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Balancing standardisation and flexibility in National complex intervention scale-up: a qualitative study of leadership experiences and management in the implementation of Proactive Health Support in Denmark

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Abstract

Background Policymakers increasingly aim to scale up healthcare interventions to a national scale to maximise reach and impact. However, scaling complex interventions presents challenges, particularly in balancing national standardisation with flexibility in local implementation across contexts. This study investigates how leaders experience and manage the national implementation of Proactive Health Support, a large-scale self-management support intervention in Denmark.

Methods The study employed a single-case study design with embedded units to examine the national implementation of the Proactive Health support intervention. Data were collected through 10 semi-structured interviews with leaders from the five Danish regions, over 25 hours of participant observation of leadership meetings and workshops, and a document analysis of 468 pages of leadership meeting minutes and reports.

Results Implementing Proactive Health Support required leaders to balance the tension between fidelity and adaptation within a standardised framework. While the national framework provided stability, leaders leveraged the flexibility of implementation strategies to preserve the core intervention components while enabling local adjustments to fit diverse contexts. Reflexive practices, characterised by real-time adjustments and operating through feedback loops, both reinforcing and self-correcting, were pivotal for balancing standardisation with flexibility. Vertical leadership mediated alignment between national and regional levels, while horizontal collaboration fostered shared learning across regions.

Conclusion This study demonstrates the complexity of scaling healthcare interventions across diverse contexts, underscoring the non-linear and dynamic nature of such processes and the significant ongoing leadership engagement required to navigate complexity and manage uncertainty. The findings highlight collaborative

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leadership as crucial for enabling real-time responsiveness, fostering alignment across levels, and balancing fidelity and adaptation in national implementations. They further suggest that fidelity and adaptation are not opposing forces but complementary in practice, with adaptation in implementation strategies supporting fidelity by allowing interventions to be applied meaningfully across diverse contexts. Finally, the findings suggest that successful national implementation processes rely less on strict adherence to standardised guidelines and more on a co-adaptive process within a standardised yet flexible framework, where intervention and context are co-constructed through ongoing, leadership-driven negotiation.

Trial Registration Part of a research programme including a registered randomised controlled trial (ClinicalTrials.gov, NCT03628469). Not applicable to this study.

Keywords Implementation, Complex intervention, Large-scale implementation, Leadership, Fidelity, Adaptation, Context, Up-scaling

Background

Policymakers increasingly seek to scale up healthcare interventions that have been developed or tested in smaller settings into large-scale national programs to maximise their reach and impact [1, 2]. This trend aims to ensure that the entire target population has access to the most effective interventions and programs available [3, 4]. However, implementing complex national interventions in healthcare, in this case, a large-scale self-management support (SMS) program, can be challenging [5]. A consistent trend in implementation science literature is that achieving widespread practice change is difficult, and successful interventions in one setting may face challenges when trialled elsewhere [6–8].

The literature on complex interventions [7, 9] and implementation science [10, 11] concludes that a key challenge in achieving successful national implementation is the ‘practical problem of context’ [10]. Interventions and their outcomes are deeply intertwined with the contexts in which they are implemented, making strict implementation across diverse settings particularly challenging. This challenge is especially pertinent when trialling large-scale interventions across multiple sites, where varying local conditions may lead to different implementation outcomes [10]. Sarkies et al. [6] similarly argue that challenges of replicating and scaling interventions pertain to the complex social processes of implementation and the need for implementation strategies that adequately match local contexts. The ‘practical problem of context’ cannot be handled by treating it as a pure operationalisation issue that can be managed with a rational prescriptive checklist of, for example, implementation strategies [6]. Instead, it is argued that the dynamic nature of contexts requires adaptive and responsive approaches to managing the complexities that arise instead of rigid standardisation [10]. Therefore, a key challenge in implementing large-scale national complex interventions is the inherent tension between striving for standardisation and a complex system characterised by dynamically changing inter-relationships and tensions [8, 12–14]. In

implementation science and complex interventions literature, this is often referred to as the tension between adaptation (i.e., flexibility) and maintaining fidelity [15, 16]. Fidelity refers to the degree to which an intervention is implemented as it was initially described, tested, or intended by the developer [17, 18]. In this study, adaptation is defined as ‘making fit’ often by modification, allowing for adjustments to the intervention itself, the implementation strategies, and the implementation context [15, 19].

In response to these challenges, various implementation frameworks and guidelines have been developed. One example is determinant frameworks [20], which identify barriers and enablers that may influence implementation outcomes, including contextual factors. Other scholars have emphasised the importance of intervention adaptation to fit with local contexts [7, 9]. Fixsen et al. [11] contribute by introducing the concept of ‘core *implementation* components’, distinguishing these from ‘core *intervention* components’ to emphasise that successful interventions rely both on core intervention and implementation components. Core intervention components refer to the most essential and indispensable components of an intervention program [11]. Implementation components, such as training, coaching, and program evaluation, are defined as the most essential and indispensable elements of an implementation program [11], thought to be crucial for achieving fidelity to core intervention components [11]. They further suggest that flexibility in the form of implementation core components (e.g. strategies and processes) allows adaptation to local contexts without compromising intervention fidelity in large-scale national implementations [11]. Similarly, recent studies increasingly suggest that flexibility in implementation strategies and processes can complement rather than compromise fidelity, enabling necessary adaptations to meet local contextual needs without necessarily undermining intervention integrity [15–17, 21]. In line with this, Schwarz et al. [17] introduce a useful distinction between adaptations in the intervention, the context, or

the implementation strategies. They propose that achieving fit between an intervention and its context does not always require adaptation of the intervention itself. They suggest that implementation strategies may act as tools to reconcile fidelity and adaptation by enabling modifications in either the intervention, the context, or both as needed.

