Behind the Scenes of a Patient Safety Leadership Intervention in Nursing Homes and Homecare: Researchers’ Tips for Success

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Reports of patient safety interventions are often straightforward, well planned, well executed, and comprehensive. However, behind the scenes, there are usually many adaptations and customizations before and during the intervention. These modifications ensure the success and sustainability of these interventions. We have conducted a patient safety leadership intervention to translate a patient safety leadership tool into practice in several Norwegian nursing homes and homecare services. In this article, we share our tips for success and elaborate on our adaptive strategies, user involvement in research, and how to keep a yearlong leadership intervention going despite organizational changes and management turnover. We also present our perspective on the possible challenges and benefits of adaptive strategies in studies of patient safety interventions.

POLISHED SURFACES AND HIDDEN DETAILS

Health care is a complex and adaptive system, which may pose several challenges when conducting implementation research on patient safety improvement interventions.\(^1\)–\(^5\) Researchers must plan for all phases in the research project, in terms of access to the field, collecting data and participants, and preparing different strategies to conduct research and analysis.\(^5\) Contextual and individual factors, organizational changes, and reorganizations will influence the implementation, resulting in differences in responses, intervention uptake, and success across settings.\(^7\)–\(^8\) Knowing whether or not an intervention is effective is not enough. We need detailed information on what the researchers did during the implementation to adapt to the challenges encountered to make the implementation a success.

Managers play an important role in the implementation of patient safety improvement interventions.\(^8\)–\(^11\) However, there seems to be a lack of tools and support to guide managers in their improvement work.\(^12\)–\(^15\) Furthermore, most research on patient safety improvement interventions is conducted in specialist health care, creating a need for more research in the nursing home and homecare settings.\(^13\)–\(^15\) We therefore developed and implemented a patient safety leadership intervention (the “Improving Quality and Safety in Primary Care—Implementing a Leadership Intervention in Nursing Homes and Homecare” [SAFE-LEAD Primary Care] project) in nursing homes and homecare services.\(^13\),\(^14\)

We have limited knowledge about what researchers do to keep interventions going despite ongoing challenges related to organizational changes, contextual factors, and participants; this information is rarely mentioned in research papers. Research processes often look good on paper, but there is a lot going on behind the scenes of an implementation process that we can learn from. In this article, we describe what the researchers in the SAFE-LEAD intervention did to keep the participants in the intervention and to customize the research activities in the face of challenges.

THE SAFE-LEAD LEADERSHIP INTERVENTION: CONTENT, CONTEXT, AND THEORETICAL ANCHORING

Our research project, SAFE-LEAD Primary Care, is a 12-month intervention study.\(^13\),\(^14\) The intervention consisted of the implementation of a research-based dialogical tool (the SAFE-LEAD guide) to support managers in nursing homes and homecare services in their patient safety improvement work. The guide is designed to help managers to systematically identify the strengths and weaknesses of their improvement work and reflect on how to operationalize this in their units. The intervention aimed at developing managers’ knowledge, skills, and methods repertoire in systematically work on improving patient
Safety. This intervention consisted of workshops with managers and their teams where researchers facilitated use of the guide, including discussions and work processes. The Knowledge to Action Framework, Organizing for Quality (OQ) framework, and the Consolidated Framework for Implementation Research (CFIR) were used as theoretical foundation in the SAFE-LEAD intervention design and implementation. The frameworks support a multilevel contextual perspective on the implementation and evaluation of patient safety improvement interventions in health care organizations. In accordance with the OQ Framework, the SAFE-LEAD guide is structured around 7 challenges that managers often face in their patient safety improvement work: structure, care coordination/organizational politics, culture, competence, engagement, physical design/technology, and external demands. The guide is structured in a 3-step process, where managers rate how their organization performs on the 7 challenges (step 1), develop specific goals to meet the challenges (step 2), and develop specific action plans for the patient safety improvement work, including how to evaluate progress (step 3). We used the Knowledge to Action Framework to guide us in the process of translating the SAFE-LEAD guide into practice. According to this framework, translating the guide to practice requires identification of problems that need to be solved by the organization, adapting and tailoring the intervention to the organization’s specific needs and context, assessment of barriers for using the guide, actual implementation, and monitoring and evaluating the implementation of the guide. The CFIR framework contributed to guide the research study’s attention to contextual factors and how to focus on the particular aspects of the varying inner and outer settings of the intervention sites.

