generating generalizable evidence for when and how to use facilitation (Baskerville et al., 2012; E. K. Proctor et al., 2013). For example, the most effective dosages and temporalities of practice facilitation for different implementation sites remains unknown (Baskerville et al., 2012; Gold et al., 2019; Liddy et al., 2015; S. M. McHugh et al., 2022). This

makes implementation efforts that use PF difficult to plan and execute, while obscuring the measurable effects of the strategy on implementation and clinical outcomes.

A key outcome of practice facilitation is improvement in a clinic's capacity for change (DeWalt et al., 2010; Nguyen et al., 2020). While we cannot directly measure capacity for change, we can measure changes in readiness using the validated survey Organizational Readiness for Implementing Change (ORIC), which scores an individual's readiness for a specific proposed change and allows us to aggregate an organization-level score of readiness (Shea et al., 2014). Readiness has been theorized as a combination of motivation, organization capacity, and intervention-specific capacities (Scaccia et al., 2015). However, measures such as ORIC are completed by participants (e.g., clinicians), adding survey burden to already overworked individuals who are committing time to implementation efforts (Bruhl et al., 2020; Grant & Goitein, 2020; Mohr et al., 2013; Temte et al., 2020).

More low-burden pragmatic measures of implementation quality and the relationship between clinicians and implementation efforts are crucial. In studies where practice facilitation is used, facilitators have a boundary-spanning role that gives them unique access to clinic and a valuable perspective on clinic progress with implementation (M. McHugh et al., 2018). Frameworks representing this phenomenon of implementation progress are available for use in implementation projects, but these research-focused tools are limited in their operational utility for iterative improvement efforts (Chamberlain et al., 2011; C. May et al., 2007; McEvoy et al., 2014). Our team developed a measure of clinic engagement with facilitated implementations, the Practice Assessment of Change Engagement (PACE)(Parks et al., 2024). This pragmatic measure

tracks clinics' engagement with implementations over time, explicating variations in capacity for change. Using measures such as PACE to capture longitudinal outcomes of facilitated implementation generates clearer pictures of clinic change over time and may better inform facilitators to drive improvements in implementation outcomes.

The objective of this study was to examine the relationships between measures of context, facilitation, and outcomes. Specifically, we pursued analyses to refine theories in the literature: (1) increased facilitator engagement improves outcomes of implementation (Baskerville et al., 2012), (2) geographical location impacts adaptations to implementations (Baumann et al., 2017), and (3) change capacities vary by location due to population differences (Edwards et al., 2000; Petermann et al., 2023), (4) readiness for change is related to engagement in the change process (C. May et al., 2007; Rogers et al., 2014; Weiner, 2009). By testing these theories with data from a large implementation trial in multiple primary care systems, we can better understand and predict the impacts of implementations in diverse clinic settings. Specifically we will examine the following hypotheses:

Hypothesis Rationale for H_1: Increased clinic interactions with facilitators increases implementation success factors.

H_{1A}: Increased clinic interactions with facilitators increases readiness for change.

H_{1B}: Increased clinic interactions with facilitators increases change engagement.

While the main goals of facilitation and implementation more broadly are to improve clinical and patient outcomes, a secondary goal of facilitation is to improve each clinic's capacity for future changes (DeWalt et al., 2010; Nguyen et al., 2020). Increased interactions with

facilitation can increase intervention adoption and effectiveness (Baskerville et al., 2012; S. N. Smith et al., 2020), however the impacts of increased facilitation on other implementation success factors such as clinic capacity for change are unclear. Implementation success factors are the aspects of an implementation effort that are crucial to achieving desirable implementation outcomes (Braithwaite et al., 2014). Measuring implementation success factors is necessary to understanding the temporary and lasting impacts of implementation strategies (e.g., facilitation) on the local context beyond intervention and implementation outcomes (Braithwaite et al., 2014; E. Proctor et al., 2011). We can evaluate the impacts of increased facilitation by leveraging existing measures for two key success factors: readiness for change and change engagement. In alignment with the goals of facilitation, the guiding hypothesis for these tests is increased interactions with facilitation to increase clinics' implementation success factors. To properly contextualize the results of tests of this hypothesis, we will also examine the relationship between the implementation success factors themselves.

Hypothesis Rationale for H_2: Clinic interaction with facilitation differs across rural and urban settings.

We know that rural and urban primary care clinics face different barriers and facilitators to implementation and have different needs during implementation (Baumann et al., 2017; Cykert et al., 2020; Khoong et al., 2014). However, the common contextual determinants in clinics with similar rurality (e.g., rural clinics tend to have fewer nearby specialty care providers) may inform similar adaptations to interventions and implementations in these contexts (Baumann et al., 2017; Watson et al., 2022). Dose is one aspect of implementation strategies like facilitation

that may be adapted to meet different needs in rural and urban contexts, directly impacting implementation cost and effectiveness (Baskerville et al., 2012; Fagnan et al., 2021; E. Proctor et al., 2011). Building on the literature examining rural-urban differences in implementation needs, we hypothesize that rural and urban clinics differ in amount of time they spend with practice facilitators.

Hypothesis Rationale for H_3: Implementation success factors differ across rural and urban settings.

H_{3A}: Clinic readiness for change differs across rural and urban settings.

H_{3B}: Clinic change engagement differs across rural and urban settings.

Further, the differences in rural and urban contexts may include differences in implementation success factors (Braithwaite et al., 2014; Halladay et al., 2020; Petermann et al., 2023). According to one study, readiness for change in rural settings is marginally higher than in urban settings (Petermann et al., 2023). Another study found that clinics in rural and medically underserved areas tended to engage in more quality improvement activities than their urban counterparts (Halladay et al., 2020). We will test the hypothesis that implementation success factors differ across rural and urban clinical settings. By examining this hypothesis using data from a unique sample of clinics and different measures, we will verify or refute past findings.

5.2 Methods

5.2.1 Study Overview and Design

This study was conducted as part of an ongoing statewide initiative titled "WI-INTUIT: Improving Nonsurgical Treatment for Urinary Incontinence" which is itself a part of a national EvidenceNOW project funded by the Agency for Health Research and Quality (AHRQ) (AHRQ, 2021; Neuner, 2023). This hybrid implementation effectiveness trial enrolled 30 primary care clinics from across the state of Wisconsin to study the implementation and effectiveness of an evidence-based intervention targeting improved screening and treatment for women with Urinary Incontinence (UI).

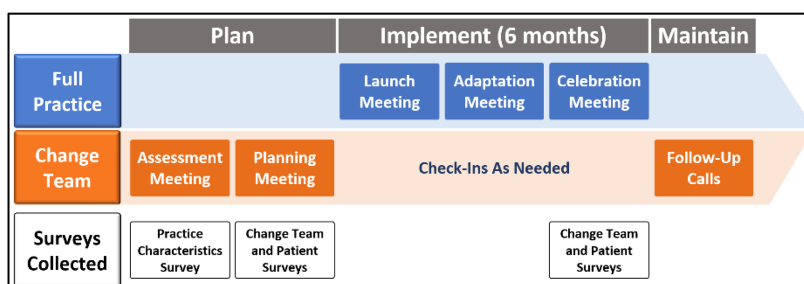
This study has exploratory comparative design, leveraging data from the parent study to compare groups of participating clinics on key implementation variables. Comparative statistical tests were used to test multiple hypotheses across groupings of clinics separated by key implementation variables (e.g., rural vs urban). Testing these hypotheses allowed us to evaluate past research findings in new contexts and identify promising areas for future research.

5.2.2 Data Collection & Measures

These data were collected from individual and clinic-level surveys, implementation facilitator notes, and meeting transcripts. Following enrollment, participating clinics completed a single practice characteristics survey in which they reported their zip code and the clinicians and staff who would serve as their main representatives for the project. These representatives formed the clinic change team and met regularly with implementation facilitators for a 2-to-4-month planning period and a 6-month implementation period. Change team members completed two

surveys that included the validated survey organizational readiness for implementing change (ORIC), which scores an individual's readiness for a specific proposed change (Shea et al., 2014). Change team members were expected to attend 5 meetings with facilitators, but many clinics added additional check-in meetings between these larger meetings. All clinic members, clinicians and staff, were encouraged to attend the final 3 planned meetings during the 6-month implementation phase. A summary of this engagement timeline can be seen below (Figure 5.2.1). For the purposes of this study, all data collected to-date as a part of the ongoing parent study were included in analyses.

Figure 1: Timeline from the WI-INTUIT project



Patient surveys were collected at each participating clinic across two timepoints: prior to beginning implementation of the new UI screening and treatment process and approximately 6-months later just before the clinic competed a final full staff meeting with the facilitator. These five question pre-/post- surveys were given to adult female patients in envelopes with a small incentive following a preventive visit at participating sites. Surveys were anonymous and included validated questions regarding the patient's UI symptoms and any screenings and

treatments offered to them during their visit. The 25 surveys collected at each timepoint were returned to the research team and responses were recorded using survey management software.

Following each meeting, facilitators and notetakers led a debrief conversation without clinic team members to document the length of the meeting, score the clinic's engagement (see section 5.2.3), and capture current intervention details in intervention menus. These intervention menus were used to track adaptations made to interventions over time. For a more detailed reporting of adaptation data collection protocols, see Chapter 4. For the purposes of the present study, we will examine the adaptations identified for a subset of participating clinics.

5.2.3 Practice Assessment of Change Engagement

In pursuit of more pragmatic measures of implementation, our team developed a five-point rubric to rate each clinic on their level of engagement with the implementation. This measure was developed to minimize the survey burden to clinician participants in implementation studies by shifting the work of assessing practices to the facilitators working with them. The practice assessment of change engagement (PACE), builds on normalization process theory and related theories of change to capture the concept of change engagement (Adelson et al., 2021; Albrecht et al., 2020, 2023; Bonawitz et al., 2020; Chamberlain et al., 2011; IHI, 2017; C. May et al., 2007; C. R. May et al., 2018; Solberg et al., 2008). Facilitators rated each clinic using the PACE rubric following each meeting, but due to the recent development of this measure, not all clinic meetings were scored by facilitators. This tool allowed us to create a longitudinal picture of clinic engagement with the implementation effort

with no additional survey requirements for the clinicians working to implement new processes. The complete PACE rubric can be found in Appendix 6.

PACE data are limited to clinic meetings that occurred after the tool was developed, but all clinics (n=30) have received at least one PACE score at the time of writing. To better understand how the concept of change engagement as implementation outcome varies across clinics and implementation projects, PACE scores were included in analyses as a measure of engagement as a proximal outcome of implementation. Additionally, we will test the hypotheses that (1) high readiness prior to implementation correlates with high PACE scores during implementation. Analyses using PACE followed best practices for ordinal variables, using nonparametric tests or average scores as necessary (Sullivan & Artino, 2013).

5.2.4 Data Cleaning

All data were exported from a survey management software and collected into a single spreadsheet. ORIC responses were scored across all change team members for each clinic and each survey timepoint (Shea et al., 2014). Patient survey responses were converted into UI screening rates and rates of patients with UI symptoms being offered treatment. Facilitation intensity was calculated for clinics who completed the 5 required facilitated meetings not including check-ins. Facilitation intensity was calculated as the product of facilitated meeting duration and count for each clinic (Baskerville et al., 2012). Other data for each participating clinic including meeting lengths, PACE scores, and rural urban classifications were arranged in the same spreadsheet. Clinics who had not yet completed 5 facilitated meetings at the time of writing, excluding optional check-ins, were excluded from comparative analyses.

5.2.5 Hypotheses Testing

Using data available from an ongoing trial, we examined the following hypotheses using comparative statistical tests in Stata 18 (StataCorp, 2023). Groups of clinics for our analyses were established based on implementation data and clinic characteristics and compared on the variables: (1) facilitation intensity, (2) readiness for change, and (3) change engagement scores. Comparisons of changes in clinical outcomes, i.e., UI screening and diagnosis rates, will be presented elsewhere as a part of the parent study.

Using t-tests to compare groups on a single variable presume normal distribution of that variable (Boneau, 1960). Prior to testing between group differences, variable distributions were inspected to assess normality with histograms and Shapiro-Wilk tests (Ghasemi & Zahediasl, 2012; Mishra et al., 2019). To address variables identified as not normally distributed, nonparametric comparison tests were used to test corresponding hypotheses.

Analysis Methods for H_1: Increased clinic interactions with facilitators increases implementation success factors.

H_{1A}: Increased clinic interactions with facilitators increases readiness for change.

H_{1B}: Increased clinic interactions with facilitators increases change engagement.