However, while much of this existing research highlights the potential coexistence of fidelity and adaptation, it often remains primarily focused on conceptual frameworks and theoretical discussions [21]. This leaves a gap in understanding how leaders experience and manage this balance, particularly in the dynamic and complex realities of large-scale, policy-driven implementation efforts. Although leadership has been studied in policy implementation research for decades [22], its role in shaping implementation processes has only more recently gained attention in implementation science [23]. Leadership is increasingly recognised as a critical factor for successful implementation within implementation science [24–26], and many implementation frameworks and theories in healthcare highlight the significance of organisational leadership in achieving high fidelity [26]. Though recent research [26] has started to investigate and support this relationship experimentally, more knowledge on practices for building and maintaining intervention and implementation fidelity has been called for [21]. Empirical research on how leaders experience and manage the actual processes involved in national-scale implementations remains limited, particularly regarding how they actively balance and operationalise the tension that may arise between adaptation and fidelity over time. This gap in empirical research may partly reflect a broader tendency in implementation research. Often, studies are front-loaded with a focus on program theories and prescriptive implementation models or end-loaded, focusing on process evaluations of past implementation practices. Fewer studies follow implementation processes over time [10]. As a result, less is known about the mechanisms that drive adaptation and sustainability over time [10], as well as how leadership is both experienced and enacted in navigating these dynamics. To address this gap, this study examines how leaders experience and manage the national implementation of a complex SMS intervention, Proactive Health Support (PaHS), in Denmark. This article is part of a multidisciplinary research program evaluating PaHS. Further findings from the broader research programme, including studies on clinical effectiveness [27, 28], cost-effectiveness [29], patient experiences [30, 31], and implementation [32, 33], are reported elsewhere [27–33].

Method

This study utilises a qualitative case study design based on interviews, observations, and documents. This study adheres to the Standards for Reporting Qualitative Research (SRQR) guideline [34].

Aim

This study aims to investigate the following research question: How do leaders experience and manage the national implementation of a complex SMS intervention, Proactive Health Support (PaHS), in Denmark?

Study setting

The Danish healthcare system offers tax-financed universal healthcare and consists of three administrative and political levels: the state, five regions, and 98 municipalities. The Danish Ministry of Health is responsible for setting the regulatory and financial framework for the healthcare system [35]. The five regional authorities govern and operate the hospitals, while general practitioners are gatekeepers to specialist services. The municipalities are responsible for prevention, community nursing, and rehabilitation outside hospitals [35].

The PaHS Intervention

The PaHS intervention was a large-scale, telephone-based SMS program designed to reduce preventable hospital admissions and improve health-related quality of life for participants. The intervention recruited participants through a prediction model identifying adults at risk of hospital admissions within 3 months. Registered nurses were trained to deliver the intervention, focusing on enhancing participants' self-management strategies and coping skills [27]. The PaHS intervention was organised in specially established PaHS units, seven in total across the five regions. These PaHS units were independent of existing organisational units such as hospital departments and rehabilitation centres. The PaHS program, including both intervention and implementation core components, is described in further detail in Table 1.

In 2016, a national–regional political agreement was made to implement the PaHS intervention at a national scale running from 2017 to 2020. The intervention had previously been developed and tested in Sweden. The policy-level processes and challenges related to the early implementation of PaHS have been addressed in a previous publication [32]. The agreement emphasised national uniformity by requiring the intervention to be developed and managed as a national program and by initiating a multidisciplinary research program, including a protocolled randomised controlled trial (RCT) [27]. While PaHS was initiated through a top-down national policy agreement, the five regions were granted authority to organise the intervention within a jointly defined

Table 1 The Proactive Health support (PaHS) intervention - intervention and implementation core components**Included citizens:**

- Adults (≥ 18 years) at high risk of hospital admission, identified monthly via a national prediction model using healthcare registry data.
- Eligible individuals received invitations via secure electronic mail and follow-up phone calls. After consent, registered nurses (RNs) performed a secondary eligibility screening prior to inclusion.

Intervention Core Components (Active Ingredients):

- Initial Session: A face-to-face session with the same registered nurse (RN) who will conduct the entire intervention.
- Telephone Follow-up Sessions: Regular phone-based follow-ups are conducted over a 6–9 month period.
- Tools: Development of personal goals and assessment of hospitalisation risk at each session.
- RNs Roles:
 - Caregiver: Provides support for the patient's health and well-being.
 - Coach: Guides the patient through self-management techniques.
 - Healthcare Professional: Offers expertise and advice on disease and treatment.
- RCT protocol
- Practice Handbook: National standardised guide outlining delivery of intervention core components, including patient engagement, coaching methods, and use of tools such as the risk management protocol.

