

Integrating the Complexity of Healthcare Improvement with Implementation Science: A Longitudinal Qualitative Case Study

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Abstract

Background

Implementation science seeks to enable change, underpinned by theories and frameworks such as the Consolidated Framework for Implementation Research (CFIR). Yet academia and frontline healthcare improvement remain largely siloed, with limited integration of implementation science methods into frontline improvement where the drivers include pragmatic, rapid change. We aimed to explore how pragmatic and complex healthcare improvement and implementation science, through the CFIR lens, can be integrated.

Methods

Our research involved the investigation of a case study that was undertaking the implementation of an improvement initiative at a large public health service. This research involved qualitative data collection methods of semi-structured interviews and non-participant observations of the implementation team delivering the initiative. Thematic analysis identified key themes from the qualitative data. We examined our themes through the lens of CFIR to gain in-depth understanding of how the CFIR components operated in a 'real-world' context.

Results

The key themes emerging from our research outlined that leadership, context and process are the key components that dominate and affect improvement work. Leadership which cultivates connections with front line clinicians, fosters engagement and trust. Navigating context was facilitated by 'bottom-up' governance. Multi-disciplinary, cross-sector capability, responded to a changing complex environment, adjusting pragmatically, and responsively. Process reflected the theoretically-informed, and iterative approach. Mapping CFIR domains and constructs, with these themes demonstrated close alignment with the CFIR. The findings bring further depth to CFIR and demonstrates that leadership that focuses on patient need as a key motivator to engage clinicians, and that applied and ensured iterative processes, which leveraged contextual factors achieved successful, sustained implementation and healthcare improvement.

Conclusions

This longitudinal study highlights profound insights that strengthen alignment between implementation science and pragmatic frontline healthcare improvement. We identify opportunities to enhance the relevance of CFIR in the 'real-world' setting through the interconnected nature of our themes. Our study demonstrates actionable knowledge to enhance the integration of implementation science in healthcare improvement.

Background

Given the pace of technological advancement and growth in healthcare demand, governments are mandating healthcare transformation. Health systems are highly complex in their design, networks and interacting components and change is challenging to enact, sustain and scale. Recent evidence shows that HCI is often delivered using simple methods that may lack rigour and efficacy.[1–3] Policy makers, academics, clinicians and those who deliver HCI at the coalface of healthcare, require greater insight into how transformative change

can be enacted in complex systems, while at the same time, delivering HCI that is pragmatic and patient centric. [1–3]

Implementation science (IS) brings rigour and evidence-based approaches to healthcare improvement, however it is a complex field involving many disciplines that bring different perspectives and often focus on generating theoretical concepts to advance academic understanding. This can contrast with the pragmatic need for “how to” approaches required to inform frontline healthcare improvement in practice. [1–3] Current IS frameworks can provide guidance for planning and undertaking improvement but more knowledge is needed about how to apply these frameworks to better understand how multi-disciplinary teams function over time. The impact of local adaptations and contexts requires further examination to inform the spread and scale of improvement work.³

Calls are increasing for integration between the IS and pragmatic HCI to integrate rigorous methods, and pragmatic approaches to improvement work.¹ The CFIR is used to design, implement and evaluate evidence-based interventions, and comprises five domains and 39 associated constructs.[4] The comprehensive nature of the CFIR makes it ideal for capturing the complexities of improvement work.[5–8] It encompasses: *intervention characteristics*: including perceived source and evidence strength and quality; *outer setting*: including community needs, resources and external policies or incentives; *inner setting*: such as perceived need for change and internal resources; *characteristics of individuals*: including knowledge and beliefs about the intervention, and *implementation process*: such as quality of planning and engaging staff. Although widely used to plan and evaluate implementation studies, information on the use of the CFIR to evaluate complex, multi-faceted, person centred interventions is scant.[9]

Some studies report difficulties translating the complex and sometimes repetitive construct definitions in the CFIR to fit their initiatives[8, 9] and little is known about its application in pragmatic and sustained healthcare improvement. Hence, the current study aimed to explore a complex healthcare improvement case study, applying the CFIR lens, to produce actionable knowledge to enhance effective, sustainable healthcare improvement.