To test these hypotheses, we compared clinics with high and low facilitation intensity, as measured by number and length of facilitated meetings (Baskerville et al., 2012; Liddy et al., 2015). High and low intensity groupings were separated on the median facilitation intensity. An independent t-test was used to determine if there is a significant difference between the change in

ORIC scores for high and low facilitation intensity clinics. A nonparametric Mann-Whitney U test was used to examine differences in PACE scores between high and low facilitation intensity clinics. Specifically, these analyses compared the groups of clinics on pre/post differences in clinic ORIC scores and average clinic PACE scores across pre-implementation phase and implementation phase meetings (see figure 5.2.1).

Analysis Methods for H_2: Clinic interaction with facilitation differs across rural and urban settings.

Primary care clinics are complex systems that involve many interacting elements. Geographical setting is one contextual determinant of a clinic's participation and performance in an implementation project like WI-INTUIT. To test the above hypothesis (H2), clinics in rural and urban settings were compared on their interaction with facilitators. Clinics were sorted into rural and urban groupings based on ZIP code using a toolkit developed at the University of Wisconsin – Madison (Health Innovation Program, 2020). These groupings of clinics were compared using independent t-tests to examine differences in clinic engagement with facilitators between rural and urban clinics.

Analysis Methods for H_3: Implementation success factors differ across rural and urban settings.

H_{3A}: Clinic readiness for change differs across rural and urban settings.

H_{3B}: Clinic change engagement differs across rural and urban settings.

To test these hypotheses, clinics will be sorted into similar rural and urban groupings. These groupings will be compared first on their clinic's readiness for change as measured by ORIC (Shea et al., 2014), then on their change engagement scores, as measured by PACE averaged over the number of scored meetings. Specifically, these analyses will compare groupings on (1) initial average clinic readiness for change, (2) final average clinic readiness for change, (3) change in average readiness for change, and (4) average PACE score, using independent t-tests. Additionally, ORIC scores and PACE scores will be examined for correlation as they measure related phenomena. These tests will determine the differences in readiness for change that are due to contextual factors (geographic location) rather than the result of facilitation.

5.3 Results

5.3.1 Summary of Data

Participating primary care clinics represented rural (n=13) and urban (n=17) areas and employed a median of 15 full-time equivalent (FTE) staff including clinicians and non-clinical support staff. Of these clinics, 4 are affiliated with academic health systems, 4 are federally

qualified health centers (FQHC) or tribal health centers, 7 are independent practices, and 15 are affiliated with non-academic health systems.

5.3.1.1 ORIC Survey Results

Prior to launch meetings, clinic representatives from 29 of 30 participating clinics completed ORIC surveys and on average scored 51/60 indicating extremely high preparedness for change. Of the 17 clinics who have completed the implementation phase of the project to date, 14 saw no change or a decrease in ORIC scores measured post-intervention. Three independent practices saw increases in their ORIC scores over the 6-month implementation period. Urban clinics had lower initial ORIC scores on average (53.4/60) than rural clinics (54.4/60). However, rural clinics saw a larger average decreases in ORIC scores (-3.9) than urban clinics (-2.6) over the implementation period. Finally, across all 29 clinics, independent practices had the highest initial ORIC scores on average (55/60) followed by non-academic health system affiliated (53/60), academic health system affiliated (48/60), and FQHC/Tribal clinics (40/60).

5.3.1.2 Facilitation Intensity Results

Using a measure from a meta-analysis of practice facilitation studies (Baskerville et al., 2012), we calculated facilitation intensity (FI) the product of total time with facilitators and total number of meetings for each clinic. This allowed us to capture quantity of facilitation across planned meetings and intermittent facilitator check-ins scheduled as needed. Clinics who have yet to complete the planned 5 change team and full practice meetings in the planning and implementation phases (See Figure 1) were omitted from analyses involving facilitation intensity.

On average, clinics had a facilitation intensity of 2,236 capturing 125 facilitated meetings and 85.4 hours of facilitation. Clinics with larger employee populations (FTE ≥ 15) had higher facilitation intensity on average (FI = 2,360) than clinics with fewer staff (FTE < 15; FI = 2,169). Further, rural clinics had higher facilitation intensity on average (FI = 2,316) than clinics in urban areas (FI = 2,147). Finally, independent clinics had lower facilitation intensity on average (FI = 2,062) than clinics in non-academic health systems (FI = 2,332).

Table 1: Summary of Data Collected

ID#	Rurality	Clinic Type	Clinic Staff (FTE)	ORIC (Initial)	ORIC (Final)	Facilitation Intensity
1	Urban	independent practice	8	55.0	53.5	1,980
2	Rural	independent practice	10	58.5	59.5	2,079
3	Urban	independent practice	17	50.7	58.0	2,205
4	Rural	FQHC/Tribal health	15	38.0		
5	Rural	FQHC/Tribal health	35	27.0		
6	Urban	non-academic health system affiliated	12	47.5	42.8	3,150
7	Rural	non-academic health system affiliated	8	47.8	44.0	3,015
8	Urban	non-academic health system affiliated	3	59.6	40.0	1,320
9	Urban	independent practice	2	53.5	57.0	1,715
10	Urban	independent practice	4	60.0	60.0	2,030
11	Rural	non-academic health system affiliated	120	45.6	36.7	2,840
12	Rural	non-academic health system affiliated	15	59.5	59.0	2,240
13	Rural	non-academic health system affiliated	16	53.0	48.0	2,100
14	Rural	non-academic health system affiliated	12	52.3	41.5	2,170
15	Rural	non-academic health system affiliated	13	55.0	49.0	3,040
16	Rural	non-academic health system affiliated	14	57.7	57.0	1,575

17	Rural	non-academic health system affiliated	4	60.0	60.0	1,785
18	Urban	academic health system affiliated	51	47.1		
19	Urban	independent practice	1	59.0		
20	Urban	academic health system affiliated	17			
21	Urban	academic health system affiliated	15	58.0		
22	Urban	independent practice	47	49.0	46.0	2,360
23	Urban	FQHC/Tribal health	n/a	51.5		
24	Rural	FQHC/Tribal health	20	44.0		
25	Urban	non-academic health system affiliated	17	51.8	49.3	2,416
26	Urban	non-academic health system affiliated	300	52.3		
27	Rural	non-academic health system affiliated	300	51.3		
28	Urban	non-academic health system affiliated	30	46.3		
29	Urban	non-academic health system affiliated	15	53.5		
30	Urban	academic health system affiliated	43	39.7		

5.3.1.3 PACE Rubric Results

Using the 5-point rubric developed as a part of this study (see Appendix 6), each participating clinic was assigned a score by facilitators following each meeting. PACE is a measure of participation used to compare clinic engagement with the implementation project across meetings. To compare clinic engagement across clinics, scores were averaged across clinic meetings into a summary variable. This summary approach for comparison testing follows recommended approaches for analyzing ordinal data such as Likert scores (Sullivan & Artino, 2013).

As this measure was introduced mid-study and the parent project used rolling enrollment, 92 of the 181 meetings across 30 practices were assigned scores. Of the 125 total meetings with clinics (n=17) who have completed the implementation phase of the project, 53 meetings received PACE scores. The average PACE score amongst these clinics was 4.43, with rural clinics (n=9) scoring slightly higher on average (PACE=4.55) than urban clinics (n=8; PACE=4.22). Further, independent clinics (n=6) saw higher PACE scores on average (PACE=4.54) than non-academic health system affiliated clinics (n=11; PACE=4.32). Among clinics that received PACE scores following more than one meeting (n=15), scores were generally constant or varied between two scores (e.g., PACE = [3,2,2,3,3]) with one unique case. One clinic (ID #8) had consistently decreased PACE scores across meetings with an overall drop of 2 points between their Launch and Celebration meeting. This clinic was also an outlier in other measures described below.

Table 2: Summary of PACE Data

ID #	Rurality	Clinic Type	Clinic Staff (FTE)	PACE (Avg, SD)
1	Urban	independent practice	8	5, 0
2	Rural	independent practice	10	5, 0
3	Urban	independent practice	17	4, N/A
6	Urban	non-academic health system affiliated	12	3.5, 0.71
7	Rural	non-academic health system affiliated	8	3.5, 0.71
8	Urban	non-academic health system affiliated	3	4, 0.82
9	Urban	independent practice	2	5, 0
10	Urban	independent practice	4	4, N/A
11	Rural	non-academic health system affiliated	120	4.75, 0.5

12	Rural	non-academic health system affiliated	15	4.75, 0.5
13	Rural	non-academic health system affiliated	16	4.75, 0.5
14	Rural	non-academic health system affiliated	12	4.75, 0.5
15	Rural	non-academic health system affiliated	13	4.75, 0.5
16	Rural	non-academic health system affiliated	14	3.75, 0.5
17	Rural	non-academic health system affiliated	4	5, 0
22	Urban	independent practice	47	4.25, 0.5
25	Urban	non-academic health system affiliated	17	4, 0.71

5.3.1.4 Outliers

One clinic (ID #8) was an outlier in these data with the lowest Facilitation Intensity (FI=1,320) of the clinics who completed all 5 core facilitated meetings and the largest drop in ORIC scores (-19.6). This small clinic was run by a highly independent clinician with the help of 2 support staff as a part of a non-academic health system. During their participation, this clinic received notice of permanent site closure, and they modified their project timeline to complete implementation activities earlier than previously planned. Clinics numbered 6, 7, 16, and 17 were also notified of permanent closures during their participation but completed implementation activities as scheduled.

5.3.2 Comparative Hypothesis Testing Results

At the time of writing, 17 participating clinics had completed at least 5 facilitated meetings, excluding optional check-ins. These clinics were included in comparative analyses and

other clinics with fewer meetings were excluded to avoid misinterpretations and biases from limited data.

5.3.2.1 High vs Low Facilitation Intensity Comparison Test Results

H_1: Increased clinic interactions with facilitators increases implementation success factors.

H_{1A}: Increased clinic interactions with facilitators increases readiness for change.

H_{1B}: Increased clinic interactions with facilitators increases change engagement.

Facilitation intensity was calculated for each clinic in the sample (n=17) using a combination of total meeting time and number of facilitated meetings (Baskerville et al., 2012). High and low groupings of clinics were separated on the 50th percentile of the calculated facilitation intensities, with 9 clinics sorted to the high facilitation group and 8 clinics in the low facilitation group. These groupings were compared on the variables: pre-/post-implementation change in ORIC score, and Average PACE scores. Using Shapiro-Wilk tests and histograms we tested the normality assumption for each variable. Comparisons of the two groups on these variables were conducted using t-tests for the normally distributed variable: Pre-Post Change in ORIC Scores; and Mann-Whitney U tests for the non-normally distributed variable: Average PACE score.

Table 3: Comparison Test Results: High/Low Facilitation Intensity

Comparison Measure	High Facilitation Intensity Group (mean, sd) n=9	Low Facilitation Intensity Group (mean, sd) n=8	P value
Pre-Post Change in ORIC Scores	-2.68, 5.56	-3.88, 6.88	0.3475

Pre-Post Change in ORIC Scores (outlier removed)	-2.68, 5.56	-1.64, 2.85	0.3306
Average PACE score	4.5, 0.53	4.28, 0.57	0.2134
*p < .05, **p < .10			

Tests comparing high and low facilitation intensity clinics indicate no significant difference in ORIC or PACE scores. Tests including ORIC scores were repeated with and without an outlier clinic (described above). With outliers removed, low facilitation intensity clinics saw a smaller drop in ORIC scores than high facilitation intensity clinics by about 1 point. However, there is relatively high ORIC measure variability within these comparison groups. High facilitation intensity clinics received higher PACE scores than low facilitation intensity clinics on average. Though these groups were not significantly different based on the Mann-Whitney U test, 6 high facilitation intensity clinics averaged over 4.5/5 in PACE scores compared to 3 low facilitation intensity clinics.

These comparative tests do not support our initial hypotheses that clinics who spent more time with facilitators would have higher changes in ORIC score and average PACE scores. Instead, these data show no statistical differences in the ORIC or PACE measures between high and low facilitation clinics. These tests fail to reject the null hypotheses of no between group differences.

5.3.2.2 Rural vs Urban Comparison Test Results

H_2: Clinic interaction with facilitation differs across rural and urban settings.

H_3: Implementation success factors differ across rural and urban settings.

H_{3A}: Clinic readiness for change differs across rural and urban settings.

H_{3B}: Clinic change engagement differs across rural and urban settings.

To test the above hypotheses, clinics in rural and urban settings were compared on their time with facilitators (Facilitation Intensity), their change in preparedness over the life of the project (Change in ORIC scores), and their change engagement during implementation (PACE scores). Clinics were sorted into rural and urban groupings based on ZIP code using a toolkit developed at the University of Wisconsin – Madison (Health Innovation Program, 2020). Using Shapiro-Wilk tests and histograms we tested the normality assumption for each variable. Comparisons of the two groups on these variables were conducted using t-tests for the normally distributed variable: Pre-Post Change in ORIC Scores; and Mann-Whitney U tests for the non-normally distributed variables: Facilitation Intensity, Average PACE score and Average PACE score (Implementation Phase).