Core Implementation Components:

1. Performance Management: System for monitoring quality and activity levels across regions, including set goals and standards for patient caseloads, conversation duration, and frequency of contact based on patient risk profiles. In addition, it serves as a method for continuous learning and development, ensuring high and uniform quality across all regional units.
 - M4 IT-System: Unified platform for data collection and patient progress tracking, enabling case monitoring by nurses and oversight by local and program management.
2. Workflow Descriptions: National guideline including standards for how the intervention should be delivered and organised, ensuring that processes (e.g., patient screening, coaching, documentation) are standardised across regions.
3. Education and Supervision:
 - Three 2 day training modules focusing on learning the roles of caregiver, coach, and healthcare professional. Provided by a private consultancy firm.
 - Supervision:
 - External supervision by private consultancy firm.
 - Peer and Internal Supervision.
 - Workshops and Team Meetings: Regional sessions for continuous professional development.
 - Communication Techniques [27, 36–39]:
 - Gamemaster Technique.
 - Karl Tomm's Interventive Interviewing.
 - Identification of essential keywords and exploring their meaning.
 - Solutions-Focused Coaching.

Actors:

- National Program Management: Responsible for coordinating and monitoring the program centrally across all regions.
- Project Leaders: Support implementation in line with national guidelines and local needs.
- Nurse Leaders: Support and oversee frontline staff in delivering the intervention.
- RNs: Deliver the intervention directly to patients through consultations and follow-ups.

Intervention Outcomes:

- Short-term Goals: Improve patient self-management.
- Long-term Goals: Reduce hospital admissions, improve health-related quality of life, and decrease healthcare costs.

Table 2 Regional organisation of the PaHS intervention

Organisation	Region 1	Region 2	Region 3	Region 4	Region 5
Number of Call Centres	1	2	2	1	2
Nurses	9	20	20	34	10
Nurse Leaders	1	2	1	1	0
Project Leaders	1	1	1	1	1

national framework. This governance structure allowed for regional flexibility in organisation, resulting in variations in the size, structure, and organisational anchoring across the PaHS units. For example, some regions had two units with a nurse leader in each unit, while others had only one unit (See Table 2).

A national program management was established prior to implementation, to oversee coordination,

standardisation, and quality assurance, in line with a formalised program governance model. In this study, standardisation refers to a national effort to ensure consistent implementation of the PaHS intervention across regions through nationally defined core intervention and implementation components. This program governance model emphasised structured collaboration between national and regional actors, with a strong focus on

implementation and organisational processes. The program management consisted of a program manager and a support secretariat. From 2017 to 2020, this national program management oversaw the overall coordination, management, and implementation of PaHS in close collaboration with regional leaders. In addition to the program manager, the national implementation of PaHS involved two other formal leadership roles. Each region employed a project leader and one or two nurse leaders responsible for the implementation and operation of the intervention. As such, the national implementation was a collective responsibility shared between national program management, regional project leaders, and nurse leaders. These leaders, ten in total (excluding region 5, see Participant section), worked closely together across all regions, meeting regularly in the capital region. Meetings were held both in peer groups (project leaders together, nurse leaders together, often with the program manager present) and jointly. While the implementation involved leadership at different levels, this study investigates leadership collectively to protect the participants' anonymity by avoiding identifying specific leadership roles and regional distinctions.

Study design

This study employs a single-case study design with embedded units, allowing for units of analysis on multiple levels and across contexts within the same case [40]. The unit of analysis is the national PaHS implementation, while the embedded units consist of six PaHS units in four regions. Paparini and Papoutsi [41] note that case study research is particularly well-suited for investigating complex interventions in their natural settings, where implementation processes are deeply intertwined with dynamic contextual factors. Thus, the case study design provides a valuable methodological approach for capturing the complexity of the national PaHS implementation.

Participants

The present study involved the following participants: 1) four regional project leaders already working as project leaders within the regions where they were assigned to the PaHS project, 2) five nurse leaders overseeing one or two PaHS units in these regions. All nurse leaders had actively applied for the position, and 3) the national program manager. In total, 11 leaders were involved in the national implementation of PaHS, and all were invited to participate in this study. All leaders were contacted via email and informed about the study; all consented to participate in qualitative interviews. One of the five Danish regions was excluded from this study because it differed from the remaining regions in several ways. In addition to having several years of prior experience with the intervention as a pilot region, it had a somewhat different

educational programme, organisational setup, and implementation process [27, 33]. These differences meant the implementation conditions did not match those of the national roll-out across the remaining four regions. The interview with the leader from that region was therefore excluded from the analysis. The final sample comprises 10 leaders from the remaining four regions - all with formal leadership responsibilities in the national implementation.

Data collection

Data collection involved multiple qualitative methods: semi-structured interviews, observations, and document analysis. Some data collection spans 2017–2020, such as the observations and documents. Interviews were conducted in the more mature phase of the implementation process, from late January to March 2019, and before trial results were known [28, 29]. The extended data collection period provided insights into the dynamics of the national implementation of the PaHS intervention. The first author, an experienced social scientist, and a research assistant collected data. The data presented in this article have not been previously published.

Observation

Participant observations were conducted [42] in workshops, including training sessions, performance management workshops, and leadership meetings with nurse leaders, project leaders, and program management, totaling more than 25 hours of observation. Access to these activities was granted through collaboration with national program management. Notes were taken during and immediately after each session by the first author, guided by an observational focus on the interactions, decision-making processes, and practical challenges faced during the implementation of the PaHS program. The observations also offered an opportunity to capture informal interactions and emergent challenges not readily accessible through interviews or documents, and they informed the development of the interview guides. The extent of observations was determined by the primary researcher, who was offered access to observe and participate in all leadership activities. Observations concluded when the material was assessed to provide sufficient depth, variation, and richness in interactions, decision-making processes, and practical challenges across the observed leadership activities, thereby supporting the analysis.