Methods

Study design and data collection

This research is embedded within a larger ‘parent study’ investigating healthcare improvement at a system level with four public health services and a government department.[10] Here, we report findings from an in-depth longitudinal case study of an improvement initiative at one health service (Service P) that aimed to implement and evaluate a routine mental health screening program into antenatal care for refugee women. Service P is the largest health service in its jurisdiction including six hospitals and highly diverse out-patient and community services, offering generalizability to a broad spectrum of larger health services. To understand how to undertake pragmatic implementation and improvement in complex healthcare settings, we utilised exploratory and qualitative methods with ‘open-ended inquiry’[11] using ethnographic observations of implementation team meetings, document reviews, and interviews with thematic analysis. The use of multiple methods allowed for an approach sensitive to context, participants, processes and behaviours and to explore the constructs and factors that have most influence on effective implementation and improvement.[12-14]

The researcher (AM) was *in situ* throughout, allowing 'real-time' data collection in a 'real-world' context to limit retrospection bias.[15] Field-level participants included the implementation team. Frontline clinicians (hereafter, referred to as target clinicians) who were expected to implement routine mental health screening, were excluded as our focus was on the "how to" of improvement work. We focused on the initiative implementation team actions, how they utilised resources, their interaction with diverse stakeholders and how they progressed the process of improvement.

Qualitative data was collected over 24 months (January 2017- December 2018). Semi-structured interviews (30-60 minutes) were completed with implementation team members involved in planning, implementing and evaluating the improvement work. Document review was undertaken across internal project documents, meeting agendas and minutes, presentations and published literature (stemming from the case study) plus researcher field notes and unstructured observations of implementation team meetings. The data collection process is illustrated in Figure 1.

Interview questions were informed by theoretical approaches of IS (particularly CFIR), complexity and improvement science.[3] General concepts explored in the interviews included constructs of leadership, context, process and content with the interview guide presented in Additional File 1. Interviews and focus groups discussions were audio recorded and transcribed. The data from interviews was transcribed, and along with field observations, was analysed using QSR NVivo 12.[16]

Themes were analysed progressively, until saturation was reached. Analysis was grounded and inductive, influenced by aspects of implementation, complexity and improvement science. Broad themes were elicited through an open-coding process,[17] allowing first order constructs to be identified. This thematic analysis was undertaken by AM, TR and HT to minimise bias and substantiate themes and constructs that emerged. Themes emerged from the data as first order constructs, which were progressively collapsed into higher order second- and third-level constructs. A thematic structure emerged made up of main themes and related sub-themes reflecting the critical features of improvement work as it progressed, to achieve its aim of successful implementation. The conduct and reporting of this research was guided by the Consolidated Criteria for Reporting Qualitative Research.[18]

The second phase of the analysis explored critical success features (themes) emerging from pragmatic 'real-world' improvement through the lens of the CFIR.[4] An analytic matrix was developed, juxtaposing our themes with CFIR components (domains and constructs) for a more in-depth understanding of how the CFIR components operated in a 'real-world' context. We also examined whether CFIR captured the observed pragmatic elements of this work. The mapping process identified commonalities, discord and revealed nuances across the CFIR.

Results

Our ethnographic case study collected data from 18 interviews, 16 non-participant meeting observations and 16 examined documents.

Characteristics of the case study

The case study is presented according to the CFIR constructs described in Appendix 1, also showing data collection timelines aligned with project progress. This provides an in-depth case description including the roles of implementation team involved, the process of improvement and the contextual issues that affected the work. [4] Appendix 1 outlines the case study with delivery of maternity care to refugee women, which is not unique to Australia.

Case Study Outcomes

The intended improvement outcomes are presented in Table 1, showing that these outcomes were generally achieved with the mental health screening tool, model of care and referral pathways implemented successfully.

Table 1
Improvement outcomes of each case

Case Study Improvement Outcomes
<ul style="list-style-type: none"> • The implementation of a screening tool and associated processes was found to be acceptable and feasible for health professionals[#] • From the perspective of patients involved, screening for mental health in pregnancy using a digital platform was found to be acceptable and feasible[#]
[#] published work, authorship withheld to protect the identity of participants and the health service

Thematic Analysis

Main themes emerged on “how to” undertake pragmatic implementation in a complex healthcare setting across:

- Leadership: characteristics of the team leading the improvement work
- Application of an evidence-based research process, with pragmatic iterative action to ensure improvement work progress (this included designing and planning for sustainability and scale) and
- Navigating context (local and broader issues, organisational and local settings, aspects of the clinical condition) that affected the improvement work

Table 2 outlines the main themes and sub-themes and the inter-related dynamism across these. The team displayed leadership qualities of agency and collaboration engaging clinicians as they navigated a shifting and complex context, while applying scientific thinking with pragmatic, responsive and iterative action. Table 3. Provides example quotes where each theme is discussed and demonstrated.