Table 4: Comparison Test Results: Rural and Urban

Comparison Measure	Rural (mean, sd) n=9	Urban (mean, sd) n=8	P value
Facilitation Intensity	1,198.3, 114.9	1,207.5, 150.78	0.6730
Pre-Post Change in ORIC Scores	-3.86, 4.18	-2.55, 7.90	0.3357
Pre-Post Change in ORIC Scores (outlier removed)	-3.86, 4.18	-0.12, 4.19 (n=7)	**0.0492****

Average PACE score	4.55, 0.54	4.21, 0.53	0.3637
**p < .05, *p < .10			

Measured with a combination variable, facilitation intensity, clinics were compared across rural and urban groupings. Rural and urban clinics did not differ significantly in their time or frequency of facilitated meetings. Accordingly, this comparison test found no evidence of differences between rural and urban groups, and we cannot reject the corresponding null hypothesis.

Rural clinics saw a larger decrease in pre-/post-ORIC scores over urban clinics. However, in initial tests the urban grouping had high variability with one outlier clinic. After removing this outlier, a t-test showed a significant difference between rural and urban clinics with rural clinics seeing a 3-point drop in ORIC scores over urban clinics. After removing this outlier, using a t-test we can reject the null hypothesis and find a statistical difference between rural and urban clinics on this measure.

Rural clinics received higher PACE scores than urban clinics on average. Though these groups were not significantly different based on the Mann-Whitney U test, 7 rural clinics averaged over 4.5/5 in PACE scores compared to 2 urban clinics. Despite these notable differences between rural and urban clinic PACE scores, we cannot reject the null hypothesis based on these data. Note: due to necessary exclusion criteria, no clinics included in these analyses received a PACE score below 3/5 at any point in the study.

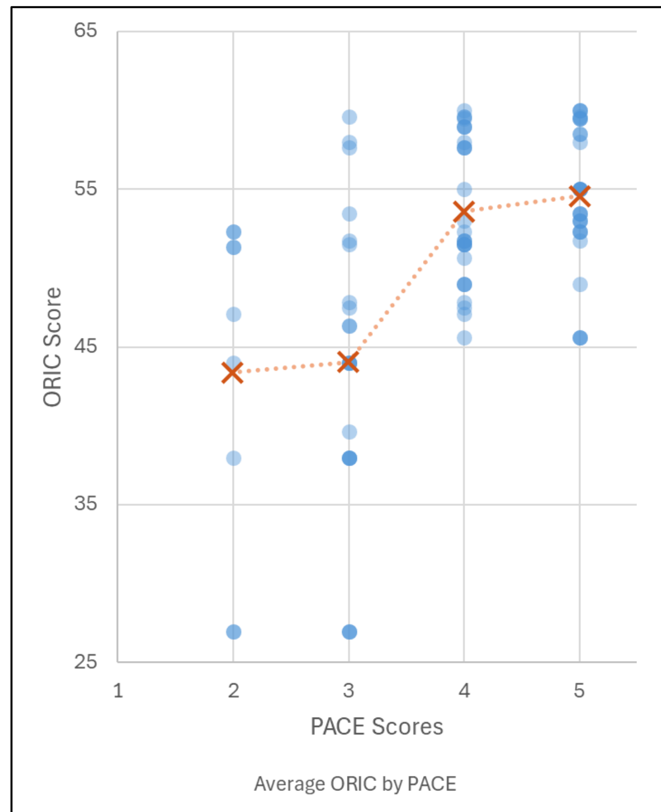
5.3.2.3 PACE Rubric and ORIC Survey Analysis Results

To better understand the relationship between the concepts of preparedness for change and engagement with change, we analyzed ORIC and PACE scores jointly using correlation and regression analyses. We hypothesized higher ORIC scores, indicating more preparedness for change, would correlate with higher change engagement and higher PACE scores over the course of the implementation project.

PACE scores were, on average, positively correlated with initial ORIC scores. We used data from all clinics that have completed initial ORIC surveys and received one or more PACE scores across their implementation efforts to date (n=29). Using Kendall's Tau-sub-b to capture ordinal-continuous variable associations, we identified a significant positive correlation ($\tau_b = 0.43; P\ value = \mathbf{0.0000**}$) between initial ORIC scores and PACE scores for the duration of the project (Khamis, 2008). This correlation was visualized in a scatter plot (see figure 1) where blue markers plot the pre-implementation ORIC score and the PACE scores for each clinic (obs.=89; n=29). Additionally, the average ORIC scores within each PACE score level are plotted and connected in orange, visualizing the positive relationship.

Further, the PACE scores (obs.=89, range: [2,5]) assigned following meetings with clinics that completed initial ORIC surveys (n=29) were analyzed using an ordered logistic regression to investigate the relationships between initial ORIC scores and each PACE score later assigned to clinics. These data met assumptions of this analysis with an ordinal response variable (PACE) and a continuous regressor (initial ORIC scores).

Figure 1: PACE-ORIC Scatterplot



Ordered regression found a significant positive relationship between initial ORIC scores, with a 1-point increase in initial ORIC score (1/60) corresponding to a 0.14-point increase (95% CI) = 0.14(0.08, 0.19)) in PACE score (see Appendix 7). However, using the Brant test we found this model violates the assumptions of the parallel-line model (Brant, 1990; R. Williams, 2016). Further analyses are required to generate a general model mapping the relationship between PACE and ORIC. A full summary of equations associated with the initial model can be found in Appendix 7. However, given the similar results of the ordered regression, correlation, and visualization of these data (see figure 1), we can presume a positive relationship between ORIC and PACE that warrants further analysis.

5.4 Discussion

Principal Findings

These analyses of implementation data from primary care clinics in a statewide trial demonstrate the complexity of implementation data and the limitations of bilateral analyses. Increased facilitation intensity (i.e., dose) did not correspond with significant differences in implementation outcomes of preparedness and engagement across clinic settings. Clinic rurality, as one element of clinic context, had a relationship with changes in preparedness over the study period. Rural clinics had larger decreases in preparedness over the study period than urban clinics. However, additional notable clinics and clinic groupings were identified through these analyses for further study despite limited statistical test power. Finally, these analyses included a new measure of change engagement, which was significantly correlated with existing validated measured while offering distinct practical and theoretical implications for the field of implementation science.

Strengths and Limitations of the Study

This study addresses the research question: how does engagement with facilitation influence clinic readiness for change across rural and urban settings? We explored this multifaceted question by analyzing measures associated with each concept therein: engagement, facilitation, readiness for change, and rurality. As a secondary analysis, our data were limited to a small number (n=30) of primary care clinics participating in an ongoing statewide implementation trial. These data were further limited by each clinic's progress, with only a subset (n=17) completing necessary data collection for most analyses. Conducting multiple

comparative analyses on a single limited dataset can increase risks of type 1 error (Armstrong, 2014). Statistical corrections for multiple tests would not alter these analyses substantively as we compared different groupings for each hypothesis and present these results as exploratory given sample size restrictions.

The variables selected for analyses in this study represent broader conceptual foundations that themselves have complex theoretical relationships (Kilbourne et al., 2023; Lewis et al., 2020; Lewis, Klasnja, et al., 2018; Ramly & Brown, 2023). Accordingly, these analyses covered targeted concepts and connections that only represent a small fraction of the underlying mechanisms that guide change in healthcare systems. Further studies of change mechanisms and practical implications of research results are crucial to continue unraveling the knot of theory surrounding implementation research.

As demonstrated by these analyses, outliers can have significant impacts on analyses involving implementation data. Specifically, we summarized ORIC data at the clinic level, despite cautions of the authors of the instrument (Shea et al., 2014), and identified a single clinic as an outlier in their preparedness for change due to external events impacting their implementation effort. Managing outliers in datasets is a point of contention in the literature (Osborne & Overbay, 2004) as inclusion can increase error rates and omission can bias results and remove potentially relevant data from analyses. We chose to present data with and without outliers to address this limitation and faithfully represent the data collected. Further case studies of implementation outliers like those identified in this study are crucial to understanding context and implementation outcomes in extreme scenarios.

Implications and Future Directions

We found differences in the impact of implementation on clinic preparedness across rural and urban groupings. While both groups saw a drop in preparedness, as measured by ORIC, rural clinics saw a larger decrease in scores across the 6-month implementation period. This overall decrease in readiness aligns with the literature, but the causes for such decreases are still speculative. Helfrich and colleagues suggesting fatigue and regression to the mean as possible explanations for this phenomenon (Helfrich et al., 2018) and our team hypothesizes that decreasing motivation and the realization of change difficulty are additional possible causes behind the decrease in readiness. Recent implementation studies have also identified differences in perceptions of readiness, and a need for alternative measures to capture the distinct conceptualizations of readiness in rural and urban settings (Petermann et al., 2023; Tabaei et al., 2024). Further research is needed to understand the changes in readiness over time and across rural and urban implementation contexts.

We did not find significant differences in outcomes between clinics with comparatively more or less time with facilitators. This adds to mixed evidence regarding the relationship between dose of facilitation and implementation outcomes (Baskerville et al., 2012; Liddy et al., 2015; Shelley et al., 2020). Trial findings conflict on the outcome effects of increased facilitation intensity (Liddy et al., 2015; Persell et al., 2020; Shelley et al., 2020), but a meta-analysis found an overall positive effect with increased facilitation correlated with increased outcome effects (Baskerville et al., 2012). However, comparing facilitation efforts across studies on time measures alone fails to capture the nuance of unique facilitation styles, strategies, and contextual

factors that impact outcomes (Nguyen et al., 2020; Stetler et al., 2006; Walunas et al., 2021). The inconclusive results in this study emphasize the limitations of quantity-focused evaluations of facilitation and the need for new measures to enable cross-application comparison of facilitation quality.

PACE allows users to measure change engagement over time, offering crucial insight into the quality of facilitation and the relationship between busy clinicians and the change effort. This study establishes the convergent and conceptual validity of PACE as a pragmatic measure of change engagement (Messick, 1984). Organizational Readiness for Implementing Change (ORIC), a validated measure of preparedness for implementation, has a statistically significant relationship with change engagement as measured using our rubric: Practice Assessment of Change Engagement (PACE). The positive relationship between these variables echoes our hypotheses and the theoretical foundations of the PACE rubric, contributing to the conceptual validity of the new measure (Adelson et al., 2021; Albrecht et al., 2020, 2023; Bonawitz et al., 2020; IHI, 2017; Solberg et al., 2008; Sonenshein & Dholakia, 2012).

This study highlights important and measurable variable for further analysis of the readiness-engagement-outcomes pathway in implementation research and the mediating and moderating roles of facilitation on that pathway (Lewis, Klasnja, et al., 2018). With high readiness scores predicting high engagement scores, we can also further establish ORIC as a useful decision tool for facilitation resource allocation and we encourage future adaptive implementation trials to leverage this measure (Shea et al., 2014). Further research is necessary to understand the relationships between engagement and outcomes, but several studies have

begun to unpack the complex motivations beyond readiness that cause engagement variability across contexts (Sonenshein & Dholakia, 2012). Future studies with higher statistical power are required to establish clear causal pathways, building on the analyses presented in this study.

This work establishes the need for attention to measures of engagement in future studies examining the causal chains connecting readiness and facilitation to implementation and clinical outcomes. Further, the development of PACE as a facilitator-facing measure of implementation engagement offers distinct benefits over existing measures building on similar theories (e.g., NoMAD), namely less survey burden to clinicians (Batterham et al., 2024; Finch et al., 2013). Future work will evaluate the time-cost and inter-rater variability of facilitators using the PACE measure across contexts and implementation efforts.

Conclusion

We tested the causal pathways that underpin crucial mechanisms in primary care implementation projects, identifying significant and promising relationships between clinic context, preparedness, facilitation, and engagement. We demonstrated the utility of a novel measure of change engagement and the conceptual and quantitative relationships between engagement and preparedness for change. By analyzing the causal relationships that drive implementation and clinical outcomes, we expand a crucial area of the literature: building evidence-based and operationalized guidance for implementation decision-making.

6.0 DISCUSSION

This chapter includes a summary of results from the research conducted in this dissertation. Discussions and results of each study are presented independently in preceding chapters. This chapter also describes the contributions to the literature from this work and directions for future work.

6.1 General Discussion and Results Overview

The purpose of this dissertation was to identify the relationships between primary care clinic context, intervention adaptations, and facilitated implementations and characterize the implications of those relationships for future evidence-based implementation efforts. To address this goal, I planned and executed parallel studies investigating those relationships using data from a statewide implementation trial supporting clinics as they adopted new screening and treatment processes for urinary incontinence in adult women (Neuner, 2023). Specifically, these studies sought answers to the research questions: (1) What are the relationships between context and intervention adaptations in facilitated implementations in primary care, and (2) How does engagement with facilitation influence clinic readiness for change across rural and urban settings. The aims of these studies were (1) to identify and describe the relationships between primary care clinic contexts and adaptations made over time to their screening and treatment processes, and (2) to inform implementation decisions by exploring the measurable relationships between context and facilitated implementation efforts.