Document analysis

The document analysis included a practice manual, workflow description, leadership meeting minutes, and a performance management catalogue. The practice manual and workflow description were collaboratively developed

by leaders during the early stages of the implementation process before the RCT launch. They were based on the trial protocol and co-created and adjusted several times during this early phase, based on input from frontline staff (nurses) to ensure practical relevance. Leadership meeting minutes were written in relation to meetings between project leaders and program management (meeting minutes=14), leading nurses and program management (meeting minutes=11), and joint leadership meetings across the leaders (meeting minutes=5). All leadership meeting minutes produced during the project period, 468 pages, were collected by the national program management secretary and forwarded to the first author. The performance management catalogue was developed by the program management with input from leaders to establish joint standards.

Semi-structured individual interviews

The first author conducted all interviews, lasting 45 to 66 minutes. Participants were recruited via email, and interviews were conducted during working hours. Interviews were conducted either in person or by telephone, depending on participants' availability and geographical location. The interview explored leaders' experience and management in relation to the PaHS implementation process, focusing on their responsibilities and leadership collaboration within and across the regional and national levels. A semi-structured interview guide was developed for this study, with minor adaptations to reflect participants' formal leadership roles in the program, nurse leaders, regional project leaders, and the national program manager, while maintaining a shared thematic structure across all interviews. The guides covered common topics such as leadership responsibilities and practices, organisational setup and local organisational adaptations, and experiences with implementing the intervention within a national framework. An English version of the interview guide is available as a Supplementary File. Interviews were digitally recorded and transcribed verbatim.

Analysis

A reflexive thematic analysis [43, 44] was used, informed by an abductive analytical approach [45]. Abduction is a mode of analysis that involves iteratively moving between empirical observations and theoretical concepts in order to develop meaningful interpretations. In this study, it supported an openness to empirical complexity and a sensitivity to patterns, tensions, and dilemmas in the data. This abductive approach allowed us to gradually refine the thematic structure by engaging theory in dialogue with emerging insights [45].

The first step involved comprehensively reading interview transcripts, field notes, and documents. During this initial exploration of the data, the broader preliminary

codes of *context*, *implementation processes*, and *outcomes* were identified as essential aspects of the leaders' experiences and management of the intervention across different regions.

The first author then developed subcodes within these broader preliminary codes. For example, within the preliminary code of *context*, subcodes like *standardisation* and *flexibility* began to take shape, reflecting early insights into how leaders experienced and balanced uniformity and adaptation. At this stage, the analysis remained data-driven, allowing patterns in the data to guide the initial coding structure.

As the analysis progressed, theoretical concepts from the implementation science literature were gradually introduced to inform and refine the preliminary codes and emerging subcodes. The preliminary code of *implementation processes* was further refined with subcodes such as *collaboration* and *monitoring*, illustrating how leadership across regional and national levels engaged with the intervention.

The coding process was iterative and collaborative. The first author led the coding, with continuous discussions to ensure reflexivity, consistency, and depth in the analysis. The second (MDT) and last (CPN) authors discussed preliminary test coding with the first author, and slight adaptations to the coding structure were made. The first author then coded all data. Alongside this interview coding, insights were continuously compared with field notes and documents. This triangulation enabled comparisons between leaders' accounts, documented decisions, and observed interactions in leadership meetings and workshops. In this way, observations and documents were used both to contextualise interview accounts and to strengthen the credibility of the analytical findings [46]. The development of themes followed an iterative process of identifying recurring patterns across interviews, documents, and observations. Codes and subcodes such as *standardisation*, *flexibility*, *collaboration*, and *monitoring* were refined and compared across the material and grouped into broader analytical categories, such as tensions between national standardisation and local realities, leadership responsiveness to and management of emerging challenges, and coordination across organisational levels and settings. These categories informed the construction of three overarching themes (see the results section). The analysis progressed until the thematic structure was considered analytically coherent. The dataset provided sufficient depth and diversity to support the development of robust and meaningful themes across the material.

Reflexivity was maintained throughout the research process. The first author, who led data collection and analysis, brought familiarity with the Danish healthcare context and prior qualitative experience. This familiarity

provided contextual understanding but also required ongoing attention to potential assumptions regarding leadership and organisational dynamics. The coding process was iterative and collaborative, and interpretive and analytical decisions were continuously discussed with the second and last authors to surface and interrogate assumptions and to secure a critically warranted reading of the material.

A Large Language Model (ChatGPT, OpenAI) [47] was used to support the translation and language editing of participants' quotes from Danish to English, to preserve the tone and clarity of the original spoken expressions. In addition, Grammarly [48] was used to check grammar, spelling, and adherence to academic English conventions. The authors retained full responsibility for the content, accuracy, and intellectual contributions of the manuscript.

Results

The analysis generated three key themes: 1) between national standardisation and local implementation, 2) navigating flexibility within a national framework, and 3) managing national-local balances through horizontal and vertical leadership. Themes two and three include related subthemes. Theme two includes the sub-themes *Managing National Standards in a Dynamic Process* and *Local Adaptation of Implementation Strategies*. Theme three includes the sub-themes *Horizontal Leadership: Cross-regional Collaboration* and *Vertical Leadership: Mediating Between National and Regional Levels*.