Table 2
Thematic Analysis and main themes.

Main Themes	Leadership	Processes applied	Navigating Context
Sub-themes	<ul style="list-style-type: none"> · Agency · Capability for engagement · Teamwork and collaborative approaches 	<ul style="list-style-type: none"> · Focus on patient need · Planning, execution, evaluation - Designed for sustainability and scale-up - Theory driven improvement and implementation - Iterative · Project management 	<ul style="list-style-type: none"> 'Bottom-up' approach - Embedded at the point of change - Co-designed

Main Theme – Leadership: Characteristics of the implementation team leading and engaging with target clinicians with improvement work

This main theme and sub-themes captured the implementation team’s demonstration of diplomacy and communication required for interaction and engagement with those involved in healthcare improvement. The sub-themes included agency, capability and teamwork.

Agency

Agency is the capacity to act with purpose, power and courage to initiate improvement in response to gaps or suboptimal quality of care.[19] Agency was exhibited in response to patient need, reinforced by national guidelines. The implementation team recognised the relevance and importance of aligning internal organisational strategic directions and external levers, such as national guidelines. The team utilised this structural lever to initiate dialogue with stakeholders, who brought added expertise to the improvement work from within the health service and externally. It galvanised the belief in the work and the desire to improve with clear the rationale for immediate action from stakeholders, fellow clinicians, health service personnel and organisational leaders, as champions. The team identified and engaged with others with additional expertise and a shared vision. The implementation team’s actions revealed passion, competence and expertise, with confidence to act and lead. As leaders of change with agency to drive the work, the team recognised and leveraged their expertise, position and role. This was a significant characteristic, consistently displayed throughout the work and with all stakeholders.

Capability for engagement

Diplomacy, or high-level communication skills were applied to achieve engagement and negotiation with change participants or adopters. The team worked hard to connect, understand and engage with clinicians around the new practice considering context and barriers and enablers of the intervention and its implementation. They adopted collaborative, shared leadership, to adapt, modify and shape the process, according to contextual issues, such as time limits, patient needs, or information technology capacities. The team consistently inspired others using strong communication skills, emotional intelligence and diplomacy skills, tacitly demonstrated and explicitly described by the team. Tacit characteristics included non-cognitive, personal traits to engage with frontline clinician adopters, to gauge their reactions and to respond to unspoken messaging within particular circumstances. This quality reflected personal motivations of the implementers and the leveraging of a shared motivation with adopters to achieve “best practice” for patient care.

Teamwork and collaboration

Teamwork was a dominant characteristic and was connected to aspects of networking, negotiating, relationship-building and connection development. In terms of explicit characteristics, strong teamwork principles of collaboration and co-design were applied including frontline managers and clinical teams (target clinicians). Implementers worked hard to build connections and relationships between adopters and improvement work, including intervention co-development and refinement. Communication and connection-building served to foster trust and enhance relevance of the improvement work with adopters. The team communicated consistently and frequently with all stakeholders.

Collaborative approaches included problem-solving, where no problem was too insignificant or too intractable. Frontline teamwork was demonstrated through consistent stakeholder engagement and on-ground coaching, with high levels of communication with frontline staff and recognition of on-ground problems and progress.

Main Theme - Process of improvement and implementation

This theme highlights key motivations for the improvement work and the structural and practical elements of implementation team action. It includes team processes utilised, and actions taken to progress the work. Sub-themes included the focus on patient need as a key motivator for clinicians and the planning, execution and evaluation of the implementation process. Other sub-themes involved intervention development, theory-driven implementation processes, consideration of sustainability and scale up issues, analysis of implementation barriers, enablers, and measurement and use of process and outcome evaluation.

Method of improvement and change process (planning, execution and evaluation)

Key activities included planning, execution and evaluation, captured across data sources. Figure 1 illustrates the implementation process. The aim to integrate routine mental health screening into antenatal care for a vulnerable population of refugee women and link them with a pathway to community care, was driven by a national guideline[20] combined with an external screening tool. The case was a hybrid of an implementation research project, but was strongly focused on sustainability and scalability, once proven effective. This team

applied an established implementation theoretical framework (the Normalization Process Theory)[21] that underpinned evaluation and measurement of practice change and health outcomes.