Summary of Research Question 1 Results

To achieve the first aim, identifying and describing the relationships between primary care clinic contexts and intervention adaptations, I proposed novel definitions of intervention adaptations and a new method to capture these complex implementation datapoints. This approach, described in Chapter 4, used the innovative intervention menus developed by our team (Parks et al., 2023), to identify the configural changes to interventions clinics made over time to better fit their contexts (Holden et al., 2013; Rutkowski et al., 2023). We used a deductive content analysis, guided by the consolidated framework form implementation research, to analyze facilitated clinic meeting transcripts and identify the contextual barriers and facilitators informing adaptations (Damschroder et al., 2009, 2022b).

We integrated the results of the analyses using code mapping to capture the relationships between adaptations and primary care clinic contexts (Saldaña, 2013). These relationships were operationalized in a set of 7 groupings describing contextual reasons for change and the impacts of context on the intervention adaptation process. These groupings serve as a preliminary framework for the ways contextual factors influence adaptation in implementations in primary care. With additional research to validate these groupings and to identify additional context-adaptation relationships in other implementation efforts across diverse settings.

Summary of Research Question 2 Results

To achieve the second aim, informing implementation decisions by exploring the measurable relationships between context and facilitated implementation efforts, we analyzed measures of rurality, facilitation intensity, clinic preparedness for implementing change, and

clinic engagement. Specifically, we used comparative and correlation analyses to quantitatively relate these measures and to identify actionable relationships that may inform future implementation efforts in primary care clinics. We found a significant difference in the impact of implementation on clinic preparedness across rural and urban groupings, with rural clinics seeing a larger decrease in preparedness over the study period. Further, we found limited differences across clinics that received different intensities of facilitation. Finally, we evaluated a novel pragmatic measure of change engagement in relation to an existing measure of preparedness for change and found a statistically significant correlation, validating a theorized conceptual relationship and suggesting utility of our new measure (Albrecht et al., 2020, 2023; Batterham et al., 2024; C. May et al., 2007; Schroeder et al., 2022). The results from these analyses produced significant and promising relationships between clinic context, preparedness, facilitation, and engagement that will guide future research and inform allocation of implementation resources.

6.2 Theoretical Contributions

The theoretical contributions of each study have been reported in previous chapters, this section summarizes the combined contributions to the literature from this dissertation.

The studies presented in this dissertation tested and advanced existing theories of change in health systems related to facilitation. Practice facilitation is a multifaceted strategy wherein designated facilitators support and manage implementations and improvement efforts in clinical settings (Kilbourne et al., 2023; Knox et al., 2011; Stetler et al., 2006). Facilitation is closely related to intervention adaptation in the literature with the program manual for practice coaching defining the goal of facilitators as "… help physicians and quality improvement teams develop

the skills they need to adapt clinical evidence [intervention] to the specific circumstance of their practice environment [context]" (DeWalt et al., 2010). The studies presented in this dissertation investigated this goal of facilitation and the results produced by this work are direct reflections of facilitator and clinician efforts in implementation efforts.

In this dissertation I developed a framework codifying the relationships between context and adaptations, identifying the ways context motivates adaptation and then how context continues to impact the process of making and maintaining adaptations. Previous literature defines and operationalizes adaptations passively as adjustments made to make interventions "fit" context (Baumann et al., 2017; G. Moore et al., 2021; J. E. Moore et al., 2013; Wiltsey Stirman et al., 2019). The framework developed in this work reframes adaptation as an active process, motivated by contextual determinants and impacted continuously even when the adapted interventions have become routine.

The studies presented in this dissertation examined facilitation, adaptation, and context and the results presented support the framing of these concepts and their interrelationships as complex and fluid. For example, a previous nationwide EvidenceNOW study identified certain facilitation strategies selected by facilitators (e.g., coaching) which resulted in better implementation outcomes (Walunas et al., 2021). However, this dissertation lays a groundwork for expanding this and related theories by providing the documentation tools (i.e., intervention menus) and the practical measures (i.e., PACE) to capture changes in the context-intervention and context-implementation relationships over time. The results presented in this dissertation highlight the variability of clinic context, interventions, change engagement, and readiness for

change over the study period. We know implementation strategies are more effective when they are tailored to context (Baker et al., 2015; Bosch et al., 2007; Fernandez et al., 2019; Powell et al., 2019). Therefore, we can say that the strategies used by facilitators ought to change, or be re-tailored, over the course of implementation as clinic contexts change. This contribution reframes the findings from the study mention above; context motivated the strategies selected by facilitators, and the outcome variability, which was associated with strategies likely also reflected contextual factors and the alignment of each facilitator's strategy selection (Walunas et al., 2021). This fundamental theoretical shift re-emphasizes the effects of context on the outcomes of facilitation and implementation and supports further research into the theoretical mechanisms that connect context, strategies, and outcomes (Kirk et al., 2020; C. R. May et al., 2016; J. D. Smith et al., 2020).

6.3 Limitations

The analyses and findings presented in this dissertation are subject to several limitations. First, the data analyzed in this dissertation are limited in quantity and scope. Analyses for the first aim used data from 15 clinics and 10 meeting transcripts while the second aim used data from four targeted measures spanning 16 to 30 clinics. These data were collected from an ongoing trial and further analyses of data following completion of the parent study may yield additional and conflicting results. Second, the novel data collection tool and engagement measure proposed and applied in these studies have yet to be systematically validated or applied in other studies. While we encourage the use of these tools, further psychometric evaluation and the development of usage guidelines are necessary. Finally, despite the extensive clinical

expertise leading the parent study, the analyses in this dissertation were led by experts in implementation science and human factors and the analysis teams had limited clinical experience. Clinical expertise is crucial on translational research teams generating conclusions that will impact clinical implementation and improvement work (Keramaris et al., 2008; J. Williams et al., 2020).

6.4 Future Work

This dissertation presents several directions for future work. First, as mentioned above, the next steps to equip implementors with the intervention menus and measures to track change engagement is validation studies and tests of these pragmatic tools in diverse project and clinical settings. Integrative proposals for future work are presented below, with future work building on each independent study presented in chapters 4 and 5 respectively.

The findings presented in these studies should motivate further explorations of the fundamental relationships that underpin implementations in clinical settings. One promising direction builds on the use of machine learning cluster analysis in previous studies to describe implementation-related concepts and to construct frameworks (Aarons et al., 2016; Cane et al., 2012; Powell, Stanick, et al., 2017). With the challenges of relating and processing complex implementation data, the use of machine learning approaches for implementation evaluation is a valuable next frontier for implementation research, using algorithms that distil the vast quantities of data available to implementors beyond surveys and time-intensive concept mapping (Powell, Beidas, et al., 2017).

The findings of limited between site differences related to facilitation intensity (see chapter 5) highlight the limitation, but not the lack of importance of this quantity-centered measure of facilitation (Baskerville et al., 2012). Several previous studies have found various amounts of facilitation to be effective, or no relationship between facilitation time and implementation outcomes (Liddy et al., 2015; Persell et al., 2020; Shelley et al., 2020). Based on the results of both studies presented in this dissertation, time is a crucial variable for comparing facilitation across implementation projects and developing best practices. Future work should examine how implementation strategies, interventions, and local contexts interact over time, rather than examining these relationships at instances or singular data collection points. These longitudinal analyses will generate practical guidance around when in the span of short-term or iterative improvement efforts are different approaches needed to achieve desired outcomes.

6.5 Conclusion

Research findings take 17 years on average to reach regular clinical practice (Balas & Boren, 2000; Morris et al., 2011). Implementation of evidence-based interventions in clinical settings is critical final step in that journey and the subject of implementation research (Curran, 2020; Glasgow et al., 2013; Holtrop et al., 2018). There is no singular best approach to implementation in clinical contexts (Oxman et al., 1995; Powell, Beidas, et al., 2017; Wensing et al., 2010), but using practice facilitators to guide efforts and making context-specific adaptations to interventions have proven effective (Baker et al., 2015; Baskerville et al., 2012). This dissertation examined data from facilitated implementations in primary care clinics. We characterized the ways clinic contexts impacted changes to evidence-based interventions,

developing a framework of the context-adaptation relationships that shape clinical evidence as it reaches everyday clinical practice. We also identified differences in the responses of rural and urban clinics to implementations. Lastly, we developed and tested practical methods for collecting data during facilitated implementations to capture changes over time and inform real-time decision making. The results of this dissertation are foundational for the development of future facilitated implementations and have broad implications for implementation research and practice. By developing more practical approaches to implementation, we can streamline the translation of research into practice while minimizing burden to clinicians and refine theories of change in health systems. Ultimately delivering research evidence and improvements that drive patient, clinician, health system, and societal outcomes.

5.0 Appendices

Appendix 1: Meeting Facilitator Guides

The interview guides in this appendix are used by the facilitator to lead semi-structured group interviews with each clinic's change team. Assessment meetings are the first formal facilitated meeting and Adaptation meetings occur 3 months after implementation kickoff (i.e., Launch).

WI-INTUIT Practice Assessment Meeting Guide

Change Team:

- Confirm change team members for practice are on the call.
- Recommend additional change team members if needed.
- Review any actions needed from clinic – surveys, change team information, etc.

Assessment Questions: (To follow Clinician Introduction to Project)

Semi-structured: try to address all, ask follow-ups as needed, and let conversation dictate order.

- How well does your practice screen for UI? (1 not at all – 10 expertly)
- How well does your practice address positive UI screens? (1 not at all – 10 expertly)
- How does your practice screen for UI?
- What happens when a patient screens positive for UI?
    - **Follow-up:** Is this the same for all providers in the practice?
- What education / resources do you provide?
    - **Follow-up:** Are there any cultural or other considerations for your patient population that may impact the way you screen and manage UI?
- What care is delivered for UI in your practice?
    - **Follow-up:** Do you prescribe medications (e.g., anticholinergics, vaginal estrogen), fit with pessaries, teach behavior modification, and/or provide physical therapy in your practice?
- What referrals do you currently make for UI?
    - **Follow-up:** Where do you send referrals? (Physical therapy, Urology, Ob/Gyn, Community based classes, Other?)
- When and how do patients follow up after screening positive for UI?
- What does your practice screen for and treat expertly (10) (e.g., depression, tobacco-use)?
    - **Follow-up:** What does that practice look like?
- How else are you connecting with your community to support care?

See next page for Wrap-up and Next Steps.

Wrap up: Facilitator provides a brief summary of what we heard.

This summary might include:

- How the practice screens for and manages UI
- Which connections & resources are used to manage UI
- Which screening & treatment processes work well in the practice

Next Steps:

- Based on what we learned today we will come back for **one more planning meeting** with several options for your practice's UI screening and treatment implementation.
- You will get to choose what you want to implement and then we will coordinate a **full practice Launch meeting.**
- Please share your excitement with this project around your practice!
- And one last thing, we'll be sending your practice a package with patient surveys and a drop box. Who is the best person to address this to?

WI-INTUIT Practice Adaptation Meeting Guide

Pre-Brief:

- Open implementation log and intervention menu from practice folder on box
- Open Adaptation meeting ppt and video
- Note any remaining tasks for clinic to complete
- Confirm meeting is being recorded

Introduction:

- Re-introduce facilitator and note-taker, ask for introductions of all attendees
- Share screen (in zoom select share Screen #, do not share specific program window, select share sound and "stereo" from the dropdown menu)

Meeting Content: Discussion

Note: This document is intended to guide conversation, but diverging to support the practice or probe on answers is encouraged. Questions may be skipped, reworded, or added if appropriate.

- Thinking about your current screening and treatment process for UI, what is working well and what isn't working so well?
    - If focused on positives, probe on negative, and vice versa.
    - How can we help you overcome barriers / challenges?
- What modifications have you made since our last meeting (processes, change team, etc.)?
    - Who made these decisions to modify and how were the decisions made?
    - When were modifications made?
    - Were they planned in advance?
- Probe specific implementation components (Who/What/Why/When) if appropriate.
    - Have you had any other meetings since we last met regarding this project? (e.g., brief calls with facilitator, practice team meetings, support from implementation team, meetings with Dr. Neuner and Dr. Brown, local champions)
    - Ask about usage of online learning community, community connections, communications with Dr. Neuner and Dr. Brown
- Since our last meeting, how many hours have your change team members spent on this project, outside of time communicating with us?
    - Developing materials, completing new tasks
- What do you anticipate will be easy to maintain moving forward? What will be challenging to maintain? (Prompt participants to think about inner & outer setting, individuals involved, components of UI-Assist, components of implementation, process, reach, impact on patients, staff, providers)
- Is there anything about the project or resources that you would change?
- How are you connecting with community resources? (If PB offer additional support)
- If some patients are harder to reach with this change, how can we reach them?