A key finding across all themes was that the leaders consistently experienced the implementation of PaHS as a success. Although the multidisciplinary research program later showed that the PaHS intervention was not cost-effective or displayed the expected outcomes [28, 29], leaders frequently expressed a strong sense of accomplishment, which is reflected in comments like: “*I think we stand quite strong in relation to what is on the agenda and standardising things, showing that it's actually possible even though we are different regions. I think we're a bit of proof that it can indeed succeed.*” (Leader 5).

Several leaders reported observing changes in nursing practice, with nurses adopting more coaching-oriented, patient-centred roles, and that these practice changes were implemented consistently across regions. This shift marked a broader normative restructuring towards a coherent ‘*PaHS Professional Practice*.’ Some leaders highlighted the ability to share nurses between regions without additional training, frequently using phrases like “*we have seen that we can share nurses across regions*” and “*the initiative is developed uniformly across regions*” (Leader 2), indicating intervention fidelity. The following analysis examines how leaders experienced and managed

the implementation process, contributing to the broadly shared perception of implementation success.

Theme 1: between national standardisation and local implementation

The overarching framework structure in PaHS was established through both top-down policy directives and national program management guidelines, including financial controls and operational boundaries such as the randomised controlled trial protocol to be followed. Initially, some leaders experienced the framework as restrictive, feeling constrained by standardised approaches and limited in their autonomy at the regional level. During observations, several participants expressed frustration with the “*heavy logic*” (Observation, Performance Management start-up meeting) imposed by the national framework, describing how its rigidity sometimes felt at odds with the need for flexibility in local implementation. One leader explained:

I think the difference here is the great uniformity and implementation consistency across the regions, which imposes different demands, both on us as leaders but also as implementation leaders. We've become that along the way. So, it definitely places demands on us. You can't autonomously decide, 'This is how I'm going to do it.' You are bound by a certain framework. (Leader 8)

This quote illustrates a core tension that leaders experienced when implementing a standardised intervention across diverse, dynamic local contexts. The framework necessitated adherence to set parameters, limiting autonomous decision-making. Over time, however, some recognised the national framework as a beneficial structure, particularly in offering legitimacy and stability in interactions with frontline staff:

In relation to the national framework for the project. That has actually been one of the biggest light bulb moments in the project. There was a lot of hassle at the beginning, with each region wanting to do things their own way: 'Can't we use iPads instead of phones, for example?' The Ministry was really adamant: 'You're getting the money for this, nothing else!' Everything we needed to adhere to was written down. But once all that was clarified, I've found that the national framework has provided peace and legitimacy (Leader 3).

Despite this recognition, leaders continued to experience the challenge of balancing adherence to national standards with addressing local, context-specific implementation. They acknowledged that while local variation was

necessary to ensure local implementation, consistency in core components was essential to maintain integrity:

We see a lot of variation across the regions. Some things are allowed to be different, but we must ensure that we are consistent in the important components (Leadership Meeting Minute 14).

Thus, leaders found themselves continuously negotiating between national expectations and local realities. The need for a balance between standardisation and flexibility created an ongoing tension, where leaders had to ensure that the intervention remained true to its core components while also working in practice within diverse local settings.

Theme 2: navigating flexibility within a national framework

This theme focuses on how leaders operationalised flexibility to navigate the tension between standardisation and local adaptation. Two related sub-themes further illustrate how this tension was managed in practice: managing national standards in a dynamic process and local adaptation of implementation strategies. Across all data material, many leaders described the implementation of PaHS as an evolving dynamic process with many uncertainties; as one leader explained during a leadership workshop: “Many things will remain uncertain, and you will not get answers to everything you want. You have to be able to tolerate that.” (Observation, Performance management start-up meeting).

The implementation process was experienced as inherently unpredictable, requiring leaders to manage emerging challenges in real-time and adapt to evolving conditions:

[...] we are working while laying the tracks sometimes, aren't we? (Leader 2).

This quote illustrates how leaders needed to remain attentive and flexible, guiding the implementation processes in new and more favourable directions to ensure successful and unified implementation of the intervention's core components across settings, as such adaptation processes were an integral and iterative dynamic part of the implementation process.

Managing national standards in a dynamic process

A key national strategy in managing this iterative implementation process was that “the components central for a possible effect should be nationally anchored” (Leadership Meeting Minute 19). This included the intervention core components and the development of national implementation core components involving standards and tools such as the workflow description, performance

management system, and M4 data monitoring system. Although this national framework provided the necessary structure and standardisation to support intervention fidelity, leaders also described the core implementation components as flexible standards and subject to ongoing monitoring, evaluation, and revision to ensure local relevance and effectiveness. As one leader noted, this process involved leaders actively collaborating to adjust standards when they no longer aligned with regional or practical realities:

Yes, those are some of the key tools. I would say the workflow description is like the tool, as it also gathers the supporting tools, like how the risk management tool works [...] There are 12 standards [...] and we're discussing whether more standards are needed, both clinical standards and organisational, structural ones, like how many patients we need to process [...] We are currently discussing how to revise, some of the standards don't make sense anymore or are not meaningful enough, so we need to change them, but most of them still hold. (Leader 10).

This collaborative flexibility allowed leaders to ensure that the national implementation standards were flexible enough to accommodate changes while still providing the structure needed for consistency across regions. This was the case, for example, when the prediction model suddenly did not include the necessary patients on the lists. Standards had to be adjusted to address this issue, as there was a requirement to process a certain number of patients for the regions to receive funding from the central Danish government.