The case included an in-depth assessment of patient needs and clinician perspectives to inform the co-designed improvement process. The team reported (and published) extensive communication with multiple stakeholders internally and externally to the health service, before and during the implementation. Specifically, barriers and enablers to implementing evidence-based, nationally recommended screening were explored to inform sustainability of a screening and referral programme in the planning phase. Iterative co-design with target clinicians, clinical leaders, technology experts and academics occurred throughout. Modifications and solution development occurred more intensely at the beginning and less so over the implementation. Coaching with target clinicians was also intense at the beginning to ensure feasibility and practical use of the newly implemented assessment tool. While the tool was designed for sustainability and spread, it deviated from usual practice. To this end, sustainability was considered and planned from the outset, but strategies were only instigated after evaluation indicated efficacy. Several implementation team members indicated, "If we can get it right in this setting [refugee, maternal health services], it should be easier to establish it in a less challenging general maternity setting".

A prevailing observation was the unremitting effort and the availability of the project officer and clinical leaders (both part of the team) for clinicians adopting new practices and tools. All team members, particularly the project officer, were readily available to observe, coach and engage frontline target clinicians as well as acting as liaison between these clinicians and the implementation team.

The recognition of patient need was demonstrated through the clear commitment to ensuring this worked for the target clinicians and of prime importance, for the refugee women. Considerable effort was committed to developing and refining the screening tool to ensure it was understood by the women, across terminology, cultural appropriateness and translation into different languages.

Project management

Project management was an important role for the improvement/change facilitator, who was also a coach and PhD Scholar, with a background as a midwife and maternal child health clinician. Tasks involved organising meetings, progressing the project and reporting updates on all aspects of project progress. This was a regular and ongoing task to articulate and investigate problems and trouble-shoot and resolve situations that reconciled both research purposes with pragmatic actions.

Main theme - Navigating context

This theme captured diverse aspects of the case study context and how the implementation team navigated this. Sub-themes included project governance at a local and organisational level, and the team positioning, allowing multi-disciplinary capability, to respond to a changing complex environment, adjusting iteratively.

Governance

Although governance represented a 'bottom-up' approach informed by implementation research, co-design and a collaborative approach to improvement, leadership and support 'on the ground' came from local leaders directly involved in service delivery with the identified vulnerable population and improvement setting. The senior clinical lead in the implementation team engaged with progress and problems with the Department head and manager, to secure ongoing support including for sustainable implementation.

Team members had roles that straddled an integrated Research Translation Centre or "implementation laboratory", firmly established as a partnership across the university and health service. The team were also largely clinicians and central stakeholders in the health service and improvement process. This leveraged the onsite partnership between the Research Centre and the health service. Team members often wore two hats, as implementers and clinician leaders. This research lens and expertise facilitated insightful perspectives about the improvement process, balanced with practical implementation 'at the coalface'. Additional academic funding was attracted to support the project, while senior researchers undertook the work as part of their academic roles. The clinician leaders in the implementation team also undertook the work as part of their role in delivering high quality care.

Table 3

Exemplar responses illustrating the major themes: Leadership; Process; Context

Leadership and engagement

I think having champions is really useful, so having people who are - and they have to be the right people, because it's not necessarily going to be the senior leader, it's someone who is respected within the space, who people listen to, who isn't necessarily the named leader - and engaging them in a meaningful way and then getting them to lead the change. So I don't think we necessarily need the senior leaders or the whole units at the table, but we need selected important people to be engaged and be able to be seen to be engaged so that they can take it forward.

But I think we do need everyone, and I think there are so many units that if we don't give the opportunity, at least, for each of them to be engaged then they can be lost. If it's just engaged at a program level there are an awful lot of people who sit under the same banner and have really, really diverse practices and workforce and everything else, so being able to have representation from areas is, I think, going to be important at the outset, rather than just bringing them in once it's been decided.

Senior Medical Lead

I think it's a very collaborative process, because...Mostly people aren't, people are pretty happy to work you know and I think there may be times in the future where for example, [X] and [Y] are interested in following up some of the children and I would be happy to hand that over, that's their areas of expertise and I don't think, I think we all recognise each other's area and we are all building to each other's strengths. And so far there hasn't really been any competitiveness.