Next Steps (Save 5-7 minutes at end of meeting, even if conversation cut short):

- Plan logistics for post-adaptation check-in meeting (2-4 weeks after launch) and celebration meeting if possible
- Confirm any task owners (e.g., "[name] will print out surveys and give them to [name], is that correct?")

Debrief (facilitation team discussion after clinic team logs off):

- Complete implementation log (first 2 tabs)
- Complete menu with intervention components discussed today (if no details discussed, okay to leave blank)
- Collect requests and to-do items for post-meeting email to practice
- Check that all files are saved to practice folder on box, plan to upload recording as soon as possible

Appendix 2: UI-Assist Intervention Menu Template

This intervention menu can be used as a template for capturing clinic-level intervention component selections at multiple timepoints throughout an implementation project. Additional columns may be added as needed to capture longitudinal intervention adaptations as shown in the example below. A change in component selections (i.e., responses to questions in the left column) indicate an intervention adaptation. Our team defined a reconfiguration as a change in the responses selected between timepoints and a respecification as similar responses with differences in facilitator notes between timepoints. Examples of each are highlighted below with reconfigurations in blue, and respecifications in pink.

Ask	[Practice Name] Planning Meeting [XXXX.XX.XX]	[Practice Name] Launch Meeting [XXXX.XX.XX]	[Practice Name] Post-Launch Check-In Meeting [XXXX.XX.XX]	[Practice Name] Adaptation meeting [XXXX.XX.XX]
When is survey delivered?				
Before				
During	X, during rooming	X, during rooming	X	X
After				
Where is survey delivered?				
Lobby				
Exam Room	X	X	X	X
Online				
Who gives the survey to patient?				
MA	X	X	X	X
RN				
Physician			X, sharing duty in case someone forgets	X, Physicians remind MA to ask if forgotten
EHR/digital notification				
Other (Specify)				
How is survey given to patient?				

On Paper			X	X
Digitally on personal device				
Digitally on clinic's device				
Verbally	X	X	X, sometimes asking verbally and filling out form	X, sounds like MAs are asking verbally
Who documents survey results?				
MA	X, in EMR	X, in EMR	X, MA fills out results in EMR and uses barcode to scan form into EMR	X, presumed
RN				
Physician				
EHR (automatic)				
Which patients receive screening?				
All adult women				
Specific range/subpop. (specify)	X, adult women over age 30	X, adult women over age 30	X, Patients over 30	X, adult women over age 30
Which visits are patients screened at?				
Physical			X	X
AWVs			X	X, presumed
All preventative visits				
Other (Specify)				
Which Screening tool?				
3-IQ (English or Spanish)				
3-IQ Question 1 only (English or Spanish)				
HEDIS				
Other (Specify)			X, ICIQ in Spanish and English	X, ICIQ in Spanish and English
Advise				
Project Resources recommending/using:				
Algorithm				
Recommended Links/Videos	X	X	X, using videos and showing on screen in exam room, 10-minuite video is a bit long	X, videos with QR codes
Dot phrases				

List of local specialists	X, only Urology	X, only Urology	X, used the list but had issues getting prompt Urogyn appointments	X, found a Urologist with open appts (Dr. Cici), got in house PT (Dr. Ramirez)
List of community resources				
Other			X, patient handouts	X, 2 patient handouts with one for exercises
How do patients receive resources?				
Paper	X	X	X, using 3-page patient handout with pictures of bladder and pessary images (stress UI handout)	X, handouts
Digital	X	X		X, videos on patient phone
Verbally	X	X		X, NP giving brief education and referrals
Who delivers resources to patients?				
MA				X, MAs giving paper handouts and QR code to watch videos while waiting
RN				
Physician	X, Doctor and NP	X, Doctor and NP	X, Doctor and NP	X, mainly NP (taking most female physicals) but Doctor is familiar as well
EHR (automatic)				
Assess, Assist, Arrange				
When are treatments/referrals provided?				
Current Visit	X, videos and medication	X, videos and medication	X	X, videos, handouts, and ideally a same day referral to PT or referral to Urologist for patients who have a previous diagnosis/treatment
Follow-up Visit	X, medication and referral	X, medication and referral	X, 4-week follow-ups have worked for some patients, need to work on making follow-up standard	X, 4-week follow up for some patients who go to Pt
Which UI management options are offered? (Can use X or specify current/follow-up)				

Exercises	X	X	X, Kegels and exercises in current visit	X, send to PT, give exercise handout
Medications	X	X		X, prescribing but infrequent so far (have in house pharmacy)
Pessaries				
Referral to Specialist	X	X	X, Referring out to PT (now in-house) or Urogyn sometimes	X, refer to PT in house (same day ideally), urologist for surgery
Referral to Community Resource				
Notes			Working with EMR representative to add UI questionnaire to EMR Offering physical therapy in the clinic starting next week! Found a local bilingual therapist Sometimes forgetting questionnaire Practice folks will be calling local specialists to check in on wait lists Make sure they have handouts for stress and urge/mixed UI	Nothing outstanding, practice is pretty much in sustainment / maintenance

Appendix 3: Adaptations Coding Summary Table

This table lists all adaptations identified from intervention menus from 14 clinics. See Appendix 2 for an example intervention menu. Our team defined a reconfiguration as a change in the responses selected between timepoints and a respecification as similar responses with differences in facilitator notes between timepoints. Adaptations were converted to standard language capturing the intervention component impacted, the previous state of the intervention, and the new state of the intervention. Adaptations were given alpha-numeric identifiers to assist in coding and notes on each adaptation from excerpt coding consensus coding can be found in column 3.

Table: Adaptations Summary and Excerpt Analysis Notes

[Clinic ID #]. [Adaptation type]. [Adaptation ID # within clinic]	**Standard Language Adaptations**	**Excerpt Coding Notes**
1.RC.1	*Changed "Who delivers survey to patient"* ***from*** *MA* ***to*** *MA and Physician if MA forgets.*	Coders agreed on excerpt for this adaptation prior to consensus discussion
1.RC.2	*Changed "Patient resources in use"* ***from*** *"no handouts"* ***to*** *"2 unique handouts"*	Coders agreed on excerpt for this adaptation prior to consensus discussion
1.RC.3	*Changed "Who delivers resources to patients who screen positive"* ***from*** *Physicians* ***to*** *MAs providing handouts and Physicians discussing the information and arranging treatment*	Coders agreed on excerpt for this adaptation prior to consensus discussion

1.RS.1	*Changed details for "When are treatments/referrals provided?"* ***from*** *videos and medication same day* ***to add*** *same day referrals.*	Coders agreed on excerpt for this adaptation prior to consensus discussion
1.RS.2	*Changed details for "When are treatments/referrals provided?" from medication and referral at follow-up* ***to add*** *a scheduled 4-week follow-up to assess impacts of PT*	Coders agreed on excerpt for this adaptation prior to consensus discussion
1.RS.3	*Changed details for "referral to specialist"* ***from*** *no details* ***to*** *include referrals to new in-house PT*	Coders agreed on excerpt for this adaptation prior to consensus discussion
2.RC.1	*Changed "When is the survey delivered?"* ***from*** *before the visit* ***to*** *before the visit on the review of systems form and additional questions during rooming for positive screens*	Consensus on coding, including both coder's overlapping excerpts gives a good representation of this adaptation
2.RC.2	*Changed "Where is the survey delivered?"* ***from*** *in the lobby* ***to*** *both in the lobby and in the exam room.*	Uncoded one excerpt (was a part of pre-brief, not in meeting), consensus gained on one excerpt capturing a part of this adaptation, but the full adaptation was not discussed in this transcript.
2.RC.3	*Changed "Who gives the survey to patients?"* ***from*** *MA, RN and Front Desk Staff* ***to*** *MA and Front Desk Staff.*	Coders agreed on excerpt for this adaptation prior to consensus discussion
2.RC.4	*Changed "Project resources in use"* ***from*** *algorithm, recommended links, list of specialists, and community resources* ***to*** *algorithm, recommended links, and list of specialists only, excluding community resources*	Coders agreed on excerpt for this adaptation prior to consensus discussion

2.RC.5	*Changed "When are treatments/referrals provided?"* ***from*** *both same-day and at follow-up* ***to*** *just follow-up visit.*	Uncoded two portion of excerpts that coders deemed irrelevant to the adaptation in consensus discussions
2.RS.1	*Changed details for "Project resources in use"* ***from*** *QR codes for patients education videos* ***to*** *showing patient education videos on an iPad.*	Coders agreed on excerpt for this adaptation prior to consensus discussion
2.RS.2	*Changed details for "How do patients receive resources?"* ***from*** *patient handouts same-day* ***to*** *handouts only at follow-ups.*	Coders reached consensus on excerpts with minimal re-coding or uncoding
3.RC.1	*Changed "Which treatment options are offered?"* ***from*** *exercises and specialist referral* ***to*** *exercises, medications, specialist referral, and community resources*	Coders reached consensus on excerpts with minimal re-coding or uncoding
3.RS.1	*Changed details for "Where is survey delivered?"* ***from*** *form/verbal screen* ***to*** *using a laminated form and marker.*	Added several sections to excerpt through consensus discussion to ensure full context for this adaptation was captured
3.RS.2	*Changed details for "How is the survey given to patients?"* ***from*** *MAs asking questions* ***to*** *MAs only asking verbally if patients do not get a laminated sheet to complete.*	Added additional context to one excerpt in consensus discussion to capture an important contextual detail for this adaptation
4.RC.1	*Changed "Who gives the survey to patients?"* ***from*** *MAs* ***to*** *Physicians.*	Uncoded a small irrelevant section in consensus discussion

4.RC.2	*Changed "How is survey given to patient?"* ***from*** *On Paper and Verbally* ***to*** *only Verbally.*	Added additional context to one excerpt in consensus discussion to capture an important contextual detail for this adaptation
4.RC.3	*Changed "Who documents survey results?"* ***from*** *MA and Physician* ***to*** *Physician only.*	Coders agreed on excerpt for this adaptation prior to consensus discussion
4.RC.4	*Changed "Which screener is used?"* ***from*** *the 3-IQ* ***to*** *unscripted verbal questions.*	Coders agreed on excerpt for this adaptation prior to consensus discussion
4.RC.5	*Changed "Which treatment options are offered?"* ***from*** *exercises and specialist referral* ***to*** *exercises, medications, and specialist referral.*	Coders reached consensus on excerpts with minimal re-coding or uncoding
5.RC.1	*Changed "How is survey given to patient?"* ***from*** *Verbally* ***to*** *On Paper.*	Coders agreed on excerpt for this adaptation prior to consensus discussion
7.RC.1	*Changed "How is survey given to patient?"* ***from*** *On Paper and Verbally* ***to*** *On Paper.*	Coders agreed on excerpt for this adaptation prior to consensus discussion
10.RC.1	*Changed "Where is the survey delivered?"* ***from*** *in the lobby or outside the clinic* ***to*** *in the lobby.*	Uncoded a small irrelevant section in consensus discussion
10.RC.2	*Changed "Who gives the survey to patients?"* ***from*** *EHR messages and front desk staff* ***to*** *front desk staff*	Uncoded a small irrelevant section in consensus discussion
10.RC.3	*Changed "How is the survey given to patient?"* ***from*** *Digitally on Patient's Device and On Paper* ***to*** *On Paper.*	Coders agreed on excerpt for this adaptation prior to consensus discussion

10.RS.1	*Changed details for "When is the survey delivered?" from before the visit with a pre-visit digital questionnaire to before the visit but only on paper when patients arrive in the lobby.*	Identified excerpts through discussion, aided by annotations made by both coders during coding.
10.RS.2	*Changed details for "Who delivers resources to patients?"* ***from*** *AVS* ***to*** *MA sharing resources via AVS with patients who do not discuss UI with their provider but do screen positive.*	Coders agreed on excerpt for this adaptation prior to consensus discussion
10.RS.3	*Changed details for "Which treatment options are offered?"* ***from*** *providing exercise information on handouts* ***to*** *linking exercise resources in the AVS via dot phrases.*	Coders agreed on excerpt for this adaptation prior to consensus discussion
11.RC.1	*Changed "Who gives the survey to patients?"* ***from*** *front desk gives iPad* ***to*** *pre-visit surveys sent via EHR or front desk gives out iPad*	Coders agreed on excerpt for this adaptation prior to consensus discussion except for one small additional reference
11.RC.2	*Changed "Which visits are patients screened at?"* ***from*** *AWVs* ***to*** *physicals, AWVs, (all preventative visits, and UI problem visits*	Uncoded two small irrelevant sections in consensus discussion
11.RC.3	*Changed "Which Screening tool?"* ***from*** *the 3-IQ* ***to*** *the 3-IQ and HEDIS*	Coders agreed on excerpt for this adaptation prior to consensus discussion
11.RC.4	*Changed "Project resources in use"* ***from*** *algorithm, recommended links, dot phrases, and list of specialists* ***to*** *algorithm, recommended links, dot phrases, list of specialists only, and list of community resources*	Coders reached consensus through discussion, including all sections coded by one or both of the coders