This collaboration and ongoing evaluation process was especially evident in discussions surrounding performance management, one of the national implementation core components. Leaders across regions were engaged in determining not only how to standardise the overall performance management system but also whether the specific methods used in the regions, such as team meetings and review processes, should be uniform or allow for variation:

Various methods are being used across the regions to ensure a shared overview of production and progress within individual PaHS units, such as board meetings. There is a need to decide whether uniform methods should be applied, and if so, which ones (Leadership Meeting Minute 10).

This discussion exemplifies how the development of national implementation tools like performance management was not a one-size-fits-all process but rather a dynamic, adaptive, and collaborative effort.

Local adaptation of implementation strategies

Leaders collaborated at the national level to define where consistency was essential and where local variation could be permitted. At the local level, leaders extended flexibility to implementation strategies in response to specific PaHS unit needs. An example of this flexibility was the shared Performance Management catalogue that was collaboratively developed by program management, project leaders, and nurse leaders. While specific standards were established to ensure consistency, such as standardised registration practices within the M4 system, regional leaders were given the flexibility to develop and adapt the performance management implementation strategies to suit their local contexts best. The catalogue outlined a framework that leaders in the different regions were responsible for filling in based on their specific contexts, as stated in the document: *“The PaHS-units themselves have been responsible for filling out [the theoretical PM framework].”* (Performance Management catalogue document)

This collaborative effort allowed for the creation of a shared theory of change, outlining the expected relationships between the organisational structure of PaHS, its activities and resources, and the desired outcomes. Project leaders and nurse leaders received training on performance management, ensuring that the foundational principles were consistent across regions, while the practical implementation strategies or methods could vary. For example, while meetings were held across all regions and PaHS units to review performance data, the frequency, terminology, and specific content of these meetings varied depending on the regional context. As one leader remarked: *“But it probably also depends on the staff group because in [another region], you maybe can’t gather 35 people around a board. It doesn’t make sense. I do not know what they do over there.”* (Leader 1). This illustrates how regional leaders adapted meetings to suit their specific team sizes and operational needs, ensuring that the national guidelines remained meaningful and practical within their local contexts. In this way, performance management, a core national implementation component, not only served to standardise practices but also became a dynamic space for regional and local adaptation, where strategies were monitored, shaped, and reshaped to fit local contexts.

Theme 3: managing national-local balances through horizontal and vertical leadership

The analysis identified two key types of leadership in the PaHS implementation, which are presented as two related sub-themes: *Horizontal Leadership: Cross-regional Collaboration* and *Vertical Leadership: Mediating Between National and Regional Levels*. Horizontal leadership describes cross-regional collaboration, enabling leaders

to share best practices and maintain consistency. This position enabled them to facilitate continuous dialogue, ensuring that adaptations in the implementation process remained aligned with the intervention’s core components while allowing local insights to shape national core implementation components. Vertical leadership refers to the top-down and bottom-up processes where leaders translate national directives into local practice and communicate local insights back to the national level, acting as mediators, ensuring alignment between national goals and local realities.

Horizontal leadership: cross-regional collaboration

Many leaders described a national leadership structure as a key precondition for successful, cohesive, and consistent national implementation:

We are completely dependent on having such a well-functioning cross-regional leadership. In that sense, having a group of project leaders and a group of nurse leaders [...] has in many ways practically functioned as part of the [national] leadership (Leader 10).

The ongoing cross-regional collaboration among leaders allowed them to maintain a shared focus and uniform implementation while also facilitating the exchange of best practices and problem-solving strategies:

We have become very aware that we can only ensure a unified and consistent effort, both across and within the regions, by continuously being curious and communicating with each other (Leader 8).

Leaders commonly experienced formal cross-regional meetings as a cornerstone of this collaboration. Regular in-person meetings created a space for regional leaders to discuss national strategies and to share local experiences. One leader described the structure of these meetings:

We have these joint meetings first, and then we each go our separate ways[...] I think our [leadership role] meetings have been good and constructive[...] it’s a forum where we are equal and where you get the chance to talk about some of the things you’ve been thinking about (Leader 3).

Much of the collaboration also occurred through informal networks. Several leaders described frequently reaching out to their peers across regions to seek advice or share solutions to practical challenges:

Personally, I do it if I have something I feel I can’t solve myself or something that puzzles me, or if I’m

in doubt whether I'm doing it right, then I write to the others and ask, 'How do you see this?' 'Do you have a challenge here, because I do?' and 'How did you solve it?' Or vice versa, if I notice something that we discussed in a meeting, I can say, 'This is how it's done,' and maybe they can use that (Leader 6).

These informal networks were an essential support system, enabling leaders access to expertise and to discuss implementation challenges:

[name of a leader from another region] is incredibly skilled with our M4 system, which extracts data ... If there's something we really need ... it's her who can help with that (Leader 1).

This example illustrates how informal collaborations were experienced as valuable for sharing technical expertise and resources, helping leaders manage the implementation process despite variations in skills and capacities among the regional leaders.

Vertical leadership: mediating between national and regional levels

Within regions, the leaders demonstrated shared responsibility for both implementing and guiding the intervention to translate national decisions into local practice. A leader reflected:

So it's me who can explain the history and make sense of why sometimes the things they [the nurses] have to do may not immediately seem meaningful in daily practice. What's the reason behind it, and why does it still make sense? (Leader 3).