In Norway, municipalities are responsible for the provision of primary health care services such as nursing homes and homecare services, general practitioners, and emergency departments. Nursing homes provide the 24-hour treatment and care that patients cannot receive at home. Homecare services coordinate and provide home-based health care services such as long-term care, home-based health care services and sheltered stay for dementia, and short-term stay. Homecare services coordinate and provide home-based health care services.

Norway has 356 municipalities, all of which are responsible for providing safe health care services to all inhabitants. The contextual setting varies from rural districts or small towns (Utsira, n = 208) to the largest city-based municipalities (Oslo, n = 694 657). In some municipalities, people seeking care need to travel by ferries and drive on roads with high risk of snow slides and floods to access hospital care.

Four nursing homes and 4 homecare services located in 5 municipalities in different parts of Norway participated in the intervention in 2018 to 2019. The units were recruited based on criteria of variability in context, size, and location, and thus represented great diversity in contextual factors that might influence the implementation process.

The size of the management team depended on the settings in the sample. The teams consisted of unit managers of the nursing home and homecare services in addition to department managers who had personal responsibility of one or more departments within the nursing home or homecare service. There were variations in the number of managers and how they were organized in the municipalities during the intervention (Table 1). Some units in the municipality (M1 and M2) had the same managers throughout the intervention period, whereas in the nursing home M4, 2 managers were replacements during the implementation period. Two units (M3 and M5) operated with the same managers in the intervention period and established a manager team responsible for the intervention, which meant that the intervention was well rooted in their units.

The intervention consisted of two 6-month phases for a total of 12 months. All 8 units (nursing home and homecare) participated in phase 1, which consisted of 4 workshops where managers and researchers collaborated on the guide. Four of the units (2 nursing homes and 2 homecare services) participated in phase 2. In phase 2, managers were followed up over time and supported by researchers in their patient safety improvement efforts.

In this article, we go behind the scenes of the SAFE-LEAD intervention study. Our aim is to illuminate and share our knowledge about the researchers’ experiences with facilitating and maintaining the SAFE-LEAD intervention in nursing home and homecare settings. We do not report on the impact, effects, or evaluation of the intervention. The following research question guided our article:

What lessons have been learnt from the SAFE-LEAD leadership intervention about adaptive research strategies?

By “adaptive research strategies,” we mean the adaptations that were done regarding the way in which the research was carried out, without changing the content of the intervention, the research questions, or the sample size. We based our reflections and experiences on a large body of data consisting of surveys, interviews, workshops, observations, site visits, context mapping, and comprehensive meeting summaries that included implementation material gathered over the course of 12 months. We have thus gained key insights into the intervention, the adaptations we made, the challenges we faced and resolved, and whether the intervention proved successful or not. We used this material when reflecting on the project and suggested the reasons for our tips for others.

TIPS FOR SUCCESS

We present tips for success in the patient safety leadership intervention and how we modified our research strategy in the face of organizational and contextual challenges to ensure implementation in all participating units. The researchers should not only develop the skills to conduct their study but also manage the complexities of facilitating and maintaining access in the intervention period in the participating nursing homes and homecare services.

We have categorized our tips into 3 groups: (1) anchoring, (2) adaptability of researchers, and (3) keeping sight of the big picture.

ANCHORING

Our first tips are to use co-researchers (department managers, nurses, nurse managers, cancer nurse) and project manager to ensure the requisite accountability and involvement.