11.RC.5	*Changed "Which treatment options are offered?" from exercises and medications to exercises, medications, referral to specialist, or referral to community resources*	Coders reached consensus through discussion, including all sections coded by one or both of the coders
12.RC.1	*Changed "Who gives survey to the patient?"* ***from*** *MA or Physician* ***to*** *MA or front desk*	Consensus on coding, but removed some irrelevant text together
12.RC.2	*Changed "How is survey given to patient?"* ***from*** *On Paper or Verbally* ***to*** *On Paper only*	Consensus with ER input on the coded excerpt that shows a portion of the adaptation
12.RC.3	*Changed "Who documents survey results?"* ***from*** *MA and Physician* ***to*** *MA only*	Consensus in coding, double-checked
12.RC.4	*Changed "Project resources in use"* ***from*** *Algorithm, List of local specialists, and List of community resources* ***to*** *Algorithm, Recommended links, List of local specialists, and List of community resources*	Removed extraneous text, and confirmed two excerpts relevant to this code.
12.RS.1	*Changed details for "When are treatments/referrals provided?"* ***from*** *same-day behavioral modifications* ***to*** *same-day PT referrals*	Added a section, similar excerpts to 12.RS.1 as they are related.
12.RS.2	*Changed details for "Which treatment options are offered?"* ***from*** *medications* ***to*** *less use of medications, referring to PT.*	Consensus gained; removed some extraneous text and agreed on a second excerpt
13.RC.1	*Changed "How is the survey given to patient?"* ***from*** *Verbally* ***to*** *On Paper.*	Coders agreed on excerpt for this adaptation prior to consensus discussion

13.RC.2	*Changed "Which patients receive screening?"* ***from*** *specific subpopulation (patients not seen in last year)* ***to*** *all adult patients*	Coders agreed on excerpt for this adaptation prior to consensus discussion
13.RC.3	*Changed "Which Screening tool?"* ***from*** *the 3-IQ* ***to*** *a modified unisex screening tool*	Initially only one coder found an excerpt for this adaptation, but through consensus discussions both coders agreed on a slightly larger section and uncoded an irrelevant excerpt
13.RC.4	*Changed "Project resources in use"* ***from*** *Algorithm, Links/videos, List of local specialists, and List of community resources* ***to*** *Algorithm, Dot phrases, List of local specialists, List of community resources, and UI patient handouts*	Coders agreed on excerpt for this adaptation prior to consensus discussion
13.RC.5	*Changed "When are treatments/referrals provided?"* ***from*** *follow-up visit only* ***to*** *both same-day and follow-up care offered.*	Coders reached consensus through discussion, including all sections coded by one or both of the coders
14.RC.1	*Changed "How is the survey delivered?" from on paper and verbally to verbally only.*	Coders reached consensus through discussion, including all sections coded by one or both of the coders
14.RC.2	*Changed "Project resources in use"* ***from*** *Algorithm, Links/videos, Dot phrases, and List of local specialists* ***to*** *Algorithm, Links/videos, Dot phrases, List of local specialists, and List of community resources*	Coders reached consensus through discussion, including all sections coded by one or both of the coders

14.RC.3	*Changed "Which treatment options are offered?"* ***from*** *exercises, medications, and specialist referral* ***to*** *exercises, medications, specialist referral, and community resources*	Coders reached consensus through discussion, including all sections coded by one or both of the coders
15.RC.1	*Changed "Which Screening tool?"* ***from*** *the 3-IQ* ***to*** *a "two-question screener found in EPIC"*	Coders agreed on excerpt for this adaptation prior to consensus discussion
15.RC.2	*Changed "Project resources in use"* ***from*** *Algorithm, Dot phrases, List of local specialists, and List of community resources* ***to*** *Algorithm, Links/videos, Dot phrases, List of community resources, and patient handouts*	Coders reached consensus through discussion, including all sections coded by one or both of the coders
15.RC.3	*Changed "Who delivers resources to patients?" from EHR(automatic) to Physician*	Consensus gained; removed one portion of extraneous text from excerpts
15.RC.4	*Changed "Which treatment options are offered?"* ***from*** *exercises, medications, specialist referral, and community referral* ***to*** *exercises, medications, pessary fitting, specialist referral, and community resources*	Coders reached consensus through discussion, including all sections coded by one or both of the coders

Appendix 4: CFIR Content Analysis Outputs

Innovation Domain

The innovation domain of CFIR 2.0 captures determinants of implementation related to the innovation, or intervention, itself (Damschroder et al., 2022b). The 8 determinants in this domain are: Innovation Source, Innovation Evidence Base, Innovation Relative Advantage, Innovation Adaptability, Innovation Trialability, Innovation Complexity, Innovation Design, and Innovation Cost. Across clinics sampled for this analysis, our team identified excerpts for each of these determinants except Innovation Complexity and Innovation Cost. The determinants identified are described below with exemplar quotes.

Innovation Source - This code included references to the people and organizations who developed the intervention or who are delivering the intervention. This project involved the collaboration of many organizations and experts who lent their credibility to the intervention. Our team interpreted most of the instances of the innovation source code as a facilitator of implementation, supporting individuals' trust in the project.

> *"The project, as you probably remember, is an Evidence Now initiative through the Agency of Healthcare Research and Quality." [15]*

Innovation Evidence Base - This code captured references to the actual evidence of the intervention's effectiveness. In this study, facilitators frequently cited past research on the prevalence of UI and the effects of different treatments on the condition. Coders identified references to the research that motivated the project as relevant for this code. Coded excerpts where research evidence was referenced generally included facilitators responding to questions

asked by clinic team members or clinics re-stating the research evidence presented to them in project resources.

> *"Research in Wisconsin shows that 60% of adult women in Wisconsin over 18 experience UI." [5-9]*

Innovation Relative Advantage – Relative advantage is the comparison of the new process, post-intervention, to alternatives or the former standard practice. This code was used when clinics reflected on progress and noted the distinct advantages or disadvantages of their new UI screening and treatment processes.

> *"I think it's been easy enough to do. [The new process] is not that dramatically different than what I was already doing. It's just better than what I was doing. And I think it's important." [13]*

Innovation Adaptability – The intervention delivered to clinics in this study was adaptable by design. With guiding recommendations, clinics chose from multiple screening questions, patient resources, and they could customize all workflow-related details. The excerpts coded to this determinant only captured the explicit statement of changes that had been, or will be, made to each clinic's intervention.

> *"But my understanding from some of these ladies is it's pretty clear-cut you know stress incontinence… I don't feel like we need to get a [urinalysis] on them if that's the only time they're leaking. So I've kind of made that executive decision." [13]*

Innovation Trialability – This code captured references to the intervention's inherent ability to be tested at a limited scale, or lack thereof. Testing an intervention in a small way before scaling is a well-established implementation approach and clinics reflecting on that capability were

identified here. One clinic trialed the intervention with patients and waited for feedback on the best continuing care options for their patients:

> *"…a lot of the patients are still probably in the first step of giving a try… So I mean, maybe in six months or so, we'd have more that we could offer… But it's pretty new that the patients are still in that period of giving their first step a try." [2]*

Innovation Design – The design of the intervention itself and the materials provided to clinics as part of the intervention are crucial determinants of implementation. For example, a well-designed patient information sheet is more likely to be used by patients and providers alike, driving positive outcomes. In this study, clinics reflected on the design of the intervention in their own clinics and were regularly encouraged to troubleshoot and identify areas for improvements in design.

> *"Once again, I don't like the paper. But until someday we have a fancy iPad for patients to do all their review of systems on, we'll have to stick with that for the time being, so." [13]*

Outer Setting Domain

The outer setting domain covers implementation determinants beyond the walls of a given clinic that may impact the implementation effort. These local, organizational, or system-wide phenomena can motivate or hamper changes within clinics in numerous ways. The 7 determinants in this domain are: Critical Incidents, Local Attitudes, Local Conditions, Partnerships & Connections, Policies & Laws, Financing, and External Pressure (Damschroder et al., 2009, 2022b). All but one of these determinants and 1 of the three sub determinants were

identified in the analyzed transcripts; Policies & Laws, Societal Pressure, and Market Pressure were not identified in our data.

Critical Incidents – Incidents beyond the control of clinics can directly impact implementation efforts. In this study, several notable events (e.g., clinic closures) impacted the ability of clinics to participate in the study and/or implement their interventions. One clinic noted the impact of a system-wide network outage on their screening process:

> *"… there was some system outages for other clinics. Is that something you all had to deal with too? Yep. How did you get through that? How did you manage that with all the stuff built into Epic? Yeah, we just did it on paper. I did it paper when I was younger, so yeah. I can imagine it's tough for the greener folks." [14]*

Local Attitudes – The attitudes of communities that overlap with the clinic and their patients can come up as barriers or facilitators during implementation. In this analysis we identified several clinics who were impacted by the ways their patients and clinicians thought about UI; often as a point of embarrassment or discomfort.

> *"And that's why this is something completely new that nobody wants to talk about [UI]… And I think it's also that it's almost like mental health before. Nobody wanted to say they were stressed out because there was stigmatism." [1]*

Local Conditions – This determinant captures the "economic, environmental, political, and/or technological conditions" which effect a clinic's implementation effort (Damschroder et al., 2022b). Our coders identified implementation barriers related to rurality as a particularly frequent reference to this code.

> *"I think a lot of things that you know in larger cities, you have a lot more options of different therapies and things like that. There's just not around here." [15]*

Partnerships and Connections - In this study, several enrolled clinics were involved in multi-site health systems and some shared staff across separately enrolled clinics. These multi-site collaboratives influenced implementations in complex ways, some of which were discussed and captured with this code. Additionally, one target of the screening and treatment intervention implemented in participating clinics was the establishment of partnerships with physical therapy and specialty care for UI. Challenges and successes related to these referral relationships are captured in this code.

> *"We have really good pelvic floor therapists in our area. So they usually communicate pretty well. If things aren't working well, they'll send them back to us... If they don't see improvement, to let us know and then we can have a discussion." [3,4]*

Financing – This determinant relates to any insurance or other financing barriers and facilitator that impact how clinics implement their interventions. Many clinics referenced financial motivators to their decisions to refer or not to refer patients to specialty care. Additionally, UI diagnoses during preventive visits increased out-of-pocket costs to some patients and in response several clinics identified workarounds to avoid these unnecessary expenses.

> *"There's definitely insurance barriers because of [three nearby health systems]. Those are options close by and if they are out of network, then [patients] have only one or two options… Generally, patients know pretty well. And if they don't, we send a referral…" [15]*

External Pressure > Performance-Measurement Pressure – Primary care clinics must pay attention to multiple requirements and measures related to clinical quality. This code captured the ways that internal or external measures related to UI diagnosis and treatment impacted clinic process decisions and their decision to participate in the project.

> *"So now that you bring it up, I can guarantee that I've probably missed 90% of my female Medicare wellness urinary incontinence screens. Which is kind of a bummer because that was part of the reason we wanted to do this is because it's like a quality metric for Medicare." [11]*

Inner Setting Domain

In this study, inner setting determinants existed within the primary care clinics enrolled and implementing new screening and treatment processes. These elements of the local context were the most frequently cited elements of context in this study and they aided and hindered implementations in numerous ways. The determinants in this domain are: Structural Characteristics, Relational Connections, Communications, Culture, Tension for Change, Compatibility, Relative Priority, Incentive Systems, Mission Alignment, Available Resources, and Access to Knowledge & Information. Apart from three sub-determinants, Culture>Human-Equity Centeredness, Culture>Deliverer-Centeredness, and Available Resources>Space, all Inner Setting determinants and their sub-determinants were identified in the data.

Structural Characteristics – This determinant contains 3 sub-determinants, Physical Infrastructure, Information Technology Infrastructure, and Work Infrastructure.

Physical Infrastructure – This code refers to the physical environment of the clinic and how it helped and hindered implementation efforts. One clinic found space for a pelvic floor physical therapist to operate within their clinic building to support patients with recently diagnosed UI:

> *"So we [physical therapists] have been here about two months… So it's been great not only on that front in terms of on-the-spot communication, but also being able to get that patient in on the spot." [1]*

Information Technology Infrastructure – This code captures barriers and facilitators related to the EHR and other digital technologies. These barriers and facilitators came up in each clinic transcript in this analysis and were often mentioned in relation to the process of sending resources to patients via the EHR and AVS.