This illustrates how some leaders ensured that national directives were understood and meaningfully applied in daily practice. The focus was not only on issuing instructions but on creating a shared understanding of why certain practices were necessary, which supported smoother implementation.

Leaders saw themselves as having a critical role in managing upward communication by ensuring that frontline staff concerns and insight were brought to the attention of higher leadership levels, e.g. the overarching cross-regional leadership group and program management:

I believe that the way we communicate is the most important part and that I listen a lot to their [the nurses'] inputs. There can be problems that I don't immediately understand or see as a problem, so I listen to them and try to figure out whether this is an issue at a staff level, something that needs to

be raised with the team [...] or the close leadership group. [cross-regional leadership group] (Leader 7).

By bringing up these issues, the leaders facilitated the recognition and timely attention of potential challenges in the implementation process, helping to resolve local concerns and preventing them from affecting the program's overall success.

This mediating leader role, based on vertical leadership, also encompassed managing uncertainties and reducing potential unwarranted turbulence within the local context:

Sometimes, I'm also kind of brought in as someone who has the professional authority when there is too much uncertainty about certain things. I'm used to setting the framework and saying, 'This is how it is done.' (Leader 8).

This balancing act was only possible because these leaders were embedded "on the ground," close to the nurses and the local contexts they were trying to influence:

We should only focus on things that we find interesting to look at and can learn from, and I really like to use all the breaks to have dialogues with the staff in the break room and try to bring up the professional dialogue about how things are going, how many we have in the process, and 'Oh, now there were five no-shows this week,' all that, just to keep a finger on the pulse with those things [...]. (Leader 4)

This interaction with frontline staff was used as an informal opportunity to gather feedback, track progress, and identify potential issues early. By being embedded in the local context, leaders knew when to "step in" or "keep out" and trust the staff to manage daily operations effectively.

Discussion

This study aims to investigate how leaders experience and manage the national implementation of a complex SMS intervention (PaHS) in Denmark.

Implementation is always a meeting between the new and the old, between intervention and context, stability and change, standardisation and adaptation. This intersection, where critical tensions and synergies arise, is essential for understanding the complexities of implementation. While these tensions, especially between intervention and context [10] and between fidelity and adaptation [15, 17], are well-known in implementation research, few studies have explored the implementation processes over time [10], including the role of leaders

in navigating these tensions during large-scale national implementations.

Prospectively identified factors can certainly play an important role in finding contextual determinants for implementation (i.e. facilitators and barriers) and thereby guide decisions about the appropriate implementation strategies for matching the needs of local contexts [49]. However, they also imply a somewhat static, formulaic, predictable understanding of the implementation context and process [10, 13]. Our findings demonstrate that leaders experienced the implementation process as unpredictable, and that the experienced successful PaHS implementation was not a result of simply following top-down directives and standardisations, but instead of embracing the complexity of a dynamic and ongoing process. Leaders managed this process by balancing stable, nationally defined intervention and implementation core components with adaptive, context-sensitive implementation strategies. May's concepts of plasticity and elasticity [10] provide valuable tools for a better understanding of the degree to which leaders could navigate this balance [10]. Plasticity refers to the degree to which an intervention can be adapted to fit varying contexts. Elasticity describes the flexibility of the implementation strategies and the context's ability to accommodate the intervention. In our study, the leaders experienced the PaHS intervention to have limited plasticity – “a heavy logic” – due to its tightly coupled intervention core components. Leaders navigated these constraints by leveraging the elasticity of the implementation strategies, ensuring both fidelity and responsiveness to the unique demands of local realities. This required leaders to engage in significant adaptive work, aligning with May's proposition that the more tightly coupled the intervention components are, the less discretion participants have, and the more adaptive work is required for integration [10].

Our analysis illustrates how the leaders' reflexive practice, characterised by real-time adjustments and feedback loops [14], was crucial in managing this balance. Through this process, leaders did not simply follow national guidelines but actively mediated between standardisation and local realities, resulting in an experienced successful implementation with fidelity across the regions. This dynamic process aligns with May's notion of understanding context as a process rather than a place where continuous interaction and adaptation are necessary to ensure effective implementation [10]. By demonstrating these real-time adaptive practices, this study provides a practical example of May's theoretical concepts, showing how leaders' adaptive work might support high-fidelity implementation in policy-driven contexts.

By leveraging the elasticity of implementation strategies, leaders experienced that they were able to preserve the core intervention components with fidelity by

creating a “fit” between intervention and context. This insight aligns well with the recent implementation science literature, which recognises that adaptations can be made both in the intervention itself and in the implementation strategies [17, 50]. Schwarz et al. [17] suggest that implementation strategies can be viewed as mechanisms for achieving a “fit” between intervention and context. Our findings extend this work by illustrating how leaders practically operationalise this “fit” in implementation strategies through real-time, context-sensitive adjustments. A study by Rodriguez et al. [16] likewise underscores that flexibility in implementation does not necessarily reduce fidelity but can enhance the adoption and penetration of interventions in real-world settings. Our findings further suggest that adaptations were not experienced as conflicting with fidelity, but rather as an essential part of the implementation process. Consistent with implementation science literature, which increasingly views adaptation and fidelity as complementary elements [16, 17, 51], we suggest that context-sensitive adaptation in implementation strategies enabled the intervention to function in diverse local contexts, while supporting perceived fidelity to the intervention's core components.