Seven co-researchers were recruited to ensure access to the field and anchoring of the intervention in the participating nursing homes and homecare services. Three were employed in 20% positions throughout the 4-year project period. They had a daily role in clinical practice and were involved in designing, intervention planning, and implementing the project from the beginning. The co-researchers had broad knowledge of and experience in the nursing home and homecare context and were responsible for recruiting all units in the sample. They were key discussion partners when assessing changes and executing the project. It was essential for the project to be anchored in practice by having co-researchers directly associated with the field. This ensured representation of the field of practice and academia in the project, making it easier to adapt the intervention to local needs, anchor it in the management teams, and understand and address the challenges we faced in the course of implementation.

The project manager has a central role in ensuring participation. Before the intervention started, the research project manager
When the department manager (M4) involved in the intervention resigned (described hereinafter). When the department manager in M4 resigned, the new department manager wanted to withdraw from the project because of other priorities. We reconnected with the unit in the municipality and talked with the manager about responsibilities of participation and their written agreement and about possibilities of learning from the intervention. We also explained to the manager how the intervention could actually be helpful and distributed the intervention material describing the SAFE-LEAD intervention program. As a result, the unit remained in the study but did not participate as much as the other units. However, this case provided an example of common practices and challenges in these health care settings. By still being able to observe and interview managers and health care professionals in the unit, we gained insight into how the unit worked in times of change and reorganization. We used the unusual case to learn about challenges associated with participating in an intervention during reorganizations and the challenges of daily patient safety work. This is of key relevance to understand patient safety work in everyday practice, which often is characterized by management turnover and organizational change.

Implementation of interventions in nursing homes and homecare settings is not a straightforward and standardized undertaking. Sudden changes, reorganizations, and challenges require flexibility and creative solutions. At one point, the nursing home in M4 considered withdrawing from the intervention. We decided to keep this unit in the study but ended the intervention activities. We continued our observations and site visits and interviews that provided rich insight into the unit’s daily work and challenges.

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KEEPING SIGHT OF THE BIG PICTURE

Our last tips are to keep the big picture in mind by being involved in the intervention, mapping the context and changes, and establishing strong collaboration between the researchers and co-researchers. Involving both researchers and co-researchers in the intervention was essential in creating relationships, facilitating participation, and not least to suggesting appropriate measures. By having the same team of researchers follow the management teams from the beginning to the end of the implementation, we

ADAPTABLEITY OF RESEARCHERS

Other tips for success are to be adaptable, to keep in touch with the participants, and to use ad hoc solutions in response to unexpected problems.

Sometimes we had to modify our plan for the intervention, such as postponing intervention activities, because of reorganizations, lack of staff, and overworked managers in the participating units. This required numerous telephone calls and e-mails with the units to get response and new time for appointments. Sometimes this took several weeks, but the flexibility ensured continuity in the project.

### TABLE 1. Data Sample and Setting

| Municipality | Municipality Size (Approximate n of Inhabitants) and Location | Units Involved: | Management: Manager Team and Changes |
|--------------|---------------------------------------------------------------|-----------------|-------------------------------------|
| M1           | <5000 Rural district. Approximately 1.5 h to hospital       | NH, HC          | The management team collaborated across nursing home and homecare. One manager was replaced during the intervention period. |
| M2           | 5–10,000 Rural district. Approximately 20 min to hospital   | NH, HC          | The same management team participated throughout the intervention period. The municipality experienced a planning phase of merger with neighbor municipality during the implementation. |
| M3           | 135–140,000 Large city. Hospital in same municipality        | NH              | The same management team participated throughout the intervention period consisting of both managers and professional development nurse. |
| M4           | 70–75,000 Medium-sized city. Approximately 15 min to hospital| NH, HC          | The management team collaborated across nursing home and homecare. Two managers left during the intervention period (1 unit manager and 1 department manager in nursing home). |
| M5           | 15–20,000 Rural district. Approximately 25 min to hospital  | HC              | The same management team participated throughout the intervention period, consisting of both managers and professional development nurse. |

HC, homecare; NH, nursing home.
came to know the managers and their units; the managers also became more confident in us. By working with the managers, we got better insight into their daily work. At the same time, the managers became comfortable enough to be candid with us and to ask questions. In addition, this involvement made it easier to observe how managers worked and what they struggled with and to provide guidance when needed. For example, we saw the benefits of offering help in the workshops, especially when there were technical issues with the leadership guide. However, we also realized that being overinvolved with the managers could create bias in the results.