Clinical Lead and senior academic

We spoke to settlement services, community members, the managers and staff I worked with at the community health centre, because you want to look at where you're going to get your referrals from. People need to know about the service, they need to know what's happening and how it's going to be implemented. Feel that they're actually a part of the process, not just left out - through meetings, chatting. I think essentially I feel I'm a good networker, and I think that's something that - when I think back to that work we did in the refugee work and this as well, I've also been really fortunate, I've worked in [X health service] for 30 years so I know a lot of people, the midwifery staff know me, I know them. I've worked with a lot of them. So all those things have helped a lot too. And because, in the sense I'm one of them, that's probably helped.

Project Officer

Process of improvement and implementation

Before we even did the formative research, the important thing was we knew we needed to speak to community members

Senior Research Fellow (Psychology)

The main driver was that it was a very high risk population and we were concerned about that gap and care for them. So as we went through we started talking to more and more people, we met more people. And then we met the CEO from a not for profit non-government organisation that has funding to provide to try and introduce screening in pregnancy for anxiety and depression and they already had - so they had tools and resources and experience that we could leverage off.

Senior Research Fellow (Health service research)

I contacted the maternity services, found out why they weren't doing it. Looked at what could we do that would enable us to try it and then the important thing for us was you know, before we even did the formative research, the important thing was we knew we needed to speak to community members. Because a lot of people anecdotally have always said that you can't scene with cultural and linguistically diverse women or women from those backgrounds. Because the screening tool doesn't work with them, because they have different concepts of mental health and therefore they won't want to engage with it. But that wasn't the message and that's why we really made an effort too.

Implementation team member

The national guidelines are for every woman. We decided to start with refugee women, acknowledging that it was a high risk population and yep, probably where the greatest unmet need was. Of course it was also the most complex population which is one of the reasons why it hasn't been done. And there was a little bit of an attitude of well if we can make it work in this population we can probably make it work in the general population. So the chances of being able to roll it out across all of the Maternity Service would be great if we could get it to work in this most challenging circumstance. If we can demonstrate that it works in this situation then there can be very little criticism or very little but what if? There are very few excuses that can come up that we have not already seen and addressed.

Senior Research Fellow (Health service research)

We need to prove the effectiveness of the assessment tool, before we set about sustaining it in practice. If it wasn't effective at achieving the set objective then we would not want to sustain it.

Senior Research Fellow

Context

We've received funding from [X health service] and [X university] and from [X research translation centre] as well. And the leverage that then gives us is that if we experience really serious barriers we can go to very high levels at those organisations who hold quite a lot of power and say, "Look, you and these other organisations have invested considerably in this project, recognising that it is a key priority for you, and we are experiencing these problems that we haven't been able to address ourselves and we need some high level support on it." And we've not had to use that because it's quite a blunt instrument. Yeah we haven't had to really call that into use yet but it's nice to have that strategic high level support.

Senior Academic Lead

I can't speak highly enough of the people above me. I think that they really are cognisant of the impact of perinatal mental health on women and newborn well-being, and they've been very keen to explore opportunities to do things differently or to do some short sharp, change management as an intervention that might make a difference to the outcomes that we're getting. Yeah, so certainly at the levels that I've been, they've been very engaged and very curious about what we can do and have been more than supportive.

Midwife - Nurse manager

But it's got to the point where a lot of the hard work has been done. But I think some of that has been because I've been quite strategic. I've been around long enough to know that research is something that buys you credibility in academic environments. And to be strategically aligned with projects like this, or other projects, buys me credibility, in terms of, you know having bargaining power and having some influence, I suppose.

Service manager

Mapping our themes with CFIR

To enhance understanding of the "how to" issues of pragmatic implementation and improvement in complex healthcare settings, themes were mapped to the CFIR. Our complex healthcare improvement case study, applied the CFIR lens to real-world longitudinal ethnographic research, could be integrated with IS. We also aimed to bring further depth to the IS and HCI.

The mapping involved aligning our themes (critical features of improvement work as explained earlier), and an in-depth examination of the CFIR domains and constructs definitions to uncover similarities and differences. Here we also explored and illustrated the complex interplay of factors operating in healthcare improvement work, highlighting the relationships between the constructs, and presenting a complex nuanced assessment of the people, contexts and process that underpin and confront change at the clinical frontline.