Braithwaite et al. [14] similarly emphasise adaptation as an essential part of implementation processes, arguing that achieving system-level change necessitates moving beyond a narrow focus on intervention fidelity to embrace iterative, recursive adaptation to context, working closely with local stakeholders, and embracing contextual complexity. Among the concepts he introduces as important in such processes are feedback loops [14]. Feedback loops are described as recursive mechanisms that create reciprocal behaviours in which outputs feed back as new inputs. In a positive self-reinforcing feedback loop, the rate of change is amplified, resulting in the production of more of its own output. In a negative, self-correcting feedback loop, outputs dampen change or adjust their direction [14]. In our study, these mechanisms became visible through leaders' reflexive practices: reinforcing loops when successful practices were shared and amplified across regions, and self-correcting loops when feedback from practice and performance management data led to the revision of standards or correction of misalignments. Together, these dynamics illustrate implementation as a non-linear and ongoing process, where interventions and contexts co-adapt over time [10, 13, 14]. In such a system, Greenhalgh and Papoutsi [13] argue that the traditional quest for certainty and predictability must be supplemented by the capacity to manage uncertainty and emergent causality in dynamic systems. In our study, this capacity was enacted through both formal and informal vertical and horizontal leadership, where leaders collaborated to foster an environment in

which reinforcing loops could spread successful practices and self-correcting loops could correct misalignments. Our findings indicate that this collective approach to leadership was critical not only for ensuring consistency and accommodating local needs but also for maintaining momentum in the implementation process. This finding empirically supports Metz and Bartley [52], who argue that successful implementation is inherently collaborative and relies on shared responsibilities rather than individual leadership. Future research could examine how vertical and horizontal leadership function as collaborative leadership practices in managing uncertainty and maintaining momentum during large-scale implementation processes.

Altogether, these findings illustrate that the experienced successful national implementation of PaHS required much more than strict adherence to a standardised implementation guideline; instead, it relied on a co-adaptive process within a national framework. This case highlights the need for implementation frameworks to move beyond static and prescriptive models, embracing a more fluid understanding of implementation where intervention and context are co-constructed through ongoing, leadership-driven negotiation, as seen in this study. In this study, leaders' descriptions of successful implementation reflected their perceptions of success in the implementation process rather than the outcomes of the intervention itself. This also illustrates an important analytical distinction in implementation research: as emphasised by Fixsen et al. [11, 53], core intervention components and core implementation components represent distinct dimensions of an intervention programme, meaning that implementation processes may unfold successfully even when the intervention itself does not ultimately demonstrate the intended outcomes. This distinction is important because leaders' perceptions of successful implementation may coexist with disappointing intervention outcomes.

Limitations

When assessing the results, some limitations should be acknowledged. First, while leadership was involved at multiple levels, we chose to treat it collectively rather than distinguishing between specific roles. This approach highlighted the collective leadership practice and preserved participant anonymity but may overlook nuances unique to different levels of leadership. Second, this study did not measure fidelity; instead, it relied on performance management measures, adherence to the intervention's core components, and leaders' accounts of these aspects. Future research could incorporate objective fidelity assessments to measure fidelity alongside adaptive leadership strategies. Third, a limitation relates to the temporal variation in data collection. While interviews were

conducted during a more mature phase of implementation, observations and documents spanned the whole implementation period from 2017 to 2020. This variation may have shaped how experiences were expressed and understood at different stages. However, triangulation across data sources helped mitigate this limitation by enabling interpretation of interview accounts in relation to documented and observed implementation practices over time.

Conclusion

This study highlights the complexity of scaling and implementing healthcare interventions across diverse contexts. The study underscores the crucial role of collaborative leadership in fostering vertical and horizontal leadership and facilitating feedback loops – both reinforcing (positive) and self-correcting (negative) – together with real-time adjustments, ultimately contributing to what leaders perceived as a successful national implementation process. It contributes empirically by demonstrating how fidelity and adaptation can, in practice, function not as opposing forces but complementary, with adaptation supporting fidelity. This dynamic interplay calls for moving beyond static, linear implementation models, recognising that success in implementing national complex interventions lies in continuous adaptation and real-time leadership-driven adjustments, where stability and flexibility co-evolve with complex and unfolding contexts. By providing empirical insights into the adaptive mechanisms, this study addresses calls for a deeper understanding of the processes that underpin successful implementation in complex systems.

Abbreviations

PaHS	Proactive Health Support
SMS	Self-management support

Supplementary information

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Supplementary Material 1

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Authors' contribution

MF conceptualised the study, designed the methodology, conducted data collection, performed the analysis, and drafted the manuscript. CPN and MDT provided substantial input during data interpretation and contributed to critical revisions of the manuscript. UT, MG, and JH contributed intellectual input and provided critical feedback to improve the manuscript's clarity and structure. All authors reviewed and approved the manuscript's final version and agreed to be personally accountable for their respective contributions to the study.

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Data availability

The qualitative datasets generated and analysed during the current study are not publicly available due to the confidential nature of the material and data protection obligations under the General Data Protection Regulation (GDPR).

Declarations

Ethics approval and consent to participate

The randomized controlled trial in the overall research program was approved by the Regional Committee on Health Research Ethics for the Region of Zealand, Denmark (SJ-677). According to Danish legislation, this kind of qualitative research does not require separate approval by the Biomedical Research Ethics Committee. All informants have given informed consent. The study was conducted in accordance with the principles outlined in the Declaration of Helsinki.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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