Context is a central concept in SAFE-LEAD project where we included different units from large and small units and municipalities, and urban and rural locations.\textsuperscript{14} We found that local changes in internal and external contextual factors during the implementation influenced how the intervention was conducted and affected researchers and participants alike.\textsuperscript{17} As part of the project, we developed a customized context mapping tool, inspired by the CFIR framework.\textsuperscript{17} This covered inner and outer contextual factors within the units and the municipalities. We used the tool to assess national strategies and support, funding, patient involvement, workforce, and part-time health care professionals, and to record changes in the units during the implementation. The mapping made us aware of why we experienced more challenges with implementation in some units than in others. The map was a useful way to identify challenges and discuss possible solutions.

The collaboration between the researchers and co-researchers during the project and the diversity of their expertise was fundamental for understanding the context and challenges we faced during the intervention. It was considered particularly important during the workshops. The members of the intervention teams that ran the intervention program in each unit were carefully chosen to complement each other’s competence. Five intervention research teams (2–3 members) were established, one for each municipality. Each team consisted of someone with extensive experience from practice field including health care education as background and a member with research training. These research teams worked closely and sometimes collaboratively. Monthly meetings were held to ensure joint reflections about opportunities and challenges of the intervention, how we could adapt to different situations that arose, and communication strategies with gatekeepers. Meetings and joint reflection in the research teams motivated the researchers and ensured transfer of experience in the project team. Through the joint meetings, the researchers became updated and supported each other. We documented reflections in the minutes of every meeting.

DISCUSSION

The SAFE-LEAD intervention required some adjustments. Therefore, we have provided insight into what happened behind the scenes and proposed our tips for a successful implementation in nursing homes and homecare services, based on the researchers’ experiences and lessons learnt.

In line with previous studies,\textsuperscript{21–25} we found that contextual factors played an important role for the implementation process. We came across numerous challenges based on local changes and reorganizations in the units. In general, contextual factors affect all parts of the research process, from the design to the implementation and evaluation of patient safety interventions. Differences in context are thought to be responsible for some of the variability in the success or failure of an intervention.\textsuperscript{17,20} Several previous studies have emphasized challenges in implementation and how to address them in the planning phase.\textsuperscript{3,16,24,27} However, unforeseen changes and reorganizations often occur during implementations processes, meaning that it is often difficult to predict the course of an implementation. In line with the recommendations in the Knowledge to Action Framework, flexibility is needed when implementing interventions in primary health care, considering the unpredictability of these clinical settings.\textsuperscript{4,28} Our study demonstrates the importance of studying “how” and “why” interventions work, instead of just focusing on “what” works by showing how the implementation of the SAFE-LEAD guide differs across units based on contextual factors. According to the OQ framework, understanding the processes and factors that enable development of structures and cultures to improve patient safety is key to achieving sustained improvement in health care.\textsuperscript{25}

Our study adds new knowledge by providing actionable suggestions for researchers who must modify their initial implementation plan. This is important to increase the likelihood of effective change in health care.\textsuperscript{5} Changes and contextual differences between organizations and units involved in implementation studies demonstrate the importance of remembering that “one size does not fit all.” Researchers need to make adjustments during implementation and must be flexible and amenable to making changes. Although all interventions include some common measures being implemented, such as the leadership guide in our project, there must be room for adjustments to fit the local needs.\textsuperscript{3} A previous evaluation study of a leadership intervention in hospitals, which used the same guide as our study is adapted from, also showed how contextual factors influenced differences in implementation and intervention responses across different hospitals.\textsuperscript{25}

The need for flexibility when implementing patient safety interventions requires transparency in the research process. It is important to track changes in what happens in the participating units during implementation and what the researchers did to adjust for and manage these disruptions. Such transparency provides a record of how the implementation was carried out and raises possibilities to learn from unusual developments. This knowledge about possible mechanisms and contextual factors might have influenced the implementation and the results.