> *"I think since the question is already in [EHR], the one we wanted to use, it's just a couple of clicks and it's mainstreamed and quick and easy to actually do the documentation. So that's going really good." [14]*

Work Infrastructure – This code captures the organization of tasks in the clinic between different roles and workflows. Additionally, excerpts related to staffing were coded to this construct.

> *"I go into the manager role, and then I forget about it a little bit… But the providers are really good at reminding me like… So if I seem to forget, they will just gently remind me and I'll go right back in there and ask questions." [1]*

Relational Connections – Individuals and groups in clinics have existing relationships that may guide implementation. Excerpts coded to this determinant related to the social and professional connections in each clinic's inner setting that impacted their intervention and implementation.

> *"We understand the community. We understand the financial hardships that they've gone through. We not only lived in this community, worked in this community, we're very familiar with those barriers. So we're not afraid to ask. And they're also not afraid to tell us because they have that connection with us." [1]*

Communications – Excerpts related to these existing and new communication channels were coded to this determinant in the Inner Setting Domain. Sharing information between individuals in the clinic is crucial to any clinical process.

> *"It's only me and [nurse], so we had [meetings] all day long... It's less difficult to change when it's face-to-face and everybody's there." [14]*

Culture – This determinant is used to describe the "values and beliefs" of each clinic as they relate to the implementation effort. Culture is broken into two sub-determinants identified in our dataset: Recipient-Centeredness and Learning-Centeredness.

Recipient-Centeredness – Excerpts relating the implementation to clinic team culture and beliefs regarding the needs and wants of recipients (i.e., patients) were coded to this sub-determinant.

> *"We go with what is insurance covered. You know So we go an extra mile for our patients. So you know that's how it should be." [2]*

Learning-Centeredness – This code was used for references to the culture of learning and updating practices with new information.

> *"I have done some pessary checks, but I've never been trained on fittings. I mean, I would be interested in being trained on that." [15]*

Tension for Change – This determinant covers references to the lack of sustainability or functionality of current processes. Clinics referenced this tension especially after clinic team members and patients learned more about UI prevalence and treatments.

> *"They're excited to actually I mean, some people are like, "Oh, I didn't know this was a common issue." So yeah, it's good to get them equipped with information and things that they can do." [10]*

Compatibility – This code was used when clinic team members discussed how well or not well the intervention fit with existing processes and workflows.

"I think with it being a part of our physical form that, hey, all women are answering this question you know when they're coming in for the preventive visits. It's at least being addressed once a year. So I think that this is probably just our norm now…" [2]

Relative Priority – Excerpts coded to this determinant in this study refer to the prioritization of the UI screening and treatment intervention over other conditions and clinic processes. UI impacts quality of life but is generally not a critical condition, several clinicians noted this as they were choosing how to allot limited time in patient visits.

".. this [UI] is one of those things that is not life-threatening, right? It's life-changing, but if I'm going to ask them to do something, I'd much rather focus on their blood pressure and diabetes needs than I would on their incontinence, right?... I kind of feel like I have bigger fish to fry sometimes…" [13]

Incentive Systems – Several participating clinics leveraged existing incentive systems to encourage clinicians to adopt the new UI screening and treatment process. Incentives identified in this study were recognition-based and did not involve any monetary or other substantive rewards.

"…we send out monthly emails with how the sites are doing. And so we could talk with [clinic manager] about including the data that [name] pulls for how many surveys are being done. And so maybe we add that to the monthly email because the nurses do get competitive about that. And so that would be a good solution." [5-9]

Mission Alignment – Existing missions or initiatives within clinics can conflict with or motivate implementation of new interventions. Clinics may have adapted interventions to match their existing missions, but in several cases, they explicitly stated their missions and how they related to the intervention.

"Facilitator: I saw some mixed facial reactions to the printed form. How do folks feel about that idea?

> *Clinic Team Member: We try to use as little paper as we can because there's so many forms and pamphlets and things." [10]*

Available Resources – Available Resources and its sub-determinants capture the existing clinic funding, materials, and equipment that are available for use with the intervention. In this study the intervention relied on screening and treatments that are generally not resource intensive, but in some cases existing resources were repurposed for new uses. In one clinic, the iPads used for patients to complete screeners in the lobby were repurposed to allow patients to watch a UI education video while waiting for their visit:

> *"I think we're still right around just under 20 patients that have come back and watched the UI video and then had a follow-up visit with their provider." [2]*

Access to Knowledge & Information – Barriers and facilitators to information flows in clinics impacted their implementation efforts. In some clinics, providers lacked clarity around treatment options for patients or had yet to see feedback from patients and specialty providers on treatment effectiveness. In other clinics, placing handouts and diagnostic algorithms in accessible physical and digital spaces was key to their providers implementing the new intervention.

> *"At [clinic 9], we have those things that are on the wall, the little flip charts for like mammograms and stress test info. Yeah. I mean, we print a lot of paper, and that's not that many more sheets, so... Other providers really appreciate it." [5-9]*

Individuals Domain

This domain was applied, per guidance from Damschroder and colleagues, with pairwise codes from each of two subdomains. When an individual was referenced in meeting transcripts, their role was identified in the Roles subdomain along with a code from the Characteristics domain capturing the individual's Need, Capability, Opportunity, or Motivation identified in the

excerpt. The roles identified in these data were Innovation Recipients (patients), Innovation Deliverers (clinic team members), Implementation Leads (clinic champions) and Other Implementation Support.

Characteristics > Need – The needs of people involved in implementations offered crucial motivators and barriers to delivering new UI screening and treatment processes. If needs were stated and addressed or not addressed by the intervention and implementation effort, they were coded here.

> *"A lot of the time, people will be like, "Yeah, great. I've had this problem for 15 years, and nobody's ever addressed it yet." Now that's awesome that somebody is finally talking about it and that I just don't have to be like this…" [3,4]*

Characteristics > Capability – In this study, capability sometimes appeared as the knowledge and abilities of change team members to carry out steps of the implementation processes. Additionally, clinic team members discussed the capabilities of patients to engage with screening questions or other aspects of the intervention.

> *"I've done PTNS, which is the peripheral or sorry, post tibial nerve stimulation. I've done that. I was trained on that. And that's to help overactive bladder. So I've done quite a few of those…" [15] {innovation deliverer, capability}*

Characteristics > Opportunity – Clinicians and patients have limited time and competing demands that restricted their opportunities to deliver or receive the new UI screening and treatment. Barriers and facilitators coded to this determinant generally involved individuals having the necessary time for the intervention. Additionally, several instances of providers having limited preventative visits where screening could take place were discussed.

> *"Just a lot of altogether a lot to address in one room and visits. Yeah So a little time to address other needs that come up." [5-9] {innovation deliverer, opportunity}*

Characteristics > Motivation – The will and desire to screen for and treat UI was frequently cited as a barrier or facilitator to implementing the new process. Patients not wanting to pursue treatment for diagnosed UI was frequently mentioned as a barrier. Clinicians being excited to use new resources and meet the previously unmet needs of their patients was a frequently cited facilitator.

> *"I haven't really had anybody take me up on any of the formal pelvic floor therapy… But it's one thing to talk about it. It's another thing to have somebody actually up in there and doing all of that biofeedback stuff. I think patients, that's a whole 'nother level they're not quite ready for yet necessarily." [13] {innovation recipient, motivation}*

Implementation Process Domain

This domain captures the aspects of the implementation project itself that influence the implementation. These determinants generally involve interactions between clinic team members and implementation facilitators to iteratively implement and improve the UI screening and treatment intervention. The determinants in this domain are Teaming, Assessing Needs, Assessing Context, Planning, Tailoring Strategies, Engaging, Doing, Reflecting, and Adapting. All were present in the transcript data except Assessing Context which captures the process of coding with the CFIR carrier out in this study.

Teaming – This determinants captures team dynamics and the barriers and facilitators to implementation that may arise from team interactions. In the transcripts analyzed in this

analysis, teaming generally referred to the use of regular team meetings to implement the intervention and remind clinicians of the new process regularly.

> *"…if they want to make any change that it goes to affect the whole office, they just tell you Vanessa and I, and then we put it in our minutes for that meeting, and then we discuss it as a group." [1]*

Assessing Needs – This determinant can relate to the needs of different stakeholders through two sub-determinants: innovation deliverers (clinic team members) and innovation recipients (patients). Barriers to assessing needs are barriers to implementation and several clinics identified patient needs regarding follow-up care that changed the way they made referrals. Additionally, facilitators frequently assessed the needs of clinic team members to understand the best ways to support their implementation projects.

> *"Elderly population is a little more afraid of the online stuff, and it's not close enough that they want to you know go to it." [15] {assessing needs>innovation recipients}*

Planning – Planning next steps or mentioning barriers to planning and executing tasks for the implementation were coded here. Participating clinics had full meetings dedicated to planning earlier in the parent study, but planning future tasks still occurred in the meeting transcripts coded for this analysis. Generally, these were longer excerpts with multiple ideas discussed and group agreement on next steps.

> *"Now that we're doing this, the urinary incontinence screening isn't in our Medicare template. And so we have to remember to actually put it in… I don't even know if you're an owner of that Medicare template that you can change. I think we can add that… I think if we did that, that would tie up almost all the loose ends." [11]*

Tailoring Strategies – Facilitators and clinic change team members changed implementation strategies to meet their needs and the needs of the clinic regularly in this project. A full analysis

of implementation strategies was not conducted, but transcript excerpts referring to the action of tailoring and related barriers and facilitators were coded here. The excerpt below captures an implementation strategy, engaging rooming staff to redesign the process to make it easier to remember, and an intervention adaptation, printing screening forms and handing them to patients.

> *"So initially, the rooming staff were having a hard time remembering. We talked about ways to remember using post-its or whatever. The idea for them that would work best were to just print the screenings and hand it to the patients. So that seems to be working best for all women's physicals 18 years and older." [5-9]*

Engaging – This determinant can relate to engaging different stakeholders through two sub-determinants: innovation deliverers (clinic team members) and innovation recipients (patients). Facilitators engaged clinic team members regularly in planned meetings and several clinics went beyond these meetings to engage other members of their practices in the change effort. Additionally, clinics strived to engage patients in the intervention by encouraging the use of treatment options and requests for feedback on care.

> *"One male provider said he advises someone with any GYN issues to see a female provider. Is that the standard for y'all, just across St. Croix sites? It's not the standard… So I guess the medical director can talk to them about that and we get more detail… that's part of core family medicine." [5-9]*

Doing – Doing captures the actions individuals are taking to implement the intervention incrementally and continuously. Several clinics implemented the intervention in stages and discussions of progress on these stages were captured in this code.

> *"We were just talking about how you remember when we originally went to [EHR Company], and the project manager created our Medicare template for us… Now that*

we're doing this, the urinary incontinence screening isn't in our Medicare template. And so we have to remember to actually put it in." [11]

Reflecting & Evaluating – This determinant covers barrier and facilitators to assessments of the intervention and the implementation separately through sub-determinants: innovation and implementation respectively. Barriers and facilitators to reflection included limited data access for formal measures of intervention progress and individuals' assessment of the implementation process as a whole.

"Facilitator: You [clinic team] have done really, really well in this project. And hearing you today, it's clear that you kind of knew what you needed at the start, and it worked really, really great. We're genuinely impressed with that ability, and we hope that you can use that in future projects." [12]

Adapting – Barriers and facilitators related to adapting the intervention and the clinic context itself to accommodate the intervention were categorized here. Several clinics reflected on adaptations that they recently made or tried to make, but many clinics noted very little change to their processes when asked directly by facilitators.

"The resources being there is fairly new. We don't have other I mean, there's you know COVID page and things like that… But no, resources being on our website is fairly new." [2]

Outcomes Addendum

This recent addition to the CFIR captures the effects of the intervention and the implementation effort on patient, provider, and clinic outcomes. Actual and perceived outcomes can influence implementation, especially in this project where iterative improvement methods were encouraged in all clinics. Accordingly, this domain is multi-leveled, with subdomains for

innovation and implementation outcomes and further subdomains within implementation outcomes to capture actual and anticipated outcomes.

Innovation Outcomes>Recipient Impacts – This determinant captures the short-term outcomes of the innovation on patients. Clinic team members referenced the recent patient outcomes they witnessed as motivation to continue using or adapting the intervention.

> *"And one of them came back for a follow-up, but didn't go [to physical therapy]. She said, "No, I just did what you told me." And she read through the pamphlet and did that, and it's better." [1]*

Implementation Outcomes>Anticipated Sustainability – Anticipated implementation outcomes are the probable and predicted outcomes of the projects and in this study, clinics discussed specifically the outcome of sustainability, or the continued use of the intervention into the future.