The mapping process demonstrated alignment between our themes and the CFIR components, as presented in Table 4, showing overlap across the Outer and Inner settings and Process domains and constructs. This is unsurprising given our research focus was on the work of implementation teams and these CFIR domains reflect much of the contextual and process aspects that impact implementation work.

The mapping process also highlighted variation including the implementation team's leadership approaches, persistent and iterative along with collaborative engagement with stakeholders, especially target clinicians at the coalface throughout the improvement work. The implementation team navigated and embraced the complex and dynamic contextual circumstances, as well as the intervention and implementation process itself. The research reflected an inter-related nature of the themes and the dynamic aspects of the improvement work. Born out in our leadership theme we observed an element that was cross-cutting and permeated all of our other themes (process and context), as well as, all aspects of the CFIR, through agency, engagement and skills. In particular, all aspects of CFIR Outer setting (B. Cosmopolitanism), Inner setting (Networks and Communications) and Process (B. Engaging) mapped to our leadership theme (Table 4). In this distributed leadership model of our case study, no one person held all responsibility and the team collaborated including individual capabilities and responsibilities and when appropriate, they led the work by engaging others and navigating context. This provides insights into a leadership model that appears to enhance implementation success.

Table 4
Mapping of themes with CFIR constructs and domains

CFIR Constructs					
Our themes	Outer setting	Inner setting	Characteristics of individuals*	Intervention characteristics	Process
Leadership	B. Cosmopolitanism	B. Networks and Communications E. Readiness for Implementation- E1. Leadership Engagement			B. Engaging B1. Opinion Leaders B2. Formally Appointed Internal Implementation leaders B3. Champions B4. External Change Agents
Context	A. Patient needs & resources B. Cosmopolitanism D. External Policies & Incentives	B. Networks and Communications D. Implementation Climate · D3. Relative priority E. Readiness for Implementation · E1. Leadership Engagement · E2. Available Resources	A. Knowledge and Beliefs B. Self-efficacy		
Process	A. Patient needs & resources	D. Implementation Climate · D4. Organisational Incentive and rewards: · D5. Goals and Feedback · D6. Learning Climate. E. Readiness for implementation:		C. Relative advantage D. Adaptability F. Complexity	A. Planning C. Executing D. Reflecting and Evaluating

* Characteristics of individuals not directly observed by the researchers, but discussed by the implementation team and observed in their actions toward/with the target clinicians.

Discussion

There is a clear need to optimise approaches to deliver effective and sustainable improvement in health care, integrating methodological rigor and theory driven implementation science with pragmatic healthcare improvement methods.[1,6,8,9] In this context, our research reports three main themes from the improvement work; leadership, context and process. Mapped to CFIR, we reveal alignment and opportunity to extend the CFIR demonstrating the cross-cutting, interconnected and dynamic nature of leading and facilitating improvement work in the complex context of healthcare.

Leadership and engagement

The importance of leadership was highlighted by Damschroder 2009[4] and the need to build a cohesive team consisting of effective champions and stakeholders, who are most likely to make the implementation a success. Here, the multidisciplinary implementation team demonstrated leadership through the agency, skills and capability to engage with target clinicians.

A recent integrative evidence review[22] described attributes of effective facilitators involved in healthcare improvement, with key qualities aligning to the leadership displayed by the implementation team. Ellegdge 2019 reported that self-awareness, self-management, social awareness, relationship management, skills, and knowledge translation and understanding represented key competencies for facilitators to effectively influence success of knowledge translation to improve practice.[22]

Our research provides an in-depth demonstration of what leadership of improvement looks like and how these leaders enacted the process of improvement with stakeholders. Key leadership capabilities included agency to lead the work and capability to engage and communicate about the improvement process with target clinicians and to facilitate the process continuously with them, learning iteratively together, but this more nuanced understanding of leadership is not fully captured in the CFIR. Illot 2012[5] noted that the issue of leadership in the CFIR is under-developed and could potentially go further to describe the connection of leadership with other constructs of implementation and describe how this component continually interacts with the stakeholders involved in the improvement process and context in a pervasive and active manner. Leadership is a complex and critical factor of implementation and improvement work, is relevant to context and process and requires more in-depth framing and investigation that captures the breadth of its influence in future research and healthcare improvement efforts.