Being overinvolved in the intervention may skew the results. All telephone calls and e-mails, site visits, and meetings ensured the continuity of the project but might have affected the implementation and the results. The use of co-production and collaborative approaches have recently gained increased popularity in research and implementation studies.\textsuperscript{29,30} Studies show that there may be several benefits of involving co-researchers in the intervention, such as knowledge creation and mobilization, collaboration, network and relationship, active participation of all stakeholders, and a commitment to shared learning.\textsuperscript{7,31} It is, however, important to be aware of the possibility of bias as a consequence of overinvolvement. Therefore, keeping track of adaptations, changes, and measures done by a tailor-made tool such as the SAFE-LEAD Context mapping tool in our study is important for ensuring trustworthiness and transparency. Our tips for success about anchoring, researchers’ adaptability, and keeping sight of the big picture are important to consider in the implementation of patient safety interventions.

CONCLUSIONS

This article shows what goes on behind the scenes of implementation processes. It highlights that we need to be aware that each implementation will be different. As researchers, we need adaptive capacity to respond to challenges and changes, despite careful planning and use of acknowledge theoretical anchoring and implementation frameworks.\textsuperscript{3,14,16} Researchers need to be aware of changes in the organizations and management turnover and reach an agreement with participating organizations about their role and contributions. Preparing for unforeseen changes
and being able to devise ad hoc solutions are important research strategies and skills. The research team should possess multidisciplinary expertise that combines a strong track record in research and extensive practical experience. Taking advantage of the expertise of co-researchers is recommended to ensure the context-specific competence that is required to adapt interventions to the nursing home and homecare settings.

ETHICAL CONSIDERATIONS

The Norwegian Social Science Data Services approved the study (ID 52324 and ID 54855). The study followed the Helsinki Declaration, and all participants gave individual informed consent to take part in the study.