> *"Facilitator: Can you think of anything that, I guess, will be easy to maintain or challenging to maintain? Clinic Team Member: I think it's going to get easier with time." [11]*

Implementation Outcomes>Actual Implementation – Clinics noted short term outcomes related to enacting the intervention fully or partially. One clinic noted a negative outcome wherein they failed to implement the intervention in one visit type, Medicare wellness visits, while implementing successfully for other visit types.

> *"So now that you bring it up, I can guarantee that I've probably missed 90% of my female Medicare wellness urinary incontinence screens. Which is kind of a bummer because that was part of the reason we wanted to do this is because it's like a quality metric for Medicare." [11]*

Appendix 5 Code Mapping Results - Expanded

Code Mapping Groupings	Description	Example Quotes	Count	All CFIR 2.0 Determinants	Frequent CFIR 2.0 Determinants
Context Driving Adaptations					
Developing an Easier to Execute Process	Adapting screening and treatment procedures to simplify process steps and reduce burden or workload.	"…staff were having a hard time remembering… The idea for them that would work best were to just print the screenings and hand it to the patients. So that seems to be working best for all women's physicals 18 years and older."	31	Innovation, Evidence-Base, Innovation Adaptability, Innovation Design, Local Attitudes, Partnerships & Connections, Financing, IT Infrastructure, Work Infrastructure, Communications, Culture>Recipient-Centeredness, Tension for Change, Compatibility, Relative Priority, Incentive Systems, Mission Alignment, Materials & Equipment, Access to Knowledge & Information, Other Implementation Support, Innovation Deliverers, Innovation Recipients, Need, Capability, Opportunity, Motivation, Assessing Needs>Innovation Deliverers, Assessing Needs>Innovation Recipients, Planning, Tailoring Strategies, Engaging>Innovation Deliverers, Engaging>Innovation Recipients, Doing, Reflecting & Evaluating>Innovation, Adapting	IT Infrastructure, Compatibility, Innovation Deliverer>Opportunity, Assessing Needs
Meeting Patient Needs / Wants	Adapting screening and treatment procedures to meet patient needs and address patient wants	"I would say not that anybody's really wanted to go to or participate in [Community Continence Classes] … I think some are maybe a little bit apprehensive	31	Innovation Source, Innovation Evidence-Base, Innovation Adaptability, Innovation Trialability, Innovation Design, Local Attitudes, Local Conditions, Partnerships & Connections, Financing, IT Infrastructure, Work Infrastructure, Communications,	Innovation Recipients + Capability/Opportunity/Motivation, Partnerships & Connections, IT Infrastructure, Access to Knowledge & Information

		about a group setting or you know for a private issue."		Culture>Recipient-Centeredness, Culture>Learning-Centeredness, Tension for Change, Compatibility, Relative Priority, Available Resources>Funding, Available Resources>Materials and Equipment, Access to Knowledge & Information, Other Implementation Support, Innovation Deliverers, Innovation Recipients, Need, Capability, Opportunity, Motivation, Assessing Needs>Innovation Deliverers, Assessing Needs>Innovation Recipients, Planning, Engaging>Innovation Deliverers, Engaging>Innovation Recipients, Doing, Adapting, Recipient Impacts	
Navigating Referrals / Insurance Coverage	Adapting screening and treatment procedures to overcome challenges with referrals and insurance coverage for treatment.	"Well, I talked to a pharmacist because they didn't approve that medication. They had to do it preoperatively. Oh, sure. So the insurance didn't go through."	18	Innovation Source, Innovation Evidence-Base, Innovation Adaptability, Innovation Design, Local Attitudes, Local Conditions, Partnerships & Connections, Financing, IT Infrastructure, Communications, Culture>Recipient-Centeredness, Compatibility, Relative Priority, Available Resources, Access to Knowledge & Information, Innovation Deliverers, Innovation Recipients, Capability, Opportunity, Motivation, Assessing Needs>Innovation Recipients, Engaging>Innovation Deliverers, Engaging>Innovation Recipients, Doing, Recipient Impacts	Partnerships & Connections, Innovation Recipients + Opportunity, Communications
Addressing EHR	Adapting screening and	"…if we had the ability for them to use the	18	Innovation Adaptability, Local Attitudes, Financing, IT Infrastructure, Work	IT Infrastructure, Planning, Innovation Deliverers + Opportunity

Limitations / Capabilities	treatment procedures based on what is possible and not possible in the clinic's EHR	[EHR] features or things ahead of time to get stuff completed, that it would reduce the nursing staff's burden in documentation."		Infrastructure, Culture>Recipient-Centeredness, Tension for Change, Compatibility, Incentive Systems, Available Resources, Innovation Deliverers, Innovation Recipients, Capability, Opportunity, Motivation, Assessing Needs>Innovation Recipients, Engaging>Innovation Deliverers, Doing, Adapting	
Meeting Clinic Needs / Wants	Adapting screening and treatment procedures to meet clinic or health system preferences and priorities	"We try to use as little paper as we can because there's so many forms and pamphlets and things."	6	Innovation Trialability, External Pressure>Performance-Measurement Pressure, IT Infrastructure, Work Infrastructure, Tension for Change, Compatibility, Incentive Systems, Mission Alignment, Access to Knowledge & Information, Innovation Deliverers, Innovation Recipients, Need, Capability, Opportunity, Assessing Needs>Innovation Deliverers, Assessing Needs>Innovation Recipients, Planning, Engaging>Innovation Deliverers, Reflecting & Evaluating>Innovation	Compatibility, IT Infrastructure, Tension for Change, Assessing Needs>Innovation Deliverers, Planning, Reflecting & Evaluating>Innovation
Adaptation Process					
Maintaining the New Intervention	Actions are being taken to preserve previous adaptations in the current context	"…when I see somebody coming for follow-up of urinary incontinence, I'll just say, 'Whoever's going to get it, don't forget to do the UA and give them the video.'"	24	Innovation Evidence-Base, Innovation Adaptability, Innovation Design, Critical Incidents, Local Attitudes, Local Conditions, Partnerships & Connections, Financing, IT Infrastructure, Work Infrastructure, Communications, Culture>Recipient-Centeredness, Tension for Change, Compatibility, Relative Priority, Available Resources, Materials & Equipment, Access to Knowledge & Information, Other	IT Infrastructure, Partnerships & Connections, Compatibility, Innovation Deliverers, Innovation Recipients, Opportunity

				Implementation Support, Innovation Deliverers, Innovation Recipients, Need, Capability, Opportunity, Motivation, Teaming, Assessing Needs>Innovation Recipients, Planning, Engaging>Innovation Deliverers, Engaging>Innovation Recipients, Doing, Adapting, Sustainability, Recipient Impacts	
Still Making the Change	Adaptations are ongoing and/or time to completing adaptations has been impacted by contextual factors	"Now that we're doing this, the urinary incontinence screening isn't in our Medicare template. And so we have to remember to actually put it in… the problem is it'll blow into anybody's, but we can just delete it."	5	External Pressure>Performance-Measurement Pressure, IT Infrastructure, Compatibility, Incentive Systems, Other Implementation Support, Innovation Deliverers, Opportunity, Planning, Engaging>Innovation Deliverers, Doing, Adapting	Incentive Systems, Innovation Deliverer + Opportunity, Engaging>Innovation Deliverers

Appendix 6: Practice Assessment of Change Engagement (PACE) Rubric

The following rubric was developed by our team building on normalization process theory, and related theories and measures to capture the concept of change engagement (Adelson et al., 2021; Albrecht et al., 2020, 2023; Bonawitz et al., 2020; Chamberlain et al., 2011; IHI, 2017; C. May et al., 2007; C. R. May et al., 2018; Solberg et al., 2008). Facilitators rated each clinic using the PACE rubric following each meeting, assigning a score based on the column most closely describing the clinic's current change engagement across the four constructs which were developed inductively by our team and mapped to the core components of normalization process theory (C. May et al., 2007).

Practice Assessment of Change Engagement (PACE) Scoring Rubric					
Construct	**1**	**2**	**3**	**4**	**5**
Summary	Clinic has completely disengaged with the project, barriers to implementation have become insurmountable and clinic cannot make progress even with maximum facilitator support.	Clinic is failing to regularly engage with schedulers or facilitators, implementation tasks are not being completed without facilitator guidance and multiple reminders.	Clinic completes project tasks with reminders, relies on facilitator support to navigate barriers and advance the implementation.	Clinic is engaged with project tasks and goals with reminders, solving problems as the arise with minimal facilitator support and guidance	Clinic is engaged with all project tasks and goals, proactively solving problems and self-directing implementation without a need for facilitation.
Cognitive Participation	Failure to respond to scheduling requests, Failure to attend scheduled meetings	Clinic is not consistently replying to scheduling requests or making adequate efforts to get attendance at facilitated meetings	Communicating with schedulers with additional reminders, mostly complete attendance in all meetings (not due to scheduling conflicts)	Communicating with schedulers with minimal additional reminders, generally complete attendance in facilitated meetings (not due to scheduling conflicts)	Prompt responses with scheduling emails and always complete attendance at facilitated meetings
Resourcefulness	Clinic is not able to problem-solve as they are failing to identify problems.	Clinic is not demonstrating ability to problem-solve independently	Some independent problem-solving with support of facilitated	Some independent problem-solving beyond facilitated discussions, but still	Demonstrated ability to problem-solve independent of facilitation

		of facilitated discussions, barriers are identified but solutions are not a priority	discussions and meetings, not clear that problem-solving would occur without these discussions	using external support to problem-solve and identify solutions	if/when barriers occur (e.g., generation of new materials to meet specific clinic needs/preferences)
Collective Action	Clinic is not dedicated to the project, complete lack of drive to continue making progress	Clinic shows some signs of dedication, but only with significant effort from external facilitator to complete tasks	Clinic team is dedicated to completing project but would not be considered driven without facilitator support	Most practice members are dedicated to goals of the project with notable exceptions OR people are dedicated to most but not all goals of the project (notable gap between highest possible dedication and current state)	Practice and change team are highly dedicated to achieving goals of this project
Progression (Coherence to support Reflexive Monitoring)	Clinic is not achieving goals, participation and project completion are in question	Stifled achievement of goals, improvements generally paired with equal or worse setbacks	Consistently meeting goals, not falling behind on planned actions but also not driving to get ahead of future tasks	Clinic is at or above the expected rate of completion of project goals (e.g., have a functioning but imperfect process before adaptation meeting)	Clinic is exceeding expected rate of completion of project goals and completing all planned actions in a timely manner. Clinic is "steps ahead" of our progress expectations.

Scores are assigned based on the column of best fit, half-scores (e.g., 3.5) are discouraged. Scores of 0 may be assigned if the clinic has disenrolled from the facilitated implementation project.

This rubric uses several terms first developed as parts of the normalization process theory (C. May et al., 2007).

Appendix 7: Ordered Logistic Regression Model

Using the estimated cut points from this model and the logistic distribution, we can predict the PACE scores for a future clinic who has completed the initial ORIC measure. Based on this model, a clinic with an initial ORIC score of 60/60, would later receive a 5/5 PACE score with a probability of $\Pr(\text{PACE} = 5) = 0.58$, a 4/5 PACE score with a probability of $\Pr(\text{PACE} = 4) = 0.30$, a 3/5 PACE score with a probability of $\Pr(\text{PACE} = 3) = 0.02$, and a 2/5 PACE score with a probability of $\Pr(\text{PACE} \geq 2) = 0.10$. These model-based predictions are limited to PACE ≥ 2/5 due to available data and further refinement of the model is required for more reliable predictions.

Table: Initial Ordered Logistic Regression Results

	Coeff.	Std. Error	P value	[95% Conf. Interval]	
Initial ORIC Score	0.14	0.03	0.000**	0.08	0.19
Cut point 1	4.10	1.27		1.63	6.59
Cut point 2	6.19	1.38		3.47	8.91
Cut point 3	7.92	1.48		5.03	10.81
**p < .05, *p < .10					

Note: Brant test finds violation of the parallel-lines model assumptions (P value = 0.021). The following equations can be used to predict probability of PACE scores for a given clinic during implementation based on pre-implementation clinic ORIC scores. These estimators of probability are based on the model above.

$$\Pr(PACE \leq 2) = 1/(1 + e^{4.11-0.14(ORIC)})$$

$$\Pr(PACE = 3) = 1/(1 + e^{6.19-0.14(ORIC)}) - 1/(1 + e^{4.11-0.14(ORIC)})$$

$$\Pr(PACE = 4) = 1/(1 + e^{7.92-0.14(ORIC)}) - 1/(1 + e^{6.19-0.14(ORIC)})$$

$$\Pr(PACE = 5) = 1 - 1/(1 + e^{7.92-0.14(ORIC)})$$

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