Context

This theme encompassed both aspects of the CFIR inner and outer setting. In terms of outer setting constructs, patient needs, especially in vulnerable groups, provided a critical trigger for the improvement work and galvanised all involved. In addition, an external best-practice guideline provided an incentive to implement evidence-informed practice. Our context theme also captures the governance of bottom-up approaches to improvement work. Cosmopolitanism and networks were reflected in this bottom-up approach, and the partnership between the implementation team members, made up of research and clinician experts externally positioned to maintain knowledge exchange, and focus to progress the work, combined with internal members (local leaders and champions) who were established and connected within the local healthcare setting as clinician managers and service directors.[23] This contextual fit supported and enabled the team to progress the improvement work, while still providing required care and aligning other local priorities. Having a team that was present at the point of change is also emphasised in research by Bonawitz 2020, who highlights this embedded aspect of having change champions who understand the practicalities at the frontline and who can leverage organisational influences, or resources, to facilitate the process to achieve the envisaged change.[24]

There is increasing recognition of the complexity of healthcare delivery and the need for improvement work to acknowledge that to achieve success in a complex setting where a responsive, bottom-up approach is better suited.[2, 25-27] Our case study demonstrated local involvement in refining the approach and when this was fostered (through the implementation team), the impact was positive (in terms of practice change). The attentive response of the implementation team to local issues, enabled a stronger feedback mechanism with “grass-root” creativity to resolve improvement process problems. An agile, attentive and engaged leadership demonstrated by the implementation team, leveraged networks within and external to the setting, communicated with each other and with clinicians about the improvement work, and connected extensively with patients around the new practices. McCullough 2015 reinforces this finding and identified key contextual elements, such as leadership, teamwork, and communication, interacting with each other and contributing to site-level uptake of the evidence-based practices.[28] Here we observe the presence of these important factors affecting the uptake of introduced practices. Further research is needed to provide insight into how specific characteristics of context, particularly the application of a bottom-up approach, can influence improvement outcomes.

Further to our context theme is the recognition of patient needs which is contained within an outer setting domain of CFIR. Our research emphasised the significance of this important driving factor in the consistent inclusion and reflection throughout the improvement process. It was a key trigger for the improvement work, and was of paramount importance to the implementation team to meet women’s mental health needs. It was highly relevant for the women involved in the process and the feedback they provided with respect to their support needs, and it dominated the purpose for delivering high quality care from the perspective of the target clinicians. Focus on patient need was woven throughout, actively and passively with the women and target clinicians. CFIR could go further to emphasise this aspect of implementation, and the significance of it as a critical motivator for target clinicians to participate in taking up new practices to benefit patients. Illot 2012[5] and Safaeinili 2019[9] undertook a validation process which examined the comprehensiveness of CFIR with healthcare improvement projects and highlighted this as an underrepresented aspect and a gap in the framework. Safaeinili 2019[9] goes so far as to suggest it should be an additional domain to the CFIR. Our work would suggest that patient need and engagement enhanced clinician engagement and was vital in this improvement work.

Process

Damschroder 2009[4] reports that process is the “single most difficult domain to define, measure, or evaluate in implementation research”. Our theme of process amalgamated CFIR intervention characteristics and process, as intervention characteristics, patient need and clinician requirements were considered and influenced our process theme. The iterative, interactive and collaborative approach used by the implementation team, aligned with the components in these CFIR domains and constructs. These approaches conferred through the leadership of the implementation team and engaged stakeholders in the vision, ensured adaptability and addressed complexity to safeguard success across the planning, execution and evaluation phases. Furthermore, the process consistently considered and addressed patient and clinician needs and resources, provided and discussed shared goals, and updated progress in an iteratively collaborative learning scenario to identify and improve where needed. The team were not deterred by uncertainty; rather they demonstrated confidence in each other’s expertise, as well as the expertise and feedback of the target clinicians they were working with to implement a new practice and tool, and in doing so, further enhanced and fostered engagement of all stakeholders in the improvement work.