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REFERENCES

1. Ree E, Wiig S. Linking transformational leadership, patient safety culture and work engagement in home care services. Nurs Open. 2019;7:256–264.
2. Dixon-Woods M, McNicoll S, Martin G. Ten challenges in improving quality in healthcare: lessons from the Health Foundation’s programme evaluations and relevant literature. BMJ Qual Saf. 2012;21:876–884.
3. Marshall M, Pagel C, French C, et al. Moving improvement research closer to practice: the researcher-in-residence model. BMJ Qual Saf. 2014;23:801–805.
4. Straus S, Tetroe J, Graham ID. Knowledge Translation in Health Care: Moving From Evidence to Practice. 2nd ed. West Sussex: Wiley Blackwell; 2013.
5. Richman M, Sklaroff LM, Hoang K, et al. Innovative use of technologies and methods to redesign care: the problem of care transitions. J Ambul Care Manage. 2014;37:100–105.
6. Patton M. Qualitative Research and Evaluation Methods. Thousand Oaks, CA: Sage; 2002.
7. Øverveit J. Understanding the conditions for improvement: research to discover which context influences affect improvement success. BMJ Qual Saf. 2011;20(Suppl 1):i18–i23.
8. Taylor SL, Dy S, Foy R, et al. What context features might be important determinants of the effectiveness of patient safety practice interventions? BMJ Qual Saf. 2011;20(Suppl 6):i161–i167.
9. Botwinick L, Bisognano M, Haraden C. Leadership Guide to Patient Safety: Safety HH Innovation Series White Paper. Cambridge, MA: Institute for Healthcare Improvement; 2006.
10. Künzle B, Kolbe M, Grote G. Ensuring patient safety through effective leadership behaviour: a literature review. Saf Sci. 2010;48:1–17.
11. Parand A, Dlopson S, Renz A, et al. The role of hospital managers in quality and patient safety: a systematic review. BMJ Open. 2014;4:e005055.
12. Tistad M, Palmcrantz S, Wallin L, et al. Developing leadership in managers to facilitate the implementation of national guideline recommendations: a process evaluation of feasibility and usefulness. Int J Health Policy Manag. 2016;5:477–486.
13. Johannessen T, Ree E, Stromme T, et al. Designing and pilot testing of a leadership intervention to improve quality and safety in nursing homes and home care (the SAFE-LEAD intervention). BMJ Open. 2019;9:e027790.
14. Wiig S, Ree E, Johannessen T, et al. Improving quality and safety in nursing homes and home care: the study protocol of a mixed-methods research design to implement a leadership intervention. BMJ Open. 2018;8:e020933.
15. Johannessen T, Ree E, Aase I, et al. Exploring challenges in quality and safety work in nursing homes and home care—a case study as basis for theory development. BMC Health Serv Res. 2020;20:277.
16. Bate P, Mendel P, Robert G. Organizing for Quality: The Improvement Journeys of Leading Hospitals in Europe and the United States. Abingdon: Radcliffe Publishing; 2008.
17. Damschroder LJ, Aron DC, Keith RE, et al. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci. 2009;4:50.
18. Genet N, Boerma WG, Kringos DS, et al. Home care in Europe: a systematic literature review. BMC Health Serv Res. 2011;11:207.
19. Genet N, Boerma WG, Kroneman M, et al. Home Care Across Europe—Current Structure and Future Challenges. Geneva: World Health Organisation (WHO); 2012. Available at: http://www.euro.who.int/__data/assets/pdf_file/0008/181799/e67575.pdf?ua=1. Accessed September 22, 2020.
20. Ringard Å, Sagan A, Sperre Saunes I, et al. Norway: health system review. Health Syst Transit. 2013;15:1–162.
21. Kaplan HC, Provost LP, Frochle CM, et al. The Model for Understanding Success in Quality (MUSIQ): building a theory of context in healthcare quality improvement. BMJ Qual Saf. 2012;21:13–20.
22. McDonald KM. Considering context in quality improvement interventions and implementation: concepts, frameworks, and application. Acad Pediatr. 2013;13(Suppl 6):S45–S53.
23. Pfadenhauer LM, Gerhardus A, Mozygomba K, et al. Making sense of complexity in context and implementation: the Context and Implementation of Complex Interventions (CICI) framework. Implement Sci. 2017;12:21.
24. Granja C, Janssen W, Johansen MA. Factors determining the success and failure of eHealth interventions: systematic review of the literature. J Med Internet Res. 2018;20:e10235.
25. Jones L, Pomroy L, Robert G, et al. Explaining organisational responses to a board-level quality improvement intervention: findings from an evaluation in six providers in the English National Health Service. BMJ Qual Saf. 2019;28:198–204.
26. Wiig S, Aase K, Johannessen T, et al. How to deal with context? A context-mapping tool for quality and safety in nursing homes and homecare (SAFE-LEAD Context). BMC Res Notes. 2019;12:259.
27. Carlforsd S, Lindberg M, Bendsten P, et al. Key factors influencing adoption of an innovation in primary health care: a qualitative study based on implementation theory. BMC Fam Pract. 2010;11:60.
28. Malterud K, Aamland A, Iden KR. (2018). Small-scale implementation with pragmatic process evaluation: a model developed in primary health care. BMC Fam Pract. 2018;19:93.
29. Voorberg WH, Bekkers VJM, Tummers LG. A systematic review of co-creation and co-production: embarking on the social innovation journey. Public Manag Rev. 2015;17:1333–1357.
30. Moullin JC, Dickson KS, Stadnick NA, et al. Ten recommendations for using implementation frameworks in research and practice. Implement Sci Commun. 2020;1:42.
31. Rycroft-Malone J, Burton CR, Bucknall T, et al. Collaboration and co-production of knowledge in healthcare: opportunities and challenges. Int J Health Policy Manag. 2016;5:221–223.