An identified gap between our process theme and CFIR was that of sustainability and scale-up. While evaluation and reflection of progress was an ongoing activity, our case set out to design an intervention and implementation strategy for sustainability and scale-up. The case study process involved activities to ensure sustainability and scale-up, which is not incorporated explicitly in the CFIR. Ilott 2012 also identifies this gap and points out the limitations of the ‘reflect and evaluation’ domain, highlighting the need for further definition and investigation on how to capitalise on organisational change efforts.[5]

Limitations And Strengths

A single health service in a public universal healthcare setting may not be broadly generalizable. However, this is one of the largest health services nationally and the project was designed to and is now scaling more broadly. Evidence of success was shown through formal evaluation with sustainability and scale up underway, but long-term impact cannot yet be assessed. The CFIR was designed to be applied prospectively to guide and inform implementation research, we acknowledge that we have applied the CFIR retrospectively, with the intention of assessing and enhancing the depth and breadth of its components to capture the ‘real life’ in-depth examination of improvement work, which is not the primary aim of this framework. We acknowledge that our approach of the *in situ* researcher has potential limitations. However, it is precisely the strength of the longitudinal immersion and insider status that enabled us to gain insights into the normally overlooked deeper and less observable aspects of the context in which HCI takes place.

Conclusions

This research on a ‘real-world’ healthcare improvement case study using the CFIR lens, provides an in-depth and rich understanding of integrated IS and pragmatic HCI. It provides an illustration of the cross-interaction of the components, and presents a nuanced picture of CFIR and the implementation processes that it aims to guide. Key themes included leadership, context and process, which mapped closely to the CFIR. Specific findings include the vital role of leadership agency to cultivate relationships with target frontline clinicians, engaging them in the process of improvement, enhancing participation through planning, execution, evaluation and

sustainability at the frontline. The importance of leaders with clinical and rigorous implementation expertise emerged, as did engagement of multi-disciplinary cross-sector support to manage complexity, contextual issues and delivery on the shared vision of improved outcomes. The vital role of stakeholder engagement and co-design emerged, with patient and clinician need key throughout the improvement work. We highlight the opportunity to integrate sustainability and scalability, not currently explicit in the CFIR, yet fundamental to pragmatic healthcare improvement. Overall, applying the CFIR lens, we produce actionable knowledge to enhance integration of implementation science and pragmatic health care improvement, to improve practice and patient outcomes.

Declarations

Ethics approval and consent to participate

The study was reviewed and approved by Service P ethical review committee (Ref # LNR/16/MonH/259). Informed consent was obtained from all subjects. All methods were carried out in accordance with relevant guidelines and regulations. [18]

Consent for publication

All authors can confirm that they have approved the manuscript for submission. All participants confirmed consent to publish this material as part of their consent to participate in the case study research.

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

All authors have no issues relating to journal policies; we have no potential competing interests to declare.

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Authors' contributions

AM: Contributed to the conceptualization, methodology, formal analysis, investigation and co-writing (original draft, review and editing). HT: Conceptualization and methodology, investigation and co-writing (original draft, review and editing). TR: Participated in investigation and analysis, and co-writing (review and editing). IM:

Conceptualization and methodology, investigation and co-writing (review and editing). RI: Contributed to investigation and analysis, and co-writing (review and editing). IM, HT, TR, RI: provided oversight and leadership responsibility for the research activity planning and execution, including mentorship to AM.

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Figures

Implementation research project – Clinician academic led, bottom-up

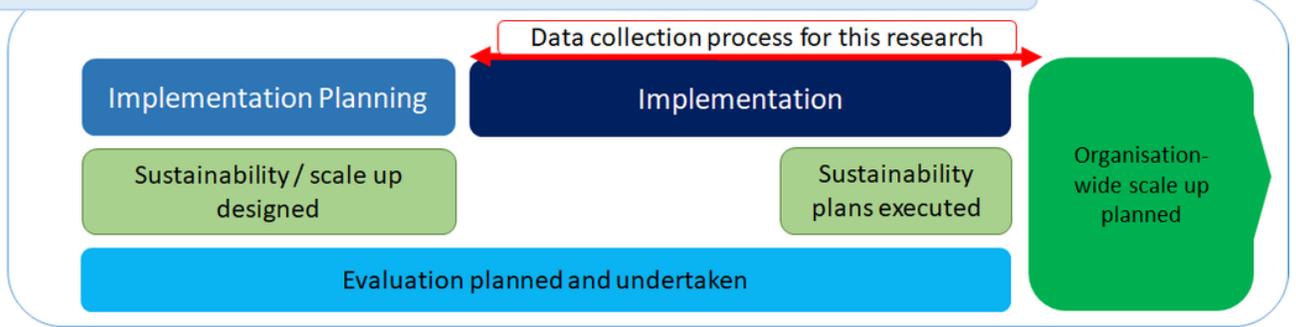


Figure 1

The data collection